ANALYTICAL SUFFICIENCY OF DRUG EVIDENCE

1 Objective

1.1 The objective of this document is to establish criteria for analytical sufficiency in the identification of controlled and non-controlled substances.

1.2 These criteria will apply to identifications of all exhibits in which the forensic chemist's report will be used for the enforcement of federal, state, local, or international laws.

2 Evidence Sampling Plan (ESP)

2.1 The DEA evidence sampling plan (*Laboratory Operations Manual-Handbook*, Appendix HA-01) provides procedures for sampling exhibits consisting of multiple units and forming composites.

2.2 Deviations from the ESP must be approved in advance by a supervisor and documented on the worksheet before a final report is issued.

2.3 Special program analyses performed at SFL1 are exempt from the provisions of the ESP.

3 Threshold Limits of Detection

3.1 There are too many variables, in terms of dosage size, concentration and multi-component mixtures, to establish practical, objective threshold limits of detection for all controlled and non-controlled substances.

3.2 Situations may occur where very low levels of a substance may be present, but further investigation is technically or administratively impractical or unnecessary. In such situations, with supervisory approval, the suspected but unconfirmed identity of the substance may be annotated on the back of the worksheet but not reported as a result on the front of the worksheet.

4 Identification of Controlled Substances

4.1 All reported identifications must be based on data which supports the identification of the controlled substance(s). Any data which does not correlate with the identification must be fully explained, or the substance cannot be reported. Analytical data obtained from confirmation techniques must be supported with corresponding data from DEA laboratory standards which have been verified as to identity. In situations where a standard is unavailable, the confirmation of identity may be accomplished by SFL1 through structural elucidation.

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5 Identification of Non-Controlled Substances

5.1 All identifications of adulterants, listed chemicals, and precursors must be based on data which support the identification of a non-controlled substance. Any data which does not correlate with the identification must be fully explained, or the substance cannot be reported. Analytical data obtained from confirmation techniques must be supported with corresponding data from a reference standard or literature data.

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6 Negative Controls (Blanks)

6.1 Negative controls will be used with instruments and chemical tests to preclude the possibility of false positives.

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6.1.2 Negative controls must be run prior to each analysis when conducting qualitative instrumental tests. Blanks need not be run between tests when analyzing multi-unit submissions with the same exhibit number from which a composite will be formed. In the case of NMR, a blank need only be run initially with each use of the instrument and with each batch of samples generated from the same deuterated solvent source.

6.2 The use of negative controls will be documented on the back of the DEA Form-86.

6.3 Resulting hard copies of all negative controls will be properly annotated and retained in the case file.

7 Quantitative Analysis

7.1 Quantitation of controlled substances will be conducted according to the policies and procedures in the *Laboratory Operations Manual- Handbook, Analysis of Drugs Manual, Basic Training Program for Forensic Drug Chemists*, or laboratory specific validated methods.

7.2 Quantitation of non-controlled substances will be conducted when required.

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11 Marijuana and related substances

11.1 The identification of marijuana will consist of a microscopic examination (which must observe plant material with cystolithic hairs), a Duquenois-Levine test, and either a chromatographic method (including, but not limited to, TLC or GC) or MS (which must include the identification of tetrahydrocannabinol).

11.2 The identification of a resinous extract of cannabis (hashish) will consist of a microscopic examination (which must observe fragments of plant material such as cystolithic hairs), a Duquenois-Levine test, and MS (which must include the identification of one or more of the tetrahydrocannabinols and at least two of the following: cannabinol, cannabidiol or cannabichromene).

11.3 The identification of hashish oil (a preparation of soluble cannabinoids derived from cannabis) will consist of a microscopic examination (in which the substance is essentially free of plant material), a Duquenois-Levine test, and MS (which must include the identification of one or more of the tetrahydrocannabinols and at least two of the following: cannabinol, cannabidiol or cannabichromene).

11.4 Single unit exhibits and A-K submissions: Each unit must be tested independently in accordance with the criteria established in paragraphs 11.1-3. It is not necessary to form a composite for further testing.

11.5 Multiple unit exhibits (excluding A-K submissions): The ESP should be applied to determine the appropriate number of units to test. Each of the selected units must be tested independently in accordance with the criteria established in paragraphs 11.1-3. It is not necessary to form a composite for further testing.

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Deputy Assistant Administrator
Office of Forensic Sciences

5/11/09
Date

Definitions

A.1 Presumptive Techniques – Presumptive techniques provide indication of sample composition. They must be appropriate for the sample and may include, but are not limited to: commercial logo comparisons, chemical tests, color tests, microcrystal tests, optical crystallography, UV-Vis spectrophotometry, and separation techniques (without selective detection).

A.2 Separation Techniques – Separation techniques provide an indication of sample composition while evaluating for possible multi-component mixtures. These tests must be appropriate for the sample and may include: TLC, GC, LC, CE, and IMS. Some separation techniques may be interfaced with non-selective (presumptive) or selective (identification) detectors. In addition, NMR, ESI/MS/MS or DESI/MS/MS may be used to evaluate samples for possible multi-component mixtures.

A.3 Confirmation Techniques – Confirmation techniques provide distinctive structural information to identify a substance. These tests must be appropriate for the sample and may include the following: IR, MS, Raman spectroscopy, or NMR. A confirmation technique can be interfaced with a separation technique (i.e., GC/MS, GC/IRD, or LC/MS).

A.4 Residue – A residue sample consists of a small quantity of substance to be examined in which there is insufficient quantity for the practical determination of a weight. Examples of a residue include, but are not limited to, material adhering to the inside of a smoking pipe stem, a straw, a beaker from a clandestine laboratory, a plastic bag, or material from a vacuum sweep.

A.5 Trace – A trace component consists of a substance present at a low-level within an appreciable amount of material. An example of a trace component includes, but is not limited to, a sample consisting of 400 mg of a material containing 99% heroin hydrochloride and 0.50% cocaine hydrochloride or a sample consisting of 400 mg of a material containing 99% sucrose and 0.20% cocaine hydrochloride.

A.6 Adulterant – An adulterant is a pharmacologically active substance, usually added to a controlled drug to enhance the affect. For example, quinine and procaine are typical adulterants added to heroin.

A.7 Diluent – A diluent is an inert ingredient used to increase the bulk of a finished product. Typical diluents are sugars, starches, tablet binders and lubricants, and inorganic salts.

A.8 Procedural Blank – A procedural blank consists of the matrix (to include, but not limited to, the solvent for a separation technique, or KBr for IR) which has been taken through every step of the analytical protocol using the same glassware, reagents, solvents and analytical instrument. The procedural blank will be evaluated to eliminate the possibility of contamination anywhere in the analytical protocol.

Laboratory Operations Handbook

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Appendix HA-01

EVIDENCE SAMPLING PLAN

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GENERAL COMMENTS

Objective of Sampling Plan

The objective of the Evidence Sampling Plan is to provide a statistically sound, uniform basis for DEA chemists to form conclusions, based upon random sampling. The sampling technique is based on the probability theory of the hypergeometric distribution and provides a completely consistent mathematical foundation for conclusions concerning the contents of multiple containers of controlled substances.

Judgment is often required in sampling exhibits. The analyst may decide that certain exhibits should be sampled so as to preserve some unusual feature, such as characteristic shape or an embossed design. If in doubt, the analyst should consult with his or her supervisor before proceeding.

Prior to forming the composite, selected containers (the minimum number determined from the Tables below) are to be analyzed as directed in the Analytical Sufficiency Document.

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NOTE: Place notations on the reverse side of the DEA Form 86 showing the use of the sampling plan and the procedure used to obtain the composite (e.g., cone and quarter, cone and sample, etc.). Most exhibits can be sampled using the procedures in this plan. Occasionally exhibits will be encountered for which these procedures are unsuitable. In such instances, the analyst is expected to use good judgment to obtain a representative sample. If in doubt, the analyst should consult his or her supervisor before proceeding. In the event the plan is not used, that fact must also be noted, and a detailed description of the sampling procedure used must be given.

DEFINITIONS

1. Cone and Quarter -- A procedure whereby the powder in a container is mixed by shaking or stirring; large fragments or particles are reduced if necessary; the material is then poured on a flat surface to form a cone. The "cone" is flattened, and the material is then divided at right angles, forming quarters.

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2. Cone and Sample -- A procedure whereby the powder in a container is thoroughly mixed, formed into a cone, and a composite is formed by withdrawing approximately 5-gram portions from the center and from each of the four quarters of the cone.

3. Probe Technique -- A procedure whereby containers are pierced and a small amount of powder is removed for screening.

4. Core Technique -- A procedure whereby portions are removed from various (i.e., 2-5) locations to form a composite.

5. Homogeneous Exhibit -- An exhibit that is uniform in physical appearance and the particle size of the entire exhibit is 20 mesh (0.1 cm) or less.

6. Mix Thoroughly -- Comminuting the powdered mixture until the powder appears to be uniform.

7. Gummy Exhibits -- Those which, by reason of moisture or other liquid content, are not amenable to grinding.

8. Screening -- The inspection of exhibits containing powders, tablets, capsules, and other solid dosage forms to detect differences in color, markings, and other morphological properties as appropriate. When applied to those units "selected" for screening per the Evidence Sampling Plan, screening must include a confirmatory test to identify any controlled substance present.

9. Composite -- Exemplar of an exhibit used for analysis

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10. Representative Sample -- Exemplar for testing and a sample aggregate portion of the whole amount seized sufficient for current criminal evidentiary practice.

11. Test Portion -- Amount withdrawn from exhibit for quantitative analysis.

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Appendix HA-02

QUALITY ASSURANCE GUIDELINES

DEA LABORATORY SYSTEM

1. The Analysis of Drugs Manual (ADM) contains a compilation of standardized qualitative and quantitative methods for the most common drugs analyzed in the DEA laboratories. Additionally, each laboratory has documented qualitative and quantitative methods specific to the needs of the individual laboratory. Controlled substances must be analyzed according to standardized methodology where such methods are available in the ADM or in each laboratories compilation of approved methods. The method utilized must be referenced on the back of the Forensic Chemist Worksheet. There is flexibility in the method to allow the chemist to modify parameters, i.e., concentration, wavelength, column, internal standard, etc. to obtain an accurate result. If an existing standardized method is insufficient, an alternate method may be developed and used with supervisory approval. Such a method should normally be included as a standardized method for future use.

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Appendix HA-04

SAFETY PROCEDURES IN CLANDESTINE LABORATORY OPERATIONS

Planning the seizure of a clandestine laboratory should include consideration of the possible hazards that may be encountered and appropriate measures to handle them in a safe manner. A DEA forensic chemist can provide valuable help in anticipating hazards, based on information obtained in the investigation. Consequently, a forensic chemist should be consulted during the early stages of a clandestine laboratory investigation and be present at the time of seizure.

Safety is a personal responsibility. Each individual at the seizure site is responsible for knowing what hazards are present and the precautions required to avoid injury. Clearly, every safety and health hazard associated with a clandestine laboratory seizure cannot be anticipated; therefore, rules cannot be developed for every contingency that could rise. All employees must maintain a constant vigilance for unsafe or potentially hazardous conditions or practices. The DEA forensic chemist present at clandestine laboratory seizures is responsible for providing technical assistance in identifying chemical hazards, and recommending precautionary measures.

To assist in safely securing a clandestine laboratory, a properly stocked Clandestine Laboratory Truck should be present at each seizure site. It is the responsibility of the agent in charge to assure that the truck is present at the clandestine laboratory site. If a lab truck is not available, the forensic chemist should coordinate with the agent in charge to ensure that all required safety equipment is available. In these cases, the forensic chemist should be able to provide the necessary sampling supplies and equipment needed.

The forensic chemist should attend the pre-raid meeting/briefing if at all possible to provide an opportunity for the chemist to brief the other seizure team members about the hazards expected in this particular laboratory.

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The appropriate level of personal protective equipment (PPE) will be worn during all stages of clandestine laboratory processing. Once the laboratory is secured, the site should be ventilated by opening doors and windows, at a minimum. If fans are used to assist in ventilation, they must be of the non-sparking type available on the lab truck or

from the fire department. Do not use electric fans which may be present in the clandestine laboratory.

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The minimum level of PPE required for members of the assessment team are:

1. Chemical resistant suits, gloves and boots.
2. Nomex hood, jacket, pants, gloves and safety shoes/boots.
3. Self-contained breathing apparatus (SBA).
4. Head protection.

Any potential routes of entry of chemical vapors to exposed skin will be taped, i.e., sleeves, pants cuffs, collar.

A certified forensic chemist and fingerprint specialist, if appropriate, will be part of the clandestine lab processing team. Members of the processing team are responsible for collecting and processing of all evidentiary material found on-site. The members of the processing team will use the buddy system and adhere to safety practices and procedures set out in the Clandestine Laboratory Safety Guide.

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HAZARDOUS WASTE DISPOSAL

All equipment and apparatus are assumed to be contaminated and should be handled as evidentiary and waste management samples. Additionally, all chemicals/solvents, and reaction mixtures are considered hazardous and will be disposed of as hazardous waste after evidentiary and waste management samples have been taken.

The DEA case agent will arrange for proper disposal of all hazardous materials using the designated hazardous waste contractor in accordance with Subsection 6674.7 of the Agents Manual and other DEA policies. Questions concerning disposal of hazardous waste should be directed to Headquarters, Hazardous Waste Unit (STSH).

Appendix HA-05

DRUG ENFORCEMENT ADMINISTRATION

OFFICE OF SCIENCE AND TECHNOLOGY

MANAGEMENT DEVELOPMENT PLAN

The purpose of the Management Development Plan is to describe the means by which the Office of Science and Technology (ST) can enhance the effectiveness of its managers. Through formalized education/training, self-study and the right job experience, individuals can obtain the knowledge, skills, and abilities, needed to be effective managers.

Although current literature provides us with different definitions of leadership and management, the fact is that for managers to be effective, they must be good leaders. Therefore, this plan uses the word manager with the understanding that the manager encompasses all the traits of a leader. The effective manager leads, trains, coaches, supervises and manages resources.

This plan consists of the following:

Section	*Title*
I	Personnel Management
II	Manager Development
III	Recommended Reading List
IV	Self-Study Courses
V	Senior Level Courses and Seminars
VI	The Individual Development Plan

SECTION I: PERSONNEL MANAGEMENT

LABORATORY CAREER DEVELOPMENT SYSTEM

Purpose. This section addresses the career development of Chemists within the DEA laboratory system.

Career Ladder

A. The "career ladder" (i.e., career progression without further competition) for Chemists within the laboratory system is:

GS-5	Chemist (entry-level trainee)
GS-7	Chemist (advanced entry-level trainee)
GS-9	Forensic Chemist
GS-11	Forensic Chemist
GS-12	Forensic Chemist (journeyman)
GS-13	Senior Forensic Chemist
GS-14	Senior Research Chemist

B. Competitive procedures are required to enter the system at the grade level for which the candidate is qualified. if initial appointment is below the journeyman level (GS-12), subsequent promotions to the journeyman level (GS-12) are noncompetitive.

Promotion to GS-13 Senior Forensic Chemist (Technical Specialist) and GS-14 Senior Research Chemist positions at the Special Testing and Research Laboratory are based on individual development of specialized scientific expertise and are subject to review and approval by the Pay and Position Management Unit, Office of Personnel. Additionally, promotion to the GS-14 Senior Research Chemist position is subject to review and approval by the Career Board. Noncompetitive promotions to the GS-13 level are also subject to approval by the Position Review Committee.

C. Supervisory and Managerial Positions. Career progression into supervisory and managerial positions within the laboratory system is subject to competitive merit promotion procedures for positions up to and including GS-15.

Supervisory and managerial positions within the laboratory system are:

GS-13	Supervisory Chemist (Support Group Supervisor)
GS-13/14	Supervisory Chemist (Field Laboratory)

GS-13/14 Supervisory Chemist (Special Testing & Research Laboratory)

GS-14 Program Manager

GS-15 Laboratory Director

GS-15 Chief, Laboratory Operations Unit

ES-01/03 Associate Deputy Assistant Administrator, Office of Science and Technology

ES-01/04 Deputy Assistant Administrator, Office of Science and Technology

SECTION II: MANAGER DEVELOPMENT

Manager development is the process by which individuals develop the knowledge, skills, and abilities (KSA's) needed to lead, train, coach, supervise, and manage resources at increasing levels of responsibility. Such development is the result of progressive and sequential education, training, and experience received throughout a career. The manager development process is based on three pillars, described below:

1. The institutional training pillar provides formal education and training that all individuals receive in preparation for service as managers within DEA.
2. The self-development pillar recognizes individual initiative and self-improvement as key to continuing professional development. The formal training system is limited and individuals must act on their own to expand knowledge and experience. Reading programs, college education, and self-study programs are among the principal self-development opportunities. While all pillars are crucial, the self-development poses the greatest challenge, since the final responsibility for development rests on the individual's shoulders.
3. The developmental assignments pillar gives individuals the opportunity to build upon the knowledge, skills and abilities (KSA's) that they acquired during formal training and self-development and use them in actual management positions.

The Office of Science and Technology Management Development Plan has three levels, MDP I, II, and III, which link and cut across all manager development pillars. Candidates for supervisory and managerial positions may be evaluated, in part, based on established KSA's. Candidates acquire KSA's from formal training provided by the organization, self-development, and developmental job assignments.

LEVEL I

GS-5

GS-7

GS-9

GS-11

GS-12

A. *General.* Each level of the Management Development Plan (MDP) has four components: KSA's component; a formal training component, a self-development component; and a job assignments component. Under Level I, the KSA's component provides entry level personnel and those at the journeyman level with the critical skills and professional knowledge subject matter that they must master. To ensure that individuals have an opportunity to develop appropriate KSA's, individuals should receive institutionalized formal training. It is also incumbent upon the individual to pursue a self-development program. The foundation for a self development program is college level course work, correspondence courses and individual reading programs. Position responsibilities within the organization will provide building blocks of experience, enabling the individual to put into practice those skills he/she has learned through education and training. This training plan lists the key job assignments for which the individual should strive.

B. *Knowledge, Skills and Abilities (KSA's).*

1. Ability to perform assigned duties with appropriate degree of supervision
2. Knowledge of chemistry as applied to the analysis of drugs and related substances
3. Knowledge of chemistry to solve difficult analytical problems
4. Knowledge of instrumentation used in chemical analysis
5. Knowledge of instrumentation sufficient to effect repairs
6. Knowledge of laboratory safety/accident prevention
7. Skill and ability to conduct scientific research
8. Skill as a peer group leader in resolving problems involving interpersonal conflicts
9. Ability to be objective, fair minded in dealings with others
10. Skills in effective oral and written communication
11. Organizational skills
12. Computer literacy

C. *Formal Training.*

1. Basic Entry Level -- An on-site Basic Chemist Training Program of 4-12 months.
2. Forensic Chemist Trainee 3 weeks in Quantico -- Provides training in DEA history, rules and regulations to the new employee. Procedures in law are described in regards to the Controlled Substances Act, evidence handling, court testimony, and mock trials. Technical training on instrumentation provided with analytical methods of analysis for drugs. Forensic Chemist Trainees are required to synthesize controlled substances in a laboratory environment. Training includes some elements of GS/MS, spectroscopy, microscopy, and chromatography. A laboratory environment is required.
3. Forensic Chemist Technical Seminar -- This one week program at Quantico is designed to provide technical instrumentation training.
4. Advanced Technical Seminar -- This one week program in Quantico is designed to provide advanced training to more experienced Forensic Chemists. A more technical, advanced discussion is provided for newer analytical techniques and instrumentation.

5. Group Supervisors School -- This one week program in Quantico is designed to provide supervisory skills training to the new group supervisor.
6. Leadership, Education and Development (LEAD) Course -- This DoD course is for GS--12's who have demonstrated outstanding leadership potential. A further description of this course is provided in the next section, level II, Formal Training.
7. Verbal/Non-verbal Communication Skills -- This one week school in Quantico is limited to 40 participants per year. The program is designed to provide laboratory employees with principles necessary for communication.
8. Computer Training -- This one week school in Quantico is limited to 40 participants per year. The program is designed to provide laboratory employees with comprehensive computer skills using a variety of software, e.g., Word Perfect, Lotus 1-2-3, Harvard Graphics, dBase IV.

D. *Self-Development.*

1. College Level Advanced Course Work -- Generally, chemists possess at least a bachelors degree at entry level. Appropriate graduate degree work will enhance promotion opportunities.
2. Self-Study --
a. Individuals should establish a reading program, in conjunction with his/her Individual Development Plan (IDP).
b. Self-study program courses are available through government and quasi-government agencies. The Domestic Section (TRD) at Quantico can provide the most up-to-date listing of available courses. Section IV of this plan provides a sample of available self-study courses. A self-study course on management is mandatory before funding is provided for other management courses.

E. *Assignments.*

1. Clandestine Lab Coordinator
2. Research Coordinator
3. Reverse Undercover Coordinator
4. EEO Counselor
5. Training Coordinator
6. Purchasing Coordinator
7. Special Projects
8. Instrument Monitor
9. Standards Monitor

LEVEL II

GS-13

GS-13/14

GS-14

GS-15

A. *General.* To have been selected for management, the individual had to master the skills and knowledge described in Level I. Level II requires a new set of technical skills and knowledge to make the individual an effective manager. A series of opportunities for management training will provide the individual with the more highly developed KSA's.

B. *KSA's.*

1. Knowledge of management principles and practices
2. Knowledge of DEA's personnel management practices and policies
3. Interpersonal skills
4. Ability to make decisions after development and consideration of alternatives
5. Technical knowledge
6. Knowledge and skills in scientific research
7. Computer literacy

C. *Formal Training.* There is a need to develop advanced leadership and management skills. Improving existing KSA's and developing new KSA's should increase job effectiveness and positively influence the effectiveness of subordinates. There are numerous courses and seminars available.

1. Leadership, Education and Development Course (LEAD)
a. A five day course sponsored by DOD where participants learn by doing. Emphasis is placed on: Communication skills, conflict resolution, problem solving, motivating others and performance counseling. Participants are placed in role play situations in which they can practice a variety of skills. Learning is reinforced by lecturettes.
b. Expected Results of LEAD:
- Increased awareness of how various management and leadership styles affect others
- Development of skills for dealing with people
- Increased listening and communication skills ability to appropriately gear management style to specific situations
- Increased performance and person counseling skills
- Improved decision making
2. Personnel Management for Executives (PME) Course.
a. Upon promotion to GS-14, individuals will attend phase I of the Personnel Management for Executives (PME). This eight-day course is DOD sponsored and is held at six locations within the U.S.
b. Expected Results of PME
- Improved self-awareness and human relations skills
- Greater insight into the analysis of the dynamics of human and organizational behavior
- Better able to manage the assets of a diverse work force
- Increased understanding of human resource management philosophies
- Better able to manage stress by incorporating the concept of total wellness into their approach to management
3. Personnel Management for Executives (PME) Course Phase II.
a. As a GS-15, individuals should complete the five day phase II of PME. PME is designed to build on the original PME experience.

b. Expected Results of PME II
- Enhanced understanding of the theory, skills, and issues of PME
- Enhanced understanding of group rapport and trust
- Enhanced understanding of the various dimensions of leadership and human resource management as primary concerns of federal executives

4. Group Supervisor School -- This two-week school is held approximately once a year and is conducted at the FBI/DEA Academy in Quantico, Virginia. Ideally, all supervisors would attend this course just prior to assuming their duties as first-line supervisors. Practically speaking, no supervisor should go more than one year without receiving this mandatory training. Subject areas include motivation, communication skills, Equal Employment Opportunity (EEO), Employee Assistance Program (EAP), stress management, leadership, performance evaluation, coaching and counseling, and other administrative issues. The school is open to all supervisors other than those in the Special Agent (1811) and Diversion Investigator (1810) series.

5. Organizational Leadership for Executives (OLE) --

a. A DOD sponsored two week course held in Kansas City, Missouri for GS-15's (middle manager). Topics include, but are not limited, to improving interpersonal communication, developing strategies for organizational excellence, influencing subordinate performance, managing innovation and change, increased self knowledge, diagnosing systemic problems, and building excellence into the leadership team.

b. Expected Results of OLE
- Ability to assess, integrate and apply practical deals for enhancing organizational achievement throughout multiple levels of an organization
- Able to develop short and long range strategies for improving organizational performance

6. Executive Development Program (EDP) --

a. A DEA sponsored one week course held at Quantico, Va. This training is targeted at GS-15's. This course emphasizes leadership skills.

b. Expected results of EDP
- Ability to solve problems and think creatively; enhanced to negotiating skills.
- Enhanced communication skills.
- Ability to hold effective meetings.

7. Supervisor Refresher Training --

This one week course, conducted at Quantico, will provide refresher training in management skills and cover ethics, contemporary issues and DEA initiatives.

8. Laboratory Directors' Conference --

This one week course conducted at Quantico is designed to provide Laboratory Directors with a comprehensive training seminar in many areas, including: management and organizational issues; budget and financial issues; employee development; and performance issues.

9. Supervisory Chemists' Advanced Training School --

This one week course is designed to cover a wide range of first line supervisory topics, e.g., overtime, travel regulations and administrative policies.

10. Supervisory Chemist Advanced Technical Training School -

This one week school is planned to be held annually and to cover management issues of concern to the first line supervisor, e.g., overtime, travel regulations, promotions, awards, etc.

11. There exists a plethora of management courses and seminars available from the American Management Association and U.S. Department of Justice Management Division. Such courses include policy administration, personnel management and a host of other pertinent subjects. Planning for such training should be part of the IDP process.

12. Requests for above mentioned courses and seminars must be submitted to DEA Training, FBI Academy, ATTN: TRD, P.O. Box 1475, Quantico, Virginia 22134-1475.

D. Self-Development

1. College Education -- If not already accomplished, managers are encouraged to complete the work necessary for a Master's degree in business administration, public administration, chemistry, or forensic science. 2. Self-Study --

a. Managers should maintain a disciplined reading program. A recommended reading list is found in Section III, pg. 14.

b. Correspondence courses are available through different agencies. (See Section IV, pg. 15).

E. Assignments

1. Supervisory Chemist (Support Group Supervisor)
2. Supervisory Chemist (Field Laboratory)
3. Supervisory Chemist (Special Testing and Research Laboratory)
4. Program Manager
5. Laboratory Director
6. Chief, Laboratory Operations Unit

LEVEL III

ES-01/03

ES-01/04

A. *General.* To be selected to this level, candidates must have clearly demonstrated knowledge, skills and abilities in a broad range of management areas. In addition to possessing the KSA's needed at Levels I and II, managers must possess additional KSA's for success at this higher level.

B. *KSA's.*

1. Knowledge of how complex bureaucracies function.
2. Ability to persuade i.e., to be effective in government and the public sector.
3. Knowledge of how national domestic policy is formed.
4. Knowledge of how outside agencies and social forces affect DEA's mission.

C. Formal Training

1. The Federal Executive Institute. Individuals must be selected for attendance by DEA Career Board.
2. American Management Association Courses
3. Executive and Management Courses
Individuals must be selected for attendance by DEA Career Board.
4. OPM Seminars. Individuals must be selected by DEA Career Board for attendance.
5. Attorney General Seminars. Career Board selected.

D. Self-Development

1. College Education -- Although Masters and PhD degrees are not mandatory for advancement, managers are encouraged to further their college education.
2. Self-Study
a. Individuals must continue with a vigorous reading program.
b. Self-study program courses are available through agencies such as the USDA Graduate School, USDA, the National Independent Study Center of the U.S. Office of Personnel Management.

E. Assignments

1. Associate Deputy Assistant Administrator Office of Science and Technology.
2. Deputy Assistant Administrator Office of Science and Technology.

SECTION III: RECOMMENDED READING LIST

Blanchard, Kenneth, and Spencer Johnson. *The One Minute Manager.*

Blanchard, Kenneth. *The Power of Ethical Management.*

Burns, James MacGregor. *Leadership.* New York: Harper and Row, 1978.

Chase, Gordon, and Elizabeth C. Reveal. How to Manage in the Public Sector. New York: Random House, 1983.

Cohen, William A. *The Art of the Leader.* Englewood Cliffs, NJ: Prentice Hall, 1990.

Covey, Stephen R. *The 7 Habits of Highly Effective People.* New York: Simon and Schuster, 1989.

Drucker, Peter F. *Managing the Non-Profit Organization: Principles and Practices.* New York, Harper-Collins, 1990.

Gabor, Andrea. *The Man Who Discovered Quality.* New York: Penguin Books, 1990.

Gardiner, Gareth. *Tough-Minded Management.* New York: Fawcett-Columbine, 1990.

Gardiner, John. *On Leadership.* New York: Free Press, 1990.

Haass, Richard N. *The Power to Persuade.* New York: Houghton Mifflin, 1994.

Keirsey, David, and Marilyn Bates. *Please Understand Me.* Gnosology Books, 1984.

Kotter, John P. *Power and Influence*. New York: Free Press, 1985.

Lynn, Laurence E., Jr. *Managing the Public's Business: The Job of the Government Executive*. London: BBC Books, 1986.

McCullough, David. *Truman*. New York: Simon and Schuster, 1992.

Ouchi, William G. *Theory Z*. New York: Avon Books, 1981.

Peters, Thomas J., and Robert H. Waterman, Jr. *In Search of Excellence: Lessons from America's Best-Run Companies*. New York: Harper and Row, 1982.

Shaara, Michael. *The Killer Angels*.

Smith, Perry M. *Taking Charge*. New York: Garden City Park, 1988.

Sun Tzu. *The Art of War*. Boston: Shambala, 1988.

De Tocqueville, Alexis. *Democracy in America*. New York: Random House, 1945.

Wilson, James Q. Bureaucracy: *What Government Agencies Do and Why They Do It*. New York: Basic Books, 1989.

Wouk, Herman. *Inside, Outside*.

Zartman, I. William, and Maureen R. Berman. *The Practical Negotiator*. New Haven: Yale University Press, 1982.

SECTION IV: SELF-STUDY PROGRAM

A. General. Self-study is an effective way to train. It enables the individual to learn at his/her own pace when and where it is most convenient. Material can be reviewed at the discretion of the individual until it is mastered.

B. The National Independent Study Center (NISC) course content has been carefully designed so that the individual can learn on his/her own. However, if difficulty is encountered regarding the subject matter, the student can call or write NISC instructors, who will gladly answer questions.

C. NISC courses must be coordinated through the Domestic Training Section (TRD), Quantico, Virginia. A sample of available courses includes: PC Literacy; Basic Labor Relations; EEO; Government Pay Setting; Personnel Procedures; Effective Work Delegation; Improving Employee Performance; Program Planning and Analysis; Writing Reports; Solving Performance and Conduct Problems; How to Write Effective Letters and Memos.

D. The USDA Graduate School offers nearly 100 self-paced courses providing the freedom and flexibility to study in your home at your own pace. Courses include: English

skills; accounting; auditing; management; computer sciences; math; personnel administration; writing and more. For more information call (202) 720-7123. These classes must be coordinated through the Field Training Unit in the Office of Training.

SECTION V: SENIOR LEVEL COURSES AND SEMINARS

COURSE	*LENGTH*
1. CONGRESSIONAL FELLOWSHIP PROGRAM This program provides an opportunity for incumbent and potential executives to develop skills and abilities to understand and work with Congress. Seminars are conducted by leading Congressional, Governmental and academic figures throughout the year, while working with members of the House of Representatives, Senate and Congressional Committees. GS-13 or equivalent.	Ten Months
2. HARVARD UNIVERSITY PROGRAM The purpose of this program is to improve the managerial effectiveness of officials who hold senior level management positions in the public sector. The focus is on the roles, tasks and skills of senior managers. It also addresses the problems associated with the development of policy in the public organization and the administrative challenges of implementing policy.	Three Weeks
3. ATTORNEY GENERAL SEMINARS A variety of individual courses for GS-11- SES candidates such as: The 90's Executives, Effective Speaking for Executives, Management Reasoning Techniques, Power negotiations, Managing Human Performance, Problem Solving and Decision Making, Middle Management Seminar and Effective Delegation. GS-11 and above.	Two Days/One Week
4. U.S. O.M. EXECUTIVE SEMINAR CENTER A variety of Programs such as; New Managers Seminar, Management Development Seminar, Executive Development Seminar, etc., focusing on specific techniques and processes needed for effective executive and management leadership. GS-13 and above.	Two Weeks
5. UNIVERSITY OF SOUTHERN CALIFORNIA This management education program is an intensive graduate level study program designed to give a working knowledge of administrative, budgetary and program management functions leading towards a masters degree in Public Administration. GS-14 and above.	Nine Months
6. NATIONAL WAR COLLEGE	Nine Months

This course involves detailed analysis of various political, economic, psychological and military factors in establishing national security policy. GM-15 and above.	
7. U.S. ARMY WAR COLLEGE The learning process is the exchange of ideas, knowledge and experience among military and civilian students from a variety of agencies. Selectees must be in a managerial or executive position. GS-14 and above.	Ten Months
8. INTER-AMERICAN DEFENSE COLLEGE Spanish speaking is helpful, but not a prerequisite. The curriculum includes a review of the current body of thought on the potential psycho-social, economic and military fields, as well as an intensive investigation of the structure of power; and examination of the world situation especially as it bears on the security and well being of the Western Hemisphere and a detailed analysis of the Inter-American situation. GM-14 and above.	Ten Months
9. BROOKINGS INSTITUTE This program is conducted though a series of conferences that contribute to the conceptual growth of senior government executives by engaging them in analysis of public issues and encouraging them to form independent judgements. The conferences also recognize that professional growth by key executives is essential if government leaders are to respond to the changing demands on society. SES Level.	One Day/Two Weeks
10. THE LEGIS FELLOWS PROGRAM Is designed to provide expertise in legislative drafting and management of legislative work at agency level. Incumbent is assigned either the House or Senate. GS-15 or equivalent.	Six Months/One Year
11. THE FEDERAL EXECUTIVE INSTITUTE A variety of programs designed to develop and increase the executive's ability to provide leadership, analyze information and interact with others in the Federal executive environment. GS-15 and above.	One Week/Four Weeks

12. EXECUTIVE POTENTIAL PROGRAM This career enhancement program for high potential individuals GS-13/14 provides training and developmental experiences to prepare them for future opportunities as supervisors, managers and executives in the federal government. GS-13/14.	One year
13. WASHINGTON EXECUTIVE SEMINAR This seminar is designed to acquaint current and future executives with a wide range of issues and topics. Particular attention is devoted to the Senior Executive Service (SES) competencies of "Integration of Internal and External Program and Policy Issues:" and "Organization Representation and Liaison." SES Level.	Two Weeks
14. COUNCIL FOR EXCELLENCE IN GOVERNMENT FELLOWS (COG) (COG) enhances leadership and managerial skills of future members of senior executive serve through interaction with successful executives from Government and private industry. While performing regular duties each Fellow participates in structured learning situations tailored to developmental needs. GS-14.	One Year
15. HARVARD LAW SCHOOL PROGRAM New Program for Federal Attorney's. The course is instructed by leading Attorney's in private enterprise. Segments relate to Criminal and Civil prosecution.	One Week

SECTION VI: INDIVIDUAL DEVELOPMENT PLAN

NAME DATE ESTABLISHED

POSITION/SERIES/GRADE DATE REVISED

I. PLANS

A. CAREER OBJECTIVES
My professional goals are as follows:
1. Short Term (1-3 years)
2. Long Term (>3 years)
B. ASSESSMENT OF KNOWLEDGE, SKILLS AND ABILITIES (KSA's)
The KSA's which I already possess (1) and those which I need to add or improve upon (2) include:
1. Attained KSA's
2. Desired KSA's

C. TRAINING
My plans are to complete the following:
1. Formal Training
2. Developmental Assignments
3. Self-Development Activities
D. SUPERVISOR'S COMMENTS
COMPLETE AS APPROPRIATE:

1. The concept of IDP development has been discussed with me; however, I am not interested at this time.

Employee's Signature Date

2. This assessment and development plan has been discussed with the employee named below.

Employee's Signature Date

Laboratory Director's Signature

II. ACCOMPLISHMENTS

A. RECORD OF TRAINING, DEVELOPMENTAL ASSIGNMENT, SELF-DEVELOPMENT ACTIVITY

Course/Assignment/Activity	*Date*	*Comments*
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		

B. EMPLOYEE'S UTILIZATION OF TRAINING RECEIVED: (An assessment by the supervisor, in consultation with the employee, should address any utilization or application of training received.)

C. EMPLOYEE COMMENT: (May be used for employee comment on career goals, course assessment, utilization on training received, etc.)

IDP INSTRUCTION GUIDE

The following instructions are intended for use in completing the Individual Development Plan (IDP).

1. The employee's name, position title, series and grade are entered in the spaces shown. The date that the IDP was originally established is also entered. Since it it expected that the IDP will be periodically reviewed, a space is provided for a revision date.

2. CAREER OBJECTIVES: The employee is expected to select goals which he/she desires to attain. It is expected that the supervisor will assist in this process by helping to identify possible advanced positions or job responsibilities. The goals are segregated into short and long term categories for convenience, as appropriate.

3. ASSESSMENT OF KNOWLEDGE, SKILLS AND ABILITIES (KSA's): It is expected that the KSA's already possessed will vary among individuals depending upon past training, experience, aptitude and a host of other factors. Thus, it is appropriate to identify those KSA's already possessed in order to direct training toward the development of other desired KSA's. Ideally, both the employee and the supervisor will develop a list of both "attained" and "desired" KSA's. If more space is required, use attachments.

4. TRAINING: Planned training is divided into three categories to emphasize the need for each.

5. SUPERVISOR'S COMMENTS: Any comments by the supervisor relative to the assessment, career goal planning and especially self-development initiatives are appropriate.

6. SIGNATURES: Signature lines are provided for the employee, the Supervisor and the Laboratory Director. A space is provided for the employee to decline IDP participation.

7. ACCOMPLISHMENTS: This section is intended for tracking both the completion of training/development assignments and the utilization of such training. It is expected that the employee will apply the skills learned from training or development assignments, essentially using the skills as a basis for further development. If the training/development assignment is not used and/or does not contribute to employee professional development in a meaningful way, then additional training may not be appropriate.

8. EMPLOYEE COMMENT: This section may be used by the employee to comment on career goals, course assessment, utilization of training, etc.

Appendix HA-06

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Appendix HA-07

CHEMIST GRADE EVALUATION GUIDE

GS-12/13 Position Review

The following criteria cover GS-12 and GS-13 grade levels for chemists assigned to the laboratory system within DEA. The GS-12 and GS-13 chemist positions are identical with the exceptions of Factor Levels 1, Knowledge Required by the Position and 5, Scope and Effect. The differences between the GS-12 and 13 levels are in Factor levels 1 and 5; all other aspects of the jobs are the same.

In determining whether an individual should be recommended for promotion to the GS-13 level, the following must be established.

1. The work situation must provide an opportunity for expansion of the job beyond the bounds established at the journeyman level. Examples of applicable higher level duties are listed below with evaluation criteria.
2. The higher level duties must be performed by the candidate and must comprise a substantial part of his/her time on the job. Substantial performance is considered to be at least 20% of the job.
3. It must be demonstrated that the candidate is currently performing at the described level, and will likely be doing so in the future.

FACTOR LEVEL DESCRIPTIONS

FACTOR 1 - KNOWLEDGE REQUIRED BY THE POSITION

This factor measures the nature, variety and intensity of knowledge, skill and ability required to perform the job successfully. How the knowledge, skill or ability is applied by the employee (or, the reason it is required) must also be considered. In order to be credited, the knowledge, skill or ability must be required by the position and actually applied, on a regular basis, by that employee. Possession of a professional knowledge of the fundamental theories, principles and methods in a scientific discipline equivalent to that obtained through the successful completion of a bachelor's degree program (or equivalent experience or training), is the minimum requirement for positions covered by this criteria.

GS-12 - Level 1-7 --- 1250 Points

At this level, the chemist possesses an in-depth knowledge of the concepts, theories, principles and methods of the speciality area. This knowledge is of sufficient depth to enable the chemist to determine the most appropriate approach to be used and to recognize the need for and to adapt and modify standard methods and procedures to meet new or unprecedented requirements. For example, the chemist may have modified the standard operating procedure for determining the amount of narcotic and dangerous drugs

found in samples to produce more consistent results. The chemist is skilled in the operations, calibration and minor repair of analytical instrumentation such as HPLC, nuclear magnetic resonance, gas chromatography, GC/MS spectrometer and ultra violet and infrared spectrophotometers and has the ability to recognize and suggest the reasons for elementary instrumentation problems, such as irregular peak shapes or poor resolution. The chemist has demonstrated the ability to plan, organize and carry out projects or studies involving collaboration with other labs within the agency. In recognition of the chemist's expertise in planning and carrying out the procedures associated with the speciality area, the chemist may have been requested to assist other chemists in performing the specialized procedures or in training other lab workers to perform them. Communication skills are applied by the chemist in one or more of the following ways: to prepare and present sessions at conferences; to testify as a technical witness in court; to draft technical reports; to train other chemists in performing specialized procedures; to document changes to standard operating procedures in lab manuals; or, to explain lab oPerations and procedures to outside groups or individuals.

GS-13 - Level 1-8 --- 1550 Points

At this level, the chemist possesses a mastery of the theories, principles and methods of the speciality area encompassing forensic drug chemistry as evidenced by recognition as one of the laboratory's experts in applying the methods peculiar to the speciality area.

Professional knowledge in the speciality area to recognize the need for and to develop new and improved experimental methods and procedures to overcome current limitations.

The following are some examples of these criteria:

1. The chemist's mastery of the specialty area results in being consulted by colleagues in solving analytical problems of a critical, highly unusual or unprecedented nature such as analyzing the more difficult controlled substances and controlled substance analogs. This may require synthesizing a sample to be used as a standard for identifying the unknown.
2. Knowledge and skills in order to develop curriculum and train other chemists, agents and police in the speciality area.
3. Evaluates new instrumentation for the laboratory and makes recommendation for or against acquisition.
4. Using expert knowledge in synthetic chemistry and the practices of laboratory operators, assists agents and other chemists in complex clandestine laboratory investigations. Advises on methods and materials, production capabilities, location and timeliness of raid and sufficiency of evidence.
5. Skill in performing nonroutine maintenance, diagnosis and repair on the instruments, i.e. beyond normal trouble-shooting, cleaning and calibration.
6. Knowledge of computer programming in order to modify existing programs in computer assisted instrumentation to simplify the instrument's operation and/or extend the instrument's capabilities.

7. Knowledge in aspects of the speciality area, e.g., application of highly sophisticated instrumentation (nuclear magnetic resonance spectroscopy, gas chromatograph-mass spectrophotometer, fourier transform-infrared spectrophotometer).
8. Skill in developing new procedures for the use of analytical instruments or for new instrumental application where there exist very limited published information about the capabilities and limitation of the particular instrument applicable to the particular aspects of the speciality area.

FACTOR 2 SUPERVISORY CONTROLS

This factor measures the degree of guidance and control exercised over the position. There are three aspects of this factor: how assignments are received, especially the specificity of instructions or directions provided at the beginning of the assignment; the amount of responsibility entrusted to the employee to plan and carry out assigned work and the extent to which advice and assistance is provided to the employee while work is in progress; and the manner in which the work is reviewed. The amount of contact between the employee and the supervisor should be examined closely before judgment is made on this factor to ascertain whether the contact is actually to provide direction or guidance. Contact with the supervisor, or with other officials in the supervisory chain, is often consultative in nature, that is, to exchange information or to arrive at a mutually agreeable decision, rather than for the purpose of requesting assistance or receiving guidance.

GS-12 and GS-13 - Level 2-4 --- 450 Points

The supervisor defines the overall scope of the work. Priorities, deadlines, and general approaches are developed cooperatively by the supervisor and the chemist in recognition of the chemist's extensive experience in the performance of established lab procedures. The chemist typically suggests new procedures or the adaptation of those described in current literature or in current use in the lab.

The chemist independently plans, organizes and carries out the work. The chemist keeps the supervisor informed through periodic oral discussions. The supervisor is consulted only on unusual or controversial matters, e.g., data that may be in serious conflict with expected results.

Completed work is reviewed for accomplishment of objective, for overall technical adequacy, and for feasibility. The chemist is responsible for the accuracy of results and for soundness of judgments and interpretations.

FACTOR 3 - GUIDELINES

This factor measures the availability, specifically, and applicability of guidelines, including policies and procedures, instructions, established practices, precedents, textbooks, manuals, professional journals, handbooks, and other reference materials. The

factor also evaluates the degree of judgment exercised by the employee in selecting, applying, adapting, interpreting, modifying, extending, or originating guidelines.

GS-12 and GS-13 - Level 3-4 --- 450 Points

Guidelines include recent developments in forensic chemistry. The chemist obtains information about these developments through reading, attendance at workshops, or personal contacts with other chemists. Newly developed methods and procedures may not be totally validated or contain certain gaps; the chemist must use seasoned judgment in applying them in the lab. In addition to adapting new methods and procedures in the lab, established methods and techniques must often be substantially modified in order to meet the requirements of the lab. Judgment is used in determining the need for new or improved methods and in applying new technological developments. The employee uses initiative.

FACTOR 4 - COMPLEXITY

This factor measures the nature, variety, and relative difficulty of the functions performed and of the systems, methods, procedures, and instrument techniques used. Also considered under this factor is the difficulty encountered in determining what needs to be done, the nature of the problems and obstacles encountered, the degree of analysis, evaluation, and insight required, and the opportunity for creativity and ingenuity. Other complicating factors, including administrative and management issues, should also be addressed under this factor. Noteworthy professional achievements or recognition should also be included in the evaluation of this factor.

GS-12 and GS-13 - Level 4-5 --- 325 Points

The assignments consist of analyzing, identifying, and testing unknown substances. Analyses involve the isolation and characterization of compounds on which a limited amount of information or conflicting data is available, e.g., controlled substance analogs. The chemist's contributions may include the origination and validation of new procedures which permit the synthesis of compounds previously unachievable using established procedures. In the support area, the chemist may have the responsibility for determining resources such as presenting proposals for the purchase of new equipment.

Accomplishments may also include the development and implementation of new analytical applications for the highly specialized instrumentation. The chemist continually reviews current literature and initiates discussions with other chemists who carry out related procedures to maintain an awareness in the field. The chemist may coordinate and participate in training sessions to explain new procedures to other chemists and to provide training to Agents and state and local police. The chemist may have received recognition for his expertise or accomplishments in a number of ways such as being invited to make presentations in seminars or training sessions, to serve on committees for special projects, or other comparable means of recognition.

FACTOR 5 SCOPE AND EFFECT

This factor measures the purpose of the work performed and the impact, influence, and importance of the employee's efforts to the laboratory's mission.

The purpose of the work is to provide expertise in the analysis of forensic drug samples and related areas. The work includes developing new approaches and methods, and evaluating existing ones for technical sufficiency. The employee's work efforts affect a variety of agency technical programs, operations of State and local law enforcement laboratories, and the work of other experts.

GS-12 - Level 5-4 --- 225 Points

At this level, the purpose of the work is to modify and adapt established methods and to develop new procedures designed to meet unusual requirements or to enhance the current capabilities of the lab. The chemist provides expertise in the performance of specialized procedures, including advising other labs on applying and implementing such procedures. For example:

- The chemist may have developed exceptional skill in highly specialized procedures to the point where other chemists require the employee's advice and guidance.
- The documentation and/or publication of refinements or other modifications to standard procedures made by the chemist extends the impact of the chemist's contributions beyond the immediate lab.

GS-13 - Level 5-5 --- 325 Points

At this level, the purpose of the work is to provide expert advice and guidance to other chemists throughout the lab in the speciality area. Aspects of the speciality area may include the application of highly specialized instrumental techniques, such as mass spectrometry, or development of new analytical procedures, or the adaptation of microcomputers to standard analytical procedures, or assistance in complex clandestine laboratory investigations.

The following are examples which demonstrate this criteria:

- The chemist conducts tests to determine validity and recommends changes to established agency programs such as the Evidence Sampling Plan, and the Quality Assurance Program.
- The chemist evaluates and recommends corrective action to laboratory management in the laboratory's internal Quality Assurance Program and procedures.
- The chemist develops new methodology or modifies existing methodology to improve upon methods of analysis currently in use in DEA or state/local laboratories.
- The chemist provides assistance to prosecuting attorneys at trial in more difficult court cases, through rebuttal testimony or preparation of questions for the cross examination of opposing experts.

- The chemist participates as a member of laboratory system committees such as technical seminars, the Ad Hoc Equipment Review, and the Ad Hoc Technical Review Committees, which provide input into system policies.
- The chemist serves as a trainer at the DEA Basic Forensic Chemist School or participates in training seminars for other agency training programs or state/locaL laboratories.
- The chemist analyzes investigative information obtained in the course of complex clandestine laboratory investigations to determine what is being manufactured, routes of synthesis, and production capabilities.

FACTOR 6 - PERSONAL CONTACTS

This factor measures the kind, level, role, and authority, of people contacted and the conditions and circumstances surrounding the contacts. Careful consideration should be give to the frequency of contracts to avoid crediting contacts made on an occasional basis only.

GS-12 and GS-13 - Level 6-3 --- 60 Points

Contacts are with other chemists and scientific personnel in DEA laboratories, academic organizations, industry and private laboratories, criminal investigators, Assistant U.S. Attorneys, State Assistant District Attorneys, and defense attorneys.

FACTOR 7 - PURPOSE OF CONTACTS

This factor measures the reason for making the contacts listed in Factor 6 and the difficulty involved in justifying, defending or persuading others to accept the information presented.

GS-12 and GS-13 - Level 7-3 --- 120 Points

The purpose of contacts is to resolve methodology problems; to convince individuals who are skeptical, uncooperative, or of differing and conflicting opinions; to advise and assist Special Agents in the performance of certain enforcement procedures, such as clandestine laboratory seizures; to confer with and advise other specialists, Assistant U.S. Attorneys, and Assistant State Attorneys on the chemical and technical aspects of clandestine laboratory operations and controlled substances seized from the defendants. Acting as an expert witness, provides courtroom testimony in which defendant's attorney attempts to discredit the chemist's credentials, methodology, results or conclusions or the chemist tries to refute or discredit the testimony of other witnesses. Contacts may be to provide expert advice to other chemists in the application of new procedures or instruments designed to improve the overall quality of experimental results.

Appendix HA-08

POSITION: _____
VACANCY ANNOUNCEMENT NUMBER: _____
NAME OF CANDIDATE: _____

SUPERVISORY EVALUATION FORM

Taking into consideration the duties of the position and the qualification requirements indicated in the vacancy announcement, please make an evaluation on each of the assessment statements below based on the applicant's demonstrated performance in the subject area. For each assessment statement, indicate the degree of opportunity to observe the applicant's performance. Add any additional explanatory narrative on the comment line provided for each assessment element. For any assessment statements which include examples of specialized activities outside the experience of the candidate, please evaluate the candidate's performance in a similar activity and so indicate on the comment line.

A. KNOWLEDGE OF MANAGEMENT PRINCIPLES AND PRACTICES, INCLUDING COMPLIANCE WITH ORGANIZATION'S POLICIES, REGULATIONS AND RULES.

1. Knowledge of written organizational policies and rules e.g., travel, overtime and leave regulations.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Knowledge of written organizational administrative regulations governing laboratory practices e.g. a Laboratory Operations Manual or local laboratory orders.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

3. Knowledge of written organizational technical or analytical procedures e.g. an Analytical Manual.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

4. Ability to locate correct source of information for procedural or policy questions.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

B. ABILITY TO PERFORM ASSIGNED DUTIES WITH APPROPRIATE DEGREE OF SUPERVISION; EFFICIENT USE OF TIME.

1. Ability to complete work product (e.g. sample analysis) in a minimum of time.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Ability to complete special project assignments in a minimum of time.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

3. Ability to organize multiple tasks appropriately and effectively.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

4. Volume of work output (e.g. sample analyses, projects completed or duties performed).

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

5. Degree to which employee is able to work independently with minimal supervision.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

6. Quality of work produced.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

C. DEGREE TO WHICH CANDIDATE SEEKS AND WELCOMES ADDITIONAL RESPONSIBILITIES AND WORK CHALLENGES.

1. Degree to which candidate seeks ancillary duty assignments or research projects.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Response to additional assignments e.g. ancillary duties, research projects, etc. in terms of enthusiasm and appropriate and timely completion.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

3. Degree to which candidate seeks training assignments to increase knowledge or technical skills related to current position.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

4. Degree to which information and/or skill obtained from traininq assignments is used to improve performance.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

5. Degree to which candidate seeks training or developmental assignments in the areas of supervision or management.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

D. ABILITY TO TAKE NECESSARY AND APPROPRIATE ACTION ON OWN; UTILIZE SOUND JUDGEMENT; ORIGINATE IDEAS AND WORK METHODS; AND FOLLOW THROUGH ON IDEAS AND PROJECTS.

1. Ability to make sound decisions and take appropriate action on field assignments involving interaction with non-scientific personnel e.g. clandestine laboratory raids, vacuum sweep operations, or other investigative initiatives.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Ability to solve problems regarding difficult analytical samples or equipment malfunction.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

3. Ability to generate ideas for research projects or new applications for instruments.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

4. Ability to turn ideas into practical projects or new and useful applications.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

5. Ability to generate ideas or initiatives related to improvements in administrative functions (as opposed to technical ideas):

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

6. Ability to bring projects/assignments to successful completion.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

E. SKILLS IN EFFECTIVE ORAL AND WRITTEN COMMUNICATION.

1. Ability to present scientific information at professional meetings or at local staff or group meetings:

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Ability to orally present technical information to non-scientists e.g. in court testimony as an "expert" witness.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

3. Ability to train other chemists as well as non-scientific personnel (e.g. law enforcement agents or attorneys) in technical, job-related duties e.g. clandestine laboratory operations, evidence handling, field testing.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

4. Ability to write research or other reports in clear, concise, accurate language.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

F. LEADERSHIP ABILITY; ABILITY TO MOTIVATE OTHERS TO ACHIEVE A GOAL.

1. Peer group acceptance demonstrated by development of an effective working relationship with peers.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Acceptance as a subject matter expert by end users of laboratory services (e.g. acceptance by prosecutors as an expert witness or acceptance by law enforcement personnel as an expert in clandestine laboratory operations).

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

3. Acceptance by local management as an objective, fair minded individual in his/her dealings with others.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

4. Skill as a peer group leader in resolving problems involving interpersonal conflicts.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

5. Ability to motivate others to perform tasks or to pursue a course of action.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

G. DECISIVENESS - ABILITY TO MAKE DECISIONS AFTER DEVELOPMENT AND CONSIDERATION OF ALTERNATIVES; SELF-CONFIDENCE.

1. Ability to quickly evaluate dangerous, volatile or otherwise critical situations and propose a correct and convincing course of action-(e.g. assisting law enforcement personnel in clandestine laboratory operations or providing advice to prosecutors during trial preparation or expert witness examination).

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Ability to independently resolve complex problems by weighing known facts and mission objectives and providing timely, correct and convincing advice.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

H. INTERPERSONAL SKILLS - ABILITY TO WORK IN HARMONY WITH CO-WORKERS AND SUPERIORS; DISPLAYS TACT AND DIPLOMACY; COMMITMENT TO EEO GOALS.

1. Ability to work effectively with others, giving consideration to their needs and opinions.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Ability to defuse potentially embarassing or awkward interpersonal situations with appropriate response or counsel.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

3. Effectiveness in using tact and diplomacy when interacting with others.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

4. Demonstrated committment to EEO goals.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

I. STRESS TOLERANCE - ABILITY TO FUNCTION EFFECTIVELY UNDER PRESSURE OR CHANGING CONDITIONS.

1. Ability to organize and handle multiple tasks including sample analyses, research or other project deadlines, commitments outside the laboratory (e.g. court commitments), without developing impaired ability to function.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Ability to function under strenuous pressure from others (e.g. cross examination by an adversarial attorney in court).

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

3. Ability to appropriately address confrontational situations with supervisors, peer group members, and end users of laboratory services (e.g. prosecutors and law enforcement personnel).

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

J. SCIENTIFIC KNOWLEDGE IN DAY-TO-DAY ACTIVITIES.

1. Knowledge of chemistry as applied to the analysis of drugs and related substances.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Knowledge of chemistry to solve difficult analytical problems.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

3. Knowledge of instrumentation used in chemical analysis.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

4. Knowledge of instrumentation sufficient to effect repairs.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

5. Knowledge of laboratory safety/accident prevention information including chemical hygiene requirements, emergency spill response and hazardous waste handling procedures.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

K. SKILL AND ABILITY TO CONDUCT SCIENTIFIC RESEARCH.

1. Ability to provide accurate technical advice to other chemists regarding research.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

2. Likelihood of other chemists to seek guidance on technical matters from the candidate.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

3. Demonstrated skill and ability to conduct scientific research.

Assessment:

Superior _ Above Average _ Average _ Below Average

Opportunity to Observe:

Frequently _ Infrequently _ Not Observed

Comments:

Additional Comments: In the space provided, please indicate any additional factors which have a bearing on the applicant's suitability to perform the duties of the position.

Comments:

Signature of Immediate Supervisor Date

The following portion should only be completed when the area of consideration is limited to DEA employees.

Concur
Nonconcur

Reviewing Official's Comments:

_____
Signature of 2nd Level Supervisor Date

TABLE OF EXHIBITS

Exhibit H-01A

SFL1 Monthly Report

Memorandum

Subject	Date
Monthly Report – Month Year (DFN: 901-04.01.01)	

To

Deputy Assistant Administrator
Office of Forensic Sciences

From

Laboratory Director
Special Testing and Research Laboratory

1. Analysis of Evidence

Exhibit Type:

A. Foreign/Referral	DEA	Other Federal	State and Local	Total
Cocaine				
Received				
Analyzed				
No Analysis				
Backlog				

Heroin				
Received				
Analyzed				
No Analysis				
Backlog				

Methamphetamine				
Received				
Analyzed				
No Analysis				
Backlog				

Source, PTP, Fentanyl, Other				
Received				
Analyzed				
No Analysis				
Backlog				

Total				
Received				
Analyzed				
No Analysis				
Backlog				

(b)(7)(E)

(b)(7)(E)

2. Authentic Samples Analyzed

(b)(7)(E)

3. Court

	Appearances	Hours
DEA		
Other		
Total		

4. Staffing

Provide an updated Table of Organization as an attachment. Include positions specific to the laboratory.

Position	Authorized	On-Board	Vacancies
Supervisory/Managerial			
Laboratory Administrative Officer			
Forensic Chemist			
Senior Research Chemist			
Forensic Chemist/Operation Breakthrough			
Quality Assurance Specialist			
Physical Scientist			
Safety/Security Specialist			
Administrative Support Specialist			
Accounting Technician			
Evidence Specialist			
Scientific Intelligence Technician			
Clerical[1]			
Physical Science Technician			
Laboratory Worker			
Contract Employee			
SCEP/STEP			
Totals:			

Narrative(s): *Include a brief narrative concerning committed vacancies and efforts to fill those which are not committed. Indicate number of interviews conducted. Identify selected candidates by name.*

5. Overtime Utilization

Provide an itemized list of overtime hours as an attachment.

6. Field Assistance

A. Reference Standards

Number of Standards	Customer	Location[2]

B. International Training Kits

Number of Kits	Customer	Location

C. Authentication

D. Canine Training Materials

Provide as an attachment.

E. Clandestine Laboratory Seizures

Date	Chemist(s)	Case Number	Location	Drug(s)	Method(s) of Production

F. Trace Evidence Collection

Date	Chemist(s)	Case Number	Location	Drug(s)	Method(s) of Collection

G. Other Operational Assistance

Date	Responder	Case Number	Location	Type of Assistance

7. Training Conducted

Date	Location	Purpose	Audience Type	Participant(s)

8. Training Received

Date	Location	Course Title	Vendor	Participant(s)

9. Meetings Attended/Public Appearances

Date	Purpose	Location	Attendee(s)

10. Liaison Activity

Date	Purpose	Agency/Location	Participant(s)

11. Recognition and Awards

Date	Individual	Type of Recognition

12. Information Requests/Media Contacts

Narrative(s): *Brief narrative describing the subject of the request, response, and a summary of all media contacts.*

13. Laboratory Visitors

Date *Name*

Title/Affiliation

14. Facility Problems and Action Taken

Narrative(s): *Brief narrative describing the nature of the problem and action taken to obtain resolution. Also include security and safety problems which affect the operation of the laboratory.*

15. Obsolete Equipment

List by month for three months all obsolete equipment along with a statement of condition. Drop the oldest month and add new month.

16. Noteworthy Events

Events determined by the laboratory director to be significant in terms of accomplishment or importance, unreported in any previous category.

17. Publications

A. Under Review

B. Published

Footnotes:
[1]Secretary, Clerk-Typist, Program Assistant, Receptionist
[2]Provide locations for all customers except DEA laboratories.

Exhibit H-01B

Laboratory Monthly Report

Memorandum

Subject	Date
Monthly Report – Month Year (DFN: 901-04.01.0_)	

To

Deputy Assistant Administrator
Office of Forensic Sciences

From

Laboratory Director
Laboratory

1. Analysis of Evidence

A. SFL___

Exhibits	DEA	Other Federal	State and Local	MPDC[1]	Backlog Assistance[2] (SFL_)	Total
Received						
Analyzed						
No Analysis						
Backlog						

B. _____ Sub-Regional Laboratory

Exhibits	DEA	Other Federal	State and Local	Total
Received				
Analyzed				
No Analysis				
Backlog				

2. Examination of Fingerprint Evidence

A. Number of Exhibits

Exhibits		DEA	From Other DEA Labs	DEA Sub-Regional Labs	Other Federal Agencies	State /Local	Total
Received	Laboratory						
	Field						
Backlog with FP cards or subject information submitted							
Backlog with no FP cards or subject information submitted							
Specimens Analyzed	Laboratory (400)						
	Field (401)						
Exhibits Processed (405)							
No Analysis							
Exhibits Compared (406)							
Total Exhibits Completed							

The number of exhibits received from another DEA laboratory will not be included in the receiving laboratory's total number of exhibits received during the month; however, the number of exhibits received from another DEA laboratory which have not been completed will be counted on the receiving laboratory's backlog.

B. Automated Fingerprint Identification System (AFIS) Searches/Results

Database	Latent Searches	Latent Identifications	Ten-Print Searches	Ten-Print Identifications
FBI				
DHS				
Regional AFIS				
Total				

3. Court

	Appearances	Hours
DEA		
Other		
Total		

4. Staffing

Provide an updated Table of Organization as an attachment. List sub-regional laboratory personnel in a separate table. Include positions specific to the laboratory.

Position	Authorized	On-Board	Vacancies
Supervisory/Managerial			
Supervisory Budget Analyst			
Laboratory Administrative Officer			
Forensic Chemist			
Quality Assurance Specialist			
Fingerprint Specialist			
Computer Forensic Examiner			
Senior Research Chemist			
Safety & Security Specialist			
Administrative Support Specialist			
Accounting Clerk/Technician			
Evidence Specialist			
Scientific Intelligence Technician			
Court Liaison Specialist			
Clerical[3]			
Physical Science Technician			
Laboratory Worker			
Contract Employee			
SCEP/STEP			
Totals:			

Narrative(s): *Include a brief narrative concerning committed vacancies and efforts to fill those which are not committed. Indicate number of interviews conducted. Identify selected candidates by name.*

5. Overtime Utilization

Provide an itemized list of overtime hours as an attachment.

6. Field Assistance

A. Clandestine Laboratory Seizures

Date	Chemist(s)	Case Number	Location	Drug(s)	Method(s) of Production

B. Trace Evidence Collection

Date	Chemist(s)	Case Number	Location	Drug(s)	Method(s) of Collection

(b)(7)(E)

D. Fingerprint Assistance

Date	Fingerprint Specialist(s)	Case Number	Number of Exhibits	Location	Type of Assistance

	Number of Cases	Number of Exhibits
Field Investigations Needed		

E. Other Operational Assistance

Date	Responder	Case Number	Location	Type of Assistance

7. Training Conducted

Date	Location	Purpose	Audience Type	Participant(s)

8. Training Received

Date	Location	Course Title	Vendor	Participant(s)

9. Meetings Attended/Public Appearances

Date	Purpose	Location	Attendee(s)

10. Liaison Activity

Date	Purpose	Agency/Location	Participant(s)

11. Recognition and Awards

Date	Individual	Type of Recognition

12. Information Request/Media Contacts

Narrative(s): *Brief narrative describing the subject of the request, response, and a summary of all media contacts.*

13. Laboratory Visitors

Date *Name* *Title/Affiliation*

14. Facility Problems and Action Taken

Narrative(s): *Brief narrative describing the nature of the problem and action taken to obtain resolution. Also include security and safety problems which affect the operation of the laboratory.*

15. Obsolete Equipment

List by month for three months all obsolete equipment along with a statement of condition. Drop the oldest month and add new month.

16. Bulk Drug Seizures

Attachments should reflect the template in the Laboratory Operations Manual-Handbook, Exhibit H-01, Attachment 1

17. Noteworthy Events

Events determined by the laboratory director to be significant in terms of accomplishment or importance, unreported in any previous category.

Footnotes:
[1] SFL3 only
[2]The laboratory receiving assistance.
[3]Secretary, Clerk-Typist, Program Assistant, Receptionist

EXHIBIT H-01B

Attachment 1

MONTHLY REPORT

BULK DRUG SEIZURES BY DIVISION

Date of Seizure	Case No.	Exhibit No.	Drug	Net Weight	Progress to Date (See numbers below)	Comments

Total Bulk Drug Exhibits received current Fiscal Year to date -

Total Bulk Drug Exhibits authorized for destruction current Fiscal Year to date -

Total Bulk Drug Exhibits received previous Fiscal Year to date -

Total Bulk Drug Exhibits authorized for destruction previous Fiscal Year to date -

Total Bulk Drug Exhibits pending final disposition by Fiscal Years not listed above -

Use the following notations for reporting Progress to Date:

0. No action taken.

1. United States Attorney notified.

2. United States Attorney agreed to destruction.

3. Exception requested by United States Attorney.

4. Exception denied.

5. Exception accepted.

6. Appealed by United States Attorney.

7. Appeal denied.

8. Appeal accepted.

9. Permission received to destroy amount above threshold after appeal.

10. Destruction completed of amount above threshold.

11. Transferred to other jurisdiction.

12. Court order issued to hold drug exhibits.

13. Not separated. Supervisory approval noted.

14. 60-day letter requested: no response to date. (Applicable for exhibits determined to meet bulk criteria after analysis.)

Exhibit H-02

SUGGESTED FORMAT OF POSTER SESSION PRESENTATIONS

SUGGESTED FORMAT OF

POSTER SESSION PRESENTATIONS

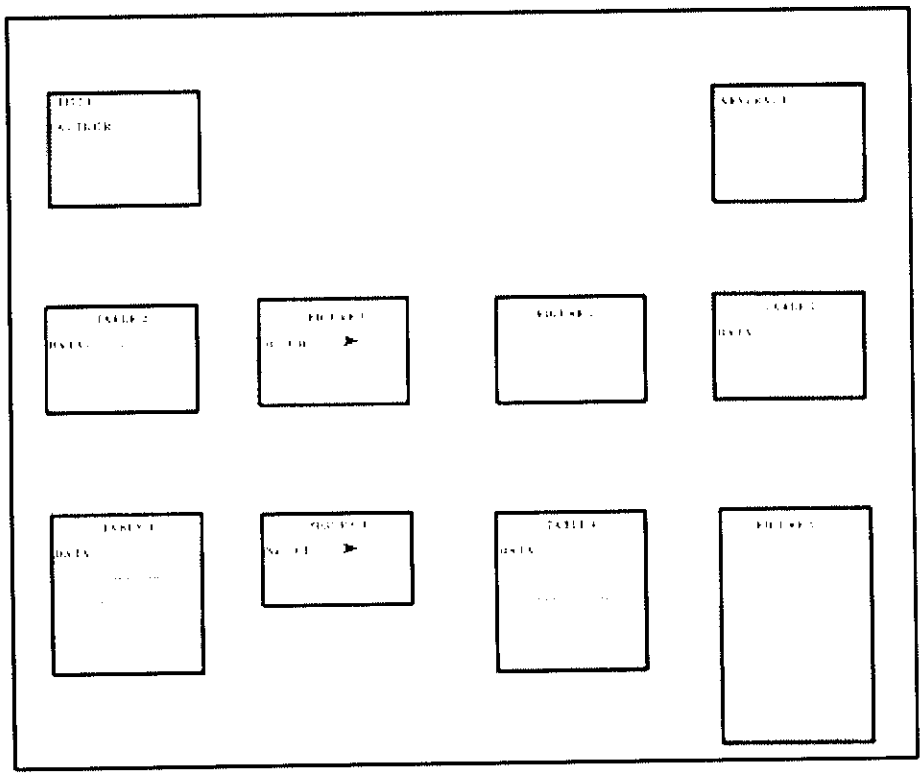

Exhibit H-03

SCHEDULE FOR ORIGINATING LABORATORY

QUALITY ASSURANCE PROGRAM

Laboratory	Month
Special Testing and Research	April, August, December
Northeast	March, July, November
Mid-Atlantic	February, June, October
Southeast	January, May, September
North Central	April, August, December
South Central	March, July, November
Western	February, June, October
Southwest	January, May, September

Exhibit H-04

QAP MONTHLY SUMMARY REPORT FORM

DEA Quality Assurance Program - Monthly Summary Report

QAP Sample Number _____

Principal Active Constituent _____

		Other		
		Substances	Quant.	Conditions (Column, temp., solvent, etc. -
Laboratory	%	Reported	Method	Include inter. std. infor. as appropriate)
Original	-	-	-	-
STL 1 (Uncomposited)	-	-	-	-
(Composited)	-	-	-	-
STL 2	-	-	-	-
STL 3	-	-	-	-
STL 4	-	-	-	-
STL 5	-	-	-	-
STL 6	-	-	-	-
STL 7	-	-	-	-
STL 8	-	-	-	-

Mean (QAP results from composite portion only) _____

Objective for Precision Limits (+ %) _____

Range (all values)_____

Exhibit H-05

Best Available Copy

BPA EXEMPLAR

Page 1

ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PAGES 1

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER: [illegible]
2. CONTRACT NO. (If any): [illegible]
3. ORDER NO.: [illegible]
4. REQUISITION/REFERENCE NO.:
5. ISSUING OFFICE (Address correspondence to):
6. SHIP TO: (Consignee and address, ZIP Code)
   [illegible] Laboratory [illegible]
   [illegible], Texas [illegible]
   [illegible] Laboratory Director
   SHIP VIA: [illegible]
7. TO: CONTRACTOR (Name, address and ZIP Code)
   [illegible]
   [illegible]
   [illegible], Texas [illegible]
8. TYPE OF ORDER
   - ☐ A. PURCHASE Reference your ______
     Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheets, if any, including delivery as indicated. This purchase is negotiated under authority of
   - ☐ B. DELIVERY – Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.
9. ACCOUNTING AND APPROPRIATION DATA
10. REQUISITIONING OFFICE
11. BUSINESS CLASSIFICATION (Check appropriate box(es)): ☐ SMALL ☐ OTHER THAN SMALL ☐ DISADVANTAGED ☐ WOMAN OWNED
12. F.O.B. POINT: [illegible]
13. PLACE OF INSPECTION AND ACCEPTANCE
14. GOVERNMENT B/L NO.
15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date): [illegible]
16. DISCOUNT TERMS

17. SCHEDULE (See reverse for Rejections)

ITEM NO. (A)	SUPPLIES OR SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)	QUANTITY ACCEPTED (G)
	This Blanket Purchase Agreement (BPA) is issued to [illegible] supplies/services as ordered by DEA personnel from [illegible] through [illegible]. The vendor will accept oral orders [illegible] the need for [illegible]. This agreement does not obligate the Government [illegible] to procure any supplies or services from this vendor except [illegible] to the extent as may be agreed upon in connection with individual orders.					
	The following personnel are authorized to place orders: (Insert names of authorized personnel)					
	The Government shall be responsible for assigning a Job Order number for each call placed against this BPA. The vendor shall submit monthly invoices, showing all Job Order numbers, date of order, items involved, unit and total costs, delivery date, and BPA number.					
	Individual Job Orders shall not exceed (insert applicable amount) per call per day. The total amount billed under this order shall not exceed (insert amount shown in first paragraph).					

17(H). TOTAL (Cont. pages)

SEE BILLING INSTRUCTIONS ON REVERSE

18. SHIPPING POINT
19. GROSS SHIPPING WEIGHT
20. INVOICE NO.
21. MAIL INVOICE TO: (Include ZIP Code)
    Insert address shown in "Ship to" block.

17(I). GRAND TOTAL

22. UNITED STATES OF AMERICA BY (Signature)
23. NAME (Typed)
TITLE: CONTRACTING/ORDERING OFFICER

NSN 7540-01-152-8083

OPTIONAL FORM 347 (10-83)
Prescribed by GSA
FAR (48 CFR) 53.213(e)

Exhibit H-06

RESEARCH PROTOCOL FORMAT FOR RESEARCH SPECIAL STUDIES

1. Name of Laboratory. (Self-explanatory.)

2. Name(s) of Researcher(s). (Self-explanatory.)

3. Date of Submission. (Self-explanatory.)

4. Title. (The title should be descriptive, yet concise.)

5. Statement of the Problem. (Briefly describe why this study is needed.)

6. Approach. (Tell how the problem is to be solved. Include any available evidence that the proposed approach will succeed.)

7. Equipment Needs. (List any equipment or materials needed to complete the proposed work that is not already available in the laboratory. Include approximate costs.)

8. Time. (Estimate the staff hours needed to complete the study.)

Exhibit H-07

PROGRESS REPORT FORMAT FOR RESEARCH SPECIAL STUDIES

1. Date of Report. (Self-explanatory.)

2. Identifying Number. (Assigned in the memorandum approving the study.)

3. Accomplishments Since Last Report. (Be specific, yet concise. Report accomplishments, not future plans.)

4. Name(s) of Researcher(s). (Only needed if changed since previous report.)

5. Recommendation of Laboratory Director to Continue or Terminate Study. (If the study is to be terminated, give reason.)

6. Ranked Priority. (Assign Number 1 to the highest ranked project.) A different consecutive number should be assigned to each project.

7. Numbers of Hours Programmed for Next Fiscal Year. (Self-explanatory.)

8. Results Anticipated for Next Fiscal Year. (Self-explanatory.)

Exhibit H-08

DEA LABORATORY NOTE INSTRUCTIONS

Date:

*Title
(Title should be brief and specific)
by
(authors[s])
(name of laboratory)

INTRODUCTION:

Provide a brief summary of the project including the reasons for doing it.

EXPERIMENTAL:

Instrumentation

Describe the instrumentation and apparatus used for this project, including model number and pertinent parameters (GC columns, temperature conditions, flow rates, etc.).

Reagents and Solutions

List chemicals and sample/standard solutions used, including source, quality and concentration. As appropriate, list stability and recommended storage conditions.

Procedures

Specify procedures used in sufficient detail to permit duplication of the procedure by another forensic chemist. Include any special hazards and safety precautions.

RESULTS AND DISCUSSION:

Summarize relevant data in sufficient detail to justify conclusions. Include limitations of the method presented, if appropriate, e.g., results of linearity, precision or reproducibility studies. Include a statement addressing whether the procedure satisfactorily solved the problem presented in the "Introduction" section.

ACKNOWLEDGMENTS:

If appropriate, thank individuals, other than co-authors, who have aided materially in the research.

REFERENCES:

List appropriate literature citations and other reference sources, e.g., "private communication."*

* Revision

Exhibit H-09

DEA LABORATORY NOTES EXAMPLE

DEA LABORATORY NOTES

Date

IDENTIFICATION OF SUGARS
USING 1- METHYLIMIDAZOLE
by
(b)(6)
South Central Laboratory

Introduction

After preparation of volatile acetate derivatives, diluent sugars encountered in drug exhibits may be identified by gas-liquid chromatography. The sugars are rapidly acetylated with acetic anhydride in the presence of N-methylimidazole (NMIM). NMIM is a liquid and thus can serve as a solvent, as a base to accept the produced proton, and as a catalyst to promote the acyl transfer reaction.

In the formation of a volatile derivative, pyridine usually serves as the nucleophilic catalyst. However, because of pyridine's unpleasant odor, its removal from the methodology is desirable. Therefore, the use of NMIM is suggested.

Procedure

The usual procedure involves washing a portion of the sample powder with chloroform, then removal of the solvent. Several washings are recommended. After excess solvent is removed by evaporation and the powder is dried, several milligrams of the diluent sugars are taken and dissolved in 3 to 4 drops of NMIM. An additional 4 to 5 drops of acetic anhydride is added and the resulting solution allowed to stand about 5 minutes. After the elapsed time period, one milliliter of chloroform is added to the solution; then approximately 3-4 ul of the reaction mixture is injected directly into the GLC column. The GLC column is a 6', 1/4" OD, glass column packed with 3 percent OV-17 on 100/120 mesh gas chrom O. The column is held isothermally at 190 degrees centigrade to 290 degrees centigrade at 8 degrees centigrade per minute. The final temperature is held for 10 minutes.

Results

This procedure will resolve dextrose, inositol, mannitol, sucrose and lactose. It is rapid and straight-forward with few steps. Wachowiak and Connors recommended similar NMIM methods for qualitative and quantitative determinations of hydroxy compounds (1).

Reference

Wachowiak, R., and Connors, K., Analy. Chem., 51, 27 (1979).

Note: 1-methylimidazole is available from Aldrich Chemical Company, Catalog No. M5, 083-4.

DRUG ENFORCEMENT ADMINISTRATION / U.S. DEPARTMENT OF JUSTICE

DEA Form - 115
(Dec. 1990)

Exhibit H-10

PHYSICIANS STATEMENT REGARDING USE OF

CONTACT LENSES IN THE LABORATORY

Use of Contact Lenses in the Laboratory
Potential Eye Hazards Found in the Laboratory

1. Spills, splashes and vapors and mists of inorganic acids (hydriodic, phosphoric, hydrochloric, sulfuric and nitric acids and others in varying concentrations), alkalies (sodium hydroxide, lithium hydroxide, diethylamine, methylamine and others), organic solvents (mostly chloroform and methylene chloride but also toluene, xylene and others) and other irritant chemicals (phosphorus trichloride, phosphorus oxychloride, formamide, benzyl chloride, thallium III nitrate, mercuric chloride, halogenated organometals and others). Some of the substances react violently with water, air or other chemicals.

2. Brief, heavy exposure to particulates from sawing or otherwise opening packages and containers (e.g., particulates of fiber glass, wood, plastic, metal, controlled substances and diluents).

3. Chemical explosion and fires with splashes, flying glass and smoke.

4. Need for emergency response and unpredictable use of a respirator.

5. Flying metal or plastic from Carver presses used to prepare discs for infrared analyses.

6. Chemicals and particulates from use of fire extinguishers.

7. Conditions of low humidity and high local air flow (i.e., as in fume hoods) which may have a drying effect on contact lenses.

8. Work with natural and synthetic local anesthetics, which are likely to become airborne and, if concentrated in the eye, could provide a level of anesthesia to the eye that could possibly mask pain from injuries.

I have reviewed the list of potential eye hazards present in the DEA laboratory and my advice on the wearing of contact lenses in this environment and guidance regarding any special first aid measures to be taken during eye injuries are the following:

_____

Health Professional

Exhibit H-11

LABORATORY PLANNING GUIDE

LABORATORY (Name)

LABORATORY PLANNING GUIDE - FY _____

DATE OF PLAN

EXHIBITS	ACTUAL FY _____	PROJECTED FY _____	PROJECTED FY _____
EXAMINED 1. DEA 2. OTHER FEDERAL 3. OTHER AGENCIES TOTAL	** PERSONS		
BACKLOG 4. DEA 5. OTHER FEDERAL 6. OTHER AGENCIES TOTAL			
ACTIVITIES	ACTUAL FY _____ REQ. HRS / CT. HRS / TOTAL HRS / % OF TOTAL	PROJECTED FY _____ TOTAL HRS. / % OF TOTAL / NOTE	PROJECTED FY _____ TOTAL HRS / % OF TOTAL / NOTE
7. EVIDENCE ANALYSIS - DEA			
8. EVID. ANAL. - FEDERAL			
9. EVID. ANAL. - OTHER			
10. SOURCE DETERMINATION ANAL.			
11. COURT - DEA			
12. COURT - FEDERAL			
13. COURT - OTHER			
14. CLAN LAB INVEST.			
15. ASSISTANCE - OTHER			
16. EVIDENCE HANDLING			
17. HEROIN SIGNATURE PROGRAM			
18. DOMESTIC MONITOR PROGRAM			
19. CHEMCON PROGRAM			
20. QUALITY ASSURANCE PROGRAM			
21. TRAINING CONDUCTED			
23. SUBTOTAL			
23. SPECIAL STUDIES			
24. METHOD DEVELOPMENT			
25. LEAVE			
26. TRAINING RECEIVED			
27. TRAINING - EXCHANGES			
28. INST./EQUIP. / LAB MAINTENANCE			
29. ADMINISTRATION / FUNCTIONS			
30. MEETINGS			
31. MISCELLANEOUS			
32. SCI. MEETING / PROF. DEVELOP.			
34. SUBTOTAL			
35. TOTAL			

36. HOURS REQUIRED TO ELIMINATE PREVIOUS YEAR BACKLOG	
37. TOTAL HOURS REQUIRED	
38. TOTAL REQUIRED STAFF YEARS	
39. STAFF YEARS AVAILABLE	
40. ADDITIONAL STAFF YEARS REQUIRED	
41. ADDITIONAL SUPERVISORY CHEMISTS REQUIRED	

STAFFING SUMMARY	ACTUAL	INCREASE	TOTAL	INCREASE	TOTAL
42. CHEMIST					
43. CLERK					
44. SUPPORT					
45. OTHER (DOD)					

** PERSONS [illegible]

Page 084 of 102

Withheld pursuant to exemption

(b)(7)(E)

of the Freedom of Information and Privacy Act

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Withheld pursuant to exemption

(b)(7)(E)

of the Freedom of Information and Privacy Act

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Withheld pursuant to exemption

(b)(7)(E)

of the Freedom of Information and Privacy Act

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Withheld pursuant to exemption

(b)(7)(E)

of the Freedom of Information and Privacy Act

Exhibit H-13

LABORATORY FINANCIAL PLAN REQUEST

LABORATORY: (NAME)
ORIGINAL LABORATORY FINANCIAL PLAN REQUEST

Estimated Chemist Staff years _____
Request for FY _____
Date of Plan: _____

UFMS SOC	SPENDING SUB-OBJECT CLASS NAME	REPORTING CATEGORY CODE	ESTIMATED Obligations: FYXX	Requested Funding FYXX	RECURRING COSTS	NOTES
	OTHER PERSONNEL COMPENSATION					
11503	Personnel Awards - OPT					
	CIVILIAN PERSONNEL BENEFITS					
12100	Professional Liability Insurance					
	TRAVEL					
21101	Travel					
	Court	XT02				
	Operational Support	XT03				
	Training Conducted	XT04				
	Training Received	XT05				
	Local	XT06				
	Professional Development	XT07				
	Administrative	XT08				
21015	TDY-ETT Waiver (GOV Station Training)	(XT--)				
	Subtotal - Travel					
	TRANSPORTATION OF THINGS					
22010	Transportation of Other Property					
	COMMUNICATIONS, UTILITIES, AND MISC CHARGES					
23311	Telecommunications - Commercial					
23312	Telecommunications - Federal Technology Services (FTS - GSA					
23313	Mobile Communication Devices					
23501	Postage					
	Subtotal - Communications, Utilities, and Misc Charges					
	PRINTING AND REPRODUCTION					
24000	Government Reproduced Materials - Non-Public					
	ADVISORY AND ASSISTANCE SERVICES					
25105	Training Courses					
	Training Registration Fee					
	Professional Development (XT07)					
	OTHER SERVICES					
25207	Storage Protection Destruction of Controlled Substances					
	OPERATION AND MAINTENANCE OF FACILITIES					
25401	Maintenance Repair of Building					
25404	Solid Waste Disposal					
	Subtotal - Operation and Maintenance of Facilities					
	OPERATION AND MAINTENANCE OF EQUIPMENT					
25701	Vehicle Operation Maintenance					
25704	Administrative Office Equip Operation Maintenance					
25705	Information Technology Operation and Maintenance					
25706	Laboratory Equipment Operation Maintenance					
25707	Telecommunications Equip Operation Maintenance					
	Subtotal - Operations and Maintenance of Equipment					
	SUPPLIES AND MATERIALS					
26101	Administrative Office Supplies					
26502	Information Technology Supplies					
26503	Publications Periodicals Subscriptions					
26505	Laboratory Supplies					
26507	Photography Supplies					
26511	Motor Vehicle Fuel and Lubricants					
26512	Motor Vehicle Supplies					
26545	Uniform Clothing and Protective Gear					
	Subtotal - Supplies and Materials					
	EQUIPMENT					
31101	Equipment - Non-capitalized					
31103	Furniture - Non-capitalized					
31501	Information Technology Software - non-capitalized					
31503	Information Technology Hardware - non-capitalized					
31705	Photographic - Non-capitalized					
	Subtotal - Equipment					
	TOTAL					

NOTES:
1
2

Authorized by Melinda A. Smith
Acting Deputy Assistant Administrator

Page 1 of 1
(March 2001)

Exhibit H-14

LABORATORY FINANCIAL PLAN REVISION REQUEST

LABORATORY: (NAME)
REVISED LABORATORY FINANCIAL PLAN REQUEST

Estimated Chemist Staff years: _____
Request for FY _____
Date of Revision: _____

UFMS SOC	SPENDING SUB-OBJECT CLASS NAME	[illegible]	APPROVED PLAN FYXX DATE: _____	ACTUAL OBLIGATIONS AS OF DATE: _____	PROJECTED FULL YEAR OBLIGATIONS FYXX	REVISED PLAN FYXX	NOTES
	OTHER PERSONNEL COMPENSATION						
11570	Personal Awards (OT)						
	CIVILIAN PERSONNEL BENEFITS						
12113	Professional Liability Insurance						
	TRAVEL						
21101	Travel						
	Court	XT02					
	Operational Support	XT03					
	Training Conducted	XT04					
	Training Received	XT05					
	Local	XT06					
	Professional Development	XT07					
	Administrative	XT08					
21114	TDY-ETT Weather (NOV Season Tag to)	(XT--)					
	Subtotal - Travel						
	TRANSPORTATION OF THINGS						
22013	Transportation of Other Property						
	COMMUNICATIONS, UTILITIES, AND MISC CHARGES						
23311	Telecommunications - Commercial						
23312	Telecommunications - Federal Technology Services (FTS) - GSA						
23313	Mobile Communication Devices						
23991	Postage						
	Subtotal - Communications, Utilities, and Miscellaneous						
	PRINTING AND REPRODUCTION						
24001	Government Furnished Materials - Non-Printing						
	ADVISORY AND ASSISTANCE SERVICES						
25104	Training Courses						
	Training Registration Fees						
	Professional Development (XT07)						
	OTHER SERVICES						
25227	Storage Protection Destruction of Controlled Substances						
	OPERATION AND MAINTENANCE OF FACILITIES						
25401	Maintenance Repair of Building						
25404	Solid Waste Disposal						
	Subtotal - Operation and Maintenance of Facilities						
	OPERATION AND MAINTENANCE OF EQUIPMENT						
25701	Vehicle Operation Maintenance						
25704	Administrative Office Equip Operation Maintenance						
25705	Information Technology Operation and Maintenance						
25706	Laboratory Equipment Operation Maintenance						
25707	Telecommunications Equip Operation Maintenance						
	Subtotal - Operations and Maintenance of Equipment						
	SUPPLIES AND MATERIALS						
26001	Administrative Office Supplies						
26002	Information Technology Supplies						
26003	Publications Periodicals Subscriptions						
26004	Laboratory Supplies						
26007	Photographic Supplies						
26501	Motor Vehicle Fuel and Lubricants						
26502	Motor Vehicle Supplies						
26043	Uniform Clothing and Protective Gear						
	Subtotal - Supplies and Material						
	EQUIPMENT						
31001	Equipment - Non-capitalized						
31003	Furniture - Non-capitalized						
31031	Information Technology Software - non-capitalized						
31033	Information Technology Hardware - non-capitalized						
31046	Photographic - Non-capitalized						
	Subtotal - Equipment						
	TOTAL						

NOTES:
1
2

Authorized by Nelson A. Cotton
Acting Deputy Assistant Administrator

Page 1 of 1
March 2007

Exhibit H-15

CLANDESTINE LABORATORY REPORT (INCLUDING INSTRUCTIONS)

Page 1

Best Available Copy

Department of Justice
Drug Enforcement Administration

CLANDESTINE LABORATORY REPORT

1. REPORT DATE: 4/01/9[illegible]
2. DEA LABORATORY: [illegible]
3. CONTROLLED SUBSTANCE(S)/TARGET COMPOUND(S):
   a. Methamphetamine Hydrochloride
   b. [illegible] Hydrochloride
   c. Methadone
4. CHEMIST (Last Name): [illegible]
5. DID CHEMIST RESPOND TO SITE? [X] YES [ ] NO
6. DATE OF SEIZURE: 3/2[illegible]/9[illegible]
7. ENFORCEMENT OFFICE & Gp. No.: [illegible] Div., Gp. 4
8. SEIZED LABORATORY LOCATION (Street Address, City & State): 1[illegible] North [illegible], San Diego, CA
9. CASE AGENT NAME: [illegible]
10. AGENCY CASE NUMBER: [illegible]-1992
11. FILE TITLE: Doe, John
12. LIST OF PREVIOUSLY UNREPORTED PRECURSORS FOUND (include amount and source of each):
   a. [illegible], 200 mls remaining from a [illegible] ml bottle
   Source: [illegible] Chemical Supply, San Francisco, CA
13. CONDITION OF LABORATORY AT TIME OF SEIZURE (Specify for each substance in Item 3):
   - [X] Set up, synthesis in progress: a, c
   - [ ] Set up, no synthesis in progress
   - [ ] Broken down or boxed at lab site
   - [ ] Broken down or boxed in storage facility
   - [ ] Broken down or boxed, being transported in vehicle
   - [X] Extraction, isolation, purification and/or salting of final product: b
   - [ ] Glassware and/or supporting materials not found at site
   - [ ] Other

14. PRODUCTION CAPACITY (Estimate Based on 100% theoretical yield)

CONTROLLED SUBSTANCE/TARGET COMPOUND	WEIGHT: Based on Most Abundant Precursor	WEIGHT: Based on Least Abundant Precursor	Capacities Based on Lab Apparatus per Single Batch
a. Methamphetamine HCl	2000 g	1[illegible] g	2[illegible] g
b. [illegible] HCl	[illegible]	27.5 g	1000 g
c. Methadone	[illegible] g	47.3 g	[illegible] g

15. AMOUNT OF EACH FINISHED PRODUCT

CONTROLLED SUBSTANCE/TARGET COMPOUND	WEIGHT OF PURE SUBSTANCE	QUANTITY: Net Weight	QUANTITY: Net Volume
a. Methamphetamine HCl	[illegible] g	[illegible] g	
b. [illegible] HCl	1[illegible] g	[illegible] g	
c. Methadone	[illegible] g	47.3 g	

16. EDUCATION OR SCIENTIFIC KNOWLEDGE OF OPERATOR (if known)
   a. John Doe has a high school diploma and has been trained by [illegible] to prepare methamphetamine and [illegible] HCl. [illegible] has a PhD in organic chemistry.
17. DESCRIPTION OF LABORATORY SITE
   The laboratory was located in a rural, single family house and detached garage. The house was approximately [illegible] yards from the main access road and approximately 1/4 mile from the nearest family dwelling.
18. CONCEALMENT EFFORTS
   The laboratory property was guarded by three dogs ([illegible]). The main house and the garage were alarmed - doors and windows. Windows in the garage were painted with black paint.
19. RECONSTRUCTION OF EACH SYNTHESIS ROUTE USED
   a. Methamphetamine was synthesized [illegible] as described in Synthesis [illegible], (19[illegible]), [illegible] 21.
   b. [illegible]: [illegible], p. 1[illegible] c. Methadone: [illegible]
20. LIST OF BOOKS, PUBLICATIONS OR NOTES
   Advances in [illegible] Research, Vol. 7, [illegible], Eds., Academic Press, 197[illegible], pp. 2[illegible]-2[illegible]
21. NARRATIVE (optional elaboration of any item)

22. DID CHEMIST INTERVIEW ALLEGED OPERATOR? XX YES ___ NO
23. TYPED NAME AND SIGNATURE: [illegible]
24. DATE SIGNED: 4/01/9[illegible]

DEA Form - 500

Exhibit H-16

Trace Evidence Collection Report

Memorandum

Subject	Date
Trace Evidence Collection Report AB-12-3456	August 5, 2004

To

Mr. Smith
Laboratory Director
Through
John Brown
Supervisory Chemist

From

Jane Brown
Senior Forensic Chemist

The following is a Trace Evidence Collection Report for AB-12-3456/Exhibits 3, 4 and 5:

Background: On May 31, 2004 Special Agent Jill Smith (Little Rock, AR RO, Group 3) requested a vacuum sweep be conducted on three hidden compartments contained in a light blue Chevrolet 1500 van with Virginia tags YMJ-8437 (VIN#12345678910). The sweep was conducted at JDTF, 200 South Quincy in Russellville, AR.

Samples: Exhibit 3 is a sweep of the compartment on the driver's side of the van. Exhibit 4 is a sweep of the compartment on the driver's side towards the rear end of the van. Exhibit 5 is a sweep of the compartment on the passenger's side towards the rear of the van. All exhibits listed above were retained for further testing and include appropriate negative control samples.

The following samples were acquired, analyzed in the field with negative results, and not retained for further testing:

Sweep of compartments in the rear ceiling
Sweep of hidden compartment beneath the back seats

Results: Exhibit 3 (123456): Presumptive (IONSCAN) positive for cocaine. Further testing via GC/MS confirmed the sample was positive for cocaine.

Exhibit 4 (123457): Presumptive (IONSCAN) positive for cocaine. Further testing via GC/MS confirmed the sample was positive for cocaine and tetrahydrocannibinol (THC).

Exhibit 5 (123458): Presumptive (IONSCAN) positive for cocaine. Further testing could not confirm the presence of a controlled substance.

Exhibit H-17

GUIDELINES FOR PREPARING REPORTS

1. Background

A brief summary of facts leading up to the search.

2. Description of the Area Searched

a. Agency case number.
b. Location (state, city, address).
c. Premises (detached home, apartment, automobile, boat, etc.).

3. Retained Samples

a. Describe all samples retained for analysis.
b. Describe the analytical results obtained for all of the retained samples.

Exhibit H-18

DEA-307

AGENCY: DEA Chicago Division
AGENCY CASE NO: 11-92-2345
LAB NO: 55672
DESCRIPTION: [X] USED [ ] ENVELOPE [ ] BOX [ ] OTHER
RECEIVED FROM: S/A Fosdick
DATE RECEIVED: 1/5/93
RECEIVED BY: F.T. Hatch
STORAGE LOCATION: 1 A-2
EXHIBITS:
SUSPECTED DRUG:
ASSIGNED TO:
DATE ASSIGNED:

EVIDENCE DELIVERY

DATE	TO	FROM	DATE	TO	FROM
1/5/93	FBT	cmd	1/8/93	Brat	Jmd
3/18/93	S/A Fodak	flt	3/21/93	gxc	S/A Fosdick

DISPOSITION:
Destroyed: 4-19-93

DEA 307 (Jun 1988) Previous edition is usable. EVIDENCE ACCOUNTABILITY RECORD

DEA SENSITIVE

Exhibit H-19

U.S. Department of Justice — FORENSIC CHEMIST WORKSHEET

J. Frost — 8/14/96 — BI-96-0190/3/52964

One sealed plastic evidence envelope containing a brown paper bag containing 3 clear plastic bags with white powder in each.

Exhibit 3 contains heroin hydrochloride, quinine hydrochloride, and caffeine.

Gross wt: 44.8 g Net wt: 15.5 g

2.0 grams removed for special program.

Exhibit No.	Lab No.	Controlled Substance	Purity	Net Wt.	Gross Wt.
3	52964	Heroin hydrochloride	9.5 %	1.5 g	11.2 g

Reserve powder placed in a new clear plastic bag. The new plastic bag and original packaging placed in original evidence envelope, heat-sealed, and returned to vault.

C.S. Chemist — 8-16-96 — BS 8/17/96

REMARKS
9200.005
8003.005
1581.000

DEA-86

Exhibit H-20

DEA-7

Page 1

U.S. Department of Justice
Drug Enforcement Administration

REPORT OF DRUG PROPERTY COLLECTED, PURCHASED OR SEIZED

1. HOW OBTAINED (Check) ☐ Purchase ☒ Seizure ☐ Free Sample ☐ Lab. Seizure ☐ Money Flashed ☐ Compliance Sample (Non-Criminal) ☐ Internal Body Carry ☐ Other (Specify)

2a. FILE NO: BI-96-0190

2b. PROGRAM CODE:

3. G-DEPID: DA4-H2

4a. WHERE OBTAINED (City, State/Country): Boston, MA

4b. DATE OBTAINED:

5. FILE TITLE:

4c. REFERRING AGENCY (Name)

6b. REFERRAL ☐ Case No. OR ☐ Seizure No.

7. DATE PREPARED: 8/13/96

8. GROUP NO.

9. Exhibit No.	10. FDNN (6 characters)	11. ALLEGED DRUGS	12. MARKS OR LABELS (Describe fully)	APPROX. GROSS QUANTITY 13. Seized	14. Submitted	15. Purchase Cost
1		Heroin	Exhibit 1 contained in three plastic bags. Further contained in one brown paper bag with multiple markings of the name "Jane Stone" printed on the outside of the bag.	45 g	45 g	

16. WAS ORIGINAL CONTAINER SUBMITTED SEPARATE FROM DRUG? ☒ NO (Included above) ☐ YES (If Yes, enter exhibit no. and describe original container to lv)

REMARKS:

Exhibit 1 was seized pursuant to a search warrant from William THOMPSON by Special Agents Butler and Johnson at 4:35 p.m. on August 13, 1996, in the kitchen of THOMPSON's residence at 4324 Maple Lane, Boston, MA. Exhibit was in open view on kitchen counter adjacent to counter top electric range.

17. SUBMITTED BY SPECIAL AGENT (Signature): /s/ W.P. Butler

18. APPROVED BY (Signature & Title): /s/ P.A. Fearless, Group 12 Supervisor

LABORATORY EVIDENCE RECEIPT REPORT

19. NO. PACKAGES: 1

20. RECEIVED FROM (Signature & Date): W.P. Butler 8/13/96

21. Print or Type NAME and TITLE: W.P. Butler, Special Agent

22. SEAL ☐ Broken ☒ Unbroken

23. RECEIVED BY (Signature & Date): J. Frost 8/13/96

24. Print or Type NAME and TITLE: J. Frost, Evidence Technician

LABORATORY REPORT

25. ANALYSIS SUMMARY AND REMARKS

Exhibit 1 was found to contain heroin, quinine, and caffeine.

Gross weight: 44.8 grams
Net weight: 43.3 grams

2.0 grams removed for special program.

26. Exhibit No.	27. Lab No.	28. ACTIVE DRUG INGREDIENT (Established or Common Name)	CONCENTRATION 29. Strength	30. Measure	31. Unit	32. AMT. OF PURE DRUG	33. RESERVE
1	52484	Heroin Comb. as HCl	4.5	%		43.3 g	41.3 g

34. ANALYST (Signature): /s/ C.F. Blatz

35. TITLE: Forensic Chemist

36. DATE COMPLETED: 8/16/96

37. APPROVED BY (Signature & Date): /s/ A.L. Lavoisier

38. TITLE: Laboratory Director

39. LAB LOCATION: New York, NY

DEA Form 7 (Sept. 1995)

Previous edition dated 4/90 may be used until stock is exhausted.

1 - Prosecution

Exhibit H-21

DEA-113

U.S. Department of Justice

Drug Enforcement Administration

LABORATORY REPORT

TO: [illegible]

Date: [illegible]

Requesting Agency No. [illegible]

FROM: [illegible]

DEA Lab. No. [illegible]

Described below is a summary of the analytical findings concerning the referenced exhibit(s) submitted by your agency with letter of transmittal dated [illegible] and received [illegible]. The reserve portion of the exhibit(s) will be returned via [illegible]. Please reference the indicated laboratory number on all future correspondence concerning this case.

Exhibit No.	Received	Found	Reserve
[illegible]	[illegible]	[illegible]	[illegible]

/s/ [illegible]
Forensic Chemist

/s/ [illegible]
Laboratory Chief

NOTE This record will be transferred to a Federal Records Center after two years and will not be readily available

DEA Form 113 (Oct. 1984) — Previous edition dated 3/77 is Obsolete

COPY 1 - ORIGINAL

Exhibit H-22

DEA-12

RECEIPT FOR CASH OR OTHER ITEMS

TO (Name, Title, Address (including ZIP CODE) if applicable)

Robert B. Rosenkranz
Evidence Custodian
Department Justice

FILE NO

FILE TITLE

DATE

G-DEP IDENTIFIER

DIVISION/D STRICT OFFICE

I hereby acknowledge receipt of the following described cash or other items which was given into my custody by the above named individual.

AMOUNT or QUANTITY	DESCRIPTION OF ITEM(S)	PURPOSE (If Applicable)

RECEIVED BY (Signature)

NAME AND TITLE (Print or Type)

WITNESSED BY (Signature)

NAME AND TITLE (Print or Type)

DEA Form 12 (Apr 1983) - 12

Previous edition dated 9-77 may be used until stock is exhausted

Exhibit H-23

DEA-48

U.S. Department of Justice
Drug Enforcement Administration

DISPOSITION OF DRUG EVIDENCE

(Do NOT Use for Non-Drug Evidence)

FILE NUMBER

DATE

FILE TITLE

ORIGINATOR *(Name of Field Office and Case Agent)*

CUSTODIAN *(Name of DEA Laboratory and Laboratory Chief)*

PART I

The following exhibits in this case are no longer needed as evidence and should be

☐ disposed of in accordance with Administration instructions.

☐ transferred to _____ *(Agency)*

AGENT			LABORATORY			
Exhibit No.	Laboratory No.	Drug	Transferred	Destroyed	Received	Stock

CASE AGENT *(Signature)* DATE

APPROVING OFFICIAL *(Signature)* DATE

PART II

On _____ *(Date)* the foregoing exhibits were disposed of as indicated above.

On _____ *(Date)* the foregoing exhibits were transferred to _____ *(Agency)*

EVIDENCE TECHNICIAN *(Signature and Date)*

WITNESS *(Signature and Date)*

LABORATORY CHIEF *(Signature and Date)*

REMARKS

DEA Form - 48
(Feb 1986)

Previous editions are Obsolete

Exhibit H-25

DEA-7A

Page 1

U.S. Department of Justice
Drug Enforcement Administration

ACQUISITION OF NON-DRUG PROPERTY AND REGULATORY SEIZURES

1. BASIS ☐ EVIDENCE ☐ FORFEITURE ☐ TEMPORARY CUSTODY ☐ Safekeeping ☐ Transfer to Another Agency	2. TYPE OF PROPERTY ☐ MONEY ☐ Recovered ☐ Seized ☐ REGULATORY ☐ FINGERPRINTS ☐ OTHER 6. CUSTOMS ORIGINATED CASE ☐ Case No. OR ☐ Seizure No.	3. FILE NO. 5. FILE TITLE 7. DATE PREPARED	4. G-DEP IDENTIFIER 8. PROGRAM CODE

9. EXHIBIT	10. NAME AND DESCRIPTION OF ARTICLES	11. COND. CODE	12. VALUE

13. REMARKS

14. SUBMITTED BY SPECIAL AGENT/INVESTIGATOR (Signature) | 15. APPROVED BY (Signature & Title)

RECEIPT REPORT

16. NO. PACKAGES	17. RECEIVED FROM (Signature & Date)	19. Print or Type NAME and TITLE
18. SEAL ☐ Agent ☐ Unsealed	20. RECEIVED BY (Signature & Date)	21. Print or Type NAME and TITLE

DISPOSITION *(FOR EVIDENCE CUSTODIAN USE ONLY)*

22. Date DEA-48	23. Exhibit	24. Authorized Name	25. Means of Disposition	26. Name

27. REMARKS

28. ANALYST (Signature)	29. DATE	30. APPROVED BY (Signature)	31. DATE

DEA Form 7a (Mar 1995) Previous edition dated 8/92 may be used until stock is exhausted.

Exhibit H-26

DEA-466

DRUG ENFORCEMENT ADMINISTRATION

FINGERPRINT EXAMINATION WORKSHEET

DEA MANUAL AUTHORITY: Laboratory Operations 7302 FES 901.31

1. CASE NO.	2. LAB. NO.	3. CONDITION OF SEALS: ☐ BROKEN ☐ INTACT ☐ NONE
4. DATE RECEIVED	5. RECEIVED FROM	6. SUBJECT NAME(S)
7. REQUESTING OFFICE/AGENCY		8. COMPARISON FINGERPRINT CARDS: ☐ AVAILABLE Submit List/Attach to ☐ NOT AVAILABLE

9. EXHIBIT NO.	10. DESCRIPTION OF ARTICLES

11. METHOD OF EXAMINATION

CHEMICAL: _____

FINGERPRINT POWDER: _____

OTHER (Specify): _____

12. FINDINGS AND RESULTS

WERE PHOTOS TAKEN OF DEVELOPED PRINTS? ☐ YES ☐ NO

13. FORWARD RESULTS OF EXAMINATION TO:

_____ SPECIAL AGENT

DISTRICT/RESIDENT OFFICE

_____ LABORATORY

_____ OTHER

14. DISPOSITION/DESCRIPTION OF RESERVE EVIDENCE

15. EXAMINER'S SIGNATURE	16. DATE REPORTED

DEA Form 466
(May 1988)

Exhibit H-27

OPERATION FOUNTAINHEAD

MAIL TO: DRUG ENFORCEMENT ADMINISTRATION
INTELLIGENCE DIVISION
OPERATION FOUNTAINHEAD
WASHINGTON, D.C. 20537

CASE AND EXHIBIT NUMBER _____

LABORATORY NUMBER _____

DRUG _____

SEIZURE DATE _____

PLACE OF SEIZURE _____

TOTAL WEIGHT OF SEIZURE (KGS) _____

MARKING/LOGO*	COLOR/TYPE WRAPPING	NUMBER OF PACKAGES

*PLEASE INCLUDE A PHOTOGRAPH OF PACKAGE MARKING/LOGO

Laboratory Operations Manual
Laboratory Operations Handbook

Table of Contents

*Approved by the Assistant Administrator of the Operational Support Division. Dates are hyperlinked to the signed Form DEA-45.

** Approved by: Nelson A. Santos
Deputy Assistant Administrator
Office of Forensic Sciences

Date: 07/12/2010

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CHAPTER 70 LABORATORY OPERATIONS

Table of Contents (cont'd.)

Table of Contents (cont'd.)

LABORATORY OPERATIONS MANUAL

DRUG ENFORCEMENT ADMINISTRATION

CHAPTER 70 LABORATORY OPERATIONS

7001 GENERAL

7001.1 SCOPE OF SCIENTIFIC AND TECHNICAL SERVICES. The Drug Enforcement Administration (DEA) laboratories are under the direction of the Office of Forensic Sciences (SF). Each laboratory will provide technical services for DEA and other federal agencies. The *laboratories* may assist state and local governmental agencies in technical matters, provided such assistance does not conflict or interfere with laboratory service to DEA *and other federal agencies.*

7001.11 Laboratory Jurisdictions

Laboratory jurisdictions are as follows:

A. Special Testing and Research Laboratory (SFL1): All foreign offices and their jurisdictions **except as noted for SFL2, SFL4, and SFL7**.

B. Northeast Laboratory (SFL2): Connecticut, Delaware, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Eastern Provinces of Canada (Labrador, Newfoundland, Nova Scotia, New Brunswick, Quebec, and Ontario) and Bermuda.

C. Mid-Atlantic Laboratory (SFL3): District of Columbia, Maryland, Virginia, and West Virginia.

D. Southeast Laboratory (SFL4): Florida, Georgia, North Carolina, South Carolina, Tennessee, Nassau and Freeport Bahamas, **Cayman Islands**, and areas of the Caribbean covered by the Caribbean Field Division including (but not limited to): Curacao, Barbados, St. Croix, Dominican Republic, Haiti, Puerto Rico, Jamaica, and St. Thomas Virgin Islands.

E. North Central Laboratory (SFL5): Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin. SFL5 is also responsible for a sub-regional laboratory in Kansas City, Missouri.

F. South Central Laboratory (SFL6): Alabama, Arkansas, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas.

G. Western Laboratory (SFL7): Alaska, California (except for counties listed as part of the Southwest Laboratory's jurisdictional area), Colorado, Idaho, Montana, Oregon, Utah, Washington, Wyoming, and the provinces of Canada from Manitoba westward.

H. Southwest Laboratory (SFL8): Arizona, Nevada, Hawaii, and Pacific Islands. The following California counties: Imperial, Los Angeles, Orange, Riverside, San Bernardino, San Diego, San Luis Obispo, Santa Barbara, and Ventura.

I. Digital Evidence Laboratory (SFL9): All domestic and foreign offices and their jurisdictions.

J. Mobile Laboratory: As assigned to one of the regional laboratories listed above.

7001.12 Collaboration with Societies and Institutions. Laboratory personnel are encouraged to collaborate with professional societies/educational institutions, with SF approval, where results may be beneficial to the government.

7001.13 Professional Development

A. Participation in Professional Societies. Laboratory employees are encouraged to broaden their professional status through participation in professional societies. Participation may include holding office, serving on committees, delivering scientific presentations at meetings, or organizing meetings. **If an employee seeks to serve in a position for an outside organization in his or her official capacity or seeks to hold an office with fiduciary obligations, they must first seek permission from SF who will coordinate with the Office of Chief Counsel.**

Although membership and participation in professional societies is at the discretion of individual employees, advance authorization must be obtained for the employee to utilize DEA resources (e.g. travel expenses and/or official time). Laboratory Directors may authorize participation in regional forensic science associations for which primary laboratory responsibility is assigned (see 7001.13.D). Official participation in an organization other than a regional forensic science association meeting assigned to an employee's laboratory, for which DEA resources will be requested, must be approved by the Deputy Assistant Administrator, Office of Forensic Sciences (SF). The authorization will continue in the event of a *Permanent Change of Station (PCS)* during the period.

B. Attendance at Scientific Meetings and Conferences. With limited exceptions, active participation in scientific or technical meetings is required in order for DEA resources (official time and travel expenses) to be authorized. Active participation is considered as one of the following:

1. Presentation of a scientific paper or poster session.
2. Serving as an officer in the organization, which requires official participation during the meeting.

3. Serving as a Committee Chair, for which active committee business (full committee meeting, report to membership during business meeting) is to be conducted at the meeting.

4. Serving as a member of a committee for which active involvement in committee business is evident and the committee's role clearly impacts on the mission of DEA.

5. Serving as a moderator of a scientific session.

C. Exceptions to the requirement for active participation are:

1. Forensic chemists *and computer forensic examiners in grades (GS-5 through GS-11)* may be authorized attendance at two meetings in a four-year period without active participation.

2. National and international experts *may* be authorized to attend specialized meetings within their areas of expertise.

3. *All Laboratory Directors, Associate Laboratory Directors, and Section Chiefs, who are members or applicants in the American Society of Crime Laboratory Directors or the American Academy of Forensic Sciences, are authorized to attend those organizations' annual meetings for liaison.*

In the event resource constraints limit the number of participants that can be funded officially, administrative leave may be authorized if the participant attends at personal expense. Approval authority for attendance at scientific meetings and conferences is delegated to Laboratory Directors for regional meetings and conferences within their areas of travel authority, and to SF for national or international meetings and conferences outside the Laboratory Directors' areas of travel authority.

D. Regional Forensic Science Associations. Primary laboratory responsibility to the various regional forensic science societies is delineated below, consistent with laboratory jurisdictional areas.

1. Northeast Association of Forensic Scientists - SFL2.
2. Mid-Atlantic Association of Forensic Scientists – SF, SFL1 and SFL3.
3. Southern Association of Forensic Scientists - SFL4.
4. Mid-Western Association of Forensic Scientists - SFL5.
5. Southwestern Association of Forensic Scientists - SFL6 and SFL8.
6. Northwestern Association of Forensic Scientists - SFL7.
7. California Association of Criminalists - SFL7 and SFL8.

**E. Training/ Professional Development Guidelines for Forensic Chemists. All forensic chemists must remain current in their field. To this end, Laboratory Directors will provide the resources and opportunities for their continued training. The following guidelines for training/ professional development are established:

1. A minimum of twenty hours of training/ professional development every year must be completed. Instruction/ training may be provided by other DEA personnel who have expertise in a specialized area.

2. Training/ professional development must be relevant to the laboratory's mission (e.g. traditional courses or workshops).

3. All training/ professional development received must be appropriately documented.

4. Active participation in scientific or technical meetings as described in Section B above, counts toward the training/ professional development time requirement.

5. Self paced learning may be allowable at the discretion of SF (e.g. computer correspondence course or other distance based course).**

7001.14 Liaison with Foreign Forensic Scientists

A. Liaison between DEA's forensic **chemists, fingerprint specialists, computer forensic examiners,** and their foreign counterparts is encouraged through: the publications Microgram *Bulletin and Microgram Journal*; the drug standards program; forensic chemists' seminars; exchange visits to each other's laboratories; and through discussions at professional meetings.

B. Instructions

1. Field Laboratories and the Special Testing and Research Laboratory.

a. *Exchange visits with foreign forensic scientist(s) will be cleared first through SF. Provide SF with the information described in section 7001.14 B 3 e.*

b. After the visit, send *correspondence providing* complete details of the visit to SF.

c. *Requests for reference standards from foreign countries will be forwarded to SFL1 for processing. Requests will be approved and filled only if the material is to be used as an analytical standard, is available, and if the requesting organization is providing support to a duly constituted law enforcement agency.*

2. Office of Forensic Sciences (SF)

a. Appropriate personnel from either SF or the laboratories will be designated to attend and to report on international meetings.

b. All requests for Microgram *Bulletin, Microgram Journal.* and other technical requests from foreign nationals will be forwarded to SF.

c. Copies of correspondence between SF and a foreign scientist will be sent to the DEA foreign field office and the **Office of ** International Programs Staff having jurisdiction, *as appropriate.*

d. Travel to foreign countries must be authorized as outlined in the DEA Supplement to the DOJ Travel Regulations. Prior to visiting a foreign official or

attending a scientific meeting in a foreign nation, approval of such travel must be obtained from SC through SF. If authorization is granted, SF will:

(1) Notify the Office of International *Programs (OI), the Office of Enforcement Operations (OE).* **the Regional Director, or** Country Attaché concerned, informing them of persons and places to be visited, and providing them with the planned itinerary.

(2) Request country clearances.

(3) As appropriate, ask the *Regional Director* or Country Attaché to make official arrangements and invited to accompany the visiting DEA official.

3. Country Attaché or *Regional Director*

a. Requests for Microgram *Bulletin and Microgram Journal* will be forwarded to SF with comment as to the eligibility of the laboratory or office requesting the publication. Normally, only requests from **law enforcement personnel or forensic scientists** serving law enforcement agencies will be approved.

b. Requests for reference standards from foreign countries will be forwarded to *SFL1 (See 7001.14 B 1 c).*

c. All scientific requests involving drug analysis will be forwarded directly to SF. If written in a foreign language, the requests should be accompanied by a translation. Problems of an urgent nature may be handled by telephone or cable. (Requests involving * pharmacological issues should be directed to the Office of Diversion Control's Drug and Chemical Evaluation Section.)*

d. Requests from foreign forensic scientists pertaining to DEA's forensic chemist seminars should be sent to the Office of Training.

e. Requests from foreign forensic scientists to visit DEA officials *must* be forwarded to SF with as much background on the individuals as possible. The purpose of this information is to make the visit as profitable as possible to both the individuals and to DEA. This information should include the following: full name; title, or rank; professional specialty; name and address of place of employment; special area of expertise; special interest **and reason for visit** (e.g., wishes to visit SFL1 and one field laboratory); a statement of the visitor's English language capability. If the visitor does not speak English, advise on language fluency and whether or not an interpreter will be necessary.

7001.2 AREAS OF RESPONSIBILITY

7001.21 Responsibility to DEA. The major responsibility of the field laboratory is to assist DEA in carrying out its mission, which includes: the analysis of evidence; research projects; assistance in crime scene investigations, such as clandestine laboratories and *trace evidence collections*; expert testimony; preparation and evaluation of field reagents and investigative aids; scientific advice; laboratory personnel training; and participation in DEA training programs.

7001.22 Responsibility of Laboratory Director. The Laboratory Director is responsible for all aspects of laboratory management. Laboratory operations shall meet the standards prescribed by SF.

7001.23 Responsibility for Training. SF is responsible for establishing and maintaining a basic training program for laboratory personnel.

7001.24 Responsibility for Analysis of *DEA Evidence*

All matters pertaining to analysis of *evidence* will be handled by the Laboratory Director **and/or designee** directly with the *appropriate representatives* of the submitting office or their respective designees.

7001.25 Responsibility of Forensic Chemists, **Fingerprint Specialists, and Computer Forensic Examiners**

Forensic chemists, fingerprint specialists, and computer forensic examiners, other than trainees, must develop a working knowledge of all DEA manuals and of the laws and regulations administered by DEA. Each forensic specialist must be prepared to assist in enforcement operations where his or her special training will be helpful, as assigned. He or she should be qualified to act as an instructor on scientific and technical subjects.

7001.3 LABORATORY SERVICES TO LAW ENFORCEMENT AGENCIES. *DEA laboratories will analyze drug, latent print, and digital evidence, for duly constituted state, county, and municipal law enforcement agencies, and for other federal agencies.* This service supplements but does not replace **service provided by** state, county, or municipal laboratories. Laboratory services will be free of cost to agencies which are officially investigating criminal matters relating to disciplines in which DEA laboratories are involved. If *testimony is required, it will be provided free of charge.*

Although it is DEA policy not to accept cases from other crime laboratories which have the capability of conducting a requested *examination, specialized forensic * examinations not available in other laboratories *may* be conducted by DEA (e.g., **purity determination**).

DEA will also assist state, county, municipal, and other federal agency laboratories in the training of their forensic chemists, **fingerprint specialists, and computer forensic examiners, as necessary, and when appropriate.**

7001.31 Restrictions

A. Examinations should not be made if the evidence has been previously subjected to a technical examination in the same scientific field for the prosecution; however, extenuating circumstances may *require* that a re-examination be performed. In these cases, re-examinations may be performed with the approval of the Laboratory Director.

B. In instances where such re-examinations are performed, it is the policy of the Office of Forensic Sciences not to furnish testimony for the prosecution if testimony on the evidence is furnished by another expert in the same scientific field on the same technical subject.

C. When a demand for testimony or reports is received in cases in which re-examinations have been made, the Laboratory Director will immediately notify the Office of Chief Counsel (CC) for direction and will proceed under guidance of 28 CFR, *Section 16.21* through 16.26.

7001.32 Request for Laboratory Examination

A. *Requests* may be made by letter **or other appropriate means** to the Laboratory Director of the DEA laboratory.
B. Name of subject, if known, and requesting agency case number should be furnished.
C. Nature of the violation should be *provided*.
D. Type of examination(s) desired should be stated.
E. Type of drugs suspected, **gross weight, and net weight** should be indicated (if applicable).
F. *Facts in the case pertinent to the laboratory examination should be provided.*
G. Previous correspondence on this case, if any, should be referenced.
H. *A statement will be included indicating that the evidence has not been and will not be examined by another expert in the same scientific field.*

7001.33 Action on Completed Laboratory Examination. After the examination is completed, DEA will send a *report of* analytical results to the contributor.

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7001.34 Restrictions on Training. Training is restricted to scientists of law enforcement agencies or those designated by such agencies to service their programs. Such training will not exceed one week without prior approval by SF.

7001.35 Drug Standards Program

A. Requests for drug standards will be sent directly to the Laboratory Director servicing the area from which the request was made.

1. Requests for standards made to a laboratory from outside its area of jurisdiction will be forwarded to the appropriate laboratory for processing.
2. *Requests for standards made to a laboratory from foreign countries will be forwarded to SFL1* as outlined in *7001.14B 1 c.*

B. Requests for standards must be made in writing. Telephone requests will only be honored in extreme emergencies **with the consent of SF**.

1. The requesting organization must be registered with DEA and must be a laboratory providing service to a law enforcement agency. All distributions of Schedule I and II controlled substances must be in accordance with 21 CFR 1305.03.

2. The Laboratory Director will be responsible for ascertaining the requesting organization's eligibility to be furnished standards under these criteria.

C. Amounts of standards furnished should not exceed 10-20 milligrams and will normally be restricted to those substances for which no commercial source exists.

1. All laboratories will maintain a list of sources for commercially available materials.

2. Under unusual circumstances, the Laboratory Director may furnish small amounts of commercially available material, with the understanding that in the future the material will be procured by the requesting agency from a commercial source.

D. *Requests for standards that are not available at the receiving laboratory.*

1. If a request is received for a drug standard which is not available, the request will be forwarded to a laboratory having a sufficient amount of the standard on hand.

2. If a request is received for a drug standard on a DEA-222, U.S. Official Order Form for Schedule I and II Substances, and the receiving laboratory is unable to fill one or more items, either:

a. The entire form must be endorsed on the reverse with the *following statement: "this form has been forwarded for filling to a laboratory found to have a sufficient supply of materials"*; or

b. The form must be returned to the requestor with directions to list the unfilled items on another form and submit it to the laboratory having the items available.

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7002 ANALYSIS OF DRUG EVIDENCE

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**7002.3 CONTROLLED SUBSTANCE ANALOGUES

7002.31 Objective. The Office of Forensic Sciences (SF) must be notified in a timely fashion when a potential controlled substance analogue case is identified by a laboratory.

7002.32 Background. A potential controlled substance analogue case may be identified in a number of ways, including, but not limited to, the following: a request may be made for an analyst to testify in an analogue case or Daubert hearing; a request may be made for an analyst to render an opinion regarding structural similarity and/or application of the analogue statute for use in legal proceedings or other actions; an analyst may identify a substance in an exhibit which is suspected of being a potential controlled substance analogue (as defined in 21 USC 802 (32A)).

7002.33 Procedure. Whenever a potential controlled substance analogue situation is identified, pertinent information must be provided, through the laboratory chain of command, to SF (via email, attention SFL). The pertinent information includes, at a minimum, the following:

a. Case and exhibit number(s)
b. Name and telephone number of the case agent
c. Name and telephone number of the prosecutor/AUSA (if applicable)
d. Name of chemist involved (if applicable)
e. Chemical name of the substance(s) in question and description of the issue.

In addition, when substances are identified which have previously been determined to be analogues, or which have the potential to be determined analogues, terms such as "no controlled substance identified" must not be used on reporting documents. When these types of substances are identified, analysts should report the name of the substance. Communication with the case agent is recommended so that he/she understands the

situation regarding the control status of the identified substance and the procedure required to make a determination as to the substance's control status. SF will coordinate questions and control status determinations regarding analogue issues with the Office of Chief Counsel, the Office of Enforcement Operations and the Drug and Chemical Evaluation Section (ODE) in the Office of Diversion Control.**

7003 ADVISORY SERVICES

7003.1 DRUG ENFORCEMENT ADMINISTRATION. The Laboratory Director shall be the principal scientific advisor for DEA offices in the laboratory's area of jurisdiction. Questions of a scientific nature may be referred to the Laboratory Director for an opinion.

7003.2 OTHER GOVERNMENT AGENCIES. The Laboratory Director may supply scientific information requested by other government agencies within the scope of laboratory activity and specialization.

7003.3 INDUSTRY. The Laboratory Director may provide information regarding technical matters within the area of the laboratory's functions to representatives of business or industry, provided that the request is in the interest of DEA **and approved by SF**.

7003.4 FOREIGN NATIONALS AND GOVERNMENTS. Requests to field laboratories for any type of information from foreign nationals of foreign governments are to be forwarded to SF for reply, with the exception of requests regarding scientific papers published in the open literature by a member of the laboratory staff.

Requests from foreign nationals and governments to SFL1 *will* be responded to by that laboratory with copies provided to SF **and to CC**.

7004 SCIENTIFIC ASSISTANCE

The Laboratory Directors will make forensic chemists, **computer forensic examiners,** and fingerprint specialists available to provide scientific assistance to agents in investigations,**as applicable.**

7004.1 DIVERSION INVESTIGATIONS. *Forensic chemists, fingerprint specialists, and computer forensic examiners will assist in conducting diversion investigations, when required. They are responsible for familiarizing themselves with manufacturing processes or other pertinent information regarding the investigation, as necessary, to perform this function. *

7004.2 CRIME SCENE INVESTIGATIONS

7004.21 Clandestine Laboratories. *As required,* forensic chemists will assist Special Agents in investigations of illicit manufacturing operations.

Except under unavoidable circumstances, a DEA forensic chemist should be present at any seizure of a clandestine laboratory. (See Agents Manual 6674).

Following the seizure of a clandestine laboratory, and after the examination of seized exhibits has been completed, the forensic chemist will prepare a written report in accordance with **LOM**7301.3.

7004.22 *Trace Evidence Collection*. Forensic chemists will assist in collection of trace evidence *by* employing a vacuum search or other applicable technique. (See **LOM** 7301.4).

**7004.23 On-Site Computer Forensics Support. Computer forensic examiners will provide on-site computer duplication support in cases where the original evidence cannot be physically removed.

7004.24 On-Site Fingerprint Examination Support. Fingerprint specialists will provide on-site fingerprint examination support in cases where the subject material (e.g., marijuana grow and clandestine laboratory equipment) cannot be transported to the laboratory.**

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7005 EXPERT TESTIMONY

7005.1 PRINCIPLES TO BE FOLLOWED. As an expert witness, the forensic chemist, **computer forensic examiner,** or fingerprint specialist is allowed to express reasons for conclusions and to offer opinions. If possible, *the expert should* first consult with the government's attorney conducting the direct examination to explain any conclusions proposed to be offered during testimony.

The expert should be able to testify in a competent and authoritative manner. Prior to the trial or hearing, he/she should review and organize data and exhibits and give thought to theoretical questions which may arise in the trial. The expert should endeavor to testify in a clear, courteous, and dispassionate manner. Testimony should be as factual as possible, but opinions may be given when permitted by the court.

Should opposing scientific testimony be presented in a trial or hearing, the **DEA** expert will be **made** available to the government attorney *to assist with* preparing questions for cross-examination or in organizing rebuttal testimony.

7005.2 ARRANGEMENTS FOR TESTIMONY OF LABORATORY PERSONNEL

Arrangements for securing testimony of laboratory personnel in DEA cases will be made with the Laboratory Director. Generally, notification for this purpose will be in writing as soon as a firm trial date is set. In situations where testimony is required on short notice, more rapid means of communication will be utilized.

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In order to minimize unnecessary time expenditures for court, every effort should be made to establish the precise date within a trial when the Forensic Chemist or other laboratory employees will be required to furnish testimony. (See 7001.31 regarding arrangements for testimony in non-DEA cases).

7005.3 TESTIMONY FOR THE DEFENSE. 28 CFR 0.103 contains the DEA authority to release information and authorize testimony of DEA officials. This authorization is only for testimony **related to controlled substances** in response to subpoenas issued by the prosecution in federal, state or local criminal cases. Therefore, the *following shall* apply when a laboratory employee is requested to testify for the defense:

A. A laboratory employee testifying as a prosecution witness may disclose, during defense cross-examination, any information the disclosure of which was authorized by the Department of Justice, for example, information which was disclosed during the prosecution's direct examination. Any question asked by the defense which requires the laboratory employee to make disclosures which were not authorized by the Department of Justice may be answered by a laboratory employee only if the defense complies with 28 CFR 16.21 et seq. That is, the laboratory employee may only answer questions (disclose information) directly related to the prosecution's direct examination unless the defense has met the requirements of 28 CFR 16.21 et seq. If the defense asks a question which requires the laboratory employee to make a disclosure which was not authorized by the Department of Justice, the laboratory employee is directed to: (1) advise the court that he or she is prohibited by 28 CFR 16.21 et seq. from disclosing the information demanded unless authorized to do so by the responsible Department of Justice official in consultation with DEA Headquarters; and (2) request an opportunity to consult with the prosecutor and the **Domestic** Criminal Law Section of the Office of Chief Counsel (CCM) to obtain the necessary authorization.

1. If the court authorizes consultation with the prosecutor and CCM, the laboratory employee shall be directed how to proceed.
2. If the court refuses to allow the laboratory employee to consult with the prosecutor and CCM, the laboratory employee shall furnish the court with a copy of the regulations and inform the court that the demand must be referred for the prompt consideration of the appropriate Department of Justice official, through, and in consultation with DEA Headquarters, and shall respectfully request that the court stay the demand pending receipt of the requested instruction.
3. If the court declines to stay the effect of the demand in response to such a request pending receipt of instructions, or if the court rules that the demand must be complied

with irrespective of instructions provided by the appropriate Department of Justice official and DEA Headquarters to not produce the material or disclose the information sought, the laboratory employee shall respectfully decline to comply with the demand in accordance with 28 CFR 16.28. That is, if the laboratory employee is instructed by the court to answer the question(s) regardless of noncompliance with 28 CFR 16.21 et seq. or instructions from the Department of Justice, the employee may not answer the question(s). If the laboratory employee is threatened with contempt, he or she should immediately contact the Section Chief of CCM. If after duty hours the laboratory employee should contact the Section Chief of CCM through the DEA Headquarters Duty Agent. The Department of Justice and DEA Headquarters will fully support the laboratory employee if found to be in contempt of court.

B. A laboratory employee who was not called to testify for the prosecution, but who has been subpoenaed to testify for the defense, may testify for the defense only if the defense complies with 28 CFR 16.21. CCM should be contacted to determine whether the defense has complied with the regulations. When such testimony is sought by the defense, the prosecuting attorney must also be notified. If the demand was not authorized by the responsible Department of Justice official in consultation with DEA Headquarters, or if the scope of the requested testimony at trial exceeds that which was so authorized, the laboratory employee will follow the procedures set forth in 7005.3(A).

C. If a state rule or procedure requires a prosecution witness to submit to a defense deposition, then DEA's authorization for a laboratory employee to testify as a prosecution witness *will* be viewed as authorization for the laboratory employee to submit to a defense deposition before trial. When subpoenaed by the defense to testify at a deposition, the prosecution attorney must be notified. To ensure that the defense attorney does not attempt to explore areas unrelated to the prosecution's case, DEA policy requires that the state prosecuting attorney attend the deposition. If the prosecutor declines, or otherwise fails to attend the deposition, the laboratory employee must contact CCM.

A laboratory employee responding to a defense deposition subpoena: (1) may testify regarding his or her individual actions; (2) may answer specific questions concerning general DEA procedures which were used in the case; (3) may not disclose information about other cases or investigations; and (4) may not disclose **sensitive** investigative techniques, policies, or procedures for which DEA traditionally asserts a law enforcement privilege. Additionally, under no circumstances are documents (reports, charts, etc.) to be provided to the defense at a deposition. These documents are available to the defense from the prosecuting attorney through normal discovery procedures.

7005.31 Disclosure of *Forensic Analysis* Worksheets. Forensic chemists, fingerprint specialists, *and computer forensic examiners* may provide copies of the front and back of their worksheet, when requested under Federal Rule of Criminal Procedure 16, or equivalent State Rule, and when authorized by the prosecuting attorney. Copies of the

worksheets will be provided to the prosecutor only. Copies of the worksheets will not be given directly to a defense attorney by laboratory personnel.

NOTE: For more information about this, review LS-08-002 Disclosure Policy and LS-08-008 Giglio Disclosure Policy.

7006 RECURRING REPORTS

7006.1 DATABASE MANAGEMENT. Data *concerning evidence* is entered from the DEA-7(or -7a) (Report of Drug Property Collected, Purchased, or Seized), **appropriate laboratory results reporting document, and appropriate discipline worksheet.** Data concerning time expenditures is entered from *the* DEA-271 (DEA Laboratory *Staff Time* Expenditures). Laboratory Directors are responsible for the timeliness and accuracy of reports prepared under their direction. SF is responsible for preparing guidelines for these reports and for reviewing accomplishments.

7006.2 LABORATORY MONTHLY REPORT. This report summarizes accomplishments of the DEA laboratories in important areas. Laboratory Directors are responsible for preparing reports for their facilities. SF is responsible for establishing and disseminating the format for these reports and for reviewing submissions (Laboratory Operations Handbook, Exhibit H-1). The report is due by the 7th of each month following the month of the laboratories' accomplishments. If the 7th falls on a Saturday or Sunday the report is due on the *next business day*.

7006.3 ANNUAL REPORT OF RESEARCH. Progress reports regarding assigned research projects are submitted to SF by each laboratory as specified in 7602.24. These reports will be used to prepare the Annual Report of Research and Methods Development. This report will:

A. Cover the period of August 1 - July 31 of each year. (See 7602.24).

B. List all projects begun, continued, or terminated during the report period.

C. Contain all information specified in Laboratory Operations Handbook, Exhibit H-07.

7006.4 BIENNIAL PHYSICAL INVENTORY **OF ACCOUNTABLE PROPERTY**

Biennially a report will be submitted as specified in Administrative Manual in 0315.1, with a copy provided to SF.

7007 TECHNICAL PUBLICATIONS AND PRESENTATIONS

7007.1 SCOPE. This section addresses publications in Microgram *Bulletin, Microgram Journal*, open scientific literature, poster presentations, and oral presentations at public scientific meetings. It is restricted to reports of findings that result from special studies

(see Chapter 76) performed by the staff of DEA laboratories or SF that are part of their officially assigned duties.

7007.11 Benefits of Dissemination. Technical publications and presentations are encouraged. Dissemination of new information by the professional staff of DEA laboratories and SF will contribute to both mission accomplishment and professional development.

7007.12 Conservation of Resources. While the preparation of technical publications and the presentation of scientific findings is encouraged, the resources available for these activities are limited. Laboratory Directors are responsible, under the overall direction of SF, for obtaining maximum benefit from these resources.

7007.2 REQUESTING AND OBTAINING APPROVALS

7007.21 General. *Materials within the scope of this section, except as specified in 7007.24, must be approved by SF before submission for publication or before presentation.*

7007.22 Recommending Officials. Materials produced by staff members of a DEA laboratory will be submitted for review to the Laboratory Director. Materials produced by staff members of the Headquarters Sections will be submitted for review to the Section Chiefs. Suitable materials will be forwarded to SF with a memorandum of transmittal. For publications, the memorandum of transmittal will indicate the proposed journal or magazine. For poster sessions and oral presentations, the memorandum will identify the date, place, and name of the scientific meeting of the proposed presentation. Oral presentations can be submitted for approval either in verbatim form or as detailed outlines. For poster presentations, include copies of all graphs, tables, data to be displayed, and a poster board arrangement. (See LOH, Exhibit H-02 for the sample format).

If materials were produced under a Research Special Study, the identifying number will be included. Materials produced by Laboratory Directors and Section Chiefs will be submitted directly to SF for review and approval.

7007.23 Review Procedures.

A. Following approval of the work by the appropriate recommending officials, an original and two copies will be submitted to SF. For oral presentations, copies of any visual aids will be supplied. The recommending official must ensure that the visual aids have been reviewed before approving their use. A Laboratory Director can request

review by SF personnel. Manuscripts and the content of presentations shall be available for SF review no later than 45 calendar days prior to any deadline imposed on the author(s).

B. *Within one week of receipt of a manuscript, SF will forward copies of the work to one or more Laboratory Director(s) for review by appropriate forensic specialists who possess an in-depth knowledge of the subject matter*. Assistance may be requested from other DEA offices where the subject of the work is in their area of expertise. Selection of the reviewer(s) will be coordinated with Laboratory Directors or office head affected.

The identity of the reviewer(s) will not be made known to the submitting laboratory. The Laboratory Director or a reviewer can suggest that a reviewer-author discussion be initiated. This discussion would be coordinated with SF, and conducted only with the approval of the author's Laboratory Director. The author's Laboratory Director can request a discussion with a reviewer. This request would be coordinated through SF and would be conducted only with the approval of the reviewer's Laboratory Director.

C. To expedite the review process, the recommending official may request a waiver to the *Headquarters review process*. The following conditions must exist and will be communicated in the submission memorandum:

1. The material will be submitted to the editor of a journal that subjects manuscripts to technical review.
2. The submitting author is a *forensic specialist* who has previously had a paper published in a refereed technical journal, or was the lead author on a group paper.
3. *The paper has been submitted to and approved by the Laboratory's in-house technical review process.*

SF reserves the right to initiate a review if it is believed that such a review could be beneficial in producing the highest quality paper. The submitting laboratory will immediately be informed if this decision is made.

D. When a Headquarters requested review is involved, the designated reviewer(s) will perform a technical review of the material presented. The reviewer will be guided by part C. "Ethical Obligations of Reviewers of Manuscripts." These are contained in the "Ethical Guidelines to Publication of Chemical Research" adopted by the American Chemical Society and printed annually in the first issue of Analytical Chemistry. Their comments will be received in SF by the deadline date set on the memorandum requesting the review. (The goal is to have the review completed within 14 calendar days of receipt by the reviewer). Comments may be submitted in rough draft form, if desired.

E. An administrative and editorial review along with appropriate coordination with other Headquarters entities will be performed by SF. Within 14 calendar days of receipt of comments from the technical reviewer(s), SF will provide a memorandum to the submitting laboratory indicating as appropriate:

1. Acceptance of the work as written. This means a manuscript can be forwarded for publication, or a presentation can be given.

2. Acceptance with recommended changes. Once the changes are made the manuscript can be forwarded for publication, or the presentation can be given, and a copy of the revised manuscript, or presentation, will immediately be forwarded to SF.

3. Disapproval of the work as written (reasons to be provided). A revised manuscript, or presentation, must be approved by SF before publication or presentation.

7007.24 Exceptions to Headquarters Approval Requirements

A. To foster rapid dissemination of technical information, oral and poster presentations at regional forensic science meetings may be approved by the Laboratory Director. Each Laboratory Director will institute internal control and approval procedures consistent with 7007.12.

B. Presentations dealing with policy issues and final reports of formal research projects will be subject to approval procedures specified in 7007.2.

C. The Laboratory Director will report presentations in the Laboratory Monthly Report.

7008 REQUEST FOR SPECIAL SERVICES

7008.1 FEDERAL WIDE DRUG SEIZURE SYSTEM (FDSS)

A. See Agents Manual 6662.3 for FDSS/FDIN information.

B. *All efforts will be made to analyze such evidence and enter the results into the STRIDE System within one month of the end of the quarter in which the exhibit was received.*

C. *deleted*

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CHAPTER 71 QUALITY ASSURANCE

7101 *FORENSIC CHEMIST PROFICIENCY TESTING PROGRAM*

7101.1 OBJECTIVE. The objective of the Proficiency Test Program (PTP) is to assess the efficacy of procedures utilized in DEA laboratories for the qualitative and quantitative analyses of drug evidence. All DEA forensic chemists who conduct evidence analysis are required to participate in the program. The program will consist of the following:

A. Interlaboratory Proficiency Test Samples. Three (3) times every year, each Laboratory Director, or designee, will select a sample to be forwarded to all eight (8) laboratories for analysis, including the originating laboratory, for this part of the program. A total of 24 interlaboratory proficiency test samples will be analyzed by each laboratory every year.

B. Internal Proficiency Test Samples. Whenever possible, the Laboratory Director will select one (1) sample per year, from each forensic chemist on staff, for reanalysis by another forensic chemist.

C. External Proficiency Test Samples. Each laboratory will obtain one (1) sample per year from an outside provider for analysis.

D. Blind Proficiency Test Samples. The Office of Forensic Sciences is responsible for *ensuring* that each laboratory receive one blind sample per year.

7101.11 Interlaboratory Proficiency Test Samples

A. SF is responsible for overall coordination of this part of the program. Specific responsibilities include maintaining a schedule for issuance of samples, preparing summary reports on a quarterly basis, and keeping laboratory personnel informed of analytical issues, which are identified by the program.

B. Laboratory Directors and their designee are responsible for the following:

1. Ensuring that Forensic Chemists receive interlaboratory PTP sample assignments on a rotational basis.

2. Ensuring that all analyses are completed and the results, with all supporting documentation, are forwarded to the originating laboratories within the established deadlines.
3. Preparing PTP summaries when they are the originating laboratory.
4. Providing timely and appropriate follow-up action.
5. Maintaining accountability for PTP samples including documentation of sample destruction.
6. Ensuring that depth of analysis, methods employed, and time spent on PTP samples are reflective of sample type and complexity.

C. Quality Assurance Managers are responsible for:

1. Ensuring that all samples selected for the program are dry, homogeneous, and reflective of the usual type of work received by DEA laboratories.
2. The samples selected are disseminated to all laboratories on a timely basis.

D. Forensic Chemists are responsible for:

1. Examining PTP samples assigned to them according to the same standards as routine evidence submissions.
2. Maintaining a sufficient reserve of the PTP sample to permit additional analysis, whenever possible.

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Withheld pursuant to exemption

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of the Freedom of Information and Privacy Act

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7101.13 Internal Proficiency Test Samples

A. Laboratory Directors are responsible for establishing an Internal Proficiency Test Program (IPTP) for drug analysis within their laboratories.

B. Each Forensic Chemist must conduct at least one (1) IPTP analysis every year. Whenever possible, the Laboratory Director will select one (1) sample per year, from each Forensic Chemist on staff, for reanalysis by another Forensic Chemist. Samples for this program will be taken from evidence available for destruction. In addition, samples pending destruction that have been re-analyzed during the year for inspection purposes may be used to satisfy this IPTP requirement. Analytical methodology employed will be consistent with procedures specified in 7101.11.B.6 and D.1 above. Results of IPTP analysis will be evaluated by each Laboratory Director by comparing them to the original analysis and taking appropriate follow-up action, if necessary.

C. The Laboratory Director will notify SF, by memorandum each year, upon successful completion of all IPTP samples. In addition, appropriate follow-up action, if indicated, will be conducted in a timely manner and the results communicated, by memorandum, to SF.

D. After all issues, if any, have been resolved the Laboratory Director will, by memorandum, authorize destruction of IPTP samples.

E. All results of analysis and documentation of follow-up action will be maintained by the Laboratory Director for a period of five (5) years.

7101.14 External Proficiency Test Samples

A. Each laboratory will obtain one (1) sample per year from an outside source approved by SF and the accrediting body.

B. The sample will be analyzed to meet all DEA and test provider requirements. Analytical methodology employed will be consistent with procedures specified in 7101.11.B.6 and D.1 above. Identified controlled substances must be quantitated.

C. Results of analysis will be returned to the test provider within the time limits established by the test provider. Provide only the controlled substance(s) identified on the test provider's document. Do not include identified adulterants and quantitative results in the "comments" section. Also, to meet accreditation requirements, Laboratory Directors must choose the option to have the test provider directly release the results to the accrediting body.

D. At the same time results are returned to the test provider, the Laboratory Director must forward to SF the complete report of analysis including identified adulterants and quantitation results. SF will be responsible for monitoring the results of analysis and notifying any Laboratory Director of possible inconsistencies as described in LOM 7101.12.E above.

E. Destruction of these samples will be authorized in the quarterly PTP report or through other correspondence.

**7102 FINGERPRINT SPECIALIST PROFICIENCY TESTING PROGRAM

7102.1 PRINCIPLE. Proficiency testing is used to test fingerprint specialists (FSs) as well as the individual laboratory that has a Fingerprint Program. The designated Test Administrator (TA) will follow the instructions set forth in the procedure for administering proficiency tests.

7102.11 Scope. Each laboratory with a Fingerprint Program will participate in one annual external latent print proficiency test. All FSs will complete one proficiency test on an annual basis.

7102.12 Proficiency Test Administration. See Fingerprint/ Photography Program Handbook Chapter 11.

7102.13 Technical and Administrative Review. See Fingerprint/ Photography Program Handbook Chapter 11.

7103 COMPUTER FORENSIC EXAMINER PROFICIENCY TESTING PROGRAM

7103.1 EXTERNAL PROFICIENCY TESTING

7103.11 Purpose. To demonstrate that the methods and procedures routinely used in the Digital Evidence Laboratory result in accurate and thorough findings.

7103.12 Scope. The external proficiency test shall be administered once annually to a randomly selected computer forensics examiner.

7103.13 External Testing Protocol. See Digital Evidence Laboratory's ASCLD/LAB-International Conformance Document.

7103.2 LABORATORY PROFICIENCY TESTING

7103.21 Purpose. To demonstrate that the methods and procedures routinely used in the Digital Evidence Laboratory result in accurate and thorough findings.

7103.22 Scope. A laboratory proficiency test shall be administered once annually to every laboratory staff member that handles or processes evidence.

7103.23 Testing Protocol. See Digital Evidence Laboratory's ASCLD/LAB-International Conformance Document.

7103.3 INTERNAL PROFICIENCY TESTING

7103.31 Purpose. The reanalysis of evidence previously examined is a means to test the quality of work performed in a forensic laboratory.

7103.32 Scope. Any case that is closed may be selected by the Quality Assurance Manager for either partial or complete reanalysis.

7103.33 Procedures. See Digital Evidence Laboratory's ASCLD/LAB-International Conformance Document.

7104 ENSURING CONSISTENCY IN LABORATORY OPERATIONS

7104.1 OBJECTIVE. To address and resolve issues of "consistency" in laboratory quality control operations in the laboratory system. These issues can involve technical or operational matters.

7104.2 BACKGROUND. "Consistency," as applied to laboratory quality control operations, is defined as conformance with established operational protocols to ensure that personnel in all laboratories accomplish similar tasks within defined parameters. Establishing consistency will improve efficiency, minimize the occurrence of issues, and establish a basis for evaluating and resolving inconsistencies.

7104.3 PROCEDURE

A. The Quality Assurance Manager (SFQ) in the Office of Forensic Science is responsible for laboratory system quality control, including issues of consistency.

B. SFQ will identify "consistency" issues and prepare the necessary documentation for presentation to the Laboratory Directors for comment.

C. SFQ will prepare a memorandum from SF to the Laboratory Directors requesting input regarding the issue.

D. The Laboratory Directors will utilize, as appropriate, the Quality Assurance Manager within each laboratory in preparing their comments for return to SF.

E. SFQ will prepare a report for discussion with the SF Quality Assurance Committee (SFQAC).

F. SFQ will convene a meeting of the SFQAC.

G. The SFQAC will be comprised of:
1. Associate Deputy Assistant Administrators (SFD and SFE)
2. Section Chiefs from the Laboratory Operations Section and the Laboratory Support Section (at least one must be present).
3. Technical specialists, as appropriate.
4. SFQ.

H. The SFQAC will meet as needed to discuss all pending consistency issues.

I. The SFQAC will evaluate all issues and make appropriate recommendations to SF to resolve the issue.

J. SFQ will prepare and forward the SFQAC recommendation via memorandum through SFD and SFE to SF.

K. SF will concur with the recommendation, remand the recommendation for reconsideration or modification, or assign the recommendation for implementation.

L. Resolution of the issue may be in the form of a revision to the Laboratory Operations Manual or the Laboratory Operations Handbook; a Laboratory System Order which will be incorporated into the LOM or the LOH at a later date; or other means, as determined by SF.

7105 ANALYTICAL INCONSISTENCIES

7105.1 OBJECTIVE. This policy defines levels of analytical inconsistencies that result from laboratory analysis of case evidence and proficiency tests. It also establishes procedures to address, **evaluate** and resolve identified **analytical inconsistencies in the laboratory system. These inconsistencies may involve technical matters which result in the improper reporting of analytical results.**

7105.2 POLICY. Important aspects of a forensic laboratory's analytical product are accuracy and reliability. It is the DEA laboratory system's goal to provide a product of the highest quality. Technical and administrative reviews of reports are carried out to ensure that the quality of analysis and reporting meets established standards. The *Proficiency Testing Programs for forensic chemists, fingerprint specialists, and computer forensic examiners* provide objective measures of reliability. An additional measure is obtained through reanalysis *of evidence* when court testimony is required and the original analyst is unavailable.

**7105.3 ABBREVIATIONS AND BACKGROUND

AI	Analytical Inconsistency
AIR	Analytical Inconsistency Report
LD	Laboratory Director
LQAC	Laboratory Quality Assurance Committee
LQAM	Laboratory Quality Assurance Manager
NFA	No Further Action
SFQ	SF Quality Assurance Manager
SF	Deputy Assistant Administrator, Office of Forensic Sciences
SFQAC	Office of Forensic Sciences Quality Assurance Committee

The term "Analytical Inconsistency" refers to a situation in which two or more conflicting conclusions exist. An investigation will normally be required to determine the correct conclusion and to determine if a reported conclusion was less than fully supportable.

AIs include, but are not limited to, issues associated with:

A. Identifying controlled substances, adulterants, precursors, or diluents during the course of an analysis.

B. Quantitating controlled substances.

C. Fingerprint identifications.

D. Digital evidence examinations.

E. Proficiency test or other analytical results.**

AIs may be identified in a number of ways (e.g., during a review of analytical data within a laboratory, pursuant to submission of Special Program samples to SFL1, during a review of a technical report within the Office of Forensic Sciences or by other means). The primary focus of investigations into analytical inconsistencies is to determine the correct result, identify the root cause of the inconsistency and effect corrective action as may be required to eliminate the recurrence of the conditions responsible for the analytical inconsistency. Typographical and other types of administrative inconsistencies identified during the technical and administrative review process, prior to issuance of a final report, are not considered AIs. However, such inconsistencies must still be resolved internally through training, performance actions, corrective action plans, and preventive action plans, as appropriate.

7105.4 LEVELS OF INCONSISTENCY.

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No type of inconsistency is acceptable without resolution and necessary courses of action may differ based on the facts of the individual case. When a laboratory becomes aware of an inconsistency within the context of this policy, it is the responsibility of laboratory management to immediately notify Headquarters (SF, SFD, or SFE) in an attempt to resolve the situation as detailed in LOM section 7105.5 below.

It is recognized that it is not possible to write policy to cover all situations. When situations occur which are not clearly covered by this policy, laboratory administration will carefully evaluate the circumstances and facts in an effort to make a fair and just determination of action utilizing this policy as a guide.

**7105.5 RESOLVING INCONSISTENCIES

The following procedure is established to address issues regarding AIs in laboratory operations and to provide recommendations for action:

A. The LD is responsible for addressing AIs in his/her laboratory, ensuring that the established procedure to resolve such inconsistencies is followed.

B. SFQ is responsible for managing the laboratory system quality control program to include maintaining files, tracking actions for each AI, and preparing recommendations for SF.

C. The LD must notify SF immediately when an AI has been identified and a written report of the known facts to SF must follow within two weeks.

D. SF will assign the follow-up action on the AI within the Office to SFQ. The LD will be notified, usually through the Associate Deputy Assistant Administrator (SFD), with instructions to conduct an investigation and/or to obtain additional information.

E. Within thirty days following the notification from SFD to conduct an investigation and/or to obtain additional information, the LD will convene a meeting of the LQAC with the following taskings:

1. Investigate and evaluate the root cause of the AI.
2. Recommend a classification of the AI as a Class I, II, III, or NFA.
3. Propose action as may be appropriate to prevent the recurrence of the AI.
4. Initiate the laboratory's corrective and/or preventive action procedures.

F. The LD will utilize the LQAM and the LQAC in conducting the investigation and preparing a response to SF.

G. Following the LQAC meeting referenced in (E) above, the LD will forward a report of investigation containing all documentation related to the AI to SF. This information will be referred to SFQ who will prepare a summation of facts for evaluation by the SFQAC. SFQAC will determine if an issue occurred and will prepare a recommendation for appropriate action.

H. SFQ will convene a meeting of the SFQAC as needed, normally during the first full calendar week each month to discuss all pending AI issues. Within five days prior to the scheduled date of the meeting, SFQ will forward a meeting agenda by email to the SFQAC and SF.

I. The SFQAC will be comprised of the Associate Deputy Assistant Administrators (SFD and SFE), the Section Chiefs from the Laboratory Operations Section (SFL) and the Laboratory Support Section (SFS) (at least one Section Chief must be present) and SFQ.

J. In the event an AI issue arises which must be addressed immediately, an ad hoc meeting of the SFQAC may be called at the discretion of SFQ with the attendees approved by SF.

K. The SFQAC will evaluate the AI by discussing all issues including LD's recommendations and the classification of the AI as Class I, II, III, or NFA. The procedures for a final classification of an analytical inconsistency are addressed in Section 7105.4 of the Laboratory Operations Manual.

L. Following the meeting, SFQ will prepare a report to SF detailing the recommendations of the SFQAC. The recommendations will include a "root cause

analysis" of the AI. Recommendations for actions will focus on effective remediation and an appropriate magnitude of response to prevent a recurrence of the AI.

M. SF will remand the QAC recommendations to SFD for implementation by the LD. The LD will usually have thirty calendar days to implement the recommendations. An exception to this thirty-day rule may be made where warranted, e.g. where long-term monitoring of an individual's performance is required. The LD must monitor corrective actions for effectiveness to ensure that the AI does not recur.

N. The LD will report back to SFD via memorandum by an established due date certifying successful implementation of all corrective actions.

O. The report of the LD certifying successful implementation of all corrective actions will be evaluated by SFQ. If all recommendations have been successfully implemented, SFQ will prepare a memorandum to SF with all documentation recommending that the AI issue be closed. Upon SF's written concurrence, the Laboratory will be notified that the AI has been closed.

P. All documentation associated with the AI will be maintained by SFQ within a secured container for at least one full accreditation cycle.

Q. The Laboratory Director will monitor all recommendations related to an AI to ensure the effectiveness of actions taken. Recurrence of an AI by the same analyst will be discussed and dealt with on a case-by-case basis at an SFQAC meeting.

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7106 HANDLING COMPLAINTS FROM WITHIN AND OUTSIDE THE LABORATORY

7106.1 OBJECTIVE. To provide specific guidance for ensuring that complaints which arise either from within or outside of the laboratory are addressed properly and promptly. These complaints may involve employees within the laboratory system, or may involve a complaint from an entity outside of the laboratory wherein a "customer" expresses a complaint about the work product of the laboratory.

7106.2 PROCEDURE

A. The procedures for addressing complaints from within the laboratory include the following:

1. For Equal Employment Opportunity (EEO) complaints (i.e., discrimination based upon race, color, religion, sex, sexual orientation, national origin, physical and mental disability and reprisal for having participated in an EEO related activity) see Subsection 2713.4 of the Personnel Manual.
2. For Sexual Harassment complaints see Subsection 2713.31 of the Personnel Manual.
3. For Grievances (i.e., matters of concern or dissatisfaction where the relief sought is personal to the employee, and which is subject to the control of management officials of DEA/DOJ) see Subsection 2771.23 of the Personnel Manual. For a list of matters excluded from this grievance process, see Subsection 2771.22 of the Personnel Manual.
4. For violations of DEA Standards of Conduct, the employee should report the incident to his/her immediate supervisor. The supervisor will report the incident to upper laboratory management (to include both the Associate Laboratory Director and the Laboratory Director). Upper management will collate the facts of the incident. If management determines that no violation occurred, the matter will be closed. If it is determined that a violation may have occurred, the matter will be reported to the Office of Forensic Sciences and to the Office of Professional Responsibility (OPR) for action. In instances where an employee prefers to remain anonymous, he/she may call OPR directly to report the allegation.
5. All employee complaints involving the Quality System will be taken to his/her immediate supervisor. If the supervisor cannot rectify the matter, it should then be referred to upper laboratory management. Upper management will review the complaint and determine the validity and the appropriate action to be taken. The employee and the supervisor will be advised of the action. If an employee feels that a Quality System complaint has not been adequately resolved, he/she has the right to request that the complaint be forwarded to the appropriate Associate Deputy Assistant Administrator, Office of Forensic Sciences.

B. The procedures for addressing complaints arising from outside of the laboratory include the following:

1. All external complaints, including complaints involving the Quality System, must be brought to the attention of a laboratory supervisor. The supervisor must document and investigate the complaint and try to rectify the situation. The Laboratory Director must be advised of the situation and its outcome. If the supervisor is unable to rectify a situation, the Laboratory Director or a designated representative will contact the complainant, discuss the situation and attempt to rectify the situation.

2. Situations, which cannot be rectified by laboratory management, will be referred in writing to the appropriate Associate Deputy Assistant Administrator, Office of Forensic Sciences within fifteen days, and, as appropriate, to relevant Headquarters offices.

3. All legal matters concerning re-weighs, re-analyses, court orders, etc., will be referred to the Office of Chief Counsel for advice and counsel.

NOTE: For information on the customer satisfaction survey, review LS-08-012.

7107 MAINTAINING TRAINING, COMPETENCY AND PROFICIENCY TESTING RECORDS

7107.1 OBJECTIVE. To define the procedures for maintaining records of training, proficiency testing, and competency testing.

7107.2 PROCEDURE

All Laboratory Directors must ensure the following:

A. Training folders must be maintained for each proficiency tested staff member. These training folders must include all documentation of required formal training which has been completed. This includes in-service training, technical training, administrative training, EEO training, and competency testing records (including all tests results).

B. Proficiency test documentation must be maintained for all proficiency tested personnel in a folder dedicated to annual proficiency test results. It is not necessary to maintain a separate file for each employee; however, the management staff must be able to access the results of each employee's performance on a specific proficiency test in a timely manner.

C. Upon completion of all training for each analyst, the Laboratory Director will ensure that appropriate documentation is forwarded to the Office of Personnel for inclusion in the employee's official personnel file. This includes a copy of the certification by the Laboratory Director that basic and technical training has been completed, a competency test has been successfully passed, and the analyst is qualified to begin (or resume) the

analysis of controlled substances, latent prints, digital evidence, or toolmark examinations.

7108 QUALITY SYSTEM DOCUMENT MANAGEMENT

7108.1 PURPOSE. Documents that specify quality requirements or prescribe Quality System activities should be controlled to ensure they are adequate, approved for use, and that only current versions of these documents are in use. The Office of Forensic Sciences Quality System Documentation Management Procedure provides the requirements and guidance for document control, approval, and document retention.

The purposes of this procedure are to:

A. Promote consistent document management within the Office of Forensic Sciences and the laboratory system;

B. Establish a uniform and consistent method for the preparation and handling of documentation within the Office of Forensic Sciences and the laboratory system;

C. Specify who approves documents prior to use;

D. Ensure that changes and the current revision status of documents are identified;

F. Prevent the use of obsolete documents and to apply suitable identification to them if they are retained for any purpose;

G. Ensure that all staff have immediate access to current versions of the documentation;

H. Identify the location of documentation both electronic and file copy (hardcopy); and,

I. Provide an accurate historical record and archive of all documentation within the Office of Forensic Sciences and the laboratory system.

7108.2 SCOPE. This applies to all documents that prescribe quality system activities, such as policy manuals, procedural handbooks, laboratory system orders, laboratory orders, standard operating procedures, and documents that specify quality requirements such as quality assurance policies and practices. Unless specified otherwise under 'Official Location' on the Quality System Document Master Lists, all quality system documents will be accessible to all personnel through the Office of Forensic Sciences Document Control Website (SFDCW) and maintained on the Headquarters share drive in the appropriate READ ONLY folder or subfolder with access limited to the Headquarters Document Control Officer (HQDCO) and alternate. All documents identified on the SFDCW are the most current approved versions and will be considered the official

version. Any copy(s) printed from the SFDCW shall not be considered official. It is the responsibility of all personnel to verify against the SFDCW that the most current version of any quality system document is being used. The procedure described will apply to all components within and under the direction of the Office of Forensic Sciences.

7108.3 DEFINITIONS

A. Associated Documentation: Documents that support the implementation of procedures, such as forms, instructions, checklists and guidelines.

B. Document Control: The process of ensuring that policy, procedure and protocol affecting the procedural activities or specifying quality requirements, including revisions, are reviewed for adequacy, approved for release, distributed to and accessible by all personnel performing the prescribed activities / tasks and obsolete copies replaced.

C. Headquarters Document Control Officer (HQDCO): Staff member responsible for posting approved documents on the SFDCW and maintaining these documents on the **appropriate** Headquarters share drive, electronically notifying all impacted staff immediately following posting, archiving obsolete documents; updating the appropriate Quality System Document Master List(s), ensuring that only the most current documents are being used, and ensuring that all personnel within their responsibility have access to these documents. The HQDCO is not responsible for developing the actual content of the documents although he/she may assist in document preparation.

D. Document Control Officer (DCO): Field laboratory staff member responsible for posting approved documents in the laboratory specific folder on the Headquarters share drive, electronically notifying the HQDCO, archiving obsolete documents, updating the laboratory specific Quality System Document Master List, ensuring that only the most current documents are being used, and ensuring that all appropriate personnel have access to these documents. The DCO is not responsible for developing the actual content of the documents although he/she may assist in document preparation.

E. Handbook: Any documentation that provides procedural guidance.

F. Manual: Documentation broadly describing policy, responsibilities and direction for managing and administering operations within the DEA laboratory system.

G. Forensic Science Document Control Website (SFDCW): A static form of current Quality System documents accessed through the Headquarters' Firebird web browser.

H. Quality System Document Master List: A typed matrix of current Quality System documents located on the SFDCW. There will be one for each field laboratory, another for SF, and another for the entire laboratory system. Each list will include the document

name, date of current revision, date of SF concurrence, date of last annual review, and location of obsolete documents.

I. Quality System Documents: Any paper or electronic conveyance of information required by, impacting upon, or pertaining to the Office of Forensic Sciences and laboratories' Quality System.

J. Record: A document stating results achieved or providing evidence of activities performed.

7108.4 RESPONSIBILITY AND AUTHORITY

All components within and under the direction of the Office of Forensic Sciences are responsible for implementation of this Procedure.

A. Deputy Assistant Administrator (DAA), Office of Forensic Sciences (SF), or designee

1. Provides final approval of SF issued manuals, handbooks and laboratory system orders (LSO).
2. Authorizes installation of the DEA Laboratory Operations Manual and SF issued manuals, handbooks, laboratory system orders, and system-wide blank forms by the HQDCO on the SFDCW.
3. Provides final approval of SF internal office orders, section orders, safety and security plans, standard operating procedures (SOP), and site specific blank forms with instructions.

B. Laboratory Director (LD) or designee

1. Reviews changes to laboratory issued manuals and handbooks, laboratory orders (LO), safety and security plans, standard operating procedures (SOP) and site specific blank forms for technical accuracy and consistency with DEA policy and SF direction.
2. Responsible for final approval of laboratory issued manuals and handbooks, LOs, safety and security plans, validated quantitative and qualitative methods, SOPs and site specific blank forms with instructions.
3. Authorizes installation of the laboratory issued LOs, safety and security plans, SOPs and site specific blank forms by the laboratory DCO on the SFDCW and in the Headquarters Share Drive in the appropriate laboratory-specific subfolder.
4. Acts in place of the laboratory DCO (when not available) by posting Quality System documents, updating the Quality System Document Master Lists for laboratory specific issuances, archiving obsolete documents, and electronically disseminating notification of a revision to the HQDCO.
5. Responsible for the overall management of all laboratory, SFDCW and Headquarters laboratory site specific subfolder share drive requirements.

C. Quality Assurance Manager (QAM - Headquarters and laboratories)

1. Reviews changes affecting Quality Systems and makes recommendations for final approval or rejection of proposed changes.
2. Develops / revises Quality System documentation in consultation with the users and other relevant personnel.
3. Ensures that documents are reviewed annually and where necessary, revised to ensure continuing compliance with applicable requirements.

D. Document Control Officer (DCO - Headquarters and laboratories)

1. Ensures that documents include the date of current revision, an authorizing signature (or other acceptable authorizing verification), author of the document, if appropriate, and, if necessary, access details for the current version of the document (e.g., a file path).
2. Posts Quality System documents as links on or within the SFDCW and maintains them as READ ONLY files in the appropriate folder or subfolder in the appropriate Headquarters share dive.
3. HQDCO advises SF headquarters personnel and all LDs via email when a revision is posted on the SFDCW. A copy of the distributed email will be saved in the Email Notification folder on the share drive. The LD or designee, if the LD is not available, will notify their staff via email of a revision.
4. DCO advises the HQDCO via email within one business day when a revision is posted in the laboratory folder (SFL_) of the **appropriate** Headquarters share drive. The distributed email notifying the HQDCO will be saved in the Email Notification folder on the **appropriate Headquarters** share drive. The HQDCO will notify the DAA or designee, appropriate LD and appropriate SF staff via email of a revision.
5. HQDCO ensures that all obsolete versions of revised / updated Quality System documents and forms are archived.
6. As required, oversees distribution of any paper copies of Quality System documents either internally or externally.
7. Ensures that all superseded copies of paper documents are collected and destroyed following accepted practice (i.e., shredding or burning).
8. Ensures that staff members do not maintain unofficial electronic copies of quality system documents.
9. Ensures that superseded / obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.
10. HQDCO maintains the connectivity of hyperlinks on the SFDCW.

E. Laboratory Staff

1. Responsible for implementing changes / revisions when they occur.

2. Responsible for suggesting changes that would enhance the overall operation of the laboratory.

7108.5 QUALITY SYSTEM DOCUMENTS UNIQUE IDENTIFIERS

A. All Quality System documents generated by DEA Headquarters, SF, or the laboratories shall be uniquely identified. Each document shall have the following unique identifiers:

1. Description or title
2. The date issued and / or effective date
3. Page numbering (e.g., 1 of 5, 2 of 5, ... 5 of 5)
4. The total number of pages, or a mark to signify the end of the document
5. Approving authority(ies)

B. In addition to the document's unique identifiers delineated above, Laboratory System Orders and Laboratory Orders will be further identified with a unique alphanumeric designator.

1. Laboratory System Orders will have a seven digit designator (XX – XX – XXX). The first two characters will be **LS**. The middle set of characters will be the last two digits of the calendar year in which the Laboratory System Order was issued. The last three characters will be a sequential number starting with 001 and going through 999.
2. Laboratory Orders will have a nine digit designator (XXXX – XX – XXX). The first four characters will identify the issuing laboratory (i.e., SFL1 .... SFL9). The middle set of characters will be the last two digits of the calendar year in which the Laboratory Order was issued. The last three characters will be a sequential number starting with 001 and going through 999.

7108.6 DOCUMENT MANAGEMENT

A. The Office of Forensic Sciences shall establish and maintain uniform procedures for creating, posting, changing and archiving laboratory system quality documents (internally generated or from external sources). All quality system documents will be posted as links on or within the Forensic Science Document Control Website (SFDCW) and will be maintained on the **appropriate** HQ Share Drive by the HQDCO, unless otherwise identified under 'Official Location' on the Quality System Document Master Lists.

B. Detailed lists of Quality System documents with revision dates, locations and retention periods are located in the Quality System Document Master List -(Headquarters System Wide Issuances) and the SF or SFL_ Quality System Document Master Lists (laboratory-specific issuances).

1. The Quality System Document Master List documents include the DEA Laboratory Operations Manual and SF issued manuals, handbooks, laboratory system orders, and system-wide blank forms. These documents delineate policy and procedure which affect laboratory operations system wide.

2. The SFL_ Quality System Document Master List documents include laboratory orders (LO), safety and security plans, standard operating procedures (SOP) and site specific blank forms. These documents are site specific and affect operations within the laboratory's area of responsibility.

3. The SF Quality System Document Master List documents include office orders, section orders, safety and security plans, standard operating procedures (SOP), and site specific blank forms. These documents are site specific and affect operations within the Office of Forensic Science's area of responsibility.

C. Procedures for document control include:

1. Designation of responsibility (refer to section 7108.4);
2. Information on document unique identifiers (refer to section 7108.5);
3. Assurance that authorized editions of appropriate documents are available to all personnel essential to the proper functioning of the laboratory;
4. Annual review and, as necessary, revision of the documents to ensure suitability and compliance with applicable requirements and policy;
5. Removal and proper marking of obsolete documents;
6. Access and changes to paper and electronic documents; and,
7. Marking of obsolete documents retained for legal or knowledge preservation purposes.

D. The Quality System Document Master Lists identify the documents and Date of Current Revision that specify which procedures shall be applied at a given time. When a Quality System document is revised, the Document Master List must be updated to reflect the date of the most current version.

E. The approving authority (Headquarters or Laboratory) will annually review and revise as needed all Quality System documents.

F. All personnel will have READ ONLY access through SFDCW to all Quality System documents.

G. All Quality System documents will be reviewed and approved for use by authorized personnel prior to distribution.

H. All quality system documents will be posted as links on or within the SFDCW and maintained as READ ONLY files in electronic format on the **appropriate** Headquarters share drive in the appropriate folder / subfolder.

I. The responsibility for posting, updating the Document Master Lists, and archiving is limited to the following individuals.

1. Headquarters – The HQDCO or alternate is authorized to carry out the duties.
2. Laboratories – The LD, the Associate Laboratory Director or the DCO is authorized to carry out the duties.

J. Documents become obsolete when the next revision is approved, the document no longer applies to current operating procedures, or the document is incorporated into another document. The Quality System Document Master List(s) will be updated with Date of Current Revision, Date of SF Concurrence, Date of Last Annual Review and Location of Obsolete Documents.

K. Document changes are reviewed and approved by authorized personnel prior to posting on the SFDCW and maintaining in the **appropriate** Headquarters share drive or controlled distribution of hardcopies.

L. All affected staff will be notified immediately following posting of a revision to a Quality System document.

M. When a Laboratory System Order (LSO) directly revises or affects policy contained in the Laboratory Operations Manual (LOM), a hyperlink must be established in the appropriate section directing the reader to the new policy. The referenced LSO will be specifically added and hyperlinked within parenthesis and double asterisks as follows: (See LS-XX-XXX).

N. If a revision of a Quality System document has an impact on analytical procedure, the following will apply.

1. If an analysis is in progress, the analysis will be completed following direction or guidance in place when the analysis was started.
2. All subsequent analyses will be conducted following the most current revision. The most current revision will be listed on the Quality System Document Master Lists.

O. The revised and new text shall be indicated by a change in font color (from black to red) in any revised document.

P. For posting purposes, all hyperlinked Quality System documents will maintain the original file name. This will limit the amount of hyperlink edits when revisions occur.

Q. For archiving purposes, each document will be given a unique file name addition. The addition will indicate the month, day and year (MMDDYY format) the document

was removed and placed in the obsolete folder. For example, the posted document will be named - Laboratory Operations Handbook.(type of file). The obsolete document will be named – Laboratory Operations Handbook_mmddyy.(type of file).

R. Obsolete electronic versions of all Quality System documents (including forms) will be archived. All archived documents will first be marked with a watermark indicating the document is obsolete.

S. Unless specifically identified as a document that must be retained, all distributed paper copies of obsolete documents will be destroyed.

T. The period of retention of original signed documents will be established by the approving official.

U. Retained copies of obsolete paper documents will be clearly annotated as OBSOLETE. Only the Headquarters or Laboratory QAM will retain copies of obsolete documents retained for legal or knowledge preservation purposes. These documents will be reviewed annually for destruction.

V. Quality system documents that have been rescinded or incorporated into another document must be maintained on the SFDCW and Document Master List(s) for one additional revision cycle. The DCO shall record either "rescinded" or the new location of that document's information in the Document Master List(s) column entry entitled "Date of Current Revision." The document's entire Document Master List(s) entry will be completely removed during the next revision.

W. Internal Audits - The internal audit will address all elements of the Quality System, including testing. Internal audits are coordinated by the QAM to review the Quality System. At least one internal audit should be conducted just before the annual review of Quality System documents to verify that activities continue to comply with the Quality System. Any noted deficiencies can be corrected as part of the annual review and the documents can be revised accordingly.

X. Management Reviews - As part of the annual management visit conducted by the ADAA, Office of Forensic Sciences, a management review of the Quality System will be conducted.

Y. All internal audit and management review findings, and any corrective actions that arise from them will be addressed, documented by the laboratory QAM, and maintained in the laboratory's files.

7109 CONTROL OF QUALITY SYSTEM RECORDS

7109.1 PURPOSE. This section establishes a documented procedure for the identification, collection, filing, indexing, accessing, storage, maintenance, and disposal of Quality System records. Any record that furnishes objective evidence of activity performed or results achieved must be retained. This procedure provides the requirements and guidance for record control.

7109.2 SCOPE. This procedure applies to Quality System records as identified on each Laboratory's Quality System Records List.

7109.3 DEFINITIONS

A. Quality System Record

A quality or technical record specifically required by the Quality System to furnish objective evidence of activity performed or results achieved.

B. Responsible Individual(s)

The individual(s) identified in the Quality System Records List responsible for generating a Quality System record(s).

7109.4 RESPONSIBILTY AND AUTHORITY

A. The individual(s) identified in the Quality System Records List as the generator of a quality record shall be responsible for:

1. Adhering to the control of Quality System records as defined in manuals, handbooks, work instructions or individual procedures.
2. Ensuring that all hard copies of Quality System records are dated and legible (e.g. instrument calibration data, instrument maintenance logs).
3. Ensuring that all electronic Quality System records are either provided to the appropriate individual identified on the Quality System Records List for storage or stored as directed on the Headquarters or Laboratory System drive, as applicable.

B. The individual(s) filing and maintaining the Quality System records shall be responsible for:

1. Maintaining the physical filing system.
2. Filing all hard copies of Quality System records.
3. Ensuring that procedures are followed for the collection, filing, indexing, accessing, storage, maintenance and disposition of Quality System records.

C. All individual(s) accessing Quality System record files shall be responsible for:

1. "Signing out" hardcopies of records, as appropriate. Any person accessing Quality System record files, with the exception of instrument manuals, index books, maintenance logs, etc., will complete an "Out" guide. At a minimum, the "Out" guide will indicate: which file has been removed; who removed the file; and the date the file was removed. The "Out" guide will mark where files have been removed.
2. Promptly returning all removed records following use.

D. The Office Head or Laboratory Director shall be responsible for:

1. Providing adequate and/or secure filing space for paper quality records.
2. Providing a computer or other data base for the storage of electronic quality records.
3. Providing access to the computer or other data base to all personnel generating and needing access to quality records.

7109.5 PROCEDURE

General

1. The Quality System Records List identifies the following: the Quality System records that shall be maintained; the generator(s) of the record(s); the individual(s) responsible for filing and maintaining the records; how the records will be stored; where the records will be stored; who has access to the records; and, the retention time frame of records in active files (generally one year) and on-site archived files before final disposition.
2. Records can be stored on any type of media, such as hard copy or electronic media.
3. Responsibility for developing, revising or completing records accurately and promptly resides with the person(s) responsible for generating the quality record.
4. All quality records must be legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage, deterioration or loss.
5. Filing of Quality Records (Hard Copy): Quality Records shall be stored in appropriate facilities in the location(s) indicated on the Quality Records List.
6. Filing of Quality Records (Electronic): The person(s) responsible for filing electronic quality records shall save the file in the appropriate headquarters or laboratory system share drive or other electronic storage and retrieval system as directed by the Office Head or Laboratory Director.
7. Copies of Quality System records shall not be stored by unauthorized individuals in any personal storage area, binder or electronic media. Such records shall not be considered official.

8. Retention of Quality System Records: Where applicable, Quality System records shall be retained in accordance with DEA filing procedures.

9. Disposition of Quality Records (Hard Copy): DEA policy will be followed for properly disposing of paper records. This may include transfer to a Federal Records Center for a required period, shredding or normal waste disposal.

10. Disposition of Quality Records (Electronic): As directed by the Office Head or Laboratory Director, computerized electronic records may be archived or deleted from the computer.

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CHAPTER 72 STAFFING AND PERSONNEL

7201 AUTHORIZED POSITIONS

7201.1 TABLE OF ORGANIZATION. Laboratories will be staffed consistent with the DEA Table of Organization. Duties and responsibilities of each position are defined in individual position descriptions.

7201.2 LABORATORY STAFFING LEVELS. The following forensic chemist staffing levels are established for the laboratories:

FORENSIC CHEMIST POSITIONS		
NUMBER OF LAB GROUPS AUTHORIZED	SUPERVISORY CHEMIST PLUS FORENSIC CHEMISTS	GROUP SIZE RANGE
1	8-15	8-15
2	16-24	8-15
3	25-36	8-15

7202 FORENSIC CHEMIST PERSONNEL

7202.1 LABORATORY DIRECTOR

The Laboratory Director is responsible for the direction of scientific operations including the operation of the laboratory in an efficient manner and the providing of scientific information to Agents, Diversion Investigators, Intelligence Analysts and to other Administrative Officials. The Laboratory Director exercises third-line supervision over the individual chemists and is accountable for the results of the laboratory. He/she must maintain sufficient contact with all phases of laboratory operations to ensure accurate and complete reports, and to assure a high standard of laboratory productivity through appropriate work programming. The Laboratory Director is responsible for:

A. Keeping laboratory personnel informed on new administrative policy and procedure, and any changes in laws or regulations.

B. Handling laboratory personnel matters, including recruiting and selecting new employees, and recommending or approving promotions and reassignments in accordance with current DEA directives.

C. Training new chemists, and the advance training and development of more experienced chemists, specialists and technicians.

D. Directing the fiscal activities of a laboratory, including budgeting operations funds, effecting procurements, and efficiently accounting for and managing overtime.

E. Evaluating the performance of subordinates.

F. Managing the resources of the laboratory in a competent manner.

G. Conducting administrative review of reports to ensure accurate and complete reports. This review will include verification of items such as case identifier information and summary of analytical results. The Laboratory Director may delegate this authority.

7202.2 ASSOCIATE LABORATORY DIRECTOR

The Associate Laboratory Director is responsible for the daily management of the laboratory and therefore serves as the Laboratory Director's key advisor in formulating policy to meet the goals and objectives of the agency and the laboratory system. He/she oversees the utilization of laboratory resources, resolves problems, develops efficient and effective operating procedures, provides technical guidance, and institutes controls as necessary to accomplish the goals and mission of the laboratory. The Associate Laboratory Director provides second-line supervision to laboratory personnel who report directly to a Supervisory Forensic Chemist. The major duties of the Associate Laboratory Director are as follows:

A. Oversees the day-to-day operations of the laboratory including but not limited to all aspects of the analysis of controlled substances, detection and identification of latent prints, court testimony, and the accountability of evidence, property, and laboratory finances.

B. Monitors changes in policies and requirements. Recommends and implements policy changes within the laboratory in order to meet agency objectives as established by Headquarters and the Laboratory Director.

C. Recommends and implements procedures to ensure that the laboratory operates as effectively and efficiently as possible.

D. Monitors and manages the career development of laboratory personnel.

E. Coordinates technical support to the field in the form of training, scientific support, and trace evidence collection/vacuum searches.

F. Ensures standards and criteria are being met sufficiently to maintain the laboratory's ASCLD/LAB accreditation.

G. Accountable for the laboratory's Quality Assurance Program.

H. Serves as Acting Laboratory Director in the absence of the Laboratory Director.

7202.3 SUPERVISORY FORENSIC CHEMIST

Participates in managing the laboratory, including program planning and policy formulation. Provides day-to-day supervision of a group of chemists, **fingerprint specialists, and other administrative or support staff**; schedules leave and court appearances, directs the workflow to ensure that it is distributed equitably; and ensures required deadlines for work accomplishment are met. Makes administrative and technical review of completed work when appropriate and provides guidance and methodology as required to Forensic Chemists, prescribing depth of analysis of evidence in certain instances. Serves as Acting Associate Laboratory Director in the absence of the Associate Laboratory Director. As first-line supervisor, conducts performance appraisals for the employees assigned to him/her. Supervises the training of basic trainees as assigned, and under the guidance of the Associate Laboratory Director identifies and arranges the training needs of more experienced chemists. Initiates personnel actions in accordance with existing DEA directives.

7202. 4 FORENSIC CHEMIST

The types of work for Forensic Chemists in grades GS-12 through 14 fall into the following four general categories:

A. Examining evidence and reporting the results, with subsequent testimony in court if necessary.

B. Training other chemists and law enforcement personnel.

C. Conducting research in the development of methods and collection of authentic data. Reporting new information through appropriate communications.

D. Performing consultative services for Special Agents, Diversion Investigators, and other law enforcement personnel; assisting in raids on clandestine manufacturers, plant inspections, and related activities; and conducting trace evidence collection, as needed.

The relative importance of each category will vary with different grades. To serve efficiently in the performance of these duties, the chemist must develop and maintain familiarity with the narcotic and dangerous drug laws and regulations, and maintain an awareness of scientific developments.

7202.5 FORENSIC CHEMIST/ENTRY LEVELS

Grades GS-5 through GS-11 are entry level grades. During the first year of career conditional status (the probationary period), a person in these grades should be given as many varied duties as possible and be unobtrusively observed by the Management Staff and other senior chemists. Depending on past experience, he/she may be trained as outlined in 7206. Prior to the expiration of the one-year probation period, an evaluation must be made to determine the individual's ability to perform the full professional responsibilities of the position. On the basis of this evaluation, the trainee may either be retained and recommended for promotion at the end of the year, or not be retained. The basis for advancement through subsequent grades is noncompetitive promotion (advancement to each grade is dependent on individual job performance and progress in mastering professional requirements of the journeyman level).

7203 COMPUTER FORENSIC EXAMINERS AND FINGERPRINT SPECIALIST PERSONNEL

7203.1 LABORATORY DIRECTOR (DIGITAL EVIDENCE)

Basic responsibilities encompass directing all operations of the Digital Evidence Laboratory servicing DEA offices worldwide, by providing forensic science support for any type of digital evidence seized or surrendered to DEA. The Laboratory Director establishes priorities and goals, and develops laboratory methods and operating procedures to ensure the efficient and effective examinations of digital evidence. The Laboratory Director is responsible for:

A. Keeping laboratory personnel informed on new administrative policy and procedure, and any changes in laws or regulations.

B. Handling laboratory personnel matters, including recruiting and selecting new employees, and recommending or approving promotions and reassignments in accordance with current DEA directives.

C. Training new Computer Forensic Examiners, and the advance training and development of more experienced Computer Forensic Examiners.

D. Directing the fiscal activities of a laboratory, including budgeting operations funds, effecting procurements, and efficiently accounting for and managing overtime.

E. Evaluating the performance of subordinates.

F. Managing the resources of the laboratory in a competent manner.

G. Conducting administrative review of reports to ensure accurate and complete reports. This review will include verification of items such as case identifier information and summary of analytical results. The Laboratory Director may delegate this authority.

7203.2 SUPERVISORY COMPUTER FORENSIC EXAMINER

Participates in managing the laboratory, including program planning and policy formulation. Provides day-to-day supervision of a group of Computer Forensic Examiners engaged in the examination of evidence in the laboratory and at times, collection and duplication of digital evidence in the field. Schedules leave and court appearances, directs the workflow to ensure that it is distributed equitably, and ensures that required deadlines for work accomplishment are met. Conducts administrative and technical review of completed work. Serves as Acting Laboratory Director in the absence of the Laboratory Director. Identifies and arranges the training needs of subordinate personnel. Initiates personnel actions in accordance with existing DEA directives.

7203.3 COMPUTER FORENSIC EXAMINER

Grades GS-9 through GS-13 Computer Forensic Examiners are responsible for recovering information from computer devices used to facilitate or perform illegal activities. The major duties include:

A. Performing digital evidence examinations utilizing technical knowledge and data recovery skills to choose technical tools to be used and designing the examination scope in a forensically acceptable manner.

B. Providing expert witness testimony.

C. Serving as a technical advisor to Special Agents, Intelligence Analysts, and prosecutors.

D. Providing technical training as required in areas relative to handling and investigation of digital evidence.

**7203.4 FINGERPRINT SPECIALIST PROGRAM MANAGER

The duties of the fingerprint specialist program manager in grades GS-13 through GS-14 include but are not limited to the following:

A. Serves as a program manager and senior fingerprint specialist for DEA.

B. Keeps abreast of and utilizes knowledge of all current and proposed programs and developments in the area of latent print analysis.

C. Directs and participates in studies to improve program operations and effectiveness.

D. Maintains liaison and coordinates program initiatives with headquarters managers and staff, field laboratory managers and fingerprint specialists, and Federal officials of other forensic science/law enforcement agencies on matters relating to the latent print analysis support program.

E. Develops concepts, methodologies, procedures, and performance criteria for the program that affects the entire laboratory system in support of DEA's and other Federal and state/local agencies' law enforcement activities.

F. Develops program requirements for the laboratory system activities such as handling of latent print evidence, research, method development, crime scene support (including clandestine laboratory seizures), laboratory information management systems, work load, specialized equipment, laboratory facilities alterations, recruitment, safety, training, and security.

G. Serves as DEA's primary authority in the specialized field of forensic science involving the development of latent prints and comparison to known impressions, and processing latent print evidence incident to major drug cases.

H. Serves as the primary technical advisor in the specialized field of forensic science involving the development of latent prints and comparison to known impressions, and processing latent print evidence for all laboratory directors, field laboratory supervisors, and fingerprint specialists.

I. Works to ensure the quality of latent print examinations throughout the laboratory by participating in management visits to review all aspects of the fingerprint specialists' work, consults with laboratory managers when requested concerning latent print quality issues, reviews laboratory orders and standard operating procedures for concurrence with established policy, etc. **

7203.5 FINGERPRINT SPECIALIST

The duties of the Fingerprint Specialists in grades GS-11 through GS-13 include but are not limited to the following:

A. Developing, *preserving* and *comparing* latent prints on various matrices and *reporting* their findings.

B. *Verifying* identification*s* made by another examiner.

C. **Searching AFIS suitable latent prints through IAFIS and regional AFIS systems.**

D. Processing and photographing crime scenes such as clandestine laboratories or other physical evidence that cannot be transported to the laboratory to be examined *for latent prints.*

E. Providing expert court testimony.

F. Assisting DEA personnel with projects requiring specialized photography.

G. Developing and conducting training to DEA personnel regarding the photography of evidence, collection of fingerprint evidence, and collection and preserving evidence in the field.

H. Reviewing the work of other fingerprint specialists to include technical and administrative reviews if necessary. Serves as liaison with SF and the Fingerprint Program Manager.

The relative importance and difficulty of each of the duties outlined will vary with different grades. In order to perform these duties efficiently, the fingerprint specialist must develop and maintain knowledge of the *examination* techniques necessary to examine latent prints *in a wide variety of circumstances.*

7204 GENERAL

The *following sections* set forth the policy and procedures for laboratory personnel actions, training, and the maintaining of credentials. (Note: The policies and procedures for the other personnel activities are set forth in the Personnel Manual, Chapters 22, 23, 24, 25, 26, and 27.)

7205 CREDENTIALS

7205.1 ISSUANCE. A pocket commission is furnished to forensic chemists, fingerprint specialists, DEA computer forensic examiners, and evidence technicians as soon as possible after appointment **and issuance of security clearance.**

7205.2 POLICY. Forensic chemists, fingerprint specialists, DEA computer forensic examiners, **laboratory administrative officers.** and evidence technicians should keep their commission in their immediate personal possession when on official duty. These

credentials shall only be presented as evidence of authority when required or when necessary for official identification purposes.

7205.3 ALTERATIONS. No change may be made in the style of the credentials issued. Any alterations, additions, or changes therein are expressly prohibited. Credentials must be kept in a clean and presentable condition.

7205.4 LOSS OF CREDENTIALS OR IDENTIFICATION CARDS. Every precaution must be exercised to prevent the loss or possible theft of credentials. See Planning and Inspection Manual 8514.2C.

7205.5 ACCOUNTABILITY. Each laboratory must maintain a strict accountability of all credentials and identification cards. A physical inventory will be made of these items on an annual basis.

7206 TRAINING

7206.1 PURPOSE. The purpose of the training program is to enable the individual to best perform his or her duties and to prepare for progression on the laboratory system career ladder.

7206.2 *ORIENTATION AND GENERAL TRAINING*. New employee orientation will be conducted in accordance with Section 2410.1 of the Personnel Manual.

7206.21 Forensic Chemist. The DEA laboratories will provide on-the-job training for Forensic Chemists through conferences, scientific meetings, literature review, technical courses and ancillary duty assignments.

7206.22 Fingerprint Specialist. The DEA laboratories will provide on-the-job training for Fingerprint Specialists through conferences, scientific meetings, literature review, technical courses and ancillary duty assignments.

7206.23 Computer Forensic Examiner. The DEA laboratories will provide on-the-job training for Computer Forensic Examiners through conferences, scientific meetings, literature review, technical courses and ancillary duty assignments.

7206.24 Basic Training of New Hired Forensic Chemists, Fingerprint Specialists, and Computer Forensic Examiners

A. The Laboratory Director should carefully review the background and experience of each newly hired Forensic Chemist, Fingerprint Specialist and Computer Forensic Examiner and tailor training to each individual with the objective of making him or her

fully functional in their job duties in the shortest possible time. Forensic Chemists hired with no previous experience in forensic drug analysis should be trained on a full-time basis using the lesson plans in the appropriate training manual as a guide.

B. Forensic Chemists and Student Career Experience Program individuals being trained using the Basic Training Program for Forensic Drug Chemists shall submit monthly narrative reports on their progress to the Laboratory Director, through their respective immediate supervisor. These reports assist the Laboratory Director in evaluating the trainee's ability to communicate in writing, as well as to gauge progress and point out any errors or weaknesses in the program itself.

C. Upon completion of the training program's lesson plans, and at such a time as the Laboratory Director considers the trainee competent to perform the duties of a Forensic Chemist, Fingerprint Specialist or Computer Forensic Examiner, a competency test must be administered. After successful completion of the test, the Laboratory Director will issue a completion of training certificate and forward a copy to the Human Resources Division (HR) so the appropriate notation may be made in the employee's official personnel file. A copy of the memo to HR should also be provided to SF.

D. As part of the training program, every new Forensic Chemist, Fingerprint Specialist and Computer Forensic Examiner will attend the DEA Basic Forensic Sciences School. Attendance at this school, however, is not a prerequisite to declaring the trainee capable of carrying out his or her assigned duties.

7206.25 Other Laboratory Personnel. Newly assigned individuals to other laboratory positions will receive on-the-job training in such areas as are required to properly perform their duties.

7206.26 Management Development Plan. A broad plan for the development of future supervisors and managers is contained in Appendix HA-05, Management Development Plan. The Management Development Plan includes a suggested format for an Individual Development Plan.

NOTE: For information on noncompetitive career ladder promotions, review LS-05-007 Noncompetitive Career Ladder Promotions.

7206.27 Funding

A. The Laboratory Director is authorized to approve requests for technical training within and outside the laboratory's geographical area of jurisdiction. This training will be provided out of laboratory operating funds.

B. Courses of instruction not technically related to the laboratory's mission or other activities intended for career development should not be funded from laboratory

operating funds. The Office of Training provides funds for this purpose, and requests for this type of instruction must be made on an SF-182 to the Office of Training through SF. In the event that the Office of Training is not able to fund the training, it may be funded using laboratory operating funds.

7206.3 OFFICE OF FORENSIC SCIENCES (SF)

A. SF will coordinate the training of newly hired Forensic Chemists, Fingerprint Specialists, and Computer Forensic Examiners by updating and maintaining the Basic Training Program for Forensic Drug Chemists Manual, the Fingerprint/Photography Handbook, the Digital Evidence Laboratory Standard Operating Procedures, and through the development of other courses in specialized topics in cooperation with the Office of Training.

B. Periodic conferences of Laboratory Directors and other laboratory personnel with SF will be held to discuss administrative and scientific matters of interest.

7207 PERSONNEL ACTIONS

7207.1 INITIATING PERSONNEL ACTIONS. The field laboratories will use the below listed procedures when initiating personnel actions on an SF-52, Request for Personnel Action. Information on promotion actions may be found in Section 2250 of the Personnel Manual.

7207.11 GS-5 through GS-12 Forensic Chemists. See Personnel Manual 2250.1.

7207.12 GS-13 Senior Forensic Chemists, GS-14 Senior Research Chemists, and GS-13/14 Supervisory Chemists. See Personnel Manual 2250.3.

7207.13 GS-13 Senior Fingerprint Specialist. This section addresses the noncompetitive promotion criteria, recommendation and review process for the GS-13 Senior Fingerprint Specialist, GS-0072 series, within the DEA Laboratory System. Promotions to GS-13 are not automatic nor are they an employee entitlement. They are contingent upon: 1) the continued availability of sufficient higher-graded work (as described in the GS-13 Senior Fingerprint Specialist position description), 2) authorized funding, 3) the employee's demonstrated ability to satisfactorily perform the *higher graded* duties, 4) the supervisor's recommendation and the Laboratory Director's certification that the above is evident and, 5) documentation that the employee's overall performance is at a "successful" or higher level. Moreover, a GS-12 Fingerprint Specialist may be considered for promotion to the GS-13 level only after s/he has been in grade at least one year and has demonstrated evidence of acquiring the appropriate specialized experience

and competencies needed to perform the GS-13 higher graded duties as described in the position description.

A. The Senior Fingerprint Specialist GS-13 Promotion Criteria are as follows:

1. The employee's supervisor must recommend him/her for promotion to the GS-13 level.

2. The employee must have completed at least one year in grade as a GS-12.

3. The employee must possess qualifying specialized experience and demonstrate the ability to successfully perform the duties at the GS-13 full performance level, as described in the Senior Fingerprint Specialist position description.

4. The employee must have received an overall rating of "acceptable" or higher on his/her most recent performance appraisal.

5. The Laboratory Director must personally concur with the first line supervisor's recommendation and certify that the Fingerprint Specialist's performance meets the GS-13 criteria. This responsibility cannot be delegated.

6. A candidate for promotion must not have been the subject of any disciplinary action within the past three years that, in the opinion of the Deputy Assistant Administrator, Office of Forensic Sciences (SF) would warrant denial of promotion to the GS-13 level.

B. The Senior Fingerprint Specialist GS-13 Promotion Process is as follows:

1. Recommendations for promotion will be initiated by the immediate supervisor and forwarded through the laboratory system chain of command to SF. The package submitted to SF must contain the following: a) a copy of the GS-13 Senior Fingerprint Specialist position description; b) a narrative prepared by the immediate supervisor, which justifies the promotion by describing the individual's accomplishments, attesting to the breadth of his/her experience, and include examples of higher level duties performed by the employee as stated in the position description; c) a copy of the SF-50, Notification of Personnel Action, showing the employee's promotion or appointment to the GS-12 level; d) a copy of the employee's most recent Performance Appraisal Record (DEA Form-460) showing an overall rating of "successful" or higher; e) an SF-52, Request for Personnel Action, signed by the Laboratory Director; f) a statement, signed by the Laboratory Director, certifying that the employee has the required time in grade, has the necessary breadth of experience by demonstrating his/her ability to perform at the GS-13 level and is currently performing the higher level duties described in the position description accompanying the promotion request.

2. SF will review the package for completeness and sufficiency of documentation. A decision will be made based upon review of the submitted documentation and an assessment of the degree to which the employee's accomplishments correspond with the higher level duties described in the GS-13 position description.

3. SF will also initiate name checks to determine if there has been any disciplinary action within the past three years which would warrant denial of promotion.

4. If the package is approved by SF, it will be forwarded to the Recruitment and Placement Section (HRR) of the Human Resources Division for review, approval and processing.

5. If the package is not approved by SF, it will be returned to the Laboratory Director with a written explanation.

6. After review, if the package is satisfactory, HRR will notify SF of the Section's approval of the promotion before processing the final action. SF will notify the Laboratory Director who will notify the employee.

If the promotion is denied, the package will be returned to the Laboratory Director with a written explanation. The Laboratory Director will forward the explanation to the employee.

7207.14 Other Laboratory Positions. See Personnel Manual 2250.1.

7207.15 Request for Personnel Action, SF-52. The Laboratory Director will furnish SF a copy of all forms SF-52 submitted directly to HRRF. See Personnel Manual Subsection 2295.1 for instructions on preparing the SF-52.

7207.2 FORMATION OF ADDITIONAL GROUPS. As the number of personnel increases in each laboratory, the number of groups will be increased. Sixteen is the suggested number of personnel for two groups. When the size of each laboratory's staff reaches the number which justifies an additional group, the Laboratory Director will initiate action by forwarding a request for change in the laboratory's Table of Organization to SF. If the request is approved, SF will forward the request to FRM for implementation.

(**NOTE:** Requesting official is the Deputy Assistant Administrator, Office of Forensic Sciences; approving official is the Assistant Administrator, Operational Support Division)

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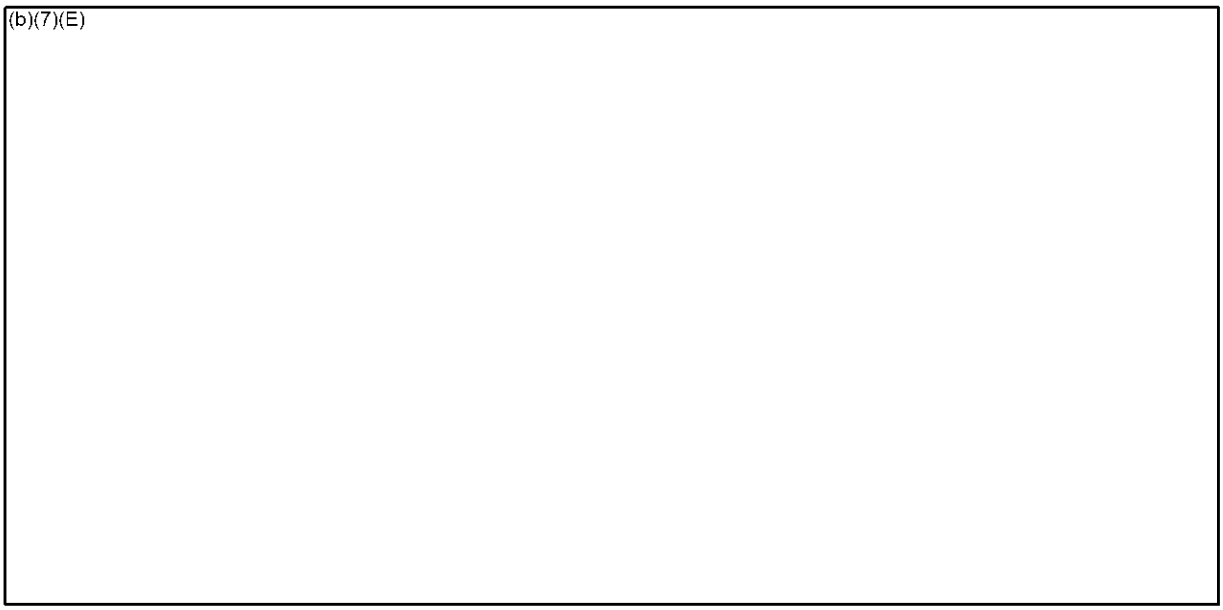
(b)(7)(E)



DISPOSITION OF EVIDENCE **7304**

HANDLING OF CONTROLLED SUBSTANCES FOR THE FORENSIC CHEMIST TRAINING PROGRAM AND OTHER TYPES OF TRAINING 7310

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CHAPTER 73 PHYSICAL EVIDENCE AND NON-EVIDENTIARY CONTROLLED SUBSTANCES

7301 COLLECTING AND PRESERVING EVIDENCE

7301.1 DEFINITIONS

7301.11 Physical Evidence.

Physical evidence may consist of drugs, chemicals, laboratory equipment, packaging, photographs, documents, latent prints, digital devices or media, money, or any other tangible property used to establish a violation of law.

7301.12 Exhibit

Physical evidence that was acquired at a different time or place from other materials *will* be treated as separate exhibits. Physical evidence that appears to be of significantly different chemical composition or is significantly different in color should be separated into sub-exhibits.

(b)(7)(E)

(b)(7)(E)

7301.3 CLANDESTINE LABORATORY EVIDENCE

A. All clandestine laboratory investigations in which DEA asserts primary authority will be coordinated through the appropriate DEA laboratory. The Laboratory Director or *other personnel, designated by the laboratory director in writing,* will be notified of the investigation by the *SA or TFO or by the SA's or TFO's supervisor.*

(b)(7)(E)

D. In addition to having a working knowledge of the procedures for processing evidence described in Subchapter 666 of the Agents Manual, the forensic chemist, *fingerprint examiners, or computer forensic examiners* should:

1. Be familiar with all information supplied to the field laboratory by the *SA or TFO* of the investigation.
2. Have a complete working knowledge of the methods of synthesis for the drugs suspected of being produced in the laboratory under investigation.
3. Ensure that the proper personal protective equipment (e.g., respirators, goggles, etc.) is at the laboratory site for use by DEA laboratory personnel.

(b)(7)(E)

7. Assist the *SAs or TFOs* in preparing a complete inventory of the laboratory. Any items seized as evidence must be appropriately annotated with unique identifying

information or documented with photographs by the *SA or TFO* to ensure that the items can be subsequently recognized in court.

8. *Direct the seizure of tableting machines, punches and/or dies.*
9. Assist the *SAs or TFOs* in determining what to seize as evidence. (b)(7)(E)
10. Assist *SAs or TFOs*, as needed, in identifying solvents and other hazardous materials present at the laboratory site for proper disposal by hazardous waste contractors.
11. Photograph, and/or videotape all essential areas of the clandestine laboratory as well as exhibits seized (see *LOM 7301.6G* for documenting seizures).

E. After participating in a laboratory seizure and completing the analysis of evidence, the forensic chemist will prepare a *DEA-500, Clandestine Laboratory Report, (see LOH, Exhibit H-15).* All copies of this report are to be stamped "DEA Sensitive." The report will contain a reconstruction of the chemical procedures used, identify unusual safety hazards, and include identifiers that will permit retrieval of detailed inventories for DEA files and data bases. For consistency, production capabilities of clandestine laboratories will be reported as 100% theoretical yields. Estimated actual yields will not be reported on the DEA-500 or attachments. Forensic chemists may offer their expert opinion regarding estimated actual yields at trial or upon receiving a written request from the prosecutor. Attach a copy of the DEA-6, *Report of Investigation,* (for DEA cases) or similar available reports from other agencies to the original of the report. Forward the report to SFL1 within 30 days of completion of analysis of the clandestine laboratory evidence with copies to:

1. *The Office Head or his or her designee of the office conducting the investigation.
2. SAC or Regional Director (RD) having line authority over the Resident or District Office, Post of Duty (POD), or Country Office (CO) conducting the investigation (if applicable).
3. Special Strategic Intelligence Section (NTS), Headquarters.
4. Drug and Chemical Evaluation Section (ODE), Headquarters.
5. Dangerous Drugs and Chemicals Section (OED), Headquarters.
6. Forward a copy of the transmittal letter(s) to the Office of Forensic Sciences.*

F. **After completing the analysis of clandestine laboratory evidence in which there was not a participating DEA forensic chemist, the analyzing forensic chemist will prepare a DEA-500 only when requested.**

7301.4 TRACE EVIDENCE COLLECTION FOR DRUG EVIDENCE

Upon request by a field office to a Laboratory Director, a forensic chemist(s) will be assigned to accompany the *SAs, TFOs, or DIs* and conduct a trace evidence collection/vacuum search for drug evidence (b)(7)(E)

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7301.41 Introduction

The following guidelines should be followed for the handling, transport and storage of the Ion Mobility Spectrometer (IMS or IONSCAN), evidence collection and processing, and analysis of trace evidence. Samples collected for testing may be collected on a filter by a vacuum technique or by a wiping technique.

7301.42 Equipment Storage and Transport

When not in use, the IMS should be stored in the manufacturer provided storage crates. All containers, including crates that store the supporting field supplies for the IMS, should be stored in a clean, dry room designated as a trace (or clean) room only. No IMS equipment or travel supplies should be exposed to moisture or controlled substances. If the units are not in the storage crates, they can be set up for laboratory use or maintenance only in the designated contaminant free, dry, clean room.

When the IMS is needed for field use, it must be transported in the manufacturer's supplied travel crates. If the equipment is being shipped it should be labeled on the outside as "FRAGILE". IMS must contain an affixed label stating "Contains a sealed radioactive source (Ni 63 at 15mCi)". The newer models have this label pre-affixed to the unit and should not be removed. Older models must have an attached sheet noting the presence of a radioactive source. The accompanying shipping papers should contain the following exact wording: "Radioactive material, excepted package-Instrument". Categorization, labeling, and shipper's declaration are not required. If the shipping company permits, lock the crates. The case chemist should hand carry the computer.

When traveling via commercial aircraft, the manufacturer's travel crates should be used. It may be necessary to pay extra baggage fees if the weight and crate dimensions exceed allowance. If airline regulations permit, transport the IONSCAN via air cargo, as the equipment is handled more gently. The same declaration of radioactive materials as listed above applies. If the airline permits, lock the crates.

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Once on scene, the equipment should be inspected for any damage. The IMS should be set up, calibrated, and shut down according to LOH 7503.22 and the operator's manual. Do not set up the IMS in an area that could lead to potential contamination or exposure to water or moisture. Under no circumstances should smoking be permitted, as it will interfere with the operation of the IMS.

7301.43 Equipment Maintenance

The instrument monitor for the IMS is responsible for routine maintenance and calibration procedures which are summarized in H7503. The operator should inspect and ensure that the IMS is operational prior to deploying it for field operation. It is the operator's responsibility to troubleshoot and correct any problems that occur in the field. Upon return to the laboratory, the instrument monitor is to be notified of any instrumental problems. After returning from a field assignment, the operator is responsible for restocking supplies and cleaning the IMS. Any maintenance conducted before, during, and after an operation must be recorded in the instrument maintenance logbook.

7301.44 Collection Filters

IMS instruments purchased from various manufacturers have different filters and assemblies. Therefore, follow laboratory preferred documented procedures for the instrument when assembling the collection filters.

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7301.47 Reporting Results

Upon completion of the laboratory analysis (see Analytical Sufficiency document), report the results on the appropriate form and forward to the investigating office. Also, prepare a narrative report, in the format below, and distribute it to the investigating office, the SAC or his or her designee, and the Office of Forensic Sciences.

The narrative report will be a memorandum from the analyst to the Laboratory Director including the case number in the subject line. It must be strictly fact-based and not incorporate opinions or assertions. Also, the report should be succinct and focus on

reporting the field results and the analytical results. Refer to Attachment #1 (LOH Exhibit-16) as an example.

1. Background: Provide a brief summary of the trace evidence collection request and ensure the following is included:

a. Name of responsible agent, task force officer, or diversion investigator.
b. Enforcement Office and Group Number of responsible agent
c. Date of Request and Date Conducted (if different).
d. Agency Case Number.
e. Location (address, state, city).

Provide additional information about the premises (e.g., detached home, apartment) and identifying numbers of the items being searched (e.g., license plate numbers, VIN numbers, serial numbers).

2. Samples: Provide a description of the area(s) searched. List the specific location(s) of each sample collected and tested in the field and specify which ones were retained (by exhibit number) for further analysis. Samples that were acquired, analyzed in the field with negative results, and not retained for further testing should be reported in this section.

3. Results: Provide the results of each exhibit (listed with corresponding laboratory identifier) tested in the laboratory. Include both the field test results and the laboratory analytical results.

7301.5 DRUG EVIDENCE SEIZED BY THE DEPARTMENT OF HOMELAND SECURITY

Drug evidence seized by the Department of Homeland Security (DHS) and submitted to a DEA laboratory for analysis will be processed in accordance with Agents Manual Section 6662.2. The same number of units submitted by DHS should be returned.

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7302 HANDLING PHYSICAL EVIDENCE IN THE LABORATORY

7302.1 RESPONSIBILITY

The Laboratory Director is responsible for evidence submitted to or received by the laboratory. The Laboratory Director must ensure that the evidence is accounted for at all times. The Laboratory Director may delegate duties and authority for receipt, handling, storage, and disposition of physical evidence to the Associate Laboratory Director, supervisory chemists, forensic chemists, *fingerprint specialists, computer forensic examiners* and other staff members to accomplish these functions. The receipt, identification, storage, and disposition procedures must be recorded as provided herein.

7302.2 RECEIVING EVIDENCE

Evidence technicians (ET), laboratory managers, or *other personnel designated in writing by* the Laboratory Director will process for receipt all evidence exhibits delivered to the laboratory. Only trash receptacles with self-closing lids will be placed in evidence receipt and processing areas. No trash receptacles of any type may be kept in the main vault. All shipping containers and wrapping paper must be carefully examined to ensure that all evidence has been removed prior to discarding the material.

A. All evidence must be properly sealed by the submitting *SA, TFO or DI* in accordance with Subchapter 666 of the Agents Manual. Identifying labels must be affixed to all exhibits, with the following information provided:

1. Case number.
2. Exhibit number.
3. Date of acquisition (by seizure, purchase, **taken into DEA custody** etc.).
4. Sealing official (sealing SA's, *TFO's or DI's* signature).

5. Witnessing official (witnessing SA's, *TFO's or DI's* signature).

B. Evidence received will be carefully checked against the DEA-7 for accuracy and completeness. Evidence received with problems will not be routinely returned to the submitting office. Efforts must be made to resolve the problems through e-mail or memoranda to the submitting SA, *TFO, DI or* group supervisor. Entries should not be made in *Laboratory Evidence Management System (LEMS) or System To Retrieve Information from Drug Evidence (STRIDE)* until the problems are resolved. The evidence must be stored in the vault, segregated from other evidence and documented in a special bound logbook for this purpose. Entries in the logbook must contain dates, identifying information, a description of the evidence, gross weight, and notes documenting communication with the submitting office *or agency*. Once the problems are resolved, the evidence should be officially received into the laboratory, and the bound logbook should be annotated to indicate resolution of the problem. If a particular problem is not resolved within 14 days the evidence must be returned to the submitting office *or agency* with an explanatory memorandum.

Whenever laboratory personnel are requested to verify an annotation or correction related to a discrepancy on any evidence related document, the person who identified the discrepancy and the person verifying the discrepancy will initial and date the document in the area where the correction has been made.

The receipt of unsealed evidence will immediately be brought to the attention of a laboratory manager and handled as follows:

1. The ET or laboratory manager, in the presence of a witness, will seal the exhibit and the original unsealed container in a substitute evidence envelope (or other acceptable container).
2. The receipt portion (e.g., Items 19-24) of the original DEA-7 will be completed by the laboratory with Item 22 annotated with the word "unsealed."
3. A memorandum documenting the receipt and handling of unsealed evidence will be prepared and sent to the submitting office *or agency*. The memorandum will document the File Number, Exhibit Number, and a description of the evidence. The memorandum will also document the sealing of the evidence in a substitute container. A copy of the memorandum will be placed in the laboratory's case file.
4. Process the exhibit as described in **LOM** 7302.3.
5. An exception to this procedure will be made in instances where a package was obviously damaged in transit or tampered with, in which case the laboratory will accept delivery, make notation of its condition, and take appropriate follow-up action which may include referral to *the Office of Professional Responsibility (OPR).*
6. Evidence that is received in the mail without the witnessing official's signature should be accepted by the laboratory, if all other criteria in paragraph A have been met. The procedure will minimize the added risk and delay in mailing the evidence back to the submitting office. However, in these situations, the Laboratory Director will notify the

submitting office *or agency* that future submissions of evidence should be properly labeled in accordance with Subchapter 666 of the Agents Manual. If the problem persists, the Laboratory Director will notify the SAC of the submitting office *or official of submitting agency.*

C. The ETs, laboratory managers, or *other personnel designated in writing by* the Laboratory Director will receive evidence if personally delivered to the laboratory, or sign the mail receipt if delivered by mail. After promptly preparing the required forms and making the necessary entries, the official will place the evidence in the vault.

D. The supervisory chemist **or his or her written designee** assigns evidence to forensic chemists, *fingerprint specialists or computer forensic examiners* for examination. If the evidence is a drug exhibit belonging to a case already in the laboratory, the evidence will normally be assigned to the forensic chemist, *fingerprint specialist or computer forensic examiner* who has previously analyzed exhibits from that case, in order to minimize the number of witnesses required to testify regarding the evidence.

7302.3 RECEIPT PROCEDURES

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The ET must burn or shred any exposed carbon paper from manifold DEA-7's. If the evidence is personally delivered to the laboratory by other laboratory personnel, follow the applicable receipting procedures. *Once received*, the ET or other individual designated in writing by the Laboratory Director must:

*A. Assign the Laboratory Number by recording the necessary information in the Laboratory Index Book (see **LOM** Subsection 7302.51).

B. Create the Evidence Accountability Record for the exhibit in LEMS using the drug type extensions found in LOM Subsection 7302.51 and print the DEA-307 card, Evidence Accountability Record.*

**C. Record the Laboratory Number on the evidence and incoming documents and place LEMS labels on the evidence packages.

D. Place their initials on the incoming evidence.**

E. *Ensure that once laboratory numbers/units are created they are not routinely deleted. Rather, when appropriate, the laboratory should utilize* the transfer option of LEMS so that all LEMS history information is maintained. The transfer function must be utilized when the number of units is reduced (e.g. combining multiple units into a single unit). When deleting a laboratory number/unit is the only appropriate action (i.e., such as the deletion of an erroneously created additional unit number), the laboratory must maintain a special bound logbook to record the laboratory number/unit that is permanently deleted from LEMS. The logbook entry must, at a minimum, include the name of the individual performing the deletion, the date, the laboratory number/unit deleted and the reason for the deletion.

F. Create the Evidence Inventory Record for the exhibit in STRIDE.

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7302.5 PREPARING AND MAINTAINING LABORATORY RECORDS

7302.51 Laboratory Evidence Management System (LEMS) and Laboratory Index Book

Within one (1) business day of receipt in the laboratory, the ET or other personnel designated in writing by the Laboratory Director will create a record of evidence in LEMS. LEMS will be maintained in such a manner as to accurately reflect the exact location and the correct number of units for each exhibit received by the laboratory. Only one (1) LEMS unit label may be used per evidence container. Multiple LEMS unit labels may not be placed on a single piece of evidence. LEMS will also be utilized to account for special program exemplars and proficiency test samples. LEMS will not be used to account for other non-evidentiary accountable controlled substances stored by the laboratory.

The following "type" identifier will be used when entering units into LEMS:

*A. Drug Evidence
1. Drug Evidence – DRG*
2. Drug Evidence and Fingerprint Evidence Sealed in the Same Container – DGF

B. Non-drug Evidence – NDE

C. Latent Print Evidence
1. Drug Evidence Packaging (before, during, and after chemist analysis) - FIN
2. Unrecoverable Latent Print - FUR
3. Non-drug Fingerprint Evidence – NDE
4. Drug Evidence and Fingerprint Evidence Sealed in the Same Container – DGF

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The evidence technician or Laboratory Director's designee will maintain a record of evidence in an index book. Within one (1) business day of receipt of evidence into the laboratory, the following information will be recorded:

F. Laboratory Number

G. Case Number

H. Exhibit Number

I. Name of File Title (optional)

J. Date Received

K. How Submitted (optional)

L. Submitting Office (optional)

M. Assigned to (optional)

N. Alleged Drug (optional)

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7302.53 Forensic Chemist Worksheet, DEA-86, and Continuation Worksheet, DEA-86a

NOTE: For information on reporting of uncertainty of weights, review LS-09-005 Determination of Net Weight and Uncertainty Measurement Estimates.

A. Front of the Worksheet

The forensic chemist *must* write or print legibly in ink of permanent nature all required entries on the worksheet. This worksheet is used to record all raw data, observations, and calculations and *must* be written to permit adequate reconstruction of the analysis or examination performed (see LOH, Exhibit H-19). All observations, data, and calculations must be recorded at the time they are made and must be identifiable to the specific task. **All weights and quantitation results will be reported to the appropriate number of significant figures and in no case should a number be rounded up.** No stamps are

allowed on the form with the exception of those used to indicate the removal of material for a special program or the entry of data into STRIDE. Any corrections to the DEA-86 and or associated data must be in ink and made by an initialed single straight line strikeout. Any additions to examination documentation must be initialed by the person making the addition. Record information on the DEA-86 as follows:

1. Page _____ of _____. Complete as appropriate.

2. Item 1. From. Name of individual from whom the evidence is physically received by the examining forensic chemist.

3. Item 2. Date. The date the forensic chemist receives the evidence for analysis.

4. Item 3. Seals. Indicate the condition of seals as received.

5. Item 4. File No./Exhibit No./Lab No. As supplied by submitting *SA, TFO or DI* on the DEA-7 or from other transmittal documents, and Lab Number as assigned by the ET.

6. Item 5. Description of Evidence. A detailed description of the physical evidence, including containers, markings and other information. This should be written so that the evidence may be readily visualized by reading the description. The description should begin with the number and type of container(s) submitted, e.g., three (3) heat-sealed evidence envelopes, one (1) cardboard box, suitcase, etc., and end with the substance to be analyzed, e.g., powder, liquid, residue, etc.

7. Item 6. Summary of Findings. This space should contain a conclusion of laboratory analysis. Information necessary to complete the *appropriate reporting form* appears in this space, along with information in Items 7-12 (below). The placement of information should be as illustrated in LOH, Exhibit H-19. The net amount must be reported in units of weight, in addition to any other appropriate units, e.g., volume, number of dosages units, etc. If a portion of the evidence was removed for a special program, enter the notation, "__ grams (or __ tablets, etc.) removed for special program" into this block, accurately reflecting the amount of material removed. For bulk exhibits, in which the exhibit exceeds the threshold amount, a statement will be placed on the DEA-86 and *appropriate reporting form* indicating the amount pending destruction. (See LOM 7301.6G3). For bulk exhibits, in which the exhibit is from a non-DEA case and exceeds the threshold amount, a statement will be placed on the DEA-86 and *appropriate reporting form* indicating the amount separated in excess of threshold where applicable.

8. Item 7. Exhibit Number. Enter the exhibit number assigned by the submitting *SA, TFO or DI* or split exhibit number(s), as necessary.

9. Item 8. Laboratory Number. Same as found in Item 4.

10. Item 9. Active Drug Ingredient. *List controlled substance(s) identified. Also, list other substances(s) identified when quantitation is performed.* Include isomer and salt form, if identified.

11. Item.10. Quantitative Results. Strength, as determined, along with unit (milligrams per tablet, etc.). For those exhibits not quantified (marijuana, *opium*, etc.) enter N/A.

12. Item 11. Amt. (Amount) of Pure Drug. Total amount of controlled substance in Item 9 (quantitative result (Item 10) multiplied by Net Weight (Item 6)). ** For those exhibits not quantified, enter N/A**.

13. Item 12. Reserve. Net weight of exhibit remaining after completion of analysis. The amount should be reported in the same units as in Item 6. For those exhibits over the threshold amount, the reserve is the entire remaining amount including the amount pending destruction.

14. Item 13. Reserve Evidence. A description of the reserve portion of the evidence, from the sample analyzed to the final container. Specifically address any major change that was made to packaging (substitute container, etc.). For exhibits with multiple containers, indicate what identifying marks were placed on the containers, e.g., containers numbered X of X; containers(s) X marked for destruction above threshold, box(es) marked as representative sample, etc.

15. Item 14. Forensic Chemist's Signature. Self-explanatory.

16. Item 15. Date Reported. Date completed worksheet is forwarded for review.

17. Item 16. Reviewed by (initials) and date. Supervisory review for completeness and scientific accuracy. Enter initials and date reviewed.

The technical reviewer in a forensic drug analysis is required to initial the DEA-86 or other worksheets. The initials of the technical reviewer on a DEA-86 or other worksheet will be interpreted as follows: After evaluating all reviewable data submitted with the DEA-86 or other worksheets, the technical reviewer agrees with the conclusions to include the identification of the controlled substance or other drugs as reported by the analyst.

The technical reviewer in a Digital Evidence analysis is required to initial the DEA-6 or alternate worksheets. The initials of the technical reviewer on a DEA-6 will be interpreted as follows: After evaluating all reviewable data submitted with the DEA-6 or other worksheets, the technical reviewer agrees with the conclusions as reported by the original examiner.

In those cases where a latent print identification has been made, the verifying examiner in the Fingerprint Program will evaluate all latent prints that were identified and the corresponding conclusions. The initials of the "verifier" on the reporting documents will be interpreted as follows: After evaluating all identified latent prints of the examination, the "verifying examiner" agrees with the conclusions as reported by the original examiner.

18. Item 17. Remarks. All other comments, including STRIDE codes for all substances identified.

B. Back of Worksheet.

To be used to record all entries pertaining to evidence handling and analysis. The worksheet must be annotated when any photos or digital images of the evidence are taken. Whenever weights are obtained, the DEA property inventory number of the balance or scale used must be recorded on the back of the worksheet. Whenever instruments are used to identify compounds, the DEA property inventory numbers of the instruments used must be recorded on the back of the worksheet or on the appropriate attachments (e.g. spectra, chromatograms, etc.). The standard lot number, or number traceable to the authentic reference material used in **any part of ** the analysis will be recorded on the back of the worksheet **or on the spectra or chromatograms**. All sections are to be completed and sections not utilized *must have* N/A indicated. **Whenever laboratory personnel are requested to verify an annotation or correction related to a discrepancy on any evidence related document, the person who identified the discrepancy and the person verifying the discrepancy will initial and date the document in the area where the correction has been made.** Record information on the back of the DEA-86 as follows:

1. File No. Self-explanatory.
2. Exhibit No. Self-explanatory.
3. Laboratory No. Self-explanatory.
4. Gross Weight. Indicate weight of sealed evidence as received.
5. Forensic chemist initials (must be handwritten) must appear in the top portion of the Worksheet.
6. Date Opened. Self-explanatory.
7. Net Weight. Show calculations, tare weights, number of units, etc., as appropriate. Weights will be recorded on the back of the DEA-86 with sufficient accuracy to meet the following requirements for reporting them on the front of the worksheet, but in no case should a number ever be rounded up:

a. Exhibit weight less than 10 grams - report to two (2) significant figures, e.g., 0.86 grams, 6.7 grams.

b. Exhibit weight between 10 and 1000 grams - report to nearest tenth of a gram, e.g., 96.2 grams, 711.0 grams.

c. Exhibit weight greater than 1000 grams - report to four (4) significant figures, e.g., 2013 grams, 327.6 kilograms.

8. Evidence Sampling Procedures. Provide details and documentation, which will include the number of units tested, tests run on each, and how the exhibit was sampled.

9. Qualitative. Indicate what methods/procedures were utilized to identify the exhibit contents. If instruments were used, record the DEA property inventory numbers of the_instruments along with the basic parameters/method conditions used, etc., either on the back of the worksheet or on the appropriate attachments (e.g. spectra, chromatograms, etc.). Record actual observations from *qualitative* tests. **The back of the DEA-86 or the ** standard spectra or chromatograms must be annotated with the lot number or identifier traceable to *a verified* reference material used to make the identification. If standard spectra or chromatograms are not required for the analysis (e.g., marijuana), the standard lot number or number traceable to *a verified* reference material will be recorded on the back of the worksheet. Another *forensic* chemist should be able to re-examine the evidence in a similar fashion based upon the information provided. **Reference the Analytical Sufficiency Document for additional details.**

10. Quantitative.

a. Method #: From validated methods or provide details of any modification to official methods with supervisory authorization.

b.Standard: Indicate the name and salt form of the standard used, lot number or identifier (see "9" above) as well as the weight, volume, dilution, and final concentration.

c. Date Prepared: Indicate on what date the standard was prepared.

d. Sample: Indicate the weight or volume of portion to be quantified. Dilutions must also be included.

11. Reserve Weight. Show calculations, tare weights, and number of units. All weights will be reported as indicated under Net Weight section.

12. Special Programs. Indicate what special program(s) for which samples were removed. Accurately report the amount of material removed, e.g., weight of substance (4.1 grams). Show calculations or tare weight, as appropriate.

13. Gross Weight After Analysis. Indicate the weight of the sealed evidence after analysis.

14. Date Sealed. Self-explanatory.

C. Attachments.

Spectral, chromatographic, or other instrumental data are to be attached to the DEA-86. Each item of data *must* be identified, at a minimum, with:

1. A unique identifier, such as Case/Exhibit Number and/or Laboratory Number.
2. Date Run.
3. Forensic chemist Initials (must be handwritten).

D. Use of Continuation Sheets

If more space is required for entries on the back or front of the DEA-86 (see LOH, Exhibit H-19), use the continuation sheet, DEA-86a, Forensic Chemist Worksheet (continuation) or another DEA-86, to record the additional entries. Submit the completed worksheet to the supervisory chemist, who performs a review, prior to the analytical results being typed on the *appropriate reporting form*.

7302.54 Report of Drug Property Collected, Purchased, or Seized, DEA Form 7 *or Substitute Laboratory Report*

(See LOH, Exhibit H-20.). After reviewing the completed worksheet, the supervisory chemist will have the results of analysis typed on the DEA-7 or substitute laboratory report and then returned to the forensic chemist for approval, signature, and forwarding to the Laboratory Director for signature (except as provided for in **LOM** 7302.6). Distribute the completed manifold DEA-7 and substitute laboratory reports (if applicable) as instructed on the form. Distribute FIREBIRD DEA-7's and substitute laboratory reports as follows:

A. Forward the original and a copy to the originating office.

B. *In cases submitted with other than DEA case numbers (e.g., FBI submissions), copy four (4) (from manifold DEA-7's) should be properly disposed of at the laboratory.*

C. Retain copy three (3) and place in the laboratory case file.

NOTE: For information on the electronic dissemination of analytical and evidence destruction reports, review the laboratory system order LS-08-004.

7302.55 Report of Non-Drug Property Collected, Purchased, or Seized, DEA Form-7a

After reviewing the completed worksheet, the *supervisory chemist* will have the results of examination of non-drug evidence typed on the DEA-7a *or other substitute report*, and will return the documents to the *analyst or examiner for approval. Distribute the completed report as follows*:

A. Forward the original (copy one (1)) and a copy to the originating office.

B. *In cases submitted with other than DEA case numbers (e.g., FBI submissions), copy three (3) (from manifold DEA-7a's) should be properly disposed of at the laboratory.*

C. Forward a copy to the appropriate submitting other agency office. Retain a copy for the laboratory case file.

7302.56 Laboratory Report, DEA Form 113

NOTE: See laboratory system order LS-05-010 Laboratory Results Reporting Form for further information on the reporting form.

The DEA-113, *Laboratory Report, may be* used by the field Laboratory Directors for reporting results of analysis by DEA *forensic* chemists to local, state, and other Federal agencies (except for those agencies which use the DEA-7). The following instructions apply in preparing this report (see LOH, Exhibit H-21):

A. To. Address of the requesting official.
B. From. Field Laboratory.
C. Requesting Agency Number. Reference number given to evidence by requesting office.
D. DEA Laboratory Number. Enter the laboratory number that is assigned to the evidence by the ET.
E. Text. Complete the text of the report.
F. Signature. The signatures of the forensic chemist and the Laboratory Director or the officially designated *in writing* Acting Laboratory Director.

7302.57 Laboratory: Case File

A. The laboratory case file for DEA cases consists of:

1.The original DEA-307 after disposition is completed.
2. The original DEA-48.
3. For exhibits whose net weight exceeds threshold amounts specified in LOH, Appendix HA-1, transmittals from the SAC notifying the appropriate United States Attorney or the responsible state/local prosecutor of destruction procedures, as well as any additional response or appeals of same.
4. DEA-12 or documentation of delivery to U.S. Postal Service or other official carrier (see **LOM** 7303.5).
5. A copy of the DEA-7 and other laboratory reporting forms, where appropriate.
6. DEA-86, original, and DEA-86a (if applicable).
7. DEA-7a copy five (5).
8. Any required source determination reports.
9. Pertinent analytical material, e.g., charts, graphs, etc.
10. Any investigative photographs and/or negatives.
11. The DEA-466.
12. A copy of the Fingerprint Report.
13. Digital records.
14. **A copy of the DEA-500 and DEA-6 from clandestine laboratory investigations.
15. All documentation, including but not limited to, handwritten notes and observations, hardcopies of computer generated notes, photographs, sketches, or diagrams generated by laboratory personnel from an investigation outside of the laboratory including crime scenes.

16. Copies of clandestine laboratory investigation documents such as defendant personal notes and synthesis notes, where applicable.

17. Administrative documentation identified with a unique identifier. If bound, the unique identifier should only be on the front page.**

B. The laboratory case file for other enforcement agency cases consists of:

1. The original DEA-307 when evidence has been returned to the submitting agency, **if applicable**.
2. DEA-12, one (1) copy or documentation of delivery to U.S. Postal Service or other official carrier (see **LOM** 7303.5).
3. DEA-7 and substitute laboratory report (if applicable) and/or letter requesting analysis.
4. DEA-113, one (1) copy (if applicable).
5. DEA-86, and DEA-86a (if applicable).
6. Any required source determination reports.
7. Pertinent analytical material, e.g., charts, graphs, etc.
8. The DEA-466.
9. A copy of the Fingerprint Report.

7302.58 Other Records

No other written laboratory records shall be maintained on analytical data associated with enforcement investigations (i.e., diaries, personal notes, etc.). *This is not to be confused* with the work of a research or method development project where these additional records may be maintained.

7302.59 Retention of Laboratory Records

A. DEA Laboratory Case Files. DEA laboratory case files may be forwarded to the Federal Records Center two (2) years after the case is closed. Prior to transferring case files to the Federal Records Center, the laboratory will ensure that the documents contained within each file correlate with the exhibits identified under the case file number. The case file will be retained in the Records Center for eight (8) years. The total retention period will be ten (10) years after the case is closed. (See Appendix A1-1 in the DEA Records Information System (DEARIS) Handbook).

B. Other Agency Case Laboratory Files. Other agency (includes all other Federal, state, and local) case files may be forwarded to the Federal Records Center two (2) years after the case is *closed*. Prior to transferring case files to the Federal Records Center, the laboratory will ensure that the documents contained within each file correlate with the exhibits identified under the case file number. The case file in the Federal Records Center will be retained for eight (8) years. The total retention period will be ten (10) years after the case is opened.

C. Laboratory Index Book. The Laboratory Index Book may be forwarded to the Federal Records Center ten (10) years after recording the last entry in the book. The "last entry" is defined as the date that the last exhibit in the Laboratory Index Book was closed.

D. Evidence Accountability Record. The copy of the DEA-307 may be destroyed at the discretion of the Laboratory Director. Maintain the original DEA-307 in the accountability file until disposition of the evidence. At the time of disposition, place the original DEA-307 in the case file (see LOM 7302.57). When bulk destruction of a portion of an exhibit is accomplished, the DEA-307 must be annotated as such and remain in the accountability file until the representative sample is also destroyed.

E. All DEA Sensitive information must be safeguarded and stored in accordance with the Planning and Inspection Manual section 8624.

7302.6 ANALYSIS OF DRUG SAMPLES FOR FOREIGN OPERATIONS

The Special Testing and Research Laboratory provides laboratory services to foreign DEA offices and foreign law enforcement agencies, except those specifically assigned to field laboratories.

A. The following procedures are to be followed to document the receipt and analysis of such evidence:

1. The laboratory will complete Items 19-24 of the DEA-7 or the laboratory will complete the appropriate reporting form and return copy five (5) as a receipt to the originating office.

2. Analytical results will be transmitted by the laboratory via teletype in lieu of a DEA-7 to the originating office. The teletype will include the case or general file number, the registry number, the amount of drugs received, and the results of analysis. Distribution will include appropriate sections in the Operations Division, the Records Management Section and other DEA offices concerned with the investigation.

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7302.7 LATENT FINGERPRINT EXAMINATION

A SA, *TFO or DI* may request a latent fingerprint examination by indicating such in Item 16 (Remarks) of the DEA-7 submitted with the sealed evidence.

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7302.71 DEA Evidence

General policy and guidance is provided below regarding the handling of latent print evidence in the laboratories. Specific procedures and additional information are located in the Fingerprint/Photography Handbook.

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All transfers of evidence between laboratory personnel will be documented according to DEA evidence handling procedures. Special precautions must be followed regarding evidence containing materials which are potentially hazardous or where drug and fingerprint evidence cannot be separated (e.g., drug impregnated paper), see LOM Subsection 7302.74.

Special circumstances (e.g., bulk seizures, rush analyses, etc.,) may dictate that the latent print examination be conducted prior to the analysis by the forensic chemist. Latent print examination procedures under these circumstances should be left to the discretion of laboratory management.**

B. Non-Drug Evidence (Items Not Submitted for Chemical Analysis). A SA, *TFO or DI* may submit non-drug evidence for latent fingerprint examination with a DEA-7a, indicating in Item 13 (Remarks) that a latent print analysis is requested.

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1. Laboratories with Fingerprint Specialists.

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e. Fingerprint Testimony. When a fingerprint specialist is required to present results of examinations in court, the *fingerprint* specialist is responsible for the proper preparation of charted enlargements (unless advised to the contrary by the prosecuting attorney).

(1) Pretrial Disclosure. If a fingerprint specialist is directed to meet with defense counsel, it must be done with the complete knowledge of the prosecutor, and the *fingerprint* specialist is strongly encouraged to recommend that the meeting be held with the prosecutor present.

f. Using a Facsimile Machine to Transmit Fingerprints. Only high resolution facsimile machines should be used to transmit prints. Prior to any facsimile transmission of prints, the individual transmitting the prints should telephonically contact the party to whom the transmission is directed to help assure that the prints are properly received.

2. Laboratories without Fingerprint Specialists.

Process evidence as indicated in **LOM** 7302.71A or 7302.74. Then transfer the evidence in sealed containers along with a copy of the DEA-7, to the ET. The submitting laboratory will prepare a DEA Form 12, and transmittal memorandum in accordance with the procedures set forth in H-7302.71D2a and b of the LOH.

7302.72 FBI Evidence

The submitting *SA* may request a latent fingerprint examination by indicating such on the FBI transmittal memorandum and/or DEA-7 submitted with the sealed evidence. **The forensic chemist who is assigned the evidence for analysis will carefully separate all non-drug physical evidence (packaging) from the alleged controlled drug substance, as outlined in LOM 7302.71 and 7302.42B. The forensic chemist will seal the non-drug

evidence in a heat-sealed evidence envelope, one exhibit per envelope. See also LOH-7302.73 (below). The forensic chemist will then transfer the sealed evidence, along with a copy of the FBI transmittal memorandum and/or copy of the DEA-7, to the ET for shipment to the FBI Laboratory Division.

1. Prepare a DEA-12, and a transmittal memorandum containing the following information:
   a. FBI File Number and Exhibit Number
   b. FBI Case Identifier (name of subject)
   c. Name(s) of individual(s) for whom comparison should be made, along with any identifying numbers and/or descriptive information
   d. DEA Laboratory Number
   e. Detailed description of the physical evidence being submitted for latent fingerprint examination
   f. Where the evidence should be sent at the conclusion of the examination by the FBI
   g. Routing of original and copies of their report of latent print examination (including one copy for the submitting DEA Laboratory)

2. Send the evidence, using a separate package for each case, along with attachments to the FBI Laboratory Division, as outlined in LOM 7302.71. **

7302.73 Requests From Other Agencies

Requests for latent fingerprint examinations from other agencies, e.g., federal, state, or local, must be approved on a case-by-case basis by the Laboratory Director.

7302.74 Special Precautions

A. Physical Evidence (Packaging) Containing Substances Which Are Potentially Hazardous. To minimize potential hazard when forwarding physical evidence to other fingerprint specialists, samples containing substances which are hazardous; e.g., LSD, fentanyl analogues, drug paraphernalia (biological hazard) must be identified in accordance with **the method set forth as follows:

1. Place a statement on the evidence envelope identifying the hazard, e.g., "Caution: Evidence contained LSD."
2. For evidence sent to a DEA laboratory with a fingerprint program or to the FBI Laboratory Division, include a statement in the transmittal memorandum identifying the potential hazard.
3. Ensure that any drug paraphernalia is packaged to prevent accidental injury, e.g., exposed hypodermic needles are covered, razor blades are separately packaged, etc.**

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7302.75 On-Site Services Furnished by FBI Latent Fingerprint Section

A. In those fingerprint cases with DEA responsibility, all evidence should normally be processed by DEA fingerprint specialists. If resources are not available in the primary laboratory, an attempt should be made to acquire assistance from another DEA laboratory, with the consent of all the DEA Laboratory Directors involved. However, in unusual circumstances, e.g., where sufficient resources are not available, the FBI, or other law enforcement agencies, may be asked to provide on-site assistance to process bulk evidence seizures for latent prints. The Laboratory Director will determine the need for such services on a case-by-case basis. Assistance by the FBI Latent Print Unit cannot be provided at clandestine laboratory sites.

B. In those laboratories with fingerprint specialists, the Laboratory Director, or *other personnel designated in writing by the Laboratory Director,* will approve all requests for on-site assistance by a DEA fingerprint specialist.

**The procedures covering crime scene and bulk seizure processing in the Fingerprint/Photography Program Handbook will be adhered to when on-site latent print processing is requested. **

7302.8 DIGITAL EVIDENCE EXAMINATION

See the Digital Evidence Laboratory Standard Operation Procedures.

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7303.51 Procedures for Use of DEA-12, Receipt for Cash or Other Items

An original and *two* copies of the DEA-12 will be prepared by the delivering party as follows:

A. To. Enter the name and title of the person releasing custody of the evidence.

B. Division/District Office. Enter the laboratory responsible for releasing custody of the evidence.

C. File number. Enter DEA case file number.

D. Date. Enter the date of actual transfer. When the evidence is transferred by mail, the date mailed will be entered by the mailing official.

E. Amount or Quantity. List the exhibit designators of the evidence being transferred.

F. Description of Items. Describe and identify the evidence being transferred, including the laboratory number. Include a description of the evidence article, whether the evidence was sealed, how the evidence was packaged, and the number/quantity of the articles involved.

G. Purpose. State the reason for transferring custody of the item (e.g., delivery to court, return to storage, etc.).

H. Received by/Name and Title. The individual receiving the evidence will sign and print or type his/her name and official title.

I. Witnessed by/Name and Title. The individual witnessing the transfer of evidence, when applicable, will sign and print or type his/her name and official title.

J. Distribution.

1. Original (Copy 1). Provide to the party delivering/releasing the evidence. (The original should be placed in the case file.)
2. Copy 2. Provide to the party receiving custody of the evidence.

Copy 3. Provide to field office originating the case.

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7306 EXAMINATION BY DEFENSE

7306.1 POLICY

The defense may request a sample of the evidence for independent analysis. A sample may be provided, without a court order, upon consultation with a federal or state prosecutor and the Domestic Criminal Law Section (CCM), DEA Headquarters. The evidence may be withdrawn from the laboratory upon receipt of a memorandum of request and authorization from a supervisory SA (GS-1811-14 or above) or a court order, if applicable. The defense expert must be properly registered to handle the controlled substances to be tested. Attempts must be made to ensure that any sample remaining after the defense analysis is returned to the DEA laboratory. DEA laboratory facilities or equipment will not be used for defense analysis purposes.

7306.2 PROCEDURE

Upon receipt by the Laboratory Director, or his/her designee, of the supervisory special agent's memorandum stating that an examination of evidence is to be performed by a defense chemist, the following procedures will apply.

7306.21 Laboratory Director, Forensic Chemist and Evidence Technician Responsibilities

A. Laboratory Director

1. The Laboratory Director shall have final approval of the amount of evidence to be provided to the defense expert. The sample will be limited to the smallest size and number mutually agreeable to the defense and the government. If the government and defense cannot agree on a sample size, a court order should be sought.

2. The Laboratory Director or his or her designee will consult with the supervisory special agent to determine whether the defense expert is registered to handle the controlled substances to be tested. If the defense expert is not properly registered with DEA, the sample(s) will not be provided. If the defense refuses to designate an expert who is properly registered to handle the schedule of controlled substance at issue, a court order should be sought which requires the defense expert be registered, and that he or she provide proof of registration before being allowed access to a drug exhibit.

3. The Laboratory Director shall assign the forensic chemist who performed the analysis, whenever possible, to complete the sampling for the defense analysis.

4. The Laboratory Director or his or her designee must prepare a letter of transmittal to accompany the samples to be shipped from the laboratory for defense analysis. This letter should provide a synopsis of the sampling and serve as written request for the defense expert to: (1) sign and return the DEA-12 accompanying the exhibits immediately upon receipt; (2) complete all analyses within 14 days of receipt of the exhibits; (3) return all remaining sample material to the DEA laboratory within five days of the completion of analyses; and (4) document in a letter to the DEA laboratory, if all sample material was consumed during testing.

5. The Laboratory Director must maintain a suspense file for all evidence released for defense analysis. If the remaining portion has not been returned (after analysis) as requested, the Laboratory Director will notify the supervisory special agent in writing, with a copy placed in the case file and provided to SF.

B. Forensic Chemist. The forensic chemist, designated by the Laboratory Director, is responsible for the following:

1. Sampling the specified amount of evidence. The complete sampling procedures will be documented on a DEA-86, reviewed by the supervisory chemist and placed in the case file along with the supervisory special agent's memorandum of request.

2. Generating an amended report that includes the statement "_____ grams removed for defense analysis."

3. Placing the sample in a suitable container and officially sealing it in a HSEE. Gross weight information must be included on the evidence label of the HSEE.
4. Returning the sample to the vault.

C. Evidence Technician. The evidence technician is responsible for the following:

1. Creating LEMS units for the samples.
2. Recording transactions of the samples in LEMS (similar to evidence out to court).
3. Preparing DEA-12's and shipping the samples.

7306.22 Method of Shipment

Ship the sample by registered mail, return receipt requested, or approved commercial carrier to the addressee provided in the supervisory special agent's memorandum. Or, arrange to have the sample transferred at the DEA laboratory.

7306.23 Addressee

The properly registered defense expert will be the addressee, unless otherwise specified in the supervisory special agent's memorandum of request. In some instances, the sample(s) may be shipped to the DEA field office nearest the defense expert for subsequent transfer.

7306.24 Receipt Procedures

A. When the sample is personally delivered, complete a DEA-12 and place it in the laboratory case file.

B. When the sample is shipped registered mail, include a completed DEA-12, a return addressed mailing envelope, and a request that the DEA-12 be signed and returned to the laboratory. File the mailing receipt, return receipt, and signed DEA-12 in the laboratory case file.

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7310 HANDLING OF CONTROLLED SUBSTANCES FOR THE FORENSIC CHEMIST TRAINING PROGRAM AND OTHER TYPES OF TRAINING

7310.1 THE FORENSIC CHEMIST TRAINING PROGRAM

7310.11 Responsibilities

Each Laboratory Director must designate in writing a training officer and an alternate training officer who will have the responsibility to maintain the controlled substances utilized by the laboratory for forensic chemist training. The training officer will be responsible for:

A. Receipt, storage (not to exceed 50 grams per drug type), and distribution of training materials.

B. Originating any request for disposal of training materials.

C. Originating and maintaining detailed records of transactions.

D. Maintaining an accurate balance of each controlled substance in the training stockpile. Stockpile is defined as controlled bulk material or sub-stockpiles created, by use of diluents and adulterants, from the main bulk material.

7310.12 Obtaining Training Materials

In general, controlled substances used as training materials will be obtained from exhibits pending destruction. The training officer, in coordination with the destruction officer, will examine submitted DEA-48's and respective case files and/or STRIDE records to determine which exhibits would be suitable for training purposes. Retention of any

controlled substances for training purposes will be documented on the appropriate DEA-48. Transfer of material from the destruction officer to the training officer will be documented on a DEA-12. The DEA-48 will be annotated in the remarks section with the amount removed, the exhibit number from which the sample was removed, and the stockpile designator to which the sample is assigned (e.g. Coc-1, Heroin-2, etc.). The original DEA-12 will be filed with the original DEA-48. The training officer will maintain a copy of the DEA-12, along with a copy of the DEA-48, in a specific file corresponding to each stock sample.

Materials to be used for training samples must be removed from the original evidence container and that container disposed of properly. Under no circumstances should a training sample be associated with the original case number, exhibit number, or other markings that might confuse the training sample with actual evidence. Once transferred, the material will be placed into a sealed envelope or box and labeled appropriately (e.g. Coc-1, Heroin-2, etc.) for subsequent storage in a locked container. If further adulteration of stock samples is necessary, then these become sub-stockpiles. These sub-stockpile samples are to be labeled appropriately (e.g. SubCoc-1, SubHeroin-2, etc.). Each sub-stockpile created must be properly annotated in order to be tracked back to the original stockpile.

7310.13 Storage of Stock Training Materials

NOTE: See the following laboratory system order for the current policy: LS-07-005 Policy Revision – Increase in Maximum Storage Quantities of Stock Training Materials. This section will be revised during the next annual review.

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All stored items must be identified and maintained in a sealed condition. Any transfer of materials to or from the stockpile, including creating individual training samples, must be witnessed. (b)(7)(E)

7310.14 Distribution of Training Materials

Training samples will be prepared from the stock supply. These training samples will be placed into suitable containers, uniquely labeled (e.g. Tng-1, Tng-2, etc.) and sealed in evidence envelopes. A DEA-307 card must be created with a unique identifier for the training sample. This DEA-307 card will be used to document the transfer of the training sample between the training officer and trainee. The training sample may be re-issued to

another trainee for analysis or destroyed. The trainee will complete a new DEA-86 consisting of net, gross, and reserve weights for each training sample.

7310.15 Accountability of Training Materials (Originating and Maintaining Detailed Records)

A. Information regarding all training materials must be maintained in a bound index book. The following information must be recorded:

1. Source of Stockpile. The source from which the stock sample was obtained (e.g. case and exhibit number) and the stockpile designated number.
2. Net Weight. The exact net weight of the initial stock material and the remaining amount after portions are removed for individual training samples.
3. Training Sample Number. A unique identifier for each training sample.
4. Final Disposition. The date of disposition of the training sample.

B. In addition to the bound index book, copies of DEA-48's and DEA-12's used to originate the materials must be maintained in individual files corresponding to each stock sample. These files will be located in the laboratory's secure file room. They will contain the DEA-12's, DEA-86's and all destruction documentation used to dispose of the materials. The DEA-307's will be maintained in the same files upon completion of destruction. Access to the secure file room will continue to be limited to authorized personnel as deemed necessary by the Laboratory Director.

7310.16 Inventory and Disposal of Training Materials

In January of each year, or after changes in personnel responsible for administering the program, a supervisor and one (1) other individual without access to the training materials will inventory the entire content of material for the program and reconcile the inventory against the bound index book. A memorandum stating the inventory has been completed will be forwarded to SF no later than the last day of January of each year. Any discrepancies must be immediately investigated. If the discrepancy cannot be immediately resolved, OPR and SF must be notified. During the inventory, any materials that are no longer needed for the program will be identified and destroyed in accordance with LOM 7317. Transfer of training materials for destruction from the training officer to the destruction officer will be documented on a DEA-12, with copies maintained in the stock sample file.

7310.2 CONTROLLED SUBSTANCES FOR OTHER TYPES OF TRAINING

Controlled substances for other types of training (i.e., field test training) will be withdrawn from the Forensic Chemist Training Program stockpile. All samples will be prepared in the presence of a witness. Information regarding the preparation of samples, the net weights, and final disposition will be recorded in the bound index book maintained for the Forensic Chemist Training Program stockpile.

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7312 HANDLING OF CONTROLLED SUBSTANCES FOR THE CANINE TRAINING MATERIAL PROGRAM

7312.1 THE CANINE TRAINING MATERIAL PROGRAM

7312.11 Responsibilities

The *Laboratory* Director of the Special Testing and Research Laboratory (SFL1) must designate a canine training material officer and alternate(s), in writing, who will have the responsibility to maintain the controlled substances utilized by the laboratory for canine training. The canine training material officer will be responsible for the following:

A. Receipt, storage, and distribution of canine training materials.

B. Originating requests for disposal of canine training materials.

C. Originating and maintaining detailed records of transactions.

D. Maintaining an accurate balance of each controlled substance in the canine training material stockpile.

7312.12 Obtaining the Canine Training Material

Controlled substances used as canine training materials will be obtained from exhibits pending destruction in DEA field laboratories. The Laboratory Director of SFL1 will request drug materials needed for the program, in writing, from the other laboratories, as needed. When preparing material for transfer to SFL1, the DEA-48 for the exhibit from which the material is removed will be annotated in the remarks section with the amount removed, the exhibit number and reason for removal (i.e. transfer to SFL1 for canine training material program). Transfer of material to SFL1 will be documented on a DEA-12. The material forwarded to SFL1 must be removed from its original container and repackaged. All original packaging material and evidence containers must be disposed of properly by the originating laboratory. The originating laboratory will include a copy of the DEA-48, completed DEA-7 and DEA-12 during the transfer of material to SFL1. The original DEA-12 will be filed with the original DEA-48 in the case file at the originating laboratory. The canine training material officer at SFL1 will maintain a copy of the DEA-12, along with copies of the DEA-48 and DEA-7, in a specific file corresponding to each stock sample.

Once transferred to SFL1, the material will be placed into a sealed envelope or container and labeled appropriately (e.g., DT-CH-001, DT-HH-001, etc.) for subsequent storage in a locked container.

7312.13 Originating and Maintaining Detailed Records for Canine Training Materials

A. Information regarding all canine training materials must be maintained in a bound index book. The following information must be recorded:

1. The source of the stockpile material – annotate the File Number, Exhibit Number, and Laboratory Number from which the stock material was obtained.
2. Weights – the gross and net weight of the stock material when initially received by SFL1.
3. The date the material was placed into the program.
4. Final disposition – annotate the date of disposition of the stockpile material.

B. In addition to the bound index book, a file will be kept for each stockpile drug. Included in this file will be all records associated with each individual batch of stockpile material to include: copies of the DEA-48, DEA-7, and DEA-12 used to originate the material; results of reanalysis of the material; records of weights for samples removed for the program; *a list of the uniquely labeled samples created from the stockpile; and the records of the final disposition of the stockpile drug material. The original completed DEA-12 received from the requesting agency will be filed in the respective agency file.* These files will be kept in a lockable container in the laboratory.

C. **Disposition of Stockpile Files. The canine training program stockpile files will be maintained until all DEA-12s related to the dispersal of materials from each particular stockpile are returned. At this point, the stockpile will be considered closed and the stockpile file can be removed from the canine training material lockable container and stored securely elsewhere in the laboratory for a period of two years. After two years, the canine training material stockpile files may be transferred to the Federal Records Center and archived for an additional eight years.**

7312.14 Storage of Stock Canine Training Materials

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All stored items must be identified and maintained in a sealed condition. Any transfer of materials to or from the stockpile, including creating individual training samples, must be witnessed.

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7312.15 Preparation of Samples for Distribution

Canine samples will be prepared from the stock supply. These samples will be placed into suitable containers, uniquely labeled (e.g., K9CH-03-001, K9MH-03-001, etc.), and placed into a heat sealed evidence envelope (HSEE).

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7312.16 Processing Requests for Canine Training Material

A. Canine training materials will only be provided to law enforcement agencies. The

request must be in writing on agency letterhead from a public law enforcement agency and be signed with an original signature by the Sheriff, Chief of Police or person with an equivalent rank. Under no circumstances will requests directly from commercial dog handlers be accommodated. Commercial dog handlers may request canine training materials from their local law enforcement agencies.

B. The Requestor must be a DEA Registrant.

C. The request must be made using a DEA-222 and in accordance with DEA regulations. The request must be accompanied by a copy of the Registrant's current Registration Form, DEA-223, *Certificate of Registration.*

D. For all requests for canine training materials, the original letter of request, the DEA-222 and copy of the DEA-223 must be forwarded to the SAC or his or her designee of the DEA Division Office from where the request originated (with a copy to the Division's Diversion Program Manager) for review and concurrence. SFL1's request for concurrence must specifically ask that the request be reviewed to ensure that:

1. the requestor's Registration Number is valid.
2. the registrant is authorized to handle the specific drugs requested.
3. the individual who signed the DEA-222 is authorized to do so.

E. Not more than 28 grams of any one (1) drug may be provided if the recipient is a single unit of an agency. Not more than 200 grams of any one (1) drug may be provided if the recipient is to redistribute the supply to agency subunits or other law enforcement agencies within the state. Requests for up to 200 grams require approval in writing from the Laboratory Director of SFL1. Requests for greater amounts may be approved by the Deputy Assistant Administrator, Office of Forensic Sciences (SF), on a case by case basis. The Laboratory Director, SFL1, will evaluate such requests and forward them to SF along with his or her recommendation and appropriate justification.

F. Requests for replacement material will be considered only if 12 months have elapsed since the preceding request was filled.

G. The Laboratory Director will not authorize subsequent requests unless *appropriate documentation indicating destruction or permanent relinquishment of custody* is received for materials previously provided.

H. Should a request be received that cannot be satisfied, the Laboratory Director will notify the requestor that the material is not available. If requested materials are not available at the time the request is received but are expected to become available in the near future, the requesting agency may be advised that the request will be held until it can be filled. Alternatively, the request may be returned to the agency for resubmission at a later date.

I. Requests for canine training material from foreign countries will not be honored.

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7312.18 Inventory and Disposal of Canine Training Materials

During January of each year, or after changes in personnel responsible for administering the program, a supervisor and one (1) other individual without access to the canine training materials will inventory all contents of the canine training material stockpile and reconcile the inventory against the program records. A memorandum stating the inventory has been completed will be forwarded to SF no later than the last day of January of each year (or as needed). Any discrepancies must be immediately investigated. If the discrepancy cannot be immediately resolved, OPR and SF must be notified. During the inventory and at other times during the year, any materials that are no longer needed for the program will be identified and destroyed in accordance with LOM 7317. Transfer of canine training materials for destruction from the canine training material officer to the destruction officer will be documented on a DEA-12, with copies maintained in the stock sample file.

7313 HANDLING OF CONTROLLED SUBSTANCES FOR PROFICIENCY TEST PROGRAM (PTP) SAMPLES

7313.1 RECEIPT OF INTERLABORATORY AND EXTERNAL PTP SAMPLES

Interlaboratory PTP and external PTP samples received into the laboratory will be handled in the same manner as evidence.

7313.2 PREPARATION OF INTERLABORATORY AND INTERNAL PTP SAMPLES

A. Interlaboratory PTP Samples will be prepared and accounted for as follows:
These procedures provide for PTP sample accountability and supplement those found in LOM 7101.

1. The PTP coordinator (as designated in writing by the Laboratory Director) will select and prepare suitable samples for the program, as directed in LOM 7101.12. Material used for this program will originate from exhibits for which a DEA-48 has been received.

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For the PTP LEMS inventory record, two (2) units should be created. The label for Unit .001 should be affixed to the 1.5g PTP sample and the label for Unit .002 should be affixed to the remaining source material.

3. Documentation will be maintained by the originating laboratory for each PTP sample. This documentation will include the following:

a. A copy of the original DEA-7, DEA-86 and data.
b. The PTP sample number.
c. Witnessed gross weight obtained prior to breaking the seal of the source material.
d. Documentation of the amount of material removed from the original evidence and disposition of this material.
e. Witnessed gross weight of the source material after sealing.
f. Copies of DEA-12's documenting all transfers of PTP material.

B. Internal Proficiency Test Program (IPTP) Samples will be prepared and accounted for as follows:

These procedures provide for IPTP sample accountability and supplement those found in LOM 7101.

1. The IPTP coordinator (as designated in writing by the Laboratory Director) will select and prepare suitable samples for the program, as directed in LOM 7101.13. Material used for this program will originate from exhibits for which a DEA-48 has been received.

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2. The IPTP sample and source material will be submitted to the evidence technician via a DEA-12 and processed as described in LOM 7302.2. For the IPTP LEMS inventory record, two (2) units should be created. The label for Unit .001 should be affixed to the IPTP sample and the label for Unit .002 should be affixed to the remaining source material.

3. Documentation will be maintained by the laboratory for each IPTP sample. This documentation will include the following:

a. A copy of the front and back of the DEA-86.
b. The IPTP sample number.
c. Witnessed gross weight obtained prior to breaking the seal of the source material.
d. Documentation of the amount of material removed from the original evidence and disposition of this material.
e. Witnessed gross weight of the source material after sealing.
f. Copies of DEA-12's documenting all transfers of IPTP material.

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7314 REFERENCE STANDARDS

7314.1 CONTROLLED DRUG REFERENCE STANDARDS

7314.11 Responsibility of the Laboratory Director

Each Laboratory Director will appoint a primary standards monitor *in writing* who will have the responsibility to administer the controlled drug standards program. Additionally, each Laboratory Director will appoint an alternate standards monitor *in writing* to perform the duties of the primary monitor as necessary and to be a readily available replacement for the primary monitor.

7314.12 Responsibility of the Standards Monitor

A. The standards monitor will be responsible for the following:

1. Obtaining standards.
2. Originating and maintaining detailed records.
3. Assuring the *verification* of standards.
4. Storage, distribution and accountability of standards.

B. Information regarding all controlled drug standards must be maintained in a bound index book. The following information must be recorded:

1. Source of Standard. The source from which the standard was obtained (e.g. the Special Testing and Research Laboratory, purchased from a commercial source, etc.).
2.Net Weight. Record the net weight of the initial stock standard material and the remaining amount after portions are removed for use as working standards.
3. Standard Number. A unique identifier for each standard.
4. Final Disposition. The date of disposition of the standard.

C. Prior to use, preferably at the time of receipt, all stock drug reference standards must be subjected to *verification* procedures that will positively establish the identity and, if necessary, the purity of the standard. Drug reference standards received from the Special Testing and Research Laboratory, as well as other DEA laboratories, need not be *verified* if accompanied by appropriate documentation *validating* identity and purity. **The initial verification data applies to all subsequent drug reference standards with the same lot number from the same source.** A record consisting of the drug standards source and lot number, analyst's name, verification date, *verification* procedure(s) used and original data will be retained for a minimum of three (3) years after the reference standard is consumed.

D. [redacted]
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[redacted] Access to routinely required working standards will be limited to forensic chemists and laboratory management. The amount of controlled substance in any working standard vial will not exceed one (1) gram. A sign-out sheet will be maintained for the working standard vials. At a minimum, the initials of the individual removing the working standard vial and the date removed and returned will be recorded on the sheet. [redacted]
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E. During January of each year *and* prior to changes in personnel that have access to the collection, a supervisor and one (1) other individual without access to the stock standards will inventory the reference standard collection. A consolidated list will be prepared indicating the amount of each controlled drug standard consumed since the last inventory

and the amount on hand. A copy of the report will be forwarded to the Office of Forensic Sciences by the end of January of each year.

7314.2 NON-CONTROLLED SUBSTANCES AND REFERENCE STANDARDS

The Laboratory Director will restrict access to significant quantities of non-controlled substances, precursors and reference standards within the laboratory.

7315 RESEARCH DRUG MATERIAL AND SAMPLES

7315.1 CONTROLLED SUBSTANCES FOR USE IN RESEARCH

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The research controlled drug collection will not generally contain materials which meet criteria for inclusion in the controlled drug reference standard collection (see LOM 7314). Examples of materials properly included in the research collection are:

A. Rare or unique samples because of some factor which makes their replacement difficult or impossible.

B. Precursors that are themselves controlled, that are needed for the synthesis of controlled substances for research.

C. Mixtures, impure materials, or crude natural products.

7315.2 RESPONSIBILITIES OF THE LABORATORY DIRECTOR

The *Laboratory* Director of the Special Testing and Research Laboratory will: implement procedures and controls to maintain security and accountability of materials in the collection; certify and transmit to the Deputy Assistant Administrator, Office of Forensic Sciences, an annual inventory of materials in the collection; and appoint a monitor and alternate monitor for the collection.

7315.3 RESPONSIBILITIES OF THE MONITOR AND ALTERNATE

The monitor and alternate monitor will follow established procedures for receipt, storage, transfer, inventory and disposal of materials in the collection. Complete and timely records will be maintained so that the location and pertinent information relative to each sample in the collection can be retrieved on request.

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7315.5 INVENTORY

During January of each year or prior to changes in personnel that have access to the collection, a supervisor and one (1) other individual without access to the collection will inventory the research controlled drug collection. A consolidated list will be prepared showing the amount of each drug consumed since the last inventory and the amount of each remaining. Drugs added since the last inventory will be identified. Drugs consumed or disposed of during the year will also be identified. A copy of the report will be forwarded to the Deputy Assistant Administrator, Office of Forensic Sciences, no later than the end of January of each year, along with the controlled drug reference standards reports.

7315.6 RECORDS OF INVENTORY AND USE OF RESEARCH DRUG MATERIAL

7315.61 Primary Records

The primary records relevant to the collection will be maintained in a bound index book. Include at least the following information for each drug:

A. Name.

B. Source (laboratory number, firm name, agency name or other, as appropriate).

C. Identification number (either the lot or batch number or some other unique identifying number as appropriate).

D. *Date of each transfer with the initials of the individual performing the transfer and the supervisor approving the transfer.*

E. Weights--gross, tare, and net. (For hermetically sealed ampules and for sealed containers, the label weight will be accepted as the net weight and no tare weight will be recorded. Net and tare weights will be recorded when the seals are broken.)

7315.62 Record of the Use of Research Drug Material

The use of research drug material by laboratory analysts must be approved in writing by the Laboratory Director or his or her designee. Laboratory analysts must document the use of research material on a DEA-86 or in an appropriate research log.

7315.7 SAMPLES FOR SPECIAL PROGRAMS OR RESEARCH

The Laboratory Director, Special Testing and Research Laboratory, is authorized to request portions of unique samples directly from other DEA laboratories for use in special program applications or research. The request must be in writing with a copy to SF, and the transfer of material must take place using a DEA-12. The front of the DEA-86 or amended DEA-86, as appropriate, must be annotated "____ gram(s) removed for Special Program."

NOTE: For exemplars of Fentanyl, review LS-06-004 Tracking of Fentanyl Exemplars.

7315.8 RESEARCH SAMPLES MAINTAINED BY FIELD LABORATORIES

Research samples maintained by field laboratories will be limited to those associated with Headquarters approved research projects or laboratory imposed special studies.

7315.81 Responsibilities of the Laboratory Director

The Laboratory Director will:

A. Appoint a monitor and alternate *in writing* for research samples maintained by the laboratory.

B. Implement procedures and controls to maintain security and accountability of research samples.

C. Certify and transmit to the Deputy Assistant Administrator, Office of Forensic Sciences, an annual inventory of research samples.

7315.82 Responsibilities of the Monitor and Alternate

The monitor and alternate monitor will follow established procedures for receipt, storage, transfer, inventory, and disposal of materials in the research sample collection. Complete and timely records will be maintained so that the location and pertinent information relative to each sample in the collection can be retrieved on request.

7315.83 Storage

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7315.84 Inventory

During January of each year or prior to changes in personnel that have access to the collection, a supervisor and one (1) other individual without access to the materials will inventory the research sample collection. A consolidated list will be prepared showing the amount of each sample consumed since the last inventory and the amount of each remaining. Samples added since the last inventory will be identified. Samples consumed or disposed of during the year will also be identified. A copy of the report will be forwarded to the Deputy Assistant Administrator, Office of Forensic Sciences, no later than the end of January of each year.

7315.85 Records of Inventory and Usage of Research Samples

A. The primary record relevant to the research sample collection will be a single bound index book including at least the following for each sample:

1. Sample name.
2. Source (laboratory number, forensic chemist or other as appropriate).
3. Unique identification number.
4. The purpose and date of each transfer, as well as the initials of the individuals completing the transaction.
5. Gross, net and tare weights, as appropriate.
6. Storage location.

B. Laboratory Analysts must document the use of research samples on a DEA-86 or in an appropriate research log/laboratory notebook.

7316 ACCOUNTABILITY AND DISPOSITION OF CONTROLLED SUBSTANCES AND HAZARDOUS WASTE MANUFACTURED DURING TRAINING AND RESEARCH

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7316.2 APPROVAL

Written approval from the Laboratory Director is required prior to the manufacture of any controlled substance for training or research. This approval cannot be delegated and must be requested by memorandum through the supervisory chemist to the Laboratory Director. The memorandum of request must document: the purpose for the manufacture; the identity of the controlled substance(s) to be manufactured; the approximate amount of the controlled substance(s) to be manufactured; an estimate of the amount of hazardous materials (solvents, reagents, etc.) required for the manufacture; and the proposed disposition of the controlled substance(s) and hazardous waste resulting from the manufacture.

7316.3 ACCOUNTABILITY RECORDS

Individual files must be created and maintained in the file room to ensure accountability for any controlled substance(s) manufactured for training or research purposes. The accountability file must include: the memorandum of request with the Laboratory Director's written approval; a memorandum to the file documenting the manufacture, listing the approximate amount of controlled substance(s) manufactured and hazardous waste generated, and signed by the witnesses of the manufacture; DEA-12's documenting the transfer of controlled substances to the destruction coordinator or another program; a memorandum documenting the destruction of controlled substances, including the signatures of an ET, witness, and the Laboratory Director; and lastly, a memorandum documenting the final disposition of hazardous materials generated as a result of the manufacture.

7316.4 DISPOSITION

The disposition of controlled substances manufactured for training or research will be completed by destruction or the immediate transfer to an appropriate standard collection. The disposition by transfer will be documented by memoranda to file signed by the forensic chemist who manufactured the controlled substance, a witness, and the Laboratory Director. The destruction will be documented by memoranda to file signed by the ET, a witness, and the Laboratory Director.

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of the Freedom of Information and Privacy Act

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CHAPTER 74 LABORATORY FINANCIAL MANAGEMENT

7401 RESPONSIBILITY

**The Laboratory Director is responsible for establishing and maintaining management and internal controls that assure operations are efficient and effective, financial reporting is reliable, the laboratory complies with applicable laws and regulations, and can prevent or detect unauthorized acquisitions. The Laboratory Director must make certain that this is done in accordance with, but not limited to: the Federal Manager's Financial Integrity Act of 1982 (FMFIA); DOJ Order 2860.3B; Office of Management and Budget (OMB) Circular A-123 (*Management's Responsibility for Internal Controls);* OMB Circular A-127; OMB Circular A-130 (*Management of Federal Information Resources)* issued under the authority of FMFIA; GAO (*General Accounting Office)* Standards for Management Control; DEA's Administrative Manual; and other applicable chapters in DEA's Laboratory Operations Manual.

Compliance through continued development and monitoring of these controls will aid in supporting the Chief Financial Officers Act of 1990, Government Performance and Results Act (GPRA), Inspector General Act of 1978, Federal Financial Management Improvement Act of 1996, Federal Information Security Management Act of 2002, Improper Payments Information Act of 2002, Clinger-Cohen Act of 1996, Government Management Reform Act of 1994, OMB Bulletin No. 01-09, Department of Justice Guidelines, Federal Accounting Standards and DEA's Financial Management Objectives.**

7401.1 AUTHORITY. *The Federal Manager's Financial Integrity Act of 1982 (31 U.S.C. Para 1105, 1113 and 3512), DOJ Order 2860.3B.6 states the following: "All elements of the Department shall maintain systems of management accountability, control, and financial management, involving all levels of management, as prescribed by law and implementing directives and guidance." *

7401.2 PLANNING. *Budget Planning and Formulation will be done in accordance with DEA's Financial Management and Policy Handbook, Chapter 2 *Budget Formulation* and the DEA Laboratory Operations Manual, Chapter 78 *Planning.* *

7401.3 ALLOCATIONS. *SF approved Laboratory Financial Plan Funds will be allocated to individual laboratories on a quarterly basis as outlined in the Financial Management and Policy Handbook, Chapter 3, *Federal Funding.* Once funding is

allocated, funds will be handled in accordance with the DEA Financial Management and Policy Handbook, DEA Administrative Manual and other relevant directives.*

7401.4 **FEDERAL FINANCIAL SYSTEM REPORTS AND RECONCILIATION

The Laboratory Director is responsible for ensuring that proper controls exist over the fund control process. Obligations by DEA laboratories are entered into the Federal Financial System through terminals in each laboratory. These obligations must be entered promptly and their accuracy verified. Verification includes the following:

A. Daily reconciliation

B. Weekly reconciliation

C. Monthly reconciliation

D. Quarterly reconciliation and certification

E. Accounts payable quarterly **reporting and reconciliation**

Instructions for completing these reports must be done in accordance with but not limited to DEA Cable 09389, the Financial Management and Policy Handbook, Chapter 5 *Fund Control*, and other relevant directives.

7402 FINANCIAL MANAGEMENT ADMINISTRATION

7402.1 PURCHASE CARD PROGRAM. The Laboratory Director must manage the purchase card program in accordance with the following: Purchase Card Handbook, Purchase Card Flashes, Purchase Card Fraud Mitigation Handbook, DEA Financial Management and Policy Handbook, Chapter 6 *Payments*, and other relevant directives.

7402.2 PURCHASE ORDERS. The Laboratory Director must manage purchase orders in accordance with the following: Federal Acquisition Regulations Handbook, DEA Administrative Manual, Chapter 2 *Purchasing, Contracting, and Transportation*, Acquisition Policy Letters, Green Purchasing, DOJ Procurement Guidance, and other relevant directives.

7402.3 FISCAL OBLIGATIONS. The Laboratory Director must manage fiscal obligations in accordance with the following: DEA Administrative Manual Chapter 5, *Financial Management*, DEA Financial Management and Policy Handbook Chapter 5

Fund Control, applicable DEA Cables, memorandums, and guidelines, and other relevant directives.

7402.4 PAYMENTS. The Laboratory Director must manage payments in accordance with the following: Prompt Payment Act, DEA Administrative Manual, Chapter 5 *Financial Management*, DEA Financial Management and Policy Handbook, Chapter 7 *Payments*, and other relevant directives.**

7403 TRAVEL AUTHORITY

7403.1 RESPONSIBILITY

A. The Laboratory Director must ensure that all travel of laboratory personnel is necessary and that travel costs are controlled. The Financial Management and Policy Handbook, Chapter 6 *Travel*, gives authority to Laboratory Directors to authorize Domestic travel. This authority may be redelegated to the Associate Laboratory Director or a GS 14 level supervisor only when the individual is acting in the capacity of the Laboratory Director. The delegation to Acting Laboratory Director must be in writing.*

B. The authority of the Laboratory Director to approve travel depends on the purpose of the travel as well as the geographic area to be visited.

1. Domestic Operational Travel. Operational travel anywhere in the United States may be *authorized* by the Laboratory Director. Operational travel is defined as travel for the purpose of court testimony, assisting agents in the performance of their duties (e.g., clandestine laboratories), participation in DEA-sponsored training programs, and participation in meetings in which the mission of DEA is involved.

2. Domestic Travel for Training. Travel for non-operational *activities* will be approved as follows.

a. Travel for any staff member (except the Laboratory Director) to receive training within and outside the laboratory's geographical area of responsibility will be *authorized* by the Laboratory Director if such travel has been approved as part of the annual operational plan.

b. Travel for any staff member (except the Laboratory Director) to attend regional scientific conferences and meetings, and other travel not satisfying operational activity criteria, as defined above, may be *authorized* by the Laboratory Director if it is within the geographic area serviced by that laboratory (See 7001.13).

c. Unless prior written authorization has been received from SF for travel requested as part of the Operating and Financial Plan *submissions*, travel for any non-operational activity outside the geographic area serviced by that laboratory must be

approved by SF. Requests for approval should be in memorandum form, giving the purpose of the travel and appropriate justification. **After SF approval, the Laboratory Director may authorize the travel.

d. For non-operational activities funded by other offices (e.g., Office of Training), Laboratory Directors are to provide SF a memorandum and a training request (SF-182) which will be forwarded to the appropriate funding office for approval. The memorandum must contain the attendee's name, justification, course title, course dates, course location, tuition cost, and travel/lodging costs.**

3. *Laboratory Director's Travel. A Laboratory Director must obtain approval from SF for his or her own official travel.*

4. Foreign Travel. All Foreign travel must be approved as outlined in 7001.14 B2 (e) through SF and SC.

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CHAPTER 75 EQUIPMENT AND SUPPLIES

7501 METHODS OF PURCHASE

7501.1 LABORATORY PURCHASES. See Administrative Manual, Chapter 02. Purchases may be made by Purchase Order, Blanket Purchase *Agreement* (BPA), credit card, and through GSA.

*Note that all BPA's issued must conform to the requirements specified in Administrative Manual Subsection 0234.7, Procedures for Blanket Purchase Agreements. (Also see Laboratory Operations Handbook (LOH), Exhibit H-5.) *

**Reference can also be made to the Acquisition Guidelines as found in the Purchase Card Handbook (Chapter 3) and the Financial Management and Policy Handbook **

7501.2 CONTRACTING OFFICERS AND ALTERNATE CONTRACTING OFFICERS. Each laboratory *should nominate* a Contracting Officer and Alternate Contracting Officer in accordance with the procedures outlined in Administrative Manual 0212.12. Authority to sign purchase or delivery orders or other obligating documents shall be limited to these **nominated individuals who have been delegated procurement authority. For laboratories that do not have a Contracting Officer, other Contracting Officers within DEA (e.g., Division, other laboratory, or headquarters) may be used to effect purchases, as necessary.**

7501.3 OPEN MARKET PURCHASES. Open market purchases shall be affected in accordance with the procedures outlined in the Administrative Manual Chapter 02.

7501.4 RESTRICTIONS. Laboratory operating funds may not be used for purchase of laboratory equipment in excess of * $1,000* per individual item.

**7501.5 PURCHASING REAGENTS, SUPPLIES, CONSUMABLES, AND SERVICES

7501.51 Objective. This section summarizes procedures Laboratory Directors must follow for ensuring that supplies, reagents, consumables, and services which affect the quality of analyses meet specific requirements of the laboratory.

7501.52 Background. The mechanics for all purchases will conform to the Acquisition Guidelines as found in the Purchase Card Handbook (Chapter 3) and the Financial Management and Policy Handbook. LOM Subsection 7707 provides guidance for storage of reagents and laboratory consumable materials. Appendix HA-02.2 provides policy for assuring the reliability of reference standards and supplies after they have been received or prepared in the laboratory.

7501.53 Procedure

A. All providers of reagents, supplies, consumables, and services (RSCS) must be evaluated prior to purchases being made. A designated laboratory representative will determine whether the provider is capable of delivering a product or service of acceptable quality and may do so by purchasing through a reputable catalogue or internet site, or by vendor screening performed telephonically or through personal contacts with a vendor representative.

B. All providers/vendors must be either ISO certified, ISO registered, or conform to recognized standards for providing quality RSCS to the United States government (See item C below).

C. A provider's ability to deliver products and services of acceptable quality can be evaluated by examining the record for past successful performance for the individual laboratory, the DEA laboratory system, or to other government entities. A record of successful past performance meets the requirement for conformance to recognized standards for providing products and services of acceptable quality to the United States government. Other recognized standards, e.g., testing of the delivered product or service, may be used at the discretion of the laboratory.

D. The laboratory will keep records of a supplier's successful delivery of required products and services. Documentation of receipt for goods and services is sufficient for this requirement. This record of success can be used to justify the use of the provider's services in making future purchases.

E. The laboratory will keep records of a vendor's failure to successfully deliver required products and services. A record of failure can be used to justify the elimination from consideration of the supplier's products or services in making future purchases.

F. When ordered products are received into the laboratory, a receiving official will inspect the packaging and contents to ensure that contents conform to the receiving documents and meet the requirements documented on the appropriate ordering document. A receiving official must document, with his or her signature, receipt of such goods. When a contracted service has been completed, a receiving official will document

successful completion of the service by signing the appropriate document.

G. By signing the appropriate document, the individual is certifying that the goods or services ordered comply with the requirements.

7501.6 LABORATORY EQUIPMENT FUNDING AND ACQUISITION – LABORATORY OBLIGATIONS

7501.61 Objective. This section provides guidance for the procurement of laboratory equipment with funds obligated by the laboratory.

7501.62 General. As funding becomes available, the Headquarters Equipment Program Manager (EPM) will request from the laboratory a current itemized cost quote(s) including shipping and handling charges. The EPM will draft correspondence to the laboratory (with the itemized quote(s) attached) for review by the Laboratory Support Section Chief (SFS), Staff Assistant (SF), Associate Deputy Assistant Administrator (SFE), and Deputy Assistant Administrator (SF).

7501.63 Procedure

A. Upon SF approval, the equipment procurement package will be forwarded to the Staff Assistant to request a fund transfer (via the Office of Resource Management, Controls & Coordination Section, FFS/Funds Control Unit) from SF's equipment account to the laboratory equipment account. Once the Staff Assistant has received notice the transfer is complete, the equipment funding package will be returned to the EPM. The EPM will make any indicated changes on the draft and transmit the updated correspondence to the laboratory. The EPM will provide a chron file copy to the SF secretary and the original equipment funding package will be maintained in the SFS equipment file. These files will be maintained by the SFS secretary. The Laboratory Director must ensure the obligation is entered into FFS and effect the order/purchase by the established deadline. The Laboratory Director will then provide SFS with the last invoice marked final payment or a copy of the government purchase card statement, and include a FAS printout showing the equipment has been entered into FAS.

B. The Laboratory Director must ensure that acquisition management, property management, and fiscal management regulations and guidelines are met. Additionally, all laboratory equipment orders/procurements must adhere to contracting regulations established by DEA and GSA, and be within the authority granted to the contracting officer within their laboratory (or Division). Any laboratory equipment order/purchase outside laboratory contracting authority will be processed through DEA's Office of Acquisition Management, Acquisition Management Section.

C. Increase(s) or decrease(s) to an equipment obligation must be requested via correspondence to SF including the amount to be increased or decreased, a detailed justification and supporting documentation. When requesting an increase the laboratory must review their equipment account thoroughly prior to submission in order to determine fund availability through deobligations. It is important to scrutinize all obligations for necessary closure and deobligation in the equipment account(s). Any deobligations/increases identified should be forwarded immediately to SF. This correspondence will be logged in by the SF Secretary and forwarded to the EPM for review. Increases up to $250 and modifications will be reviewed and approved by the EPM and those over $250 will require SF approval. The EPM will monitor all increase and decrease requests in order to identify available funds and effectively manage the equipment program. All approved requests will be forwarded to the Staff Assistant for processing.

When available funds are not identified by the EPM, the Staff Assistant will search for available funds in other Laboratory System and SF accounts. Once available funds are identified the Staff Assistant will request a transfer of funds (via the Office of Resource Management, Controls & Coordination Section, FFS/Funds Control Unit) from the available source to the appropriate equipment account.

D. Once the Staff Assistant has received notice of the transfer, the correspondence will be returned to the EPM. The EPM will transmit the correspondence to the laboratory and provide a chron file copy to the SF secretary and the original equipment increase/decrease package(s) will be maintained in the SFS equipment file. The Laboratory Director must ensure the obligation is entered into FFS and effect the order/purchase by the established deadline.

7501.7 LABORATORY EQUIPMENT FUNDING AND ACQUISITION – HEADQUARTERS OBLIGATIONS

7501.71 Objective. This section provides guidance for the procurement of laboratory equipment with funds obligated at headquarters.

7501.72 General. As funding becomes available, the Headquarters Equipment Program Manager (EPM) will request from the laboratory a current itemized cost quote(s) including shipping and handling charges. A printout of the FFS inquiry table VNDA (Alternate Vendor Inquiry Table) reflecting the correct billing address for the vendor, FFS vendor code, and tax identification number must be attached to the quote(s). The EPM will draft correspondence to the laboratory (with the itemized quote(s) attached) for review by the Laboratory Support Section Chief (SFS), Staff Assistant (SF), Associate Deputy Assistant Administrator (SFE), and Deputy Assistant Administrator (SF).

7501.73 Procedure

A. Upon SF approval, the equipment procurement package will be forwarded to the Staff Assistant for funding. The original equipment funding package(s)will be returned to the EPM. The EPM will make any indicated changes on the draft and transmit the updated correspondence to the laboratory. The EPM will provide a chron file copy to the SF secretary, the original equipment funding package will be maintained in the SFS equipment file and a copy of the package will be filed in the procurement file maintained by the Staff Assistant. The Laboratory Director will affect the order/purchase by the established deadline. The Laboratory Director will then provide SF with a copy of the purchase order or indicate that the order was made with a government purchase card. After receipt of the equipment, the Laboratory Director will also transmit to SF, copies of all processed invoices, government purchase card statements, and the signed receipt of goods and services. A copy of the last invoice marked final payment and a FAS printout showing entry into the property system for capitalized and accountable equipment must be sent both to the Staff Assistant and the EPM.

B. The Laboratory Director must ensure that acquisition management, property management, and fiscal management regulations and guidelines are met. Additionally, all laboratory equipment orders/procurements must adhere to contracting regulations established by DEA and GSA, and be within the authority granted to the contracting officer within their laboratory (or Division). Any laboratory equipment order/purchase outside laboratory contracting authority will be processed through DEA's Office of Acquisition Management, Acquisition Management Section.

C. Increase(s) or decrease(s) to an equipment obligation must be requested via correspondence to SF including the amount to be increased or decreased, a detailed justification and supporting documentation. This correspondence will be logged in by the SF Secretary and forwarded to the EPM for review. Increases up to $250 and modifications will be reviewed and approved by the EPM and those over $250 will require SF approval. The EPM will monitor all increase and decrease requests in order to identify available funds and effectively manage the equipment program. All approved requests will be forwarded to the Staff Assistant for processing.

D. Once the Staff Assistant has received notice of the transfer, an increase will be processed and the original will be returned to the EPM. After the increase/decrease is processed, the EPM will transmit the correspondence to the laboratory and provide a chron file copy to the SF secretary and the original equipment increase/decrease package(s) will be maintained in the SFS equipment file. The Laboratory Director must ensure the order/purchase is placed by the established deadline.**

7502 *PROPER OPERATION* OF EQUIPMENT

7502.1 GENERAL. It is the responsibility of the Laboratory Director to see that all laboratory equipment is properly *calibrated and maintained. It is mandatory that each employee using an instrument be familiar with its proper operation.* Any deficiency in the instrument's operation should be reported to the instrument monitor. All maintenance and repairs will normally be paid from the operating budget of the laboratory.

7502.2 INSTRUMENT MONITOR. The Laboratory Director shall appoint a staff member as instrument monitor for each item of capitalized laboratory equipment. Each instrument monitor will be responsible for:

A. Maintaining *records and logbooks for all calibration checks and for* all adjustments, repairs, and preventive maintenance using a format specified by the Laboratory Director. **Other instrument users may assist with these responsibilities. At a minimum, these records will include the following:

1. The identity of the item of equipment and its software;
2. The manufacturer's name, type identification, and serial number or other unique identification;
3. Checks that equipment complies with the specifications;
4. The current location, where appropriate;
5. The manufacturer's instructions, if available, or reference to their location;
6. Dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
7. The maintenance plan, where appropriate, and maintenance carried out to date;
8. Any damage, malfunction, modification, or repair to the equipment.**

B. Assuring that the instrument is properly maintained and *calibration checks are done* in accordance with manufacturer's recommendations. Equipment checks and adjustments listed in a summary of maintenance procedures issued by SF, or *more in-depth local* maintenance procedures, may be utilized at the discretion of the Laboratory Director.

C. Providing prompt notification to laboratory management of any instrument malfunction brought to his or her attention by other staff members.

D. Being thoroughly familiar with the operation of the instrument and providing instruction as needed in its operation.

E. Effecting minor repairs within his or her capability to do so.

F. Verifying that service personnel perform stated repairs and certifying this on obligating documents as required.

7503 INSTRUMENT CALIBRATION AND MAINTENANCE PROCEDURES

7503.1 GENERAL. The procedures outlined below are to be considered as the minimum levels of calibration checking and maintenance that will be performed. These check and adjustment procedures are generic in nature due to the instrumental differences within the laboratory system. These procedures may be supplemented by those outlined in instrument manuals, other sources, detailed calibration checking procedures, etc., at the discretion of the Laboratory Director.

7503.2 CALIBRATION CHECKING AND MAINTENANCE CHECKING PROCEDURES

A. The maintenance and calibration checking procedures contained in this section conform to the requirements of *ASCLD/LAB International (ISO) Requirement 5.5 and* ASCLD/LAB International (ISO) Supplemental Requirement 5.6.1.1. All maintenance and calibration checks, including results if appropriate, will be documented *in the instrument logbook.*

B. The procedures to check calibration of equipment/ instrumentation have been established and are based on requirements of the DEA Laboratory system to carry out its mission to identify and, when required, to quantitate controlled and/or non-controlled substances. *The following table provides the minimum calibration checking schedule for the laboratory's instrumental equipment. For hyphenated techniques (e.g., GC-MS, GC-IR, LC-MS, CE-MS, etc.), the chromatographic equipment must be checked as well as the confirmatory component. Specific instrument calibration checking procedures with acceptable tolerances can be located in Section 7503.3.*

**

Type of Equipment	Frequency of Check	Parameters	Standards or Reference Materials	General Procedures and/or Remarks
Chromatographic				
Capillary Electrophoresis	Monthly	System check	Appropriate standard mixture	Ensure pressure system, voltage and detector are functioning within tolerance.
High Performance Liquid Chromatograph	Monthly	System Check	Appropriate standard mixture	Ensure injection system, pump system and detector are functioning within

				tolerance.
	Monthly	Column check	Appropriate standard mixture	Ensure resolution and capacity are within tolerance.
Gas Chromatograph	Monthly	System check	Appropriate standard mixture	Ensure injection system, oven and detector are functioning within tolerance.
	Monthly	Column check	Appropriate standard mixture	Ensure resolution and capacity are within tolerance.
Confirmatory				
Mass Spectrometer (MS) with GC	Monthly	System check	PFTBA (FC43) or other calibration test	Check calibration of system with test gas and adjust as necessary.
Mass Spectrometer (MS) with HPLC	Monthly	System check	Refer to manufacturer's recommendations	Check tune with appropriate calibrant and adjust as necessary.
Fourier Transform Infrared Spectrophotometer	Monthly	Resolution and Wavelength Accuracy	Polystyrene or suitable reference material	Scan total range for wavelength accuracy and resolution.
Fourier Transform Infrared Spectrophotometer with GC	Monthly	IRD Mirror Alignment	Refer to manufacturer's recommendations	Adjust mirror locations for maximum signal strength.
	Annually	IRD Wavelength Calibration	Atmospheric carbon dioxide and water	Perform calibration if necessary. Manual optical alignment of stationary mirror. Electronic alignment of moving mirror.
Fourier Transform Infrared Spectrophotometer (ATR)	Monthly	Resolution and Wavelength Accuracy	Suitable reference material	Scan total range for wavelength accuracy, resolution and interference.
Fourier Transform Raman Spectrophotometer	Monthly	Resolution and Wavelength Accuracy	Polystyrene or suitable reference material	Scan total range for wavelength accuracy and resolution.
Fourier Transform	Every 2 years	Gradient shim	Doped 2 Hz test	Update shim map

Nuclear Magnetic Resonance Spectrometer		map	sample	if necessary.
	Every 6 months	Spectra performance	2-ethyl-1-indanone test sample	Record 1D / 2D spectra.
	Monthly	Proton line shape	Chloroform in /acetone-d6	Record 50%, 0.55% and 0.11% of height of the chloroform peak.
	Monthly	Proton sensitivity	Ethyl benzene in chloroform-d6 test sample	Record signal to noise.
	Monthly	Proton decoupled, 90 degree	Methyl iodide	Update probe file if needed.
	Monthly	Carbon decoupled, 90 degree	Methyl iodide	Update probe file if needed.
	Monthly	Gradient calibrate	Methyl iodide	Update probe file if needed.
	Monthly	C/H gradient ratio	Methyl iodide	Update probe file if needed.
The above probe parameter checks are for the probe in use. When a different probe is installed, it is necessary to perform the monthly checks and those calibrations that are pertinent to that probe and the experiment(s) it will perform.				
Inductively-Coupled Plasma Mass Spectrometer (ICP-MS)	Daily (or per use)	System check	Refer to manufacturer's recommendations	Check tune and adjust as necessary.
	Daily (or per use)	System check	Multi element standard	Set response for each element.
Elemental Analysis-Isotope Ratio Mass Spectrometer (EA-IRMS)	Every 6 months	System check	CO_2 reference gas	Check calibration of system and adjust as necessary.
	Daily (or per use)	System check	Run standard "on-off" method	Ensure pulses are within tolerances.
	Daily (or per use)	System check	Nitrogen and CO_2 reference gases	Check Ar, H_2O and vacuum.
Other Equipment				
UV-Visible Spectrophotometer	Yearly	Wavelength accuracy and reproducibility	Holmium or other appropriate reference material	Check wavelength over appropriate UV-Visible range.
	Date of operation	Photometric accuracy and reproducibility	Appropriate standard reference material	Scan spectrum over appropriate wavelength range for standard used. Check absorbance at local maxima and/or minima.
Polarimeter	Date of Operation or	Specific Rotation	Appropriate standard reference material	Ensure standard readings compare

	Yearly			to literature values.
Balances/Microbalances	Monthly	Accuracy	ASTM equivalent	Check accuracy to level of readability.
	Yearly	Accuracy	ASTM equivalent	Work to be performed by ISO Certified service representative or staff member qualified through specialized training.
Ion Mobility Spectrometer (e.g., IMS or IONSCAN)	Date of operation	System check	Appropriate standard reference material	Check calibration of system and adjust as necessary.

**

C. *No instrument will be used for case work until initial or scheduled calibration checks have been performed and documented.*

D. Calibration checks at required intervals will ensure that the instrument responses to calibration standards (PFTBA, polystyrene, specified solvents, or laboratory prepared calibration standards) are adequate to address the analytical work performed by the instrument. Each instrument log book will include performance criteria to be used in the evaluation of the calibration check. *Calibration checks may be performed by any instrument user, however, calibration check documentation will also be initialed and dated by the authorized instrument monitor, and filed in the appropriate log book.* The calibration check data will be archived in the laboratory for one ISO 17025 accreditation cycle (Five Years). When applicable, data from a known calibration and the data from the calibration check will be compared and evaluated in the same way data from an unknown is compared to data from a standard. When the data from the two calibration checks are consistent with one another **and within acceptable tolerance ranges.** the instrument will be considered properly calibrated.

E. Problems which are identified during the required periodic calibration check will be documented and the instrument will be immediately taken out of service until the problem has been resolved. **Also, instruments subject to overloading and mishandling will be taken out of service pending appropriate service and labeled as such, appropriately.** Calibration checks will be required after any instrument shut down, following service or other substantial maintenance.

F. **The following table provides the minimum maintenance schedule for the laboratory's instrumental equipment. For hyphenated techniques (e.g., GC-MS, GC-IR,

LC-MS, CE-MS, etc.), the chromatographic equipment must be properly maintained as well as the confirmatory instrument.** *Laboratories are required to perform necessary maintenance immediately whenever a problem is identified.*

**

Type of Equipment	Frequency of Check	Parameters	General Procedures	Remarks
Chromatographic				
Capillary Electrophoresis	Date of operation	Cleanliness	Inspect buffer reservoirs/vials for potential microbial growth, fill reservoirs and check electrodes	Determine if buffer needs to be replaced.
	Monthly	Detector	Perform Diode Array Detector test	Replace deuterium lamp when necessary.
	Every 3 months	Pressure system	Examine inlet and outlet seals	Replace air filter if applicable.
High Performance Liquid Chromatograph	Monthly	Detector	Column eluent	Diode array detector intensity check for max and min levels and perform wavelength calibration.
	Every 2 years	Cleanliness	System check	Check and clean or replace solvent inlet filters, buffer reservoirs, as needed.
	Every 2 years or if system performance deteriorates	System parts	Take down instrument and examine	Change column, pre-column, lamp(s), replace pump head seals, pistons, and check valves as needed.
Gas Chromatograph	Monthly	Septum	Refer to manufacturer's recommendations for longer lasting septums	Replace septum
	Every 3 months	Split liner	Take down instrument and examine	Replace split liner
	Yearly or if system performance deteriorates	Gold seal and syringe	Take down instrument and examine	Replace gold seal and syringe if necessary

	Yearly	FID	Take down instrument and examine	Clean and replace if necessary.
	Yearly	Gas flow	Ensure all gas flow is in accordance with manufacturer's recommendations	Clean and replace as necessary.
Confirmatory				
Mass Spectrometer (MS) with GC	Yearly	Source	Clean source	Replace if necessary.
	Every 6 months	Pump	Check pump oil	Replace and fill as necessary.
Mass Spectrometer (MS) with HPLC	Every 3 months or if system performance deteriorates	Source (Electrospray)	Clean spray chamber and capillary spray shield	Clean and replace if necessary.
	Every 3 months or if system performance deteriorates	Source (APCI)	Clean corona needle if in use	Clean and replace if necessary.
	Every 3 months	APCI	Replace corona needle if in use	Replace if necessary.
	Every 6 months or if system performance deteriorates	Capillary Spray Shield	Abrasively Clean	Clean and replace if necessary.
	Every 6 months	Pump	Change rough pump oil	Replace and fill as necessary.
	Every 6 months	Gas Conditioner	Replace if in use	
	Yearly	Source	Replace Nebulizer needle (API-ES) if in use	
	Every 5 years	Detector	Replace Electron Multiplier horn	
Fourier Transform Infrared Spectrophotometer	Monthly	Cleanliness	Ensure area is free of possible contaminants	
Fourier Transform Infrared Spectrophotometer with GC	Monthly	Cleanliness	Ensure area is free of possible contaminants	
Fourier Transform Infrared Spectrophotometer	Monthly	Cleanliness	Ensure area is free of possible contaminants	

(ATR)				
Fourier Transform Raman Spectrophotometer	Monthly	Cleanliness	Ensure area is free of possible contaminants	
Fourier Transform Nuclear Magnetic Resonance Spectrometer	Weekly	Liquid nitrogen	Fill to capacity	
	Every 4 months or if it drops below 50% full	Liquid helium	Fill to capacity	
Inductively-Coupled Plasma Mass Spectrometer (ICP-MS)	Daily	Lab Conditions	Check for Safety	
	Daily	Argon Gas	Check Pressure and Volume	
	Daily	Drain Vessel	Empty (if needed)	
	Daily	Sample Tray, etc.	Wipe acid, etc. if spilled	
	Daily	Peristaltic pump tube	Inspect for damage	Replace if necessary.
	Daily	Sampling Cone/ Skimmer Cone	Check orifice	
	Weekly	Torch, Spray Chamber, End Cap	Wipe Clean	
	Weekly	Nebulizer	Rinse Clean	
	Weekly	Carrier Gas Tubing	Check for Leaks	
	Weekly	Cooling Water	Inspect Chiller Pressure and Water level	
	Weekly	Water Filter	Inspect for green film	
	Monthly	Sample Tubing	Replace	
	Monthly	Peristaltic pump tube	Clean	Replace if necessary.
	Every 3 months	Nebulizer	Clean	Replace if necessary.
	Every 3 months	Rotary Pump	Check oil level and color	
	Every 3 months	Oil Mist Filter (Rotary Pump)	Check	Replace if necessary.
	Every 3 months	Cooling Water Filter	Check	
	Every 6 months	Sampling Cone/ Skimmer Cone	Clean	Replace if necessary.
	Yearly	Rotary Pump	Replace Oil	
	When Empty	Tuning Solution Preparation	Prepare	
	Yearly	Lenses	Clean	Replace if necessary.

	Every 2 years	Plasma Gas Tubing	Inspect for leaks	
	Every 2 years	Carrier Gas Tubing	Inspect for leaks	
	When Pump Oil is Changed	Oil Mist Filter of Rotary Pump	Inspect for leaks	
	Every 6 months	Torch	Clean	Replace if necessary.
	Every 3 years	Electron Multiplier	Evaluate	Replace if necessary.
Elemental Analysis-Isotope Ratio Mass Spectrometer (EA-IRMS)	Yearly	Source	Check and clean if necessary	Replace if necessary.
	Yearly	Pumps	Change vacuum pump oil	
Other Equipment				
UV-Visible Spectrophotometer	Yearly	Cleanliness	Ensure area is free of possible contaminants	
Polarimeter	Yearly	Cleanliness	Ensure area is free of possible contaminants	
Microscopes	Yearly	Cleanliness	Clean objectives and eye pieces	Maintenance check to be performed by a qualified service representative or specially trained chemist
Balances / Microbalances	Monthly	Cleanliness	Ensure area is free of possible contaminants	
Ion Mobility Spectrometer (e.g., IMS or IONSCAN)	Monthly	Gasket, Inlet door, O-rings	Inspect and clean	Replace if necessary.
Instrument Data Systems	Monthly	Inlet liner	Inspect and clean	Replace if necessary.
	Every 6 months	Source	Perform radiation leak test	National Leak Test Center or Nuclear Regulatory Commission
	Monthly	Condenser	Visually inspect and clean	Change material when one-half

				discolored.
	Date of Operation or monthly	Air purification unit	Check for visual discoloration	Change desiccant and charcoal.
	Installation	New software	Scan for viruses (if possible) prior to loading on hard disk	
	Yearly		Run Scan Disk	Delete unnecessary files, and back-up hard
	Yearly		De-fragment hard disk	

G. Digital evidence and fingerprint examination equipment maintenance and calibration checking procedures can be found in the Digital Evidence Laboratory's Standard Operating Procedure and the Fingerprint/Photography Handbook, respectively.

H. Equipment used outside the permanent facility have additional procedures associated with them.** See *7503.21* for instructions on the "TRAVEL IR", storage, transportation and setup. See *7503.22* for instructions on the "IMS" storage and transportation.

7503.21 Travel IR

A. Storage

When not in use, the TravelIR should be stored in such a manner as to protect it from damage.

B. Transportation[1]

The TravelIR should only be shipped in the shipping case received with the system. If the TravelIR is to be hand carried, an alternative carrying case is acceptable.

C. Set-up for Field Deployment[1,2]

1. Use care to set up the TravelIR in a location which will protect it from rain, sleet, snow, or any inclement weather.
2. After set-up and power on, allow approximately 20 minutes for the instrument to warm up.
3. Perform the add-in *DEA Performance Test* found in the QualID software. The *DEA Performance Test* utilizes an interactive interface to adjust and/or check:

i) System Alignment and Electrical Settings
ii) Signal-to-Noise
iii) ATR Pathlength/Sensitivity Test (Acetone)

Pass/Fail criteria are defined within the *DEA Performance Test* report.

D. Maintenance Procedures[2]

Monthly – Perform the Qual-ID *Performance Validation* routine found in the Qual-ID software. The *Performance Validation* routine utilizes an interactive interface to adjust and/or check:

1. System Alignment and Electrical Settings
2. Signal-to-Noise Ratio
3. Baseline Stability
4. ATR Pathlength/Sensitivity Test (Acetone)
5. Wavenumber Accuracy Test

Pass/Fail criteria are defined within the *Performance Validation* report.

E. References

1. TravelIR Portable FT-IR Spectrometer User's Guide, Revised 6/23/2000.
2. Personal Communication with Arran Bibby, SensIR Technologies 3/23/2004.

7503.22 Portable Ion Mobility Spectrometer

A. Storage

When not in use, the IMS should be stored in the manufacturer provided storage crates. All crates, including crates that store the supporting field supplies for the IMS, should be stored in a clean, dry room designated as a trace (or clean) room only. No IMS equipment or travel supplies should be exposed to moisture or controlled substances. If the units are not in the storage crates, they can be set up for laboratory use or maintenance only in the designated contaminant free, dry, clean room.

B. Transportation

When the IMS is needed for field use, it must be transported in the manufacturers supplied travel crates. If the equipment is being shipped it should be labeled on the outside as "FRAGILE". IMS must contain an affixed label stating "Contains a sealed radioactive source (Ni 63 at 15mCi)". The newer models have this label pre-affixed to the unit and should not be removed. Older models must have an attached sheet noting the presence of a radioactive source. The accompanying shipping papers should contain the following exact wording: "Radioactive material, excepted package-Instrument".

Categorization, labeling, and shipper's declaration are not required. If the shipping company permits, lock the crates. The case chemist should hand carry the computer.

(b)(7)(E)

C. Set-up for Field Deployment

Once on scene, the equipment should be inspected for any damage. The IMS should be set up, calibrated, and shut down according to the operator's manual. Do not set up the IMS in an area that could lead to potential contamination or exposure to water or moisture. Under no circumstances should smoking be permitted, as it will interfere with the operation of the IMS.

**7503.3 CALIBRATION CHECKING OF INSTRUMENTS. Specific calibration checking procedures that a Laboratory Director must incorporate into their laboratory's protocol are found in the LOH. The referenced calibration checking mixtures, parameters, measurements, and tolerances must be followed. Laboratory Directors may add additional procedures or perform them more frequently, as necessary. Instrument software should be used wherever possible to facilitate calibration checking measurements. Before other types of instrumentation can be used for evidence analysis, the Laboratory Director must develop appropriate calibration checking procedures and obtain SF approval.

7504 PROPERTY ACCOUNTABILITY

7504.1 GENERAL. DEA's property accountability program is the responsibility of the Chief, Facilities and Property Management Section, with each Laboratory Director designated as Property Custodian of his/her laboratory.** Administrative Manual Chapter 03 states DEA policy regarding property accountability and provides the necessary guidelines in carrying out the property accountability responsibilities of DEA. (See memoranda dated December 12, 1996, and July 15, 1997, by the Assistant Administrator for Operations Support.)

7504.2 BIENNIAL INVENTORY LISTINGS OF EQUIPMENT. This report will be submitted on a biennial basis as directed in Subsection 7006 of the Laboratory Operations Manual and Section 0315 of the Administrative Manual, **unless directed by SF to complete on an annual basis.**

See memorandum dated July 7, 1999, subject: Property Custodial Assistant Retention and Use of Funding and Other Documents for Property Items. See CFO Bulletin 98-3 dated June 12, 1998, subject: Allowance Holder Responsibilities for Accountable Property.

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7601 DEFINITION AND OBJECTIVES

7601.1 DEFINITION. Special studies are scientific investigations into policy, technical and procedural questions performed by members of the laboratory system as part of their official duties. Special studies are primarily directed toward, but are not limited to, research related to the forensic examination of drug evidence, fingerprint evidence and digital evidence.

7601.2 OBJECTIVES. The principal objective of special studies is to provide factual technical information needed by the Drug Enforcement Administration (DEA) in the performance of its mission. These studies also increase the professional competence of the laboratory system staff by providing opportunities for independent study and opportunities for applying knowledge and experience to the solution of non-routine problems. Where appropriate, publication of the results of special studies in technical journals is encouraged. (See LOM 7007).

7602 CATEGORIES OF SPECIAL STUDIES

There are three categories of special studies: Headquarters Imposed (610), Research and Methods Development (620), and Laboratory Imposed (600). Each category differs in scope, method of assignment, and format for reporting the results.

7602.1 HEADQUARTERS IMPOSED SPECIAL STUDIES. These studies are of wide scope, generally combining technical problems with policy or procedural questions.

7602.11 Topics. The Deputy Assistant Administrator, Office of Forensic Sciences (SF), or designee, will assign topics for Headquarters Imposed Special Studies.

**7602.12 Procedures. SF will use the following procedures to initiate Headquarters Imposed Special Studies:

A. SF will assign topics in writing to one or more Laboratory Directors. The assignment will contain at a minimum a description of the area of the study, background, a deadline, a description of the expected product of the study, and a research project number.

B. Under special circumstances, topics may be assigned to specific individuals by SF with the concurrence of the Laboratory Director.

C. When a topic is assigned by SF, the responsible Laboratory Director(s) may be required to furnish a completed protocol to SF within 30 days of the date of assignment.

D. If a protocol is required, SF will reply in writing either approving or disapproving the Headquarters Imposed Special Study Protocol within two weeks of receipt.

E. SF will maintain a list of approved research projects on the share drive under hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\ Headquarters Imposed Special Studies.xls.

7602.13 Research Protocol. A research protocol is a detailed description of the research project and is required for each Headquarters Imposed Special Study. Exhibit H-06 illustrates and explains the format to be used in preparing protocols. The protocol should also include an exhaustive search of the relevant literature to ensure that the proposed topic has not been previously addressed and to ensure that a proper foundation is established for the research to be conducted. SF will post approved protocols on the share drive under hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\Protocols.

7602.14 Progress Reports. The Laboratory Director will submit an annual progress report for every Headquarters Imposed Special Study, covering the period from August 1 to July 31, for review by SF with the Operating Program Plan.

Exhibit H-07 in the Laboratory Operations Handbook shows the format to be used for progress reports. If no time is spent on a project during the reporting period, an explanation will be provided. SF will collate and post all progress reports as the Annual Report of Research on the share drive under hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\Annual Research Reports.

7602.15 Study Termination. Headquarters Imposed Special Studies can be terminated at any time by SF. Written notice will be provided to the Laboratory Director, including the reason for termination. A final report is required for each terminated project unless an exemption is requested by the Laboratory Director and approved by SF.

7602.16 Study Assignment. Each Laboratory Director has authority to reassign Headquarters Imposed Special Studies within the laboratory. If a researcher is transferred to another laboratory, projects can only be reassigned to the new laboratory after SF receives concurrence from both Laboratory Directors.

7602.17 Final Report. Final report format requirements for Headquarters Imposed Special Studies will be determined at the conclusion of the study. Final reports intended for distribution outside DEA must be submitted to SF for approval and coordination with other Headquarters elements, where appropriate (see LOM 7007.1 and 7007.2).

When the findings of a study are of limited interest and extent, and are not intended for distribution outside DEA, the final report will be in the form of a Laboratory Note (see LOM 7603.2). If a Laboratory Note is not appropriate, an alternate format may be used with approval from SF. Approvals from SF are necessary for all Headquarters Imposed Special Studies reports before distribution.

7602.18 Staff Time Reporting. All staff time expended for Headquarters Imposed Special Studies will be recorded using DEA Form-271 (Daily Laboratory Staff Time Expenditures Form) utilizing task code 610 and the appropriate SF assigned research project number.**

7602.2 RESEARCH AND METHODS DEVELOPMENT SPECIAL STUDIES

These studies are generally restricted to technical questions related to the forensic examination of drugs, fingerprints, digital media and related evidence. Policy or procedural matters may be addressed, but are not central issues.

7602.21 Topics. Topics for Research and Methods Development Special Studies can be suggested by any member of DEA. SF reviews and approves the suggested topics.

7602.22 Procedures. The following procedures will be used in initiating a study:

A. The person who wishes to do the study will complete a research protocol, and submit it to the Laboratory Director who will review it for clarity and completeness and forward it to SF for approval.

B. If a topic for a proposed research study is announced by SF, the announcement will include a partially completed research protocol containing information required in Items 4 and 5 of Exhibit H-06. Announcements will generally request volunteers to work on the topics. Volunteers will submit a complete research protocol. These protocols will be forwarded to SF by the appropriate Laboratory Director as in paragraph A of this section.

C. Under special circumstances, topics may be assigned to specific individuals by SF with the concurrence of the Laboratory Director.

D. When a topic is assigned by SF, the responsible Laboratory Director is expected to furnish a completed protocol to SF within 30 days of the date of assignment.

E. Within two weeks of receiving a protocol, SF will reply by memorandum either approving or disapproving the Research and Methods Development Special Study. Approved studies will be assigned identifying numbers.

F. SF will maintain a list of approved research projects on the share drive under hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\Research and Method Development.xls.

7602.23 Research Protocol. A research protocol is a detailed description of the research project and is required for each Research and Methods Development Special Study. *Exhibit H-06 illustrates and explains the format to be used in preparing protocols. The protocol should also include an exhaustive search of the relevant literature to ensure that the proposed topic has not been previously addressed and to ensure that a proper foundation is established for the research to be conducted. SF will post approved protocols on the share drive under hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\Protocols.*

7602.24 Progress Reports. One progress report for every assigned project, covering the period from August 1 to July 31, will be submitted for review by SF with the Operating Program Plan. (See LOM 7802.3).

Exhibit H-7 in the Laboratory Operations Handbook shows the format to be used for progress reports. If no time is spent on a project during the reporting period, an explanation will be provided. All progress reports are collated and posted as the Annual Report of Research by SF on the share drive under hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\Annual Research Reports.

7602.25 Study Termination. Research and Methods Development Special Studies initiated by the laboratory can be terminated at any time by the Laboratory Director or by SF. Research and Methods Development Special Studies initiated by SF can be terminated at any time by SF. Written notice will be provided to the other party, including the reason for termination (e.g., completion of the study, changes in circumstances which make the study unnecessary, or continued lack of progress). If no significant work is done on a project for two consecutive years, the study will be automatically terminated. A final report is required for each terminated project unless an exemption is requested by the Laboratory Director and approved by SF.

The primary researcher may appeal the termination of a project, in writing, through the chain of command. The appeal will be answered, in writing, by the office that terminated the project. The decision will be final.

7602.26 Study Assignment. Research and Methods Development Special Studies are part of the operating plan of the laboratory. Each Laboratory Director has authority to reassign studies within the laboratory. If a researcher is transferred to another laboratory, projects can only be reassigned to the new laboratory after SF receives concurrence from both Laboratory Directors.

7602.27 Final Report. Final reports for Research and Methods Development Special Studies that are not law enforcement sensitive, and produce findings of interest to forensic examiners outside DEA, should be in the form of technical reports suitable for publication in scientific journals, or for oral presentations at scientific/technical meetings. Some studies are dedicated to building databases or assembling resource materials. Formats for final reports for these studies are left to the discretion of the Laboratory Director. Final reports intended for distribution outside DEA must be submitted to SF for approval and coordination with other Headquarters elements, where appropriate (see LOM 7007.1 and 7007.2).

When the findings of a study are of limited interest and extent, and are not intended for distribution outside DEA, the final report will be in the form of a Laboratory Note (see LOM 7603.2). If the Laboratory Note is not appropriate, an alternate format may be used with approval from SF.

7602.28 Staff Time Reporting. All staff time expended for Research and Methods Development Special Studies will be recorded using DEA Form-271 utilizing Task Code 620 and the appropriate Headquarters assigned Research Project Number.

7602.3 LABORATORY IMPOSED SPECIAL STUDIES

*A. These studies are very narrow in focus. They do not address policy or procedural matters and are restricted to limited investigations of a particular substance, instrument, or analytical method. Allotment of time for studies which involve analytical methods should be limited.

B. Projects requiring more than 40 work hours should be submitted to SF requesting approval as a Research and Method Development Special Study. (See LOM 7602.2).*

7602.31 Topics. *Topics for Laboratory Imposed Special Studies can be suggested by any member of the laboratory staff. The Laboratory Director reviews and approves the suggested topics.*

**7602.32 Procedures. The Laboratory Director will use the following procedures to initiate Laboratory Imposed Special Studies:

A. The Laboratory Director will assign a staff member(s) to a particular project.

B. The staff member(s) will furnish a completed protocol to the Laboratory Director within the time specified by the Laboratory Director.

C. The Laboratory Director will ensure that these studies do not constitute duplication of prior work performed in the field by reviewing the research lists on the headquarters share drive at hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\. The Laboratory Director will assign identifying research project numbers to approved protocols. The research project numbers will be in the format "Laboratory Number-CY-XX (e.g. 10502, for the second project initiated at the Special Testing and Research Laboratory in calendar year (CY) 2005; or 80601, for the first project initiated at the Southwest Laboratory in CY2006).

D. Approved projects must be posted on the Headquarters share drive at hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\Laboratory Imposed Special Studies.xls.

7602.33 Research Protocol. A research protocol is a detailed description of the research project and is required for each study. Exhibit H-06 illustrates and explains the format to be used in preparing protocols. The protocol should also include an exhaustive search of the relevant literature to ensure that the proposed topic has not been previously addressed and to ensure that a proper foundation is established for the research to be conducted. The laboratory's document control officer will post approved protocols on the share drive under hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\Protocols\Laboratory Imposed Special Studies.**

7602.34 Study Record. *Each laboratory will maintain a record of these studies on the headquarters share drive. A format for recording this information will be developed in each laboratory. The minimum information to be recorded is outlined below; additional items can be added to this list by the Laboratory Director. A spreadsheet containing a summary of all projects will be maintained by each Laboratory Director on hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\Laboratory Imposed Special Studies.xls. This spreadsheet will contain the project number, title, date initiated, names of researchers, links to the research protocol and study records, and a citation for the final report, if applicable.

A. Title

B. Research Project Number

C. Date the study was initiated.

D. Date study was terminated.

E. Name(s) of the researcher(s).

F. Description of the problem.

G. Summary of the results.

H. Number of hours used.*

**The study record will be posted on the shared drive under hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Research and Special Studies\Study Records. File titles for the study records will be in the format: laboratory number, project number and date (i.e. SFL1 10502 01-16-05, for a record posted by the Special Testing and Research Laboratory for project number 10502 that was dated January 16, 2005).

7602.35 Study Termination. Laboratory Imposed Special Studies can be terminated at any time by the Laboratory Director. Written notice will be provided to the researcher, including the reason for termination. This termination notice must be included with the study record.

7602.36 Study Assignment. Each Laboratory Director has authority to reassign Laboratory Imposed Special Studies. If a researcher is transferred to another laboratory, projects can only be reassigned with the concurrence of both Laboratory Directors.**

7602.37 Dissemination of Findings. If, in the opinion of the Laboratory Director, findings of a particular study are of interest in other DEA laboratories, they can be disseminated as a Laboratory Note. Any other dissemination of findings requires approval (see LOM 7007 and 7603).

7602.38 Staff Time Reporting. All staff time expended for Laboratory Imposed Special Studies will be recorded using DEA Form-271 utilizing task code 600 and the appropriate research project number assigned by the Laboratory Director.

7603 INTERLABORATORY COMMUNICATION OF TECHNICAL FINDINGS

Prompt dissemination of technical findings avoids duplication of effort and improves the efficiency of the laboratory system. Delays in disseminating findings should be avoided.

7603.1 DISSEMINATION FOR REPORTS PRESENTED. After the in-house review process is completed (see LOM 7007), the Laboratory Director will submit the report, via electronic copy, to SF. The document will identify the meeting (including the date), or the publication for which the report is intended and the identifying number of the

Research Special Study (when appropriate) under which the work was performed (see LOM 7602.23E).

7603.2 DISSEMINATION FOR REPORTS NOT PRESENTED. *A report not intended for oral presentation at a scientific meeting or for publication in a scientific journal may be distributed as a Laboratory Note, using the format found in Exhibit H-08 and H-09. The Laboratory Note will be posted by the SF document control officer on the headquarters share drive at hq-s-n-00\Lab System\Information Exchange\Laboratory System Information\Laboratory Notes.*

7604 LABORATORY NOTES

*7604.1 LABORATORY NOTES SUBMITTED TO *MICROGRAM JOURNAL*

Laboratory Notes submitted for publication in *Microgram Journal* will follow the *Microgram Journal* format.*

*7604.2 FORMAT. The format of a Laboratory Note is shown in Exhibits H-08 and H-09. This format should be used as a guide except in instances where it is obviously inappropriate.

A. Notes submitted for publication in *Microgram Journal* should be submitted in electronic format.

B. Only commonly accepted acronyms and abbreviations should be used.

C. Art work, graphs, charts, spectra, etc., should be in done in *Microgram Journal* format.*

7604.3 POSTING OF LABORATORY NOTES. Laboratory Notes received by SF will be posted on the Laboratory System share drive by the SF document control officer.

7605 LIBRARY FACILITIES

Each laboratory will maintain a library. The library environment will be one that protects the collection and provides a suitable place for study. The collection will be indexed to facilitate retrieval of specific items. Within available resources, each Laboratory Director will authorize purchases of books and journals needed to accomplish the laboratory's mission. To supplement the laboratory's resources, assistance may be requested from the DEA Headquarters Library.

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7701 GENERAL

7701.1 PURPOSE AND OBJECTIVES. The purpose of the Laboratory Safety Program is to provide safe and healthful working conditions; to safeguard personnel and property by formulating, maintaining, and coordinating an overall safety plan; to ensure that laboratory practices and procedures meet the requirements of the program; **and to educate and influence personnel in adopting safety, health, and environmental policies, practices, and procedures.

The objectives of the Office of Forensic Sciences Safety Program are:

A. To promote and to maintain the well being of laboratory personnel by the prevention of occupational accidents, injuries, and illnesses.

B. To identify and eliminate hazards that endanger the health and safety of personnel.

C. To reduce work interruptions and delays occasioned by accidents; and to investigate near misses and minor accidents.

D. To prevent destruction of or damage to property and equipment resulting from accidents due to poor safety practices.

E. To develop safety consciousness in personnel through their active participation in the safety program.

F. To maintain and to evaluate the effectiveness of the safety program through periodic inspections and review of practices and procedures.

G. To train personnel in the proper use of personal protective equipment, to recognize and report hazards, and to know appropriate actions in the event of an emergency.**

7701.2 STANDARDS. Applicable occupational health and safety standards contained in section 2792.5 of the Personnel Manual, 29 CFR 1910, and such applicable consensus standards or changes in standards promulgated by the Occupational Safety and Health

Administration (OSHA), the Environment Protection Agency (EPA), the Laboratory Operations Manual, and the Laboratory Operations Handbook.

7701.3 Medical Examinations

A. Due to the rigorous nature of the duties related to enforcement activities required to be performed and the potential exposure to hazardous chemicals, all DEA laboratory personnel, regardless of age, are required to obtain annual physical examinations from physicians contracted to perform this service. Procedures to be followed to ensure compliance with this requirement are contained in section 2792.22 of the Personnel Manual. The following procedures should be followed for routine physical examinations:

1. Newly hired laboratory employees. A memorandum listing the name, date of birth, series and title of the new employee should be directed to the Chief, Health Services Unit, by the Laboratory Director, requesting that they be placed on the roster to receive future medical examinations.

2. Current laboratory personnel. Prior to the employee's birth month, a physical examination package will be forwarded to the Laboratory Director with a cover memorandum listing the employee's name, name of the medical provider and fund citation. To ensure that all employees due a physical examination are scheduled, the Laboratory Director or designee may call or send a memorandum to the Chief, Health Services Unit, during the month prior to the month that examinations are scheduled. This notification should include the employee's name, birthday, series and title.

B. Annual physical examinations normally include the following procedures:

Routine procedures/tests:

1. Medical history, occupational history, interval history with attention to duty performance.
2. General physical examination.
3. Visual acuity with/without correction.
4. Blood Tests: CBC with differential, SMA-12 or equivalent to include total cholesterol, HDL cholesterol, Triglycerides, Liver function panel, FBS, Creatinine and Bun, Blood iron screening, Serology (VDRL or RPR [tests for syphilis]).
5. Urinalysis.
6. Stool for occult blood (age 40 and older if medically indicated).
7. Tuberculin Intradermal testing with PPD (intermediate strength).
8. Electrocardiogram, 12 lead.
9. Audiometry.
10. Spirometry.
11. Tonometry (Glaucoma test) - age 40 and older.
12. Voluntary vaccination for Hepatitis B.

C. Optional tests if recommended by examining physician and with Headquarters approval:

*1. Chest X-ray.
2. Exercise electrocardiogram (treadmill).
3. Tetanus booster (normally given according to U.S. Public Health Service recommendation every 10 years).
4. Antibody test for Hepatitis B.
5. Color Vision (Ishihara color plates, 14 minimum) - Applicants only.
6. Blood Group and Type - Applicants only. *

D. In addition to the routine physical examination, chemists and other laboratory personnel are authorized to have medical consultation and medical examinations conducted, as necessary, if they develop signs or symptoms associated with a hazardous chemical to which they may have been exposed as a result of a clandestine laboratory seizure or other job related incident, e.g., chemical or biohazard spill at worksite, evidence vault exposure, etc. The type of testing will be determined by the examining physician depending upon the extent of the exposure.

E. The following procedures should be followed when requesting additional screening tests/physical examinations:

1. Requests should be directed to the Chief, Health Services Unit, by the Laboratory Director, at which time a fund citation can be given (by phone, if necessary) and the employee will be directed to the medical provider in his or her geographical area.
2. In emergency situations, where medical care is needed immediately, the affected individual should proceed (or be transported, if required) to the nearest medical facility for evaluation. The employee should assume personal responsibility for payment, to expedite medical care. The Laboratory Director will issue a CA-16 to the medical facility within 48 hours of the incident to permit payment through the Office of Workers' Compensation (OWCP).
3. The exposed employee must fill out an OWCP form CA-1 or CA-2 and a DEA-484 (if exposure is due to participation in a clandestine laboratory seizure). Instructions for forms completion are contained in 2810.14, of the Personnel Manual. The CA-1 or CA-2 should be sent through the chain of command to the Employee Relations Unit at Headquarters. The Employee Relations Unit will review the information and send the form to the OWCP office in the geographical area where the incident occurred. This procedure will enable DEA to provide better protection for the employee if a future disability results from the exposure. The DEA-484 should be sent to the DEA Safety Manager.

F. Upon completion of the medical examination, and when all the reports and results of the examination have been received by the Health Services Unit for review, the employee

will be counseled as to the need for any remedial action concerning his or her health. Employees will be encouraged to remedy correctable medical deficiencies within a reasonable amount of time after being notified of such deficiencies. The results of annual physical examinations may be sent to the employee's personal physician at the written request of the employee to the medical provider. Written notification will be provided to the Laboratory Director, granting or denying clearance for the use of respiratory protection.

G. These medical examinations are separate and distinct from fitness for duty examinations, which may be required for any DEA employee as described in 2339.1 of the Personnel Manual.

7702 RESPONSIBILITIES

7702.1 LABORATORY DIRECTOR. The Laboratory Director is responsible for the laboratory's overall safety program. The Laboratory Director will **ensure that the following responsibilities are supported and sustained by all laboratory managers:**

A. Appoint a Safety and Occupational Health Specialist (Safety Specialist) and ensure that he or she is adequately trained to coordinate the safety program and carry out the day-to-day duties. A Safety Officer and a Deputy Safety Officer, if needed, will be appointed from the professional staff for a period of not less than 2 years to assume the duties of the Safety Specialist in his or her absence or if the position should become vacant. Notification of changes in appointment will be made in writing to the Office of Forensic Sciences (SF) and the DEA Safety Manager.

B. *Ensure that a site-specific Chemical Hygiene Plan based on 29 CFR 1910.1450 and an Occupant Emergency Plan are prepared and maintained as described in the Planning and Inspection Manual, 8517.2, and the Personnel Manual, 2792.5. (See 7705.1.) *

C. Forward to SF and the DEA Safety Manager an annual safety inspection report to include report of accomplishments and deficiencies related to safety and health programs and inspections. The report for the fiscal year is due in November upon receipt of a memorandum of request from *the Human Resources Division.*

D. Maintain a log of occupational injuries and illnesses for five years (*OSHA form 300, Log of Occupational Injuries and Illnesses*).

E. Ensure that a safety education program is presented to the staff at least quarterly.

F. Encourage safety by setting a good example *and encouraging participation in safety committee meetings.

G. Ensure compliance and proper enforcement of the laboratory safety and health programs.*

H. Ensure a safe and healthful workplace by correcting safety hazards/deficiencies promptly.

I. Ensure that sufficient resources are available for operating an effective safety and health program.

**J. Motivate all employees to observe safe work practices and ensure compliance with all directives.

K. Ensure that employees exposed to chemicals during clandestine laboratory seizures complete a DEA-484 detailing their chemical exposure and a CA-1 or CA-2 form. Treat the DEA-484 as "medically confidential" and forward to the DEA Safety Manager. The CA-1 or CA-2 should also be sent to the Employee Relations Unit, Workers Compensation Staff.**

7702.2 SAFETY SPECIALIST. The Safety Specialist will assist laboratory management in providing a safe and healthful workplace by doing the following:

A. *Develop a safety education program and train laboratory personnel in the requirements of the program, the use of safety equipment, and new safety developments.*

B. Conduct inspections at least annually and prepare reports following the inspection procedure outlined in guidelines issued by SF.

C. Inspect first aid and safety equipment *monthly* and recommend the repair or replacement of it as necessary.

D. Investigate laboratory accidents and prepare reports as outlined in sections 2810 and 2792.5 of the Personnel Manual.

E. Notify laboratory management of unsafe working conditions and make recommendations for corrective action. Participate in other safety matters, as necessary, in an effort to achieve a safe working environment.

F. Oversee compliance with safe work practices and section 2792.5 of the Personnel Manual; in conjunction with this, the Safety Specialist will conduct safety audits and inspections. A report should be prepared and submitted to the Laboratory Director

relating to the results of the review. The frequency of this internal report is left to the discretion of laboratory management. A minimal requirement, however, is annually. (See 7702.2B).

G. Oversee compliance with provisions of the Hazard Communication Program as described in section 2792.54 of the Personnel Manual.

H. **Participate in** federal and/or local safety council and attend pertinent meetings.

NOTE: The term "Safety Specialist" applies to the Safety and Occupational Health Specialist or the Safety Officer/Deputy Safety Officer Acting in place of the Principal.

7702.3 LABORATORY PERSONNEL. All laboratory personnel must:

A. Consider safety and compliance with the safety program as a basic part of their responsibilities.

B. Take necessary precautions to protect themselves and their coworkers by using safe procedures and protective equipment.

C. Advise their supervisor or the Safety Specialist of unsafe working conditions that may affect DEA employees.

D. Be familiar with all aspects of the OSHA Laboratory Standard (29 CFR 1910.1450).

E. Comply with all applicable Federal regulations, and DOJ and DEA directives pertaining to occupational safety and health.

F. Report to their supervisors all job-related occupational injuries and illnesses.

G. Use personal protective equipment as required.

H. Never work alone in laboratory areas, due to potentially hazardous conditions.

I. **Attend scheduled mandatory safety related training.**

7703 SAFETY TRAINING

7703.1 EDUCATIONAL MATERIALS. The Office of Forensic Sciences safety guidelines *shall be provided to all laboratory staff members, who shall be responsible for the information pertaining to their duties. In addition, a suitable reference library of books, standards, pamphlets, and other educational materials* shall be maintained.

7703.2 SAFETY SEMINARS AND TRAINING. **Safety training can be in-house or sponsored by Federal, state, local, or private safety organizations. The Laboratory Support Section maintains a library of safety training videotapes available for loan that meets this requirement. Safety training should be in compliance with the requirements set forth in 29 CFR 1960.54-59.**

A. Each new employee shall be given instruction in occupational safety, accident prevention, and the *Laboratory Standard 29 CFR 1910.1450 * (Hazard Communication Program) by the Safety Specialist as part of the basic training program within 30 days of entry on duty.

B. Safety matters of current interest shall be included in laboratory seminar programs, including clandestine laboratory safety.

C. Each laboratory shall have at least four individuals with formal first aid **and CPR/AED** training, received from the American Red Cross, Civil Defense, or other comparable institution.

D. Laboratory supervisors, the Safety Specialist, and the Safety Officer\Deputy Safety Officer shall be required to attend a safety training course within one year of appointment.

E. The Safety Specialist and Safety Officer\Deputy Safety Officer shall complete a course dealing with the OSHA Laboratory Standard **within one year of appointment**. Such courses are available from the National Safety Council or American Chemical Society.

F. **All employees shall complete a fire safety training course once a year.**

G. *All members of the management staff should complete a Supervisory Safety Training Course.*

H. The Safety Specialist and the Safety Officer\Deputy Safety Officer shall keep abreast of new safety developments by attending meetings and training courses, and by reading safety and health publications.

I. All employees must receive annual training involving the Bloodborne Pathogens Plan and Respiratory Protection Plan. After the initial training, employees must be given updates when there are changes to the Chemical Hygiene Plan, Crisis Management Plan, and Occupant Emergency Plan. All employees must be able to reference the laboratory safety plans on the laboratory share drive.

7704 INSPECTION PROGRAM

7704.1 SAFETY EQUIPMENT. As required in 7702.2C, safety equipment shall be inspected *monthly* to ascertain if it is in usable condition. Necessary repair or replacement shall be made immediately and written records kept to indicate such checks have been made.

7704.2 OCCUPATIONAL SAFETY. An annual inspection shall be made and report filed with the Office of Forensic Sciences and the Safety Manager. (See 7702.1C.)

7704.3 ANNUAL SAFETY AND HEALTH INSPECTION. A representative of the Office of Forensic Sciences, or the Safety Manager or another *Laboratory Safety Specialist*, shall make an annual inspection of each laboratory for compliance with applicable occupational safety and health standards. (The inspection may be made jointly with the laboratory's Safety Specialist as part of the requirement of 7704.2.)

7704.4 CORRECTION OF DEFICIENCIES. The Laboratory Director must promptly initiate appropriate action to eliminate or control any occupational safety or health hazard and agree to resolve or correct any safety and health deficiency within 15 days as reported to them by their Safety Specialist as the result of a safety professional visit. Assistance can be solicited from the Office of Forensic Sciences, the Office of Administration, or the Safety Manager.

7705 EMERGENCY PROCEDURES

7705.1 WRITTEN PLAN. *The Occupant Emergency Plan, required under 7702 of this Manual and section 2792.5 of the Personnel Manual, will cover fire, bomb threats, or other safety evacuations of the facility. It shall be made available to all personnel and be posted in several conspicuous places. The Plan will be reviewed and updated each July and January to ensure that it is current and copies of the semiannual update filed with the Plan. *

7705.2 EVACUATION DRILL

A. A fire and evacuation drill shall be scheduled and carried out at least once a year. Additional drills shall be carried out if appreciable numbers of personnel are added to the staff between scheduled drills or if practice is necessary.

B. Evaluation of the evacuation exercise shall be made by the Safety Specialist in writing and the results and conclusions discussed with the staff. Modifications *to* the Occupant Emergency Plan shall be made based on any deficiencies uncovered by the exercise.

7705.3 INJURY OR ILLNESS. Whenever an employee experiences an occupational injury or illness, he or she should complete an appropriate CA form (Federal Employees Notice of Traumatic Injury and Claim for Continuation of Pay/Compensation) and forward it through channels to the Employee Relations Unit. **All appropriate CA forms are available on Jet Form, in the Miscellaneous Forms Section.**

NOTE: For more information, review LS-06-007 Medical Accommodations and Limited Duty.

7705.4 EMERGENCY TELEPHONE NUMBERS. *A list of emergency telephone numbers shall be conspicuously posted near each telephone and provided to each staff member.* Numbers shall be verified at least annually.

7705.5 WORKING UNACCOMPANIED IN THE LABORATORY. No chemist or other staff member shall be permitted to work in the laboratory area outside normal duty hours without the Laboratory Director or a member of management present.

7705.6 ACCIDENT REPORTING. All accidents involving laboratory personnel shall be reported in a timely manner by the Laboratory Director to the Office of Forensic Sciences, with a copy to the DEA Safety Manager in the Health Services Unit. The report will be in writing stating the cause, effect, and recommendations for prevention of recurrence. The Office of Forensic Sciences will review the report and, if necessary, take corrective action to prevent possible repeat accidents by other laboratories.

7706 PROTECTIVE CLOTHING AND EQUIPMENT

A. Each laboratory shall maintain an adequate supply of protective clothing and equipment for an effective safety program.

B. The laboratory shall identify and designate by means of signs, Laboratory Orders, etc. those areas requiring the use of personal protective equipment (e.g., safety glasses, laboratory coats, etc).

C. Safety glasses shall be worn by all employees and visitors in designated areas of the laboratory.

D. All chemists, laboratory workers, evidence technicians, evidence clerks, fingerprint specialists, and physical science technicians will wear a full length laboratory coat in *designated laboratory areas. The laboratory coat should* be changed at least weekly and removed prior to leaving the laboratory area.

E. All evidence processing, preparation of chemical reagents, and any other operation that can cause dusts or mists shall be performed in a fully operational fume hood.

F. Whenever an employee handles hazardous chemicals, evidence, or solvents, protective gloves shall be worn.

G. Whenever an employee handles hazardous dry chemicals or powders, a particulate respirator shall be worn. Whenever an employee handles hazardous materials, he/she must work in a properly functioning laboratory hood. In addition, the employee may need to use an air purifying respirator (APR). See section 2792.55 of the Personnel Manual (Respirator Policy) for detailed information regarding use of respirators.

H. Wearing protective clothing, consistent with the hazards of the situations involved, shall be considered routine.

I. The following safety items should be made available for employees' use and, if disposable, stocked in different sizes:

1. Safety glasses, **face shields**, and/or goggles. Eye injuries can be a major problem in the laboratory. Injuries may occur from splashes, flying objects, powders, or ultraviolet radiation. *Each laboratory employee is required to wear safety glasses with attached side shields upon entering any designated laboratory area.*

A pair of safety glasses will be provided for each laboratory employee. Arrangements for the glasses should be made with the Safety Specialist to make sure that they meet or exceed all standards established by the American National Standards Institute Z87.1-1989, Practice for Occupational and Educational Eye and Face Protection.

Safety glasses are designed to provide protection from impact of flying objects. If unusual hazards are inherent in certain operations, i.e., chemical splashes, special or extra eye protection shall be used. Indirect vented splash goggles or full face shields are available in each laboratory for chemical liquid pouring operations, and other procedures where appreciable hazards from splashes may occur.

2. Protective clothing, such as laboratory coats, rubber aprons, coveralls, etc. Rubber aprons are available, and should be worn when handling or carrying hazardous liquids, or when dangerous spills are possible.

3. Protective gloves, such as heat and/or low temperature resistant, cut resistant, heavy rubber, disposable polyethylene, latex, **nitrile** etc. Heat resistant gloves for handling hot objects are located near ovens and furnaces. Cut resistant gloves are available for handling objects that require the use of scalpels or razor knives.

4. Self-contained breathing apparatus (minimum of two). Detailed requirements are contained in Paragraph 2792.55, Personnel Manual (DEA Respiratory Protection Policy).

a. Each laboratory is equipped with a minimum of two SCBA units for emergency rescue operations. The apparatus is certified by the National Institute for Occupational Safety and Health (NIOSH) for up to 30 minutes of protection while performing moderate to heavy work.

The SCBA is supplied with compressed air contained in a cylinder worn by the user. Air is supplied through a pressure reducing valve. There is no recirculation of air, and exhaled breath is released to the atmosphere. The air mask is a pressure-demand apparatus, designed to maintain a slight positive pressure of air inside the face piece during inhalation and exhalation. This helps to prevent contaminants from seeping in around the face piece, even if there should be small breaks in the face-to-face piece seal. The breathing regulator is equipped with an alarm to warn the user of a diminishing air supply. The alarm sounds when there is 20 to 25 percent air supply left in the cylinder. The warning is to alert the user to leave the hazardous area.

Instructions for use are furnished with the equipment. Each chemist is required to read the instructions and to become acquainted with the use of the unit. At least three people in each laboratory must be proficient in the use of the air pak.

There are several rules that must be observed when the SCBA is used:

1. Leave the hazardous area at once if an abnormal odor is detected.
2. Leave at once when the low air warning alarm sounds.
3. The pak must not be removed until the wearer is out of the hazardous area.
4. Always use the pak under the "buddy" system. At least two SCBA's are available in each laboratory.

b. Each laboratory has air purifying respirators, commonly referred to as a dust or fume respirator, available for use. The respirator is NIOSH approved for a variety of specific contaminants. It is intended to be used in the following situations:

1. When handling evidence where appreciable dust is present or anticipated to be generated (e.g., sampling or destroying).
2. When entering or working in any dusty environment.
3. When processing clandestine laboratories or chemical spills.

It is important to realize that there are limitations on the use of air purifying respirators. They are intended for use with specific types of contaminants, so the identity and concentration of the hazardous material must be known. A more in-depth discussion of respirators, including a partial list of substances for which air-purifying respirators are not effective, is contained in Part C (Respiratory Protection), DEA Clandestine Laboratory Safety Guide.

Air purifying respirators do not supply oxygen, so when in doubt use a SCBA.

Directions for use should be followed and the respirator cleaned and disinfected after use. A commercially available sanitizer or mild cleaning solution followed by a germicide solution should be utilized, followed by a thorough rinsing with warm water. Alcohol should not be used as a germicide as it may deteriorate the rubber.

5. Eyewashes. An eyewash facility has been installed in each main laboratory, or near the entrance to each main laboratory. Water faucets, particularly those with tubing attached, may also be used as an emergency eyewash. Portable eyewash stations may also be provided; however, they do not supply a sufficient amount of water to adequately flush the eyes and may contain possible bacterial contamination.

6. Protective masks and respirators.

7. Protective shields. Shatter proof shields are available and should be used when glass vacuum systems or pressurized operations are involved (e.g. preparation of infrared pellets). These shields should also be used whenever there are hazards of any type that expose the face or upper body to injury. The handling of reactive metal hydrides, e.g., lithium aluminum hydride, is an example of a procedure that requires use of a safety shield.

8. Fire blankets. Fire blankets located in each main laboratory can be used as a protective screen to smother an ignited spill or to extinguish a clothing fire. It should be noted that there is some controversy among safety professionals concerning use of fire blankets in cases of clothing fires. Some problems include infection from non-sterile blankets, mechanical damage to severe burn wounds caused by tightly wrapped blanket and concentration of heat and toxic fumes in the area of the victim's head from burning synthetic clothing (chimney effect). To prevent further injury, the blanket should be wrapped loosely and the victim removed from the blanket immediately after the fire is extinguished.

9. Emergency showers. *Safety showers can prevent severe injury and serious burns.* These showers are available in DEA's laboratories and are intended for quick drenching in emergency situations where acids, strong alkali, *chemical reagents, or hazardous waste* have splashed onto skin or clothing.

10. Fire extinguishers--type determined by intended use.

11. Rubber bulbs for pipettes.

12. First aid kits. First aid supplies for minor cuts, burns, and bruises are available in each main laboratory.

13. *Automatic External Defibrillator (AED).* *An AED is available in each laboratory for emergencies.*

14. Decontaminants, suitable for counteracting alkali and acid spills or contamination.

15. Gas cylinder carts and straps for tanks.

16. Battery powered lanterns and flashlights. Flashlights are located throughout the laboratory and are available for emergency situations.

17. Clandestine laboratory protective equipment.

**18. Spill kits and spill supplies.

19. Fume Hoods. Laboratory fume hoods are the most important components used to protect laboratory workers from exposure to hazardous chemicals and agents used in the laboratory. There are several rules involved with the safe operation of fume hoods.

a. They should not be used for disposal of hazardous volatile materials by evaporation.

b. Reactions and hazardous chemicals must be kept at least six (6) inches behind the plane of the hood.

c. Never use the hood as a storage case for the accumulation of apparatus and equipment.

d. On a vertical rising sash, the sash glass should be no higher than eighteen (18) inches from the work surface.

e. When the hood is not in use, keep the sash closed to maintain laboratory airflow.

f. Never put your head inside an operating laboratory fume hood to check equipment or process.**

7707 STORAGE

A. Suitable storage areas shall be provided for chemicals, glassware, and laboratory apparatus. Care shall be exercised to separate chemicals which may react to produce dangerous fumes or violent reactions if containers are accidentally broken.

B. Quantities of chemicals shall be limited to reasonable needs. Annually, an inventory of chemicals will be made and unstable chemicals will be immediately disposed of by proper means. Material Safety Data Sheets (MSDS), where available, shall be kept on

file for all chemicals present in the laboratory. MSDS's may be obtained from the chemical manufacturer or the Health Services Unit, if necessary.

C. Where refrigeration is required for flammable materials, approved design or explosion-proof refrigerators shall be used.

D. All chemical containers entering the laboratory will be labeled at a minimum with the date received and for those chemicals that can form peroxides, the date opened.

E. All secondary chemical containers located at the chemists' benches shall be properly labeled and capped.

7708 DISPOSAL OF HAZARDOUS WASTE MATERIALS

The following guidelines are presented based on the assumption that the laboratory is a conditionally exempt small quantity generator (no more than 100 kilograms of hazardous waste generated per month) meeting all the requirements as defined in 40 CFR 261.5. See *Subsection 7708.1* for more information on determining generator status.

A. Proper containers shall be provided for disposal of various waste materials and distinctly marked to identify the contents. Containers used in the collection and storage of laboratory waste shall:

1. Be leak proof;
2. Be compatible with the waste it contains;
3. Be kept closed (except when necessary to add or remove waste);
4. Be handled in such a way as not to cause the container to leak;
5. Be marked with the date the container was filled **and moved to the hazardous waste accumulation area**; and
6. Be **clearly** labeled or marked with the words "Hazardous Waste."

For proper waste identification, documentation on the contents of each container shall be maintained. The documentation must include the amounts of each waste, the date each container was placed in storage, and the chemical identity of the waste. This data can be captured on weekly hazardous waste inspection logs. The container must also be labeled with this information.

B. No water immiscible or volatile waste solvents shall be poured down a sink, basin, or drain. Evaporation shall not be used as a method of disposal. Waste solvents should be segregated into halogenated and non-halogenated waste.

Waste ethers will be collected or stored in metal containers. Transportation of hazardous wastes shall be performed by a transporter with an EPA identification number *and state

hazardous waste permit, where applicable. *Disposal of hazardous wastes shall be performed by a permitted treatment, storage, or disposal facility.

C. *For water miscible waste materials, such as acids, alkalis, and alcohol, the Laboratory Director shall check with the authorities of the local wastewater treatment plant to determine whether these materials are permitted to be flushed down the drain. Written authorization from the local authorities must be kept on file.*

D. Discretion is required when disposing of uncommon solid or liquid wastes. The Laboratory Director must comply with all applicable Federal, state, and local environmental protection laws. Consult with the waste disposal company or known authoritative sources prior to conducting the disposition.

E. Until contracts are in place with hazardous waste disposal companies that are licensed to handle controlled substances, solvents containing small amounts of controlled substances shall be distilled to separate the controlled substance, or the controlled substance may be removed by other suitable techniques, e.g., precipitation. The distillate shall be handled the same as any waste solvent and disposed of by a hazardous waste disposal company. The residue shall be treated as a controlled substance and disposed of by incineration.

F. Biohazardous evidence (body carry) shall be decontaminated prior to analysis and disposed of as evidence.

7708.1 HAZARDOUS WASTE GENERATOR STATUS

NOTE: This information is a synopsis of the Federal regulations. All Laboratory Directors should consult with the state and/or local waste management agency to identify local hazardous waste requirements.

Any solid, liquid or gas waste, that when improperly disposed of can cause injury or death and can damage or pollute land, air or water, is considered a hazardous waste. The Environmental Protection Agency (EPA) regulates hazardous waste under the Resource Conservation and Recovery Act (RCRA) which was designed to control the management of waste from its generation to ultimate disposal. RCRA is also known as the "cradle-to-grave" law.

The EPA considers a waste to be hazardous if it possesses the characteristics of ignitability, *corrosiveness*, reactivity, or toxicity and/or if it is on a list of specific wastes known to be harmful to health or the environment. Presently, there are over 400 hazardous wastes identified by the EPA. Consult a current 40 CFR Part 261 for a listing of hazardous wastes and characteristic definitions.

The EPA considers some wastes as acutely hazardous. These wastes are considered to be so dangerous in small amounts that they are regulated in their commercial form the same way as are large amounts of other hazardous wastes. Consult a current 40 CFR Part 261.33e for a listing of commercial chemical products considered to be acutely hazardous wastes.

Categories of Hazardous Waste Generators

1. Conditionally-Exempt Small Quantity Generator.

Generates no more than 100 kilograms of hazardous waste and no more than 1 kilogram of acutely hazardous waste in any calendar month.

2. Small Quantity Generator.

Generates more than 100 kilograms and less than 1000 kilograms of hazardous waste and no more than 1 kilogram of acutely hazardous waste in any calendar month.

3. Large Quantity Generator.

Generates 1000 kilograms or more of hazardous waste or more than 1 kilogram of acutely hazardous waste in any calendar month.

Reporting Requirements. The EPA requirements for conditionally-exempt small quantity generators are to identify all hazardous waste they generate, dispose of the waste through a licensed facility and never store more than 1000 kilograms of hazardous waste in the laboratory. (Smaller amounts, however, may be accumulated in the hoods prior to transfer to *accumulation areas*, but the aggregate at the laboratory may not exceed 1000 kg.)

Although the requirements for a conditionally-exempt small quantity generator allow for disposal of hazardous waste in a landfill or other facility approved by the state for industrial or municipal wastes, such wastes must be disposed of through a hazardous waste cleanup and disposal contractor who is contracted by DEA to perform this activity.

The EPA requirements for a small quantity generator are the following:

- Identify all hazardous waste they generate
- Obtain an EPA Identification Number
- Store no more than 6000 kilograms of hazardous waste in the laboratory storage area for up to 180 days, or for up to 270 days if the waste must be shipped to a treatment, storage or disposal facility that is located over 200 miles away.

- Mark the hazardous waste containers with the words "Hazardous Waste" and the date you transfer the container from the hood to the storage area. This date starts the 180 day maximum storage requirement.

- Keep the containers in good condition: handle them carefully and replace any leaking ones.

- Do not store hazardous waste in a container if it may cause rupture, leaks, corrosion or other failure.

- Keep containers closed except when you fill or empty them.

- Inspect the containers for leaks or corrosion every week. (Keep a log of these inspections as documentation.)

- Never store wastes in the same container that could react together to cause fires, leaks or other releases.

- Designate an employee as the Emergency Coordinator who will be on call 24 hours a day.

- Post the name and telephone number of the Emergency Coordinator next to each telephone as well as the locations of fire extinguishers, spill control material, fire alarms and the telephone number of the local fire department.

- Train employees on proper waste handling and emergency response procedures.

- In the event of an emergency threatening public health outside the laboratory or if a spill has reached surface water, immediately notify the National Response Center at 800-424-8802, SF and the Health Services Unit.

The reporting requirements for large quantity generators are nearly the same as small quantity generators and include the following:

- Identify all hazardous waste they generate
- Obtain an EPA Identification Number
- Store any amount of hazardous waste in the laboratory for no longer than 90 days.
- Prepare a biennial report and submit a copy to the EPA Regional Administrator.

The report is due by March 1 of each even numbered year. The Biennial Report must be submitted on EPA Form 8700-13A.

Hazardous Waste Manifest. A hazardous waste manifest is a multi-part form used as a shipping document to accompany hazardous waste shipments. It is designed as a tracking form to document the movement of hazardous waste from the generator to its final destination. All parties (generator, hauler and designated facility) must sign the form and keep a copy. The designated facility must also send a copy back to the generator within 45 days so that the laboratory is assured that the shipment has arrived. This copy must be kept on file in the laboratory for three years.

In order to close out the tracking of each shipment of hazardous waste from a laboratory, the notation "CD REQUIRED" should be made in Box #15 of the manifest. This will serve to notify the ultimate disposal firm to issue a "Certificate of Disposal" (CD) to confirm that all items on the manifest have been destroyed or disposed.

Some states have their own manifest form. The laboratory should check with the local waste management agency to determine which form to use.

Waste Management. DEA must attempt to reduce the amount of hazardous waste generated through management techniques such as integrated purchasing strategy, inventory control, employee training and housekeeping methods.

Integrated Purchasing Strategy. Chemical manufacturers offer quantity discounts when purchasing large amounts of chemicals. These excess chemicals often go unused and accumulate on storeroom shelves, under benches, in hoods and various other places. It is estimated that unused chemicals account for as much as 40% of the hazardous waste generated in the laboratory. Disposal costs can be many times greater than the original cost of the chemical. Smaller quantity purchases reduce the costs associated with disposal while decreasing the amount of unused chemicals being stored and the potential for chemical exposure.

Inventory Control. An inventory system will assist in knowing what chemicals are present in the laboratory and estimating future disposal costs. Dating all chemicals upon receipt permits the older chemicals to be used first and helps to identify those chemicals that have outlived their useful life.

Employee Training. Training employees about the efficient use of chemicals can help reduce the amount of waste generated. Stressing the need to use minimal amounts of chemicals or substitution of less hazardous chemicals can help to minimize hazardous waste.

Housekeeping Methods. Don't mix hazardous wastes with non-hazardous wastes. Separate different kinds of wastes (e.g., halogenated and non-halogenated wastes) to lower costs of disposal. Disposal costs are much greater if the waste disposal contractor has to determine the identity of the wastes.

7709 RADIATION HAZARDS

A radiation hazards safety program shall be developed if the laboratory operates equipment that produces radiation. Adequate provisions shall be made for routinely monitoring radiation from x-ray equipment and for providing shielding, dosimeters, and hazard warning signs consistent with the rules and guidelines of the Nuclear Regulatory Commission.

Laboratory personnel who use x-ray equipment shall be adequately trained in its use and be instructed on radiation hazards.

All instruments containing radioactive material must be tested for leakage. Follow the Nuclear Regulatory Commission guidelines for testing and frequency. For example, the IONSCAN instrument must be swipe tested ever six months.

7710 SAFETY PROCEDURES

7710.1 HOUSEKEEPING

A. A minimum one hour block of time shall be established weekly for general laboratory cleanup.

B. There will be no eating, drinking of any liquid or food preparation in the laboratory area.

C. To prevent contamination of eating areas laboratory coats will be removed prior to entering the eating areas. No forms and paperwork used in the laboratory area will be taken into the eating area. **Laboratory coats and gloves should not be worn in other administrative areas such as the library and restroom areas.**

7710.2 BIOHAZARD MATERIAL

A. *All laboratory personnel will be familiar with DEA Bloodborne Pathogens Program (see section 2792.56 of the Personnel Manual) and guidelines on the handling of biohazardous material. *

B. Needles and syringes shall not be accepted for analyses unless such items are the only evidence available in a case **or unless authorized by the Laboratory Director**. Upon completion of analysis, all needles and syringes *must* be placed in appropriate containers designed for storage of syringes and potential biohazards.

C. Evidence suspected of being contaminated with body fluids (i.e., body cavity evidence, needles and syringes) will be considered biohazardous in nature. Extreme care should be taken in processing this kind of evidence to include wearing of appropriate personal protective equipment. (See section see 2792.56 of the Personnel Manual). Body cavity evidence will be decontaminated, using chemical disinfection or steam autoclaving, as soon as possible after receipt in the laboratory (see Subsection, *7711.11*). Chemists will not process biohazardous evidence if open sores or wounds exist on the hands, face, or arms. Disposable equipment will be used whenever possible and all work will be performed in a fume hood. Those items that are not disposable will be disinfected after the completion of the analyses.

D. A biohazard warning label will be placed on the outer packaging of evidence suspected to be contaminated.

7710.3 USE OF CONTACT LENSES

A. Contact lenses will not be worn in the laboratory area. Employees who require contact lenses for treatment of medical diseases of the eye may be provided an exemption to this policy. A written statement supporting the use of contact lenses for treatment of medical conditions must be received from the employee's health care provider. This statement should be an informed opinion based on a full description of the eye hazards present in the laboratory. (See Laboratory Operations Handbook, Exhibit H-10). The Laboratory Director shall forward a copy of this documentation to the Chief Medical Officer. The following items must be adhered to if an employee wears contact lenses in the laboratory:

1. Prescription spectacles must be available for use when unable to wear contact lenses.
2. Employees cannot use contact lenses when wearing a respirator or full face mask.
3. Employees will not wear contact lenses when participating in clandestine laboratory activities.
4. Employees will wear non-vented safety goggles for eye protection at all times when in the designated area requiring eye protection.
5. If an eye emergency develops with an employee while wearing contact lenses, immediate medical assistance should be sought to help remove the contact lens.
6. Employees who wear contact lenses will read the information contained in the Laboratory Operations Handbook, Exhibit H-10, concerning the use of contact lenses in chemical settings so they are informed about the problems associated with their use.

**7711 GUIDELINES FOR SAFETY IN THE CHEMICAL LABORATORY

7711.1 INTRODUCTION. The purpose and objectives of the Office of Forensic Sciences Safety Program are detailed in Laboratory Operations Manual 7701.1.

7711.2 SUMMARY: ROUTINE SAFETY GUIDELINES. To assure safe and healthful working conditions it is necessary to establish certain basic guidelines, precautions, and rules. Many accidents have resulted from an indifferent attitude, failure to follow instructions or failure to use common sense. Be aware of what your neighbors are doing because you may be the victim of their mistakes.

Some of the suggestions stated in this chapter are axiomatic, but basic to any safety program. In some instances, there may appear to be a conflict between the most efficient way of performing certain tasks, or achieving certain objectives, and the necessity to follow prescribed rules for the sake of safety. Nevertheless, failure to abide by these

suggestions and recommendations has caused countless accidents. Unless a conscious effort is made to follow the guidelines, a quality safety program cannot be achieved.

The following warnings, rules, and precautions are considered essential and obligatory in the Office of Forensic Sciences safety program:

1. Remember at all times to be alert to your own safety and the safety of your colleagues.
2. The laboratory is a place for serious work, and no place for "horseplay."
3. Food preparation, eating, drinking, **and storing of food** in the laboratory area is prohibited. Laboratory glassware is not to be used for the preparation or consumption of food or beverages. Items used for the preparation or consumption of food or beverages are not * to be * washed in the laboratory dishwasher.
4. Food, for personal use, can only be stored in a designated area(s), or a designated refrigerator, and never with chemicals or solvents.
5. *Smoking is prohibited in the laboratory area. Personnel Manual Subsection 2735.19 contains DEA's smoking guidelines.*
6. Become familiar with safety practices, and potential hazards associated with equipment, or chemicals.
7. Personal protection equipment, such as safety glasses, shields, gloves, coats, dust masks, etc., shall be worn as appropriate in the laboratory area and whenever chemicals, evidence or powders are handled.
8. Use "danger" or "caution" signs when working under hazardous, or potentially hazardous conditions. (See 29 CFR 1910.145.)
9. Never taste chemicals or evidence for any reason.
10. Always use a fume hood for operations which might result in a release of chemical vapors or dusts. Fume hoods shall be used for all evidence processing.
11. Never return unused chemicals to stock bottles.
12. Mouth pipetting is prohibited. (Suitable pipetting adjuncts are available.)
13. Fire polish the ends of glass tubing and rods after cutting. Use caution while inserting tubing or rods into stoppers. Use a towel or gloves and a suitable lubricant when inserting glass tubing or rods into stoppers.
14. Do not use excessive force to remove frozen stopcocks or stoppers.
15. Do not use chipped, or cracked glassware. (Dispose of all damaged glassware in designated glass waste containers.)
16. When diluting an acid, pour the acid slowly into water, never the reverse.
17. Learn the location and proper use of safety equipment, such as emergency showers, fire extinguishers, fire blankets, eye washes, self contained breathing apparatus, etc.
18. Learn where exits, fire alarms, and posted emergency telephone numbers are located, and become familiar with the bell warning system for evacuation of the building.
19. Keep routes to exits free of impediments or obstructions.

20. Keep your workbench clean and orderly, and free of unnecessary chemicals and apparatus.

21. Keep hoods clean and orderly. Remove glassware and apparatus after use. Hoods are not intended primarily for the storage of chemicals.

22. Use electrical devices with caution in hoods. (Do not use devices that may "spark", or non-explosion proof hot plates when flammable solvents are being evaporated, or when hazardous reactions may be taking place.)

23. Do not pour any chemicals into sinks or drains unless permission is granted from the local wastewater treatment facility.

24. Do not store incompatible chemicals close to each other. Store large volumes of flammable solvents in *approved flammable* storage areas.

25. Return gloves and tongs, after use, to designated locations near ovens and furnaces.

26. Use a cylinder truck to transport gas cylinders and make sure cylinders are securely fastened to the wall or bench top when placed in use.

27. Empty and rinse glassware after use, in order to protect the laboratory worker from unnecessary hazards.

28. Use an approved ladder, or step stool, for placing materials on or removing materials from high shelf locations.

29. Never use chemicals from unlabeled bottles. All unlabeled bottles should be brought to the attention of the Safety Specialist or Laboratory Supervisor.

30. Use sensible caution in the analysis of unknown evidence.

31. Warn nearby colleagues when toxic or potentially hazardous materials are being handled. (This is for your protection, and theirs, if an accident should occur.)

32. Use of benzene is prohibited without consent of the Laboratory Director.

33. Turn powerstats and centrifuges off by use of the "on-off" switch. (Full line voltage may exist across terminals, even when the rheostat dial is in the "off" position.)

34. Do not use electrical equipment that is not properly grounded, or when wiring is frayed or worn. Use only electrical equipment that conforms to the National Electrical Code Requirements.

35. Place vessels with flammable solvents that must be cooled or stored under refrigeration in explosion-proof refrigerators.

36. Do not use a vacuum pump or other belt driven equipment unless it has a suitable belt guard.

37. Use a wire mesh guard or other protecting shield around glass vacuum desiccators.

38. Use round bottom flasks only when performing vacuum distillations.

39. All spills must be cleaned up as soon as possible. Particular attention should be paid to spills of acutely toxic materials, e.g., LSD or fentanyl derivatives, and biohazard materials. Ensure that all residues are completely cleaned up. Example: An ultraviolet lamp can be used to detect residues from LSD samples.

40. Carefully monitor experiments and processes employing flammable or combustible reagents.

41. When flammable or combustible reagents must be heated, use a steam bath, electric mantle, or hot plate approved for the purpose. Never use an open flame.

42. Do not look down the opening of a test tube; observe the contents through the sides of the test tube.

43. If you must smell the contents of a container, do not place your nose over the opening and take a deep breath; wave your hand gently over the opening toward your nose.

44. Do not use or handle any unfamiliar chemical until you have read and understood the label and MSDS for that chemical.

45. Shoes made of non-absorbent material covering the entire foot should be worn at all times in the laboratory. Do not wear open toe shoes, sandals, or cloth sneakers.

Most of all, use common sense, and think of safety all the time you are in the laboratory. (There are many other precautions that should be observed that are not listed.)

7711.3 FIRE FIGHTING EQUIPMENT. *Planning, precaution, education and other preventative measures are essential tools for fire prevention. Fire and smoke detection devices, alarm systems, and plans for containment, extinguishment, and evacuation of personnel are also essential in preventing injuries or fatalities to personnel and minimization of property loss and damage.*

This chapter considers, for the most part, fire containment by use of portable fire extinguishers, and comments on area carbon dioxide or Halon extinguishing systems, installed in the laboratory solvent storage areas. All fire extinguishers located in the laboratory must meet or exceed the local fire code and/or GSA recommendations.

Portable Fire Extinguishers

The National Fire Protection Association, Inc., in its pamphlet NFPA No. 10 "Portable Fire Extinguishers *2002*", suggests that "Fire extinguishers can present an important segment of any overall fire protection program. However, their successful functioning depends on the following conditions being met:

1. The extinguisher is properly located and in working order.
2. The extinguisher is of proper type for the fire which may occur.
3. The fire is discovered while still small enough for the extinguisher to be effective.
4. The fire is discovered by a person, ready, willing and able to use the extinguisher.

The pamphlet recommends that the fire department be notified as soon as a fire is discovered, and the alarm not be delayed awaiting results of application of portable fire extinguishers. Giving the alarm and notifying the fire department will be discussed in a later chapter.

Fires are classified by basic types as Classes A, B, C, and D. Portable fire extinguishers are classified for use on certain classes of fires and rated for relative extinguishing effectiveness by recognized testing laboratories.

There are a number of general requirements for locating and placing extinguishers:

1. Portable extinguishers shall be maintained in a fully charged and operable condition, and kept in their designated places at all times when they are not being used.
2. Extinguishers shall be conspicuously located where they will be readily accessible and immediately available in the event of fire. They shall be located along normal paths of travel.
3. Extinguishers shall not be obstructed or obscured from view. Means shall be provided to indicate location and intended use of all extinguishers.
4. Extinguishers having a gross weight not exceeding 40 pounds shall be installed so that the top of the extinguisher is not more that 5 feet above the floor. Extinguishers having a gross weight greater than 40 pounds shall be installed so that the height of the top of the extinguisher is no more than 3 1/2 feet above the floor.

The number and types of fire extinguishers and their location is a rather complex problem and depends on the size of the installation, contents of the building, types of fires that can be expected, etc. As a general rule the travel distance to an extinguisher should not exceed 50 feet. Location and number of extinguishers is the responsibility of the Laboratory Director and the Safety Specialist. It is, however, the responsibility of all employees to be aware of the locations of the extinguishers, as well as how to use them. Training will be provided by the Safety Specialist to all new employees, and refresher training will be given on **an annual basis** to all laboratory personnel.

The various classes of fires and extinguishing agents are divided into four classes by the nature of the burning material, as follows:

Class A. Class A fires are fires in ordinary combustible materials, such as wood, cloth, paper, rubber and many plastics. The quenching and cooling effects of water are used to fight such fires.

Extinguishers effective against such fires are all types, but pressurized water is the most common. The 2 1/2 gallon size weighs about 30 pounds and has a solid stream range of 30-40 feet. Under continuous use it has a discharge time of about 55 seconds.

There are also pump type extinguishers, but they are not recommended because they cannot be operated while being carried.

Class B. Class B fires are fires in flammable liquids, flammable gases, tars, grease, oils, oil base paints and lacquers. For these a blanketing or smothering effect is essential.

Extinguishers effective against such fires are:

1. *Carbon Dioxide.* Carbon Dioxide is discharged in the form of a gas/snow cloud and has a relatively short range of 3 to 8 feet. The principal advantage of carbon dioxide is that it does not leave a residue after use. Minimum discharge time varies from 8 to 30 seconds depending on size.
2. *Dry Chemical.* All dry chemical extinguishers less than 10 pounds in size discharge their entire contents in 8 to 10 seconds. Since there is little time for experimentation, it is important that the contents be applied correctly from the outset. The discharge stream has a range of 5 to 30 feet. Several types of chemical agents are available, all of which leave residues.
3. *Liquid Gas Extinguishers.* Extinguishers such as bromochlorodifluoromethane (Halon 1211) and bromotrifluoromethane (Halon 1301) have features and characteristics similar to carbon dioxide extinguishers in that they are noncorrosive and do not leave residues. Halon extinguishers weigh considerably less than carbon dioxide extinguishers. Care must be exercised in their use since their decomposition products can be hazardous. Do not use Halon extinguishers in confined areas, since respiratory exposure to the gases or thermal decomposition products can be hazardous.

Class C. Class C fires are fires which involve energized electrical equipment where the electrical non-conductivity of the extinguishing media is of importance.

Extinguishers of the carbon dioxide or Halon type are ideal. They do not present shock hazards or leave harmful residues which can damage instruments and equipment within the vicinity of a fire. Dry chemical extinguishers are effective, but leave residues which may cause further damage to instruments. Halon is recommended for use near computer equipment since the -110 degrees Fahrenheit temperature with carbon dioxide discharge can damage computer components.

NOTE: USE OF HALON IS BEING PHASED OUT DUE TO ENVIRONMENTAL CONSIDERATIONS. *WHEN REPLACING HALON, ONLY USE AN APPROVED FIRE EXTINGUISHING AGENT (SUCH AS CLEAN GUARD).*

Class D. Class D fires are fires which involve combustible and/or water-reactive metals, such as magnesium, titanium, sodium, lithium and potassium.

Extinguishing agents of the Class D type are generally available in the form of powders. The powders are discharged by pressure and they must be spread evenly over the surface

of a fire to a depth sufficient to smother the fire. The two most common agents are G1 powder and Met LX powder.

Extinguishers suitable for "Class A" fires are generally identified by a triangle containing the letter "A". If colored the triangle is colored green.

Extinguishers suitable for "Class B" fires generally identified by a square containing the letter "B". If colored the square is colored red.

Extinguishers suitable for "Class C" fires are generally identified by a circle containing the letter "C". If colored the circle is colored blue.

Total Flooding Carbon Dioxide Extinguishing Systems

Great care must be exercised in using total flooding carbon dioxide extinguishing systems; personnel should be educated on what to expect. The carbon dioxide released is generally in the form of "snow", which can interfere with visibility during and immediately after discharge. The noise of discharge of the carbon dioxide can be frightening to anyone who has not experienced a discharge episode previously. Anyone in the area, or entering the area, after discharge can be overcome by the carbon dioxide and asphyxiated.

For these reasons a number of precautions are essential:

1. A sign shall be posted stating that the area is equipped with a carbon dioxide extinguishing system.
2. A pre-discharge alarm system shall be installed to warn of impending discharge.
3. All persons are required to leave the area when the alarm is sounded and the system activated.
4. No one shall be permitted to enter the area, until the local Fire Department determines it is safe to do so.

7711.4 GLASSWARE HAZARDS. More accidents occur in the laboratory from the mishandling of glassware than from any other cause. Laboratory personnel cannot afford to be casual in handling glassware. Broken glassware shall be discarded in specially marked containers separate from regular laboratory trash.

Intelligent selection and use of glass equipment can prevent breakage and injury from the broken glass, or from the contents of containers. The use of shields can serve to prevent serious consequences from glassware rupture during chemical reactions. Safety glasses can prevent eye injuries from flying glass.

Glassware storage areas should be well lighted. Heavier pieces of glassware should be stored on lower shelves, preferably no higher than an individual can easily reach without the use of a ladder or step stool. Delicate pieces of glassware should be stored in cartons, clearly marked as to contents.

Glassware should never be carried by projections, such as the sidearm of a distilling flask. Beakers full of liquids must never be carried by their rims. Shaking one liter or larger volumetric flasks by the neck should be avoided, since this invites breakage. Chipped, cracked, badly stained, etched, or poorly annealed glassware should be properly discarded.

Ends of glass tubing and rods must be fire polished before use. A towel, or gloves, should be used when cutting glassware, or when inserting tubing or rods into stoppers.

Glassware prepared or altered by glassblowing needs to be properly annealed to relieve thermal stress.

Glass vacuum vessels should be enclosed in suitable shields before evacuation, and only glass containers designed for vacuum work utilized. A transparent shield should be used around equipment under reduced atmospheric pressure, or around a reaction vessel when there is danger from explosion, runaway reaction, or boil-over, which may endanger the analyst and/or others working in the immediate area.

Freezing of glass stoppers can result from contact with strong alkalis over a prolonged period of time. An accident can occur when excessive pressure is applied or hard tapping employed in an attempt to free a frozen stopper.

Heavy glass apparatus should be supported with rigid, padded clamps. Use of more clamps than necessary to support assemblies may also cause safety problems.

7711.5 HAZARDOUS CHEMICALS. The Federal Hazardous Substances Act defines a hazardous substance as a substance or mixture of substances that is toxic, corrosive, a strong sensitizer, flammable or combustible, an irritant, or generates pressure through combustion, heat, or other means. Chemicals can fit this definition in one or more categories. Many can cause external or internal injuries, or both, from careless contacts and exposures. External injuries may result from skin contact with caustic or corrosive substances such as acids, bases, or strong salts. Internal injuries may come from toxic or corrosive substances absorbed by the skin, by ingestion, or by inhalation. The hazardous chemicals may be liquid, solid, or gaseous. (Three good references on hazardous reactions are contained in (1) *The Handbook on Laboratory Safety*, published by the Chemical Rubber Company, (2) *The Guide for Safety in the Chemical Laboratory*, published by the Manufacturing Chemists Association, and (3) *Prudent Practices in the Laboratory - Handling and Disposal of Chemicals*, published by National Academy

Press. All of these volumes should be in the laboratory library, and used as part of the training of new forensic *scientists*.)

Material Safety Data Sheets. The Occupational Safety and Health Administration (OSHA) requires a material safety data sheet (MSDS) for every hazardous chemical on the premises and available for any employee who requests it. Since there is some level of hazard associated with every chemical, OSHA has regarded all chemicals as hazardous. OSHA has developed a standardized worksheet (OSHA-20, Material Safety Data Sheet) on which can be recorded the properties and potential hazards of chemicals. The form covers the chemical name and synonyms, chemical family, hazardous ingredients of mixtures, physical data, fire and explosion hazard data, health hazard data, reactivity data, spill or leak procedures, special protection information, and special precautions. Each laboratory shall attempt to obtain and maintain a file of MSDS for chemicals on hand. If the laboratory cannot obtain a MSDS, contact The Health Services Unit or SF which subscribe to commercial MSDS data services. As updated MSDS are received, a file of obsolete MSDS is to be maintained. The file and its contents should be clearly marked "obsolete." All employees shall be informed of the file's location.

Reading and Understanding Material Safety Data Sheets (Reprinted with permission from the *Chemical Safety Manual for Small Businesses*. Copyright 1989 American Chemical Society.)

There is a specific list of items that are required to be on a MSDS. Each such item, with an explanation of its meaning, follows:

A. Chemical name, usually the IUPAC (International Union Of Pure and Applied Chemistry) or Chemical Abstracts Service chemical name is given, but it also may be a common name for the chemical (e.g., ethylene glycol is acceptable instead of 1,2 ethanediol). Trade names may be supplied, but the chemical name is also required unless it is considered to be a trade secret.

B. CAS Registry Number - This number is not required by OSHA but most state Right-to-Know laws require it. This number is assigned to each chemical by Chemical Abstracts Service. There are few instances where a chemical has several different numbers, a few chemicals have no assigned number and most mixtures do not have assigned numbers.

C. Date Prepared - OSHA requires that the date of preparation or latest update be on the MSDS.

D. Composition of Mixtures - This includes all hazardous materials over 1%, and all carcinogens over 0.1%. Trade names can be used but chemical names must also be included unless this information is considered a trade secret.

E. OSHA PEL - This is either a time-weighted average limit for an 8 hour day or a maximum concentration exposure limit for those items on the OSHA list. The figures may be in parts per million (ppm) or milligrams per cubic meter (mg/m3).

F. ACGIH TLV - Maximum exposure limits recommended by the American Conference of Governmental Industrial Hygienists. The same measuring units specified in the OSHA PEL are applicable. The ACGIH TLV list is updated each year.

G. Health Effects - Identification of target organs or systems adversely affected by overexposure.

H. Physical/Chemical Characteristics - This usually includes the following items where applicable:

1. Boiling point (the value may be at reduced pressure and either in degrees Celsius or Fahrenheit).
2. Melting point.
3. Vapor pressure usually in mm Hg: the temperature must be specified (usually in the range of normal room temperature).
4. Specific gravity (density with respect to water at a specific temperature).
5. Solubility in water (approximate values are acceptable).
6. Appearance and odor.
7. Evaporation rate (usually relative to butyl acetate).

I. Fire and Explosion Hazard Data - this usually includes the following items:

1. Flash point - the flash point of a chemical is the temperature at which its vapor can be ignited.
2. Auto ignition temperature - the temperature at which a chemical ignites spontaneously in the air.
3. Flammability limits - Most volatile chemicals have lower and upper concentrations in air below and above which they cannot be ignited.
4. Recommended extinguishing media.
5. Unusual fire and explosion hazards.

J. Reactivity Hazard data - Information should include whether the material is unstable and under what conditions instability exists, incompatibilities, and whether hazardous decomposition products can be produced.

K. Health Hazard data - This topic includes one or more of the following:

LD50 (lethal dose 50) - This is the lethal single dose (usually oral) in mg/kg (milligrams of chemical per kilogram of animal body weight) of a chemical that is expected to kill 50% of a test animal population.

LC50 (lethal concentration 50) - This is a concentration dose expressed as ppm for gases and vapors or as micrograms of material per liter of air for dusts and mists expected to kill 50% of a test animal population in one exposure.

In the Health Hazard Data Section, MSDS's often use words or phrases such as avoid contact, flammable, and others. Generalized descriptions of many of these phrases and the precautions to be practiced follow:

AVOID CONTACT: General rule for all chemicals, even if they are considered non-hazardous. *PRECAUTIONS*: Do not *breathe* vapors and avoid contact with skin, eyes, and clothing for all chemicals handled.
CARCINOGEN: Substances which are suspected or known to cause cancer. Some may have threshold limits of exposure. *PRECAUTIONS*: Exercise extreme care when handling! Do not *breathe* vapors and avoid all contact with skin, eyes and clothing by wearing suitable protective equipment and using appropriate confining apparatus.
CORROSIVE: Living tissue as well as equipment is destroyed on contact with these chemicals. *PRECAUTIONS*: Do not *breathe* vapors and avoid contact with skin, eyes and clothing. Use suitable protective equipment.
DANGER: Substances that have known harmful effects or which may have harmful effects, but have no available literature citing such effects. *PRECAUTIONS*: Treat as if these are the most dangerous chemicals that exist. There may or may not be serious hazards associated with these chemicals.
EXPLOSIVE: Substances known to explode under some conditions. *PRECAUTIONS*: Avoid shock (dropping), friction, sparks and heat. Isolate from other chemicals which become hazardous when spilled.
FLAMMABLE: Substances which give off vapors that readily ignite under usual working conditions. *PRECAUTIONS*: Spontaneously flammable. Avoid contact with air. flammable liquids, gases, vapors. Keep away from heat, sparks, or open flame. Sensitive to moisture. Keep dry.
IRRITANT: Substances that have an irritant effect on skin, eyes, respiratory tract, etc. *PRECAUTIONS*: Do not *breathe* vapors and avoid contact with skin and eyes.
LACHRYMATOR: Substances that have an irritant or burning effect on skin, eyes or respiratory tract. Dangerous in very small quantities (opening the cap has an immediate effect on the eyes). *PRECAUTIONS*: Open only in a hood! Do not *breathe* vapors. Avoid contact with skin and eyes. Avoid heating.
MUTAGEN: Chemical or physical agents that cause genetic alterations. *PRECAUTIONS*: Handle with extreme care! Do not *breathe* vapors and avoid contact with skin, eyes and clothing.

PEROXIDE FORMER: Substances which form peroxides or hydroperoxides upon standing or when in contact with air. *PRECAUTIONS*: Many peroxides are explosive! Do not open bottle if a residue is present on the outside of the cap or inside of the bottle!
POISON: Substances which have very serious and often irreversible effects on the body. Hazardous when breathed, swallowed, or in contact with the skin, and in sufficient quantity lead to death. The Department of Transportation regulations classify many poisons for transportation. *PRECAUTIONS*: Avoid all contact with the body. When handling use suitable protective equipment.
STENCH: Substances which have or generate bad smelling odors. *PRECAUTIONS*: Open only in a hood.
TERATOGEN: Substances that cause the production of physical defects in a developing fetus or embryo. *PRECAUTIONS*: Handle with extreme care! Do not *breathe* vapors and avoid contact with the skin, eyes and clothing. Use suitable protective equipment when handling.
TOXIC: Substances which are hazardous to health when breathed, swallowed, or in contact with the skin. Danger of serious damage to health by prolonged exposure. *PRECAUTIONS*: Avoid all contact with the body. When handling use suitable protective equipment.

L. First Aid. Appropriate procedures for emergency first aid should be given in the MSDS.

M. Precautions for Spills and Cleanup. Appropriate steps for safe cleanup of a spill or release should be given. An appropriate waste disposal method including whether the material can be put in a landfill or other EPA approved disposal facility should be supplied in the MSDS.

N. Control Measures. Types of protective clothing, gloves and respiratory protection should be listed. If the material should always be handled in a hood, glovebox or with extra ventilation, it should be listed under this heading.

Liquid Irritants generally cause the greatest number of external injuries because of direct skin contact. Liquid chemicals may react chemically with the skin, dissolve or abstract essential components, or disturb the equilibrium in the skin cells. Caution should be exercised in handling these substances, and adequate protective equipment utilized. If accidental exposure occurs, the affected area should be flushed with copious amounts of water.

Typical examples of liquid irritants are:

1. Concentrated acids and bases
2. Chlorinated hydrocarbons
3. Esters and ketones

Solid Irritants may also cause damage by contact with the skin. Injury generally results from their solubility in the moisture of the skin. The contact can be insidious, and by the time pain is felt, the injury can be more than superficial.

Typical examples of solid irritants are:

1. Sodium hydroxide
2. Silver nitrate
3. Phenol
4. Metallic sodium
5. Reducing agents

Here again, if exposure occurs, the affected area should be cleaned with copious amounts of water.

Gaseous Irritants attack the respiratory tract. The damage may vary from local intense inflammation of the pharynx to lung damage, with acute edema.

Typical examples of gaseous irritants are:

1. Ammonia
2. Chlorine and bromine
3. Acetic anhydride
4. Phosphorous trichloride
5. Thionyl chloride
6. Formaldehyde

The best protection against irritation from these chemicals in the laboratory is working with them in the hood. If exposure is more than superficial, and injury seems to have occurred, emergency treatment should be obtained from a medical facility.

There are several groups of chemicals encountered in our laboratories that can cause problems if they are not given special care in handling:

Alkaline Metals. The most hazardous property of this class of chemicals is their violent reaction with water. Hydrogen is evolved in the reaction; if conditions are right, the hydrogen may ignite with explosive force. Sodium and potassium react violently in this manner. Lithium reacts slowly with water at room temperature, but may react explosively at higher temperatures. Under certain conditions these metals may ignite spontaneously on exposure to air. For this reason the metals should be stored under kerosene. Under no circumstances should these metals be allowed to come in contact with the skin, or even with gloves. Metal tongs should be used in handling or moving the metals to a reactive vessel. Small amounts of the metals can be destroyed safely by

allowing them to react with alcohol, at room temperature, in a hood, away from an ignition source.

Aromatic Amines. This group of chemicals can cause rapid systemic poisoning by absorption through the skin. Absorption can occur from clothing, shoes, and porous gloves; therefore, care should be taken to prevent spills of liquids or powders.

Caustic Alkali. The major danger from this class of chemicals is their corrosive action on tissue. Severe, painful tissue damage can rapidly result from acute exposure when significant amounts of the caustic material is inhaled, splashed on the skin, or swallowed. Even small amounts can cause damage, which may range from an annoying irritation to a deep flesh burn.

Cyanides and Nitriles. These compounds are powerful poisons, which prevent the utilization of oxygen by the body tissues. Cyanides appear in the blood very rapidly after they are inhaled, swallowed, or absorbed through the intact skin. At first breathing is rapid, then irregular and gasping. Convulsions and even death can occur in a few minutes. Minute doses can cause dizziness and headaches. Cyanides must be kept away from acids. Nitriles are somewhat less toxic than metal cyanides, but they cause irritation of the nose and eyes. After absorption their toxic action is similar to that of the cyanides.

When cyanides are disposed of, the Safety Specialist should be consulted.

Ether. Ethers are not, generally, considered as highly toxic, but they can cause disorders from transient dizziness to fatal poisoning. The ethers are volatile and are highly flammable; under certain conditions they form explosive peroxides. Ethyl ether has a flash point of 45 degrees C. The vapors are heavier than air, and they can accumulate in a low spot, flow to an ignition source, and then flash back. Work with any quantities of ether should be carried out in a hood. When a small amount of ether is to be evaporated, it should be done in a hood, using a steam bath and not a open flame.

Exposure of ether to air, sunlight, and elevated temperatures (above 30 degrees C) can hasten the formation of peroxides. Anhydrous ethers are especially susceptible to peroxide formation. The peroxides are less volatile than the ether; evaporation or distillation tends to concentrate the peroxide, which can explode spontaneously.

Tetrahydrofuran, dioxane, ethyl and isopropyl ethers are the most common offenders. Of these, isopropyl ether appears to form peroxides more readily than the others. Before undertaking distillation of ethers, they should be tested for peroxides. To ascertain the level of peroxides in ether, a simple dipstick kit can be purchased. (These kits are available from Aldrich or EM Science.) If found, and the peroxide level is below 100 ppm, the ether should be filtered through a column of 80 Mesh activated alumina or shaken with ferrous sulfate, sodium sulfite, or another suitable reducing agent. Ethers

with peroxide levels above 100 ppm should be disposed of by a hazardous waste disposal company.

Ether is not to be used in a container larger than one liter. When a new can of ether is opened, it should be dated. If unused, the ether should be destroyed after 3 months. The empty can should be flushed with water to remove all residues before being discarded. Stocks of ether should be held to a minimum necessary for uninterrupted operation.

Halogenated Hydrocarbons. The most general toxic effect of this group of compounds is their anesthetic or narcotic action. Inhalation is the most common absorption route. Symptoms vary, but may include dizziness, fatigue, headache, and nausea.

Several of these compounds can cause irritation of the eyes, nose, and throat before other more serious conditions are noted. Kidney, liver, and nervous system damage can occur from continued exposure. Solvent-proof gloves, SCBA or a suitable vapor respirator should be worn for cleanup or large spills, or when large volumes are handled or transferred. Washing with soap and water is the manner for removal of organic halides splashed on the skin.

Hazard Identification Symbols. The basic form of the hazard identification symbol is a diamond, which is commonly recognized as a danger signal. Signs are color coded to indicate hazard characteristics:

RED LABEL - Flammable liquid. Keep all sources of ignition away. Heat can cause container to rupture with resultant spread of contents over a wide area. Inhalation of smoke and vapors, or skin contact may be harmful. A red label may also denote a flammable gas.
GREEN LABEL - Nonflammable gas with pressure to 2200 psi. Container rupture is likely in the event of rough handling or severe heat.
YELLOW LABEL - Oxidizers. Commodities bearing this label include such materials as peroxides, metallic sodium, lithium, and aluminum hydride which can cause fire when moistened by contact with combustibles, friction, and strong impact.
WHITE LABEL - Corrosive liquids, such as mineral acids.
ORANGE LABEL - Sensitive to heat, flame and shock.
POISON LABEL - Marked with skull and crossbones. Can be lethal even in small quantities.

7711.6 COMPRESSED GASES. Compressed gases, because of their unique properties and potential hazards, must be handled and used with care. Unique properties such as high pressure, rapid diffusion, low flash points for flammable gases, lack of odor and color for most gases, transparency and the cooling effect on rapid release demand that every precautionary measure be exercised when handling compressed gases. Diffusion of leaking gases may cause rapid contamination of the atmosphere, giving rise to toxic, or

anesthetic effects, asphyxiation, or rapid formation of explosive concentrations of flammable gases.

The procedures necessary to safely handle compressed gases are mainly centered on containment of the gases to prevent their escape to the atmosphere, and on management of systems through proper control of pressure and flow.

As a safety measure, newly employed chemists shall receive instructions on handling compressed gas cylinders and compressed gas systems before undertaking analytical work.

Compressed gas cylinders should be examined when received. If there is any indication of damage or leakage, or improper identification, the cylinders shall be removed to an isolated area, and then returned to the supplier as soon as possible.

Care must be exercised in handling cylinders. They must never be dropped or banged against each other. They should be stored in a separate room, or in an enclosure designed especially for this purpose. Cylinders shall be stored upright in racks, or secured in position, away from sources of heat and direct sunlight. Except when cylinders are in use, the steel protective caps must be threaded onto the cylinder body down to the last thread.

When a cylinder is moved, a special hand truck shall be used. The cylinder shall be lashed to the cradle on the truck in as near an upright position as possible.

Once a gas cylinder is placed in use, it shall be secured in position away from heat or ignition source and never used without a pressure regulator. The regulator shall be compatible with the gas for which it is being used.

The following general precautions are recommended for storing, handling and using compressed gases:

1. Store cylinders together, in racks, or secured in position in designated areas.
2. Avoid dropping, or permitting cylinders to strike each other violently.
3. Never drag, roll, or slide cylinders, even for short distances.
4. Leave the valve protection cap in place on cylinders until they are secured in place and ready for use.
5. Use a suitable hand truck for moving cylinders and make sure they are secured and in an upright position.
6. Do not store full and empty cylinders together.
7. Use cylinders in rotation as secured from the suppliers: first in, first placed in use.
8. Close the valves, replace the protective cap, and tag empty cylinders before returning them to the supplier.

9. Use compressed gases in well ventilated area.

10. Check the label and be sure you know the purpose for which the cylinder is to be used.

11. Use specifically designed wrenches for opening or closing cylinder valves. Gas regulators have brass threads that are easily damaged if forced. Damaged threads can cause leaks.

12. Make sure compressed gas systems are secure and not leaking.

13. Never use regulators as off-on control for cylinders.

14. Always close the cylinder valve, and bleed the pressure in the regulator to atmospheric pressure when shutting down a system for an extended period of time.

15. Never attempt to refill a cylinder by transfer of a gas from a full cylinder to an empty one.

16. Do not store compressed air cylinders, oxygen or any other oxidizing gas closer than 20 feet from any flammable gas cylinder or install a barrier of noncombustible material at least 5 feet high and having a fire rating resistance of at least hour to separate them. (NFPA-51)

17. Do not use any form of lubricating oil on gas cylinder threads, especially cylinders containing oxidizing gases.

18. Do not overuse teflon tape on gas cylinder threads; excessive tape can cause distortion of brass threads upon compression.

Pressure Regulator Handling and Use. A pressure reducing regulator is normally attached to each gas container before use and adjusted to a setting to limit the pressure to a level consistent with the specific use of the gas. The following procedures suggest how the regulator is to be attached and adjusted, and how it is checked to determine that it is functioning properly:

Regulator Attachment and Adjustment

1. The regulator should be attached to the cylinder without forcing the threads. If the inlet of the regulator does not fit the cylinder outlet, no effort should be made to force this fitting. A poor fit may indicate that the regulator is not intended for use on the particular gas or cylinder.

2. After the regulator has been attached to the cylinder valve outlet, turn the delivery pressure adjusting screw counterclockwise until it turns freely.

3. Open the cylinder valve slowly until the tank gauge on the regulator registers the cylinder pressure. At this point, the cylinder pressure should be checked to see if it is at the expected value. A large error may indicate that the cylinder is leaking.

4. With the flow control valve at the regulator outlet closed, turn the delivery pressure-adjusting screw clockwise until the required delivery pressure is reached.

5. Open the flow control valve to the system.

Pressure Regulator Check

1. Drain all pressure from the system: gauges should read zero.

2. Open cylinder valve and turn adjusting screw counterclockwise until it turns freely. The high pressure gauge should register the cylinder pressure, and the delivery pressure gauge should not indicate any pressure.

3. With the regulator outlet needle valve closed, the delivery pressure gauge should not indicate a pressure increase after 10 minutes, which would indicate leakage across the internal valve system.

4. Turn the adjusting screw clockwise until a normal delivery pressure is indicated. The inability to obtain a proper delivery pressure setting or abnormal adjustment of the screw indicates improper operation. Continued wear on a regulator valve and seat assembly will cause pressure to rise above the set delivery pressure, termed "crawl". Regulators showing crawl should not be used.

5. Close the cylinder valve and observe the pressure on both inlet and delivery gauges. A drop in the pressure reading after 10 minutes may indicate a leak in the system, possibly at the inlet or through the needle valve or diaphragm.

6. An excessive fall in delivery pressure under operating conditions and normal flows indicates that an internal blockage exists or that the cylinder valve has not been sufficiently opened.

Any deviation from normal in the above checkout will require repair of the regulator. Regulators should be repaired only by qualified personnel.

Properties of Some Common Compressed Gases

Argon - colorless, odorless, tasteless gas; nontoxic, but can act as an asphyxiant.

Chlorine - extremely powerful vesicant (blistering agent) and respiratory irritant; corrosive.

Helium - colorless, odorless, tasteless gas; nontoxic, but can act as an asphyxiant.

Hydrogen - nontoxic, flammable, can act as an asphyxiant.

Hydrogen Chloride - colorless, pungent, corrosive, highly toxic.

Nitrogen - nontoxic, but can act as an asphyxiant.

Oxygen - accelerates oxidation and combustion.

Propane - toxic, flammable, can act as an asphyxiant.

7711.7 STORAGE SAFETY. Each laboratory has one or more storage rooms for chemicals, glassware, equipment, and supplies. Provisions have been made for adequate

ventilation, adequate lighting, fire control and means for emergency exit. Care has been exercised to separate incompatible chemicals, and for the storage of flammable solvents and compressed gas cylinders. For flammable chemicals that must be stored under refrigeration, explosion-proof type units have been purchased. It has not always been possible, because of space limitations, to design optimum storage facilities. There are differences in opinion among experts as to whether centralized storage is most advantageous. Regardless of the details of the materials storage system, supplies must be maintained in good condition, and safe practices in storage and distribution observed.

The minimum vertical clearance between sprinklers and stored materials shall be eighteen (18) inches.

It is essential that storeroom aisles be kept free of debris, storage containers, and equipment. Apparatus and glassware shall not project beyond front shelf limits.

Bulky equipment, apparatus, or glassware should be placed well back on shelves, or installed in such a manner that will ensure stability, as well as prevent inadvertent movement by brushing as people walk through the aisles.

Heavy items should be stored on or as near to the floor as possible. Drums should no longer be used for the storage of hazardous waste and/or for the storage of solvents. Exceptions can be made for the storage of evidence. If your location contains drums of liquid be aware that they should be mounted horizontally, and securely braced to prevent rolling. A faucet, with a spring closing action, and locking pin is recommended for withdrawal of the contents from a drum. A static grounding wire should be attached to drums containing flammable solvents before dispensing the contents.

Safety siphons or inclinators should be used when dispensing acids or other liquids from carboys. Protective clothing and equipment should be available and used as necessary.

Chemicals which have deteriorated or are found to be unfit for use shall be withdrawn from storage and called to the attention of the Safety Specialist or a Laboratory Supervisor.

Storage of quantities of chemicals in individual laboratory areas is necessary for efficient operations. Chemical storage cabinets are provided for such storage. Chemicals from stock bottles should be withdrawn near the cabinets and the bottles returned promptly to the designated locations. Private stocks of flammable solvents should not be maintained by chemists at their benches, except for minimum amounts of such solvents that are used regularly during the day.

Incompatible chemicals should be separated in storage areas. Although their admixture is not likely under normal conditions, accidental combination can cause explosion, fire, and asphyxiation.

The following is a partial list of potentially dangerous combinations:

Chemical	**Keep out of contact with:**
Acetic Acid	Chromic acid, nitric acid, hydroxyl compounds, ethylene glycol, perchloric acid, peroxides, permanganates.
Alkaline metals, such as powdered aluminum, magnesium, sodium	Water, carbon tetrachloride or other chlorinated hydrocarbon, carbon dioxide, *halogens*.
Ammonia, anhydrous	Mercury (in manometers, for instance), chlorine, calcium hypochlorite, iodine, bromine, hydrofluoric acid (anhydrous).
Ammonium Nitrate	Acids, metal powders, flammable liquids, chlorates, nitrites, sulfur, finely organic or combustible materials.
Aniline	Nitric acid, hydrogen peroxide.
Bromine	Ammonia, acetylene, butadiene, butane, methane, propane, (or other petroleum gases), hydrogen, sodium carbide, turpentine, benzene, finely divided metals.
Carbon, activated	Calcium hypochlorite, all oxidizing agents.
Chlorates	Ammonium salts, acids, metal powders, sulfur, finely divided organic or combustible materials.
Chlorine	Same as for bromine.
Flammable liquids	Ammonium nitrate, chromic acid, hydrogen peroxide, nitric acid, sodium peroxide, nitric acid, sodium peroxide, the halogens.
Hydrocarbons (butane, propane, benzene, gasoline, turpentine, etc.)	Fluorine, chlorine, bromine, chromic acid, sodium peroxide.
Hydrogen Sulfide	Fuming nitric acid, oxidizing gases.

Hydrogen Peroxide	Copper, chromium, iron, most metals or their salts, alcohols, acetone, organic materials, aniline, nitromethane, flammable liquids, combustible materials.
Iodine	Acetylene, ammonia (aqueous or anhydrous), hydrogen.
Mercury	Acetylene, fulminic acid, ammonia.
Nitric Acid (concentrated)	Acetic acid, aniline, chromic acid, hydrocyanic acid, hydrogen sulfite, flammable liquids, flammable gases.
Perchloric Acid	Acetic anhydride, bismuth and its alloys, alcohol, paper, wood.
Silver	Acetylene, oxalic acid, tartaric acid, ammonium compounds.
Sodium	Carbon tetrachloride, carbon dioxide, water.
Sodium Peroxide	Ethyl or methyl alcohol, glacial acetic acid, acetic anhydride, benzaldehyde, carbon disulfide, glycerin, ethylene glycol, ethyl acetate, methyl acetate, furfural.
Sulfuric Acid	Potassium chlorate, potassium perchlorate, potassium permanganate (or compounds with similar light metals such as sodium, lithium), acetone.
(Adapted from the Dangerous Chemicals Code, 1951. Bureau of Fire Prevention, city of Los Angeles Fire Department.)	

7711.8 FIRST AID PROCEDURES. Each laboratory shall have at least four people who have received formal first aid training from the American Red Cross, Civil Defense, or other comparable sources. These trained individuals should be consulted, and their expertise utilized, when first aid is necessary. This chapter comments on a few of the common injuries that occur in laboratories and suggests simple emergency treatment. The book First Aid and Personal Safety of the American National Red Cross is an excellent source for a more comprehensive treatment of the subject.

Burns. The first thing to learn about burns is that for the most part they are preventable. Time spent in eliminating hazardous conditions is well worth the effort.

There are three major causes for burns in the laboratory: heat or thermal, chemical, and electrical. Burns are grouped in order of their severity: (a) first degree burns show

reddening of the skin, but no damage to the deeper layer, (b) second degree burns involve blistering of the skin, and (c) third degree burns occur where the skin is burned off or severely damaged. The seriousness is determined not only by the degree of its severity, but also by the extent of the area.

Burns are probably the most painful of all injuries. Pain is most severe at the time of the burn and shortly thereafter. Shock may occur if the burn is extensive.

Thermal Burns. If the burn is relatively minor, the burned area should be immersed in cold water as quickly as possible. The cold water treatment should be continued until the pain is relieved, and does not return when the burned area is removed from the water. Prompt application of cold tends to ease pain, and tends to reduce the severity of the burn. When the wound has dried, it should be bandaged with a sterile gauze bandage. If there is more than superficial blistering, with consequent risk of infection, the burn should be seen by a physician. In the meantime, the blisters should not be disturbed.

For serious thermal burns, the Safety Specialist or one of the staff trained in first aid will provide emergency aid. The Safety Specialist or a Laboratory Supervisor shall arrange for medical attention.

Chemical Burns. Burns produced by chemicals should be flushed off immediately with copious amounts of water, and the flushing continued *until the chemical* has been washed away and pain is reduced, or eliminated. Treatment is then similar to that for thermal burns.

If clothing has been contaminated, the clothing should be removed, or cut away as quickly as possible. If an emergency shower is available, it should be used and the contaminated clothing removed while the individual is under the shower. No neutralizing or buffering agents should be used. If the burn is severe, medical attention should be obtained.

Chemical burns of the eye are particularly dangerous and immediate action must be taken to prevent serious damage to vision.

The eye should be flushed immediately with copious amounts of cold water. The eye lid should be held open, forcibly if necessary, so that the entire surface of the eye is flushed. Promptness is of great importance, so the injured individual should not be taken any great distance to an emergency eye wash fountain. A low pressure stream of water from a cold water faucet should be used if available, or have the individual lie down and gently pour water into the inner corner of the eye so that the water will flow across the eye and out the outer edge. Continue the treatment for at least 15 minutes. The injured individual should be seen promptly by a physician, preferably an ophthalmologist.

Electric Shock. Electric shock is the injury produced by the passage of an electric current through the body. It can be caused by any of a number of situations: frayed electric cords, improperly grounded receptacles, short circuited equipment, contact with a source of current and a water faucet, or standing on a wet surface.

Moderate electric shock can produce a dazed condition or mental confusion, and/or surface burn or deep burn. Severe shock can produce unconsciousness and death.

The injured person must be removed from contact with the source of current, or the current turned off immediately. To free the victim from contact with the source of current, he should be pulled with a dry rope or dry clothing looped around a hand or foot. Send for medical aid immediately.

Foreign Bodies in the Eye. A foreign body may lodge on the inner surface of either the upper or lower eyelid or on the eyeball itself. Bringing the upper eyelid down over the *lower eyelid*, and holding it there for a moment may cause tears to flow, often washing out the foreign body. If the loose object is found under or on the lid, it can usually be removed safely with the corner of a clean handkerchief, or with a wet piece of sterile cotton, or a Q-tip. If the particle is attached or embedded in the eyeball, no attempt should be made to remove it; professional emergency treatment should be sought.

Bleeding. For small wounds, clean with soap and warm water. To stop bleeding apply steady pressure directly over the wound with a sterile pad or compress. If bleeding is more than superficial and a gauze pad is not immediately available, any clean cloth may be used. The pad should not be removed to see if the bleeding has stopped. If blood saturates the pad, apply more layers and maintain the pressure. If a limb is involved, raising the injured limb will help to reduce the flow of blood.

Poisoning by Inhalation. Remove the victim from exposure and get him to fresh air as quickly as possibly by carrying or dragging. If exposure has been severe, or the person is unconscious, call a physician or the rescue squad at once. Keep the person warm and lying down.

<u>7711.9 EMERGENCY PROCEDURES</u>. The Laboratory Operations Manual requires each laboratory to prepare *an Occupant Emergency Plan (OEP)* to meet the requirements of the Federal Property Management Regulations 101-20.504-2 Facility Self Protection. Subsection 7705.6 requires the investigation of laboratory accidents and the preparation of reports. Detailed reporting requirements regarding Occupant Emergency Plans are contained in Subsections 8512.5 and 8517.2 of the Planning and Inspection Manual.

This chapter will cover, in general, suggestions of elements that should be included in the facility protection plan, and how to report injuries.

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Fires. When a fire occurs it is important to try to keep it small and to localize it to the area of origin until it can be brought under control. Equally important is the need to alert all personnel of the fire, so that they can be safely evacuated if the fire cannot be controlled. The first person who discovers the fire should give the alarm. In the event of evacuation of the facility, the evidence vault(s) should be closed and locked after insuring that all personnel have left the vault, and if this can be accomplished without undue risk to any employee. Designate a primary and backup employee to this task in the Occupant Emergency Plan.

If it is judged that the fire can be put out by the use of a fire extinguisher, this action should be taken. If it appears that the fire may be serious, every effort should be directed toward confinement to limit the extent of damage. Methods of confinement include closing doors, pulling down the sash on the fume hood or turning off the power, turning off gas cylinders and systems, etc. The area should be searched to make sure that all personnel have left. Evacuation procedures shall be in conformance with the Laboratory Occupant Emergency Plan (see Subsection 7705.1). It is good practice to notify the fire department as soon as a fire is discovered. The alarm should not be delayed awaiting the results of attempts to extinguish the fire. Fire departments are more often grateful than critical for being called, even if the fire is out by the time they arrive. A fire that has gained headway before the fire department is called is often quite difficult to extinguish. Once on the site, the fire department can check the area to make sure that there is no likelihood that the fire will rekindle itself, and that the building is safe to permit reentry of personnel. They can also provide assistance in the treatment of injured, and in making arrangements to move injured person to a medical facility.

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No visitors or workmen should be allowed in the laboratory until cleared by the *security specialist*, and assigned a visitor's pass. Any unaccompanied, unknown person shall be challenged, and his or her presence called to the attention of the Laboratory Director or a Laboratory Supervisor.

The Occupant Emergency Plan requires that each laboratory should include attention to the following:

1. Delegating responsibilities (for evacuation of the building, notification of the fire department or police bomb squad, fire fighting, handling injuries, etc.).
2. Training personnel (in use of fire fighting equipment, fire confinement, alarms, evacuation procedures, etc.).
3. Fighting small fires.
4. Dealing with large fires (shutdown of electrical, mechanical, and gas flow systems, use of carbon dioxide area extinguishing system, confinements procedures, etc.).
5. Dealing with bomb threats.
6. Evacuating personnel (general plan, alternate plans, etc.)
7. Safeguarding classified documents.
8. Emergency treatment of injured personnel (first aid, removal to medical facility, etc.).
9. Assessing damage, and reporting.
10. Returning to normal operations.
11. Location of utility shutoffs.

The Occupant Emergency Plan shall be reviewed and updated every July and January to ensure currency. Copies of the semiannual updates shall be filed with the Plan.

Accidents. Job-related accidents, such as cuts, burns, inhalation of solvents, accidental ingestion or inhalation of drugs, etc., no matter how trivial must be reported to a Laboratory Supervisor, or the Safety Specialist. First aid should be administered by qualified personnel only.

For accidents requiring professional attention, the patient should be accompanied to the emergency room of the nearest hospital following previously made arrangements. A form CA-16 should be filled out and sent to the District Medical Director in order for compensation to be paid to the hospital. In addition, the necessary forms called for in the Personnel Manual, Section 2810 - Federal Employees' Compensation, should be prepared.

Evacuation Drills. An evacuation drill program shall be established. Programmed fire and evacuation drills shall be performed at least once a year and more frequently if new personnel are added to the staff between scheduled drills.

7711.10 INSPECTION PROCEDURES. Because safe conditions depend on inspections for possible hazards and their immediate correction, periodic inspections are an essential aspect of a successful safety and health program. The Safety Specialist should conduct the monthly and annual inspections while the entire laboratory staff should be alert for unsafe practices. Time must specifically be set aside to conduct safety inspections. Checklists serve to prevent oversight of critical elements of the safety inspection. However, exclusive reliance on a checklist may lead to neglect of unsafe conditions that may have been inadvertently omitted from the list.

Monthly Inspections. Safety equipment should be checked to be certain it is in usable condition. The Safety Specialist should perform or monitor these checks, and necessary repair or replacement should be made immediately. A written report shall be *submitted monthly* to the Laboratory Director **identifying any unsafe condition or equipment and the proposed corrective action**.

The following items should also be covered and included in the report:

A. Hoods

1. Check of drawing velocity in opened and closed position. Note changes from previous month. Velocity shall be reported in feet per minute (fpm). Note: The American Conference of Government Industrial Hygienists (ACGIH) recommends a velocity of 100 fpm for moderately toxic materials.
2. Do glass safety shields open and close properly?

3. Are the lights working?

B. Fire Extinguishers

1. Are all fire extinguishers in their designated places?
2. Are all extinguishers properly supported?
3. Are all fire extinguishers fully charged (carbon dioxide extinguishers are to be weighed to determine if fully charged)?

NOTE: The NFPA requires that carbon dioxide extinguishers be tested at least semiannually and that they be refilled if testing reveals a loss of more than 10% (NFPA 12, 1-10.3.5, 1993).

4. Are discharge orifices clear and unobstructed?
5. Are connections between the shell, hose, and nozzle secure?

C. Self-Contained Breathing Apparatus

1. Check that regulator is connected to cylinder properly.
2. Check cylinder gauge for "full" indication.
3. Open cylinder valve pressuring regulator and immediately close cylinder valve.
   (a) Compare regulator gauge to cylinder gauge (plus or minus 50 psi is allowable).
   (b) Watch regulator gauge for drop in reading which would indicate possible leakage. (Pressure drop of one increment on gauge in 5 minutes is acceptable).
4. With regulator still under pressure, and cylinder valve in closed position, open by-pass valve slowly and allow pressure in regulator to bleed down until pak alarm sounds, which should occur approximately 1/4 of full indication on regulator gauge. When pak alarm stops ringing, open bypass valve allowing remaining air to exhaust; close by-pass valve. To expel remaining air in regulator, cup index finger and thumb over regulatory outlet port and breath regulator.
5. Check regulator diaphragms for possible damage.
6. Check mask and hose for cracking and deterioration.

D. Eye Washes, Safety Showers

1. Are they in good operating condition?
2. *Monthly*, allow water to flow for several minutes to clean lines for rust that may have accumulated.

E. First Aid Kits

Are all necessary supplies present and in good condition?

F. Fire Blankets

G. Particulate Filter Respirators

Are they clean and dry, and in their specified location?

H. Solvent Storage Area

I. General Housekeeping

J. Exits/Egress

Annual Inspection. A more detailed annual check shall be made with a written report prepared and forwarded to the Laboratory Director, Office of Forensic Sciences and the DEA Safety Manager. The following shall be covered during the inspection:

A. Fire Extinguishers

1. Are extinguishers clean and well cared for?
2. Have they been hydrostatically tested within the prescribed period?
3. Are the shells of the extinguishers corroded, damaged or dented so as to suggest possible weakness?
4. Are the extinguishers readily accessible and their locations plainly visible from a distance?
5. Have monthly inspections been marked on the tag attached to the extinguishers?

B. Self-Contained Breathing Apparatus (Face piece and Hose Assembly)

1. Examine interior of face piece for contamination, damage and deterioration: specifically the periphery of the seal area.
2. Remove the exhalation valve guard and check exhalation valve for damage or deterioration. Replace exhalation valve guard.
3. Check exterior of face piece for damage.
4. Stretch breathing tube assembly and inspect for cracking.
5. Stretch breathing tube at face piece inhalation port and quick connect coupling joint for tightness of assembly.
6. Ascertain that quick connect coupling "0" ring seal is in place, in threaded portion of coupling.
7. Examine head harness for cracking and degradation by stretching each individual strap over its entire length.
8. Are monthly checks marked on tags attached to the equipment?

C. Electrical

1. Are there exposed wires, frayed cords, and deteriorated insulation?
2. Are junction boxes, outlets, switches and fittings covered?
3. Are all metallic fixed electrical pieces of equipment grounded?
4. Does equipment connected by cord and plug have grounded connections?
5. Are all portable electrical hand tools grounded? (Double insulated tools are acceptable without grounding.)
6. Are all breaker switches identified as to their use?
7. Are flexible cords free from splices?

D. Exits

1. Are all exits marked with an exit sign and illuminated?
2. Is the direction to exits, when not immediately apparent, marked with visible signs?
3. Are all exit routes kept free of obstructions?

E. Glassware

1. Are broken and chipped pieces of glassware discarded?
2. Are all drains free of broken glass?
3. Are step stools available for reaching high shelves?
4. Are articles of glassware for laboratory workers rinsed thoroughly?
5. Are glass disposal containers being used?

F. Solvents

1. Are hoods free of residues from waste solvents?
2. Are spill supplies readily available?
3. Are water immiscible solvents discarded by evaporation in the hoods?
4. Are flammable liquids kept in closed containers?
5. Are bulk drums of flammable solvents grounded?
6. Is there a strong solvent odor anywhere in the laboratory?
7. Are accurate inventories of all flammables and combustibles kept on file?

G. Emergency Operations

1. Are at least four employees in the laboratory qualified to render first aid?
2. Are emergency phone numbers posted?
3. Are all employees aware of the evacuation plan outlined in the Facility Self-Protection Plan (Occupant Emergency Plan)?

H. Records

1. Are records kept on all safety checks?

2. Are records (including *OSHA Form 300s*) kept on occupational accidents and illnesses?

3. Are Material Safety Data Sheets kept on file for all chemicals present in the laboratory?

4. Is the OSHA poster (Occupational Safety and Health Protection for Employees of the Drug Enforcement Administration) in a prominent location where it can be seen by all employees?

5. Are safety committee meetings held quarterly, chaired by the Laboratory Director or management designee, and is the report of the meeting kept on file?

I. Air Quality. Laboratory air shall be tested using a Bendix Gastic Precision Detector System or its equivalent to conform with current OSHA requirements. The following TLV limits will be monitored for:

1. Chlorinated Hydrocarbons
2. Acetone and Alcohols
3. Ozone (in the vicinity of UV light sources)

J. Fire Prevention

1. Is the fire detection system in working order?
2. Are fire doors in working order?
3. Is all fire protection equipment identified with the color red?
4. Are "No Smoking" signs posted where smoking is prohibited?

5. Is there a minimum of eighteen (18) inches of clearance between sprinklers and stored materials?

K. Compressed Gases

1. Are all cylinders legibly marked with name of contents?
2. Are all tanks secured?
3. Are all protective caps on, except for cylinders in use?
4. Are all cylinders visually intact?
5. Are tanks equipped with proper regulators?
6. Is the cylinder transport cart in good condition?

L. Miscellaneous Housekeeping

1. Are safety glasses worn **when required**?
2. Are bench tops free of unnecessary clutter?
3. Are all acids, alkali and other chemicals compatibly stored?
4. Are all belts on vacuum pumps guarded?
5. Are all chemicals properly labeled and dated?

6. Is the storage of food restricted to areas strictly for that purpose?

M. Employee Involvement

1. Does the laboratory participate in the activities of the Federal Field Safety and Health Council in its area?
2. *Before beginning their duties, have new employees been given safety instructions and safety training involving work related hazards and potential exposures? Employees must also be trained when they are introduced to new potential exposures or process changes.*
3. Have *all laboratory management* been given safety and health training within 1 year of appointment?
4. Has safety training been held quarterly?

7711.11 MEDICAL GUIDELINES FOR MANAGING EXPOSURE TO BODY FLUIDS. These guidelines have been developed because of concern about contracting contagious diseases through exposure to body fluids during work. DEA regulations regarding handling of potential biohazardous material is contained in the DEA Bloodborne Pathogens Program, Paragraph 2792.56, Personnel Manual.

During law enforcement activities that involve confrontation, control and arrest of suspects or emergency response, exposure to blood, feces, saliva and other body fluids may occur. Injury from needles or other contaminated items may also occur during searches and handling or analysis of evidence. There is a risk of harm to the employee from contagious diseases that can be transmitted by contact with body fluids (e.g., hepatitis, AIDS, tuberculosis, etc.). The degree of risk is unknown. However, because there may be no specific treatment for these diseases (e.g., AIDS) and because the result of infection may be serious or life-threatening, the following guidelines are recommended:

Precautions to Prevent Harmful Exposure - General Precautions.

1. Since the infectious status of individuals will usually be unknown, all body fluids from all individuals should be considered to be hazardous. All evidence containing or suspected of containing body fluids should, therefore, be considered to be contaminated. Evidence likely to contain body fluids should not be analyzed unless the evidence is essential to the case and no other evidence can be used to support the case. These precautions should be consistently used for all individuals.
2. All personnel should routinely use appropriate barrier precautions to prevent skin and mucous membrane (i.e., mouth, eye, *and nose*) contact with blood or other body fluids of others. Latex type gloves should be worn for touching blood and body fluids, mucous membranes, or non-intact skin of others and for handling items or surfaces soiled with blood or body fluids. Gloves should be changed after contact with an individual's

body fluids. Paper masks and protective eyewear or face shields should be worn during operations that may generate droplets of blood or other body fluids. Gowns or aprons should be worn during procedures that are likely to generate splashes of blood or other body fluids.

3. Hands should be washed immediately after gloves are removed. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other body fluids. If washing facilities are unavailable, disposable towelettes may be used until the individual can wash with soap and water.

4. All personnel should take the following precautions to prevent injuries caused by hypodermic needles and other sharp instruments that may be contaminated with body fluids:

a. Searches of luggage, clothes, boxes, trash and other items should be done carefully without advancing unprotected hands into areas that cannot be seen to be free of sharp instruments. Latex type gloves and tongs should be used for these search situations.

b. Needles should not be capped or recapped, purposely bent or broken (even in commercial mechanical devices), removed from syringes or otherwise manipulated by hand.

c. Needles, syringes and sharp objects, likely to be contaminated with body fluids, that are retained as evidence should be placed in puncture resistant containers and sealed in plastic bags to prevent leakage. The plastic bags should be clearly labeled with a biohazard label to warn others that the container contains hazardous biologic material. The recommended procedure is to package such evidence in this way prior to submission of the evidence to forensic laboratories for analysis.

d. Disposal of needles, syringes and sharp objects, likely to be contaminated with body fluids, should be done by placing the objects in puncture resistant containers such as are used in health care facilities for disposal of needles.

5. To minimize the need for emergency mouth to mouth resuscitation, mouthpieces, resuscitation bags, or other ventilation devices should be available in areas in which the need for resuscitation may predictably occur.

6. Work surfaces and materials contaminated by blood or other body fluids should be decontaminated with an appropriate chemical germicide. (See Guidelines for Disinfection, below).

7. Employees who have skin sores or weeping skin rashes should avoid the possibility of contact with body fluids and should not work with objects or materials contaminated with body fluids until the skin condition resolves.

Laboratory Precautions

1. Chemists analyzing evidence considered to be containing body fluids should do so in a functioning laboratory hood and should wear latex gloves, paper face masks and protective eyewear. Gloves should be changed and hands washed thoroughly after completion of specimen processing.

2. Class I or II biological safety cabinets should be used to analyze evidence containing body fluids whenever procedures are conducted that have a high potential for generating droplets. These include activities such as blending, sonicating and vigorous mixing.

3. Mechanical pipetting devices should be used for manipulating all liquids in the laboratory. Mouth pipetting must not be done for any fluids in the laboratory.

4. Contaminated materials used in laboratory tests should be decontaminated before being reused or be placed in bags and disposed of in accordance with the laboratory policies for disposal of infective waste. (See Guidelines for Disinfection, below).

5. Scientific equipment that has been contaminated with blood or other body fluids should be decontaminated and cleaned before being reused, repaired in the laboratory or transported to the manufacturer. (See Guidelines for Disinfection, below).

6. All persons should wash their hands after completing laboratory activities and should remove protective clothing before leaving the laboratory.

Guidelines for Disinfection

A. General

1. Gloves should be worn during cleaning and decontamination procedures used for dealing with spills of blood or other body fluids. First, visible contaminated material should be removed and placed in a sealed plastic bag for disposal. Then the contaminated area should be flooded and cleaned with a liquid germicidal chemical.

2. Examples of some commercially produced germicides are included as an appendix to Paragraph 2792.56, Personnel Manual. Additional information on commercial germicides can be obtained by writing to the Disinfectants Branch, Office of Pesticides, Environmental Protection Agency, 401 M. St., SW, Washington, DC 20460.

3. In addition to commercially available chemical germicides, a solution of sodium hypochlorite (household bleach) prepared daily is an inexpensive and effective germicide. Concentrations ranging from approximately 500 ppm (1:100 dilution of household bleach) sodium hypochlorite to 5000 ppm (1:10 dilution of household bleach) are effective if used as outlined above.

Commercially available chemical germicides may be more compatible with certain devices or materials that might be corroded by repeated exposure to sodium hypochlorite. If in doubt, check with the manufacturer of the contaminated item before disinfecting.

B. Evidence. Evidence suspected of being contaminated with biohazardous material, e.g., internal body-carry samples, will be decontaminated using the procedure outlined below.

C. Scientific Instruments. The manufacturer's instructions for use of germicides should be followed. It is important that the manufacturer's specifications for compatibility of the scientific device with chemical germicides be closely followed.

D. Housekeeping. Environmental surfaces such as walls, floors and other workspace surfaces are not associated with transmission of infections in hospitals and are, therefore, not likely to be related to contagion in the non-hospital workplace. Extraordinary attempts to disinfect or sterilize these environmental surfaces are not necessary. However, cleaning and removal of soil should be done routinely. Disinfection as described in the general guidelines above should be done only if surfaces are visibly soiled with body fluids. Disinfectant fogging or aerosols are an unsatisfactory method of decontaminating air and surfaces and should not be used.

E. Laundry. The risk of actual disease transmission from soiled clothing or other cloth is negligible. Hygienic and common sense storage and processing of soiled clothing is recommended. Clothing soiled with blood or body fluids should be handled as little as possible with minimum agitation to prevent gross contamination of the air and people handling the items; gloves should be worn when handling contaminated materials; an individual wearing items that have become soiled should remove these items as soon as possible and thoroughly wash the skin in the area of contamination; soiled clothing should be placed in plastic bags for transportation and storage to prevent leakage. During cleaning, if hot water is used, clothes should be washed with detergent in water at least 71 degrees C (160 degrees F) for 25 minutes. If low temperature (below 70 degrees C, 158 degrees F) laundry cycles are used, chemicals suitable for low temperature washing at proper use concentration should be used.

F. Disposal of Infective Waste. There is no evidence that even most hospital waste has caused disease in the community as a result of improper disposal. However, prudent procedures should be used to prevent the possibility of harmful exposure to others: blood, secretions and excretions no longer to be retained as evidence may be carefully poured down a drain connected to a sanitary sewer; materials such as syringes and needles that are contaminated with blood and body fluids and are no longer to be retained as evidence should be placed in puncture resistant containers such as are used in health care facilities for disposal of needles; the containers should be labeled to warn others that the container contains infective waste, and the container should be incinerated.

These guidelines have been modified for DEA use from the Recommendations for Prevention of HIV Transmission in Health Care Settings published by the Center for Disease Control in the Morbidity and Mortality Weekly Report (Supplement) Vol. 36, No. 2S, August 21, 1987 (USDHHS, PHS, CDC).

Decontamination Procedures for Potentially Biohazardous Evidence

Note 1: For Safety purposes, all internal body-carry evidence is assumed to be biohazardous.

Note 2: *Pursuant to advice from the Health Services Unit and the National Institutes of Health (NIH), adequate pre-cleaning of samples, e.g., with soap and water, to remove organic contaminants is necessary in order that disinfection methods be effective.* The presence of these contaminants may inactivate chemical disinfectants or protect the microorganisms from the decontamination process. If necessary, a brush or similar implement may be used to ensure that contaminants are removed from crevices or creases in the packaging material.

Note 3: Non-chemist personnel, e.g., evidence technicians, who come in contact with potentially biohazardous evidence should routinely use appropriate barrier precautions, i.e., latex type gloves, safety glasses, etc. (see General Precautions, above).

1. As soon as *practical, after* internal body-carry evidence is received in the laboratory and logged in, it shall be assigned to a chemist for decontamination.
2. The chemist should photograph the plastic evidence envelope to ensure that all labels, initials and other identifying notations are documented.
3. The chemist will decontaminate the evidence by one of the following methods. Prior to initiating the decontamination process, the chemist must ensure that he/she is wearing appropriate personal protective equipment and that the procedures are carried out in a functioning fume hood or biological safety cabinet (see Paragraph 7710.2C).

A. Chemical Decontamination:

1. Remove the entire contents of the heat-sealed evidence envelope and place in appropriate chemical disinfectant. Ensure that any visible foreign material is washed from the surface of the containers (Note 2, above). Leave the containers in the disinfectant for 20 to 30 minutes.
2. Rinse the containers with tap water and allow to air-dry. An additional rinse with a small amount of isopropyl or methyl alcohol (caution) may be used to facilitate drying.
3. Either proceed with the analysis in accordance with the DEA Evidence Sampling Plan, or re-package the evidence in a new heat-sealed evidence envelope for subsequent analysis.
4. Decontaminate the heat-sealed evidence envelope, utilizing the same procedure, as above, or via steam-autoclaving (Procedure B, below). If the labels and markings on the original heat-sealed evidence envelop are legible, the disinfected envelope should be maintained with the evidence. Otherwise, it may be disposed of and the photographs maintained in its place.

B. Decontamination by Steam-Autoclaving:

1. Inject two ml. of water into the sealed evidence envelope.
2. Place the evidence *envelope* in the autoclave and sterilize at 121 degrees F for 15 minutes. The total cycle time is 25 minutes (10 minutes exhaust time and 15 minutes

heating time). Place heat-sensitive indicator tape on the envelope to verify proper operation of the autoclave. Dry heat may be used but requires higher temperatures or longer heating cycles.

3. Upon completion of the heating cycle, open and remove the contents of the evidence envelope. If an odor is present or if visible foreign material remains on the containers, the containers may be placed in a deodorant soap solution.

4. Either proceed with the analysis in accordance with the DEA Evidence Sampling Plan, or re-package the evidence in a new heat-sealed evidence envelope for subsequent analysis.

1 Internal NIH memorandum dated April 4, 1990, from Harry Mahar, Chief, Occupational Safety and Health Branch, Division of Safety, National Institutes of Health, to NIH Laboratory Staff.

7711.12 CLANDESTINE LABORATORY SAFETY. Law enforcement personnel face the most serious potential exposures to chemical hazards during the seizing and processing of clandestine laboratories. Forensic chemists, knowledgeable in clandestine laboratory operations, can provide valuable assistance in anticipating these hazards. Specialized training in identifying the potential hazards and developing proper hazard control measures is also necessary.

Clandestine Laboratory Safety Program. This program was instituted to ensure the safety of employees while investigating clandestine laboratories. The objectives of the program are to properly train employees to assess the clandestine laboratory site, identify all the hazards present and take the necessary precautions to protect themselves from these hazards.

To accomplish these objectives the program is divided into 4 basic areas: policies and procedures, training, protective equipment and medical monitoring.

Policies and Procedures. Those agents who have satisfactorily completed the clandestine laboratory safety training program will be certified to conduct raids. Chemists, Fingerprint Specialists, and Hazardous Waste Specialists will be certified to provide assistance at the clandestine laboratory sites.

Only certified employees may enter a clandestine laboratory site. (Certified chemists, Fingerprint Specialists, and Hazardous Waste Specialists are not to enter the laboratory site until the area is secure and all suspects are arrested.) Once the area is determined to be non-hazardous, non-certified employees may enter.

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Completion of Forms. All employees participating in clandestine laboratory seizures should complete a DEA Form 484, Clandestine Laboratory Exposure Report, and a Form CA-1 to provide documentation in the event of a future occupational injury or illness that may arise as a result of participation in this activity. The following procedure should be followed:

1. Submit the Form 484 to the Health Services Unit through the laboratory chain of command within 5 days of the seizure.
2. Submit a Form CA-1 to the Employee Relations Unit in accordance with Paragraph 2810.14, Personnel Manual.
3. If time is lost from work or medical bills are incurred following submission of more than one Form CA-1 and their illness cannot be identified as having resulted from a specific day or exposure, complete and submit a Form CA-2 to the Employee Relations Unit (Paragraph 2810.15, Personnel Manual).

**Training*. The Clandestine Laboratory Safety Certification provides instruction in the history of clandestine laboratories, initiation and development of clandestine laboratories, roles of agents, chemists and prosecutors, proper raid planning, actual synthesis of controlled substances and bomb and booby trap recognition. Also, the training consists of instruction in basic toxicology, chemical and physical hazards, hazard evaluation and assessment, work practices and personal hygiene, protective clothing and equipment, respiratory protection, regulations involving chemical handling, site control and decontamination and site emergency preparation.* Field exercises and hands on experience with different kinds of air monitoring equipment is also provided. Advanced clandestine laboratory safety training is also offered, as well as, annual refresher training for certified employees.

Protective Equipment. Each certified employee will be provided with personal protective equipment. The following is a list of equipment supplied to each certified employee:

1. Flame retardant suit
2. Hood
3. Gloves
4. Two plaques and one patch
5. Respirator with nose cup
6. Face mask
7. Flashlight
8. Carry bag
9. Boots
10. Eye wash
11. Goggles
12. Hard hat with visor
13. NIOSH's book, "Pocket Guide to Chemical Hazards"
14. Spectacle kit, if necessary.

Laboratory Directors will be responsible for providing the disposable suits, gloves, etc., as well as replacement of any worn or damaged equipment.

When a certified employee retires, resigns or transfers to a different job series, all recyclable items, namely, respirator, face piece and flame retardant suit are to be cleaned and returned to the Office of Forensic Sciences for reissue.

Medical Monitoring. Medical monitoring is crucial to the safety of employees in this program. It determines whether an employee can enter the program and how long someone can participate. Medical monitoring is performed for the following reasons:

1. to ensure employees, entering the program, are physically fit and capable of using the safety equipment.

2. to determine, through annual physical examinations, if an employee has developed health problems as a result of clandestine laboratory activities.

3. to identify the health effects whenever an employee is accidentally exposed to hazardous chemicals.

7711.13 REFERENCES. The following safety references are considered essential and shall be kept in each laboratory library.

1. Handbook of Laboratory Safety, Norman V. Steere, Ed., Chemical Rubber Company, Cleveland, Ohio (1967).
2. Fire Protection Guide on Hazardous Materials, National Fire Protection Association, Boston, Massachusetts.
3. Applicable OSHA Safety and Health Standards (29 CFR 1910).
4. Occupational Safety and Health for the Federal Employee (29 CFR 1960).
5. EPA Hazardous Rules and Regulations (40 CFR 260 - 268).
6. Standard First Aid and Personal Safety, The American Red Cross.
7. Prudent Practices in the Laboratory - Handling and Disposal of Chemicals, National Academy Press, Washington, D.C. (1995).
8. Managing Safety in the Chemical Laboratory, James Dux and Robert Stalzer, Van Nostrand Reinhold Company, New York, New York.
9. Safe Storage of Laboratory Chemicals, David Pipitone, Wiley Interscience, New York, New York.
10. Improving Safety in the Chemical Laboratory, 2nd Edition, Jay Young, Wiley Interscience, New York, New York.

The following references are recommended, but not considered mandatory.

1. Chemical Reference Manual Safety Handbook, Matheson, Coleman and Bell, Norwood, Ohio.
2. Matheson Gas Data Book, Matheson Gas Products, East Rutherford, New Jersey.
3. Fundamentals of Industrial Hygiene, National Safety Council, Chicago, Illinois.
4. Basic Industrial Hygiene, American Industrial Hygiene Association.
5. Dangerous Properties of Industrial Materials, North Irving Sax, Rheinhold Book Corporation.
6. NFPA Inspection Manual, National Fire Protection Association, Boston, Massachusetts.
7. Safety in the Chemical Laboratory, Volumes 1 through 3, Norman V. Steere, Ed., Division of Chemical Education, American Chemical Society, Eason, Pennsylvania (1974).
8. Biosafety in the Laboratory, National Academy Press, Washington, D.C. (1989). **

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CHAPTER 78 PLANNING

LABORATORY OPERATIONS MANUAL

DRUG ENFORCEMENT ADMINISTRATION

CHAPTER 78 PLANNING

7801 GENERAL

Laboratory system planning will be reported in three documents: the Operating Program Plan, which expresses the personnel requirements of the laboratory for the coming fiscal year; the Financial Plan, which expresses the funding requirements of the laboratory for the coming fiscal year; and the Laboratory Equipment Request, which expresses the equipment and instrumental requirements of the laboratory for the coming fiscal year.

These plans will be submitted to SF annually as follows:

A. The Financial and Operating Plans must be submitted together, and are usually due to SF in late August;

B. A revision must be submitted after the agency Financial Plan is approved usually sometime during the 1st or 2nd quarter. SF will provide the Laboratory Director with the amount of funding available for the fiscal year. The Laboratory Director will use this figure to review and revise his or her original Financial and Operating Plan submissions.

Financial Plan revisions will not be required by SF when the Laboratory Director re-programs funds within the various object classes to cover expenses, irrespective of the amount or percentage transferred. Operating Plan revisions will follow the same criteria for reprogramming hours when warranted. Laboratory Directors are responsible for operating within their respective budget appropriations and programmed hours, providing appropriate oversight and ensuring the efficient expenditure of funds and staff time on a quarterly basis. Laboratory Directors should submit revised Financial and Operating Plans at any time when actual expenditures become significantly out of balance with planned expenditures. The Laboratory Director will explain significant changes from the originally approved plan.

C. The Laboratory Equipment Request will be submitted in December of each year as specified by SF in an annual memorandum.

7802 OPERATING PROGRAM PLAN

SF will notify each Laboratory Director to submit a plan (Fiscal Year Planning Call). This notification will contain planned resource availability, any other information that will affect the laboratory in the next fiscal year, and a submission deadline.

7802.1 PREPARATION. The initial step in preparing the Operating Program Plan will be to complete a Laboratory Planning Guide, DEA-331 (See Laboratory Operations Handbook, Exhibits H-11 and H-12), printed form or computer generated, which will specify the personnel requirements. The column headed "actual" will indicate accomplishments as of July 31 of the current fiscal year. The first two columns headed "projected" will indicate the projected accomplishments for both the current fiscal year and the coming fiscal year.

7802.2 OTHER MANPOWER - COMPLETION OF LABORATORY PLANNING GUIDE

A. Exhibit H-12 defines the various tasks to report for each activity, along with the corresponding line number on the computer spreadsheet. Exhibit H-11 (or optional DEA Form 331). These tasks are the same as those reported in STRIDE on the Laboratory/Staff Time Expenditures Report (72/1) and the Summary Number & Time of Analysis by Laboratory report (72/8). Another source of information is the Laboratory Operations Resource Summary report (72/9C). Any significant differences between the "actual" and "projected" categories leading to a request for increased staff must be footnoted and explained in writing.

B. Line 36, Hours Required to Eliminate Previous Year Backlog, is computed by multiplying the average time of analysis of an evidence category as reported in STRIDE by the number of backlogged exhibits in that category and summing the products for all categories.

C. Line 37, Total Required Hours, is obtained by adding lines 35 and 36.

D. Line 38, Total Required Staff Years, is obtained by dividing line 37 by 2008 hours.

E. Line 39, Staff Years Available, is the total number of Chemist positions available from the previous fiscal year.

F. Line 40, Additional Staff Years Required, is obtained by subtracting line 39 from line 38.

G. Line 41, Additional Supervisory Chemist, must be fully justified. For DEA laboratories, a group size of 8 to 15 Chemists for the first group and 8 to 12 Chemists for subsequent groups (including the Supervisory Chemist) is considered to be the most efficient span of control.

H. Line 42, Chemist Increase, is obtained by adding lines 40 and 41.

I. Support Staff. Requests for staff increases of support personnel must be fully explained and based on statistical data.

J. Other Professionals. Requests for additional positions must be fully explained.

7802.3 RESEARCH PLAN. The Research Plan for the coming fiscal year is part of the Operating Program Plan. A progress report for each assigned project will be formatted as indicated in Exhibit H-07 of the Laboratory Operations Handbook. The Research Plan will rank projects by priority and will include an estimate of the number of hours programmed and anticipated results for each project. Because SFL1 biannually submits separate Research Reports, SFL1 is not required to submit a Research Plan with the Operating Plan.

7803 FINANCIAL PLAN

The Financial Plan consists of funding requirements for laboratory operations and requests for: **professional development, technical training, administrative training, safety training, additional space, and administrative equipment.** *SF will notify each Laboratory Director to submit a plan (Fiscal Year Planning Call). This notification will contain guidance, other information affecting the laboratory during the next fiscal year, and a submission deadline.* **At this time, Laboratory Directors should also begin preparing the Laboratory Equipment Request as detailed in section 7804.**

7803.1 PREPARING THE LABORATORY FINANCIAL PLAN REQUEST

A. Operating funds are used for day-to-day laboratory operations. Expenditures such as trial costs, purchase of glassware and solvents, and rental charges for a copier are examples for which funds should be requested. Differences in funding from the previous fiscal year must be fully explained. Examples that may form a basis for increased or decreased funding are:

1. Identified approved changes in operations.
2. Proposed changes in operations.
3. Proposed changes to the Table of Organization.
4. Increased costs of travel, supplies, rental fees, etc.

B. Exhibit H-13, Laboratory Financial Plan Request (Original Request), is used to request laboratory operating funds. The amounts requested are reflected in the *spending sub-object class* categories as indicated in Exhibit H-13. The *spending sub-object class* for which data is reported in more than one category is to be sub-totaled. The estimated total obligations for the current fiscal year are to be shown for comparison purposes.

Costs which are considered recurring and uncontrollable (fixed) are to be separately identified.

Estimated travel costs are to be provided for seven categories and their associated *Reporting Category* Codes within *Spending Sub-Object Class* *21010* (Travel): Trial (XT02), Operational Support (XT03), Training Conducted (XT04), Training Received (XT05), Local (XT06), Professional Development (XT07), and Administrative Travel (XT08). Estimated registration fees for professional scientific meetings are to be provided in Reporting Category Codes XT07 within *Spending Sub-Object Class*25104*. All training and professional development requests will be attached to this funding request.

7803.2 ADMINISTRATIVE EQUIPMENT. All requests for administrative equipment will be listed separately in priority order.

7803.3 SPACE. This request must be identified by a square foot requirement, not a funding requirement.

7804 LABORATORY EQUIPMENT REQUESTS

**The Laboratory Equipment Request consists of the prioritized equipment request with justifications, the Equipment/Instrument Survey, and the Laboratory Equipment Module. Annually, SF will notify each Laboratory Director to submit a Laboratory Equipment Request. This notification will contain guidance and any other information that will affect the laboratory during the next fiscal year and a submission guideline.

SFL9 shall prioritize their Laboratory Equipment Request and handle their equipment funding separately from the Ad Hoc Equipment Review Committee.**

7804.1 PRIORITIZED AND JUSTIFIED EQUIPMENT REQUESTS

All items on the Laboratory Equipment Request will be listed in priority order with an instrument cost and a justification. New equipment items or deviations from the Laboratory Equipment Module must be clearly identified and explained. SF will assign priorities to individual requests based on the justifications provided.

7804.2 EQUIPMENT/INSTRUMENT SURVEYS

Annually, SF will provide each Laboratory Director with the necessary Equipment/Instrument Survey to itemize all the analytical, fingerprint and photographic items in the laboratory. The surveys must accurately list equipment type, acquisition or in-service date, age, condition, and compatibility with LIMS.

Along with the Equipment/Instrument Survey, each laboratory will provide a separate listing of all items of laboratory equipment that are five (5) years old or older as of the last day of the coming fiscal year. For each item, provide type of equipment, model number, DEA serial number, year placed into service, and a brief description of operating condition.

7804.3 LABORATORY EQUIPMENT MODULE

SF will provide each Laboratory Director with the revised Laboratory Equipment Module, annually, after the Ad Hoc Equipment Review Committee meeting.

7804.4 AD HOC EQUIPMENT REVIEW COMMITTEE

A. There will be an Ad Hoc Equipment Review Committee that shall meet at the discretion of SF, normally once per year. Each laboratory will budget in the FY Financial Plan to provide the selected individual for a five day meeting at DEA Headquarters in Arlington, Virginia. The committee will: 1) prioritize all Laboratory Equipment Requests, 2) review and update as necessary the Laboratory Equipment, Fingerprint Program Equipment, Computer Forensic, and Photographic Equipment Modules, 3) review and consider other topics brought to the committee's attention, 4) review and update the instrument/equipment evaluation protocol and 5) provide a report to the Deputy Assistant Administrator, Office of Forensic Sciences.

B. The Ad Hoc Equipment Review Committee will be composed of the following representatives, no two of whom will represent the same laboratory:

Voting members:
SFL#1 - Forensic Chemist
SFL#X - Forensic Chemist (FC)
SFL#Y - Laboratory Director, Associate Laboratory Director, or Supervisory Chemist (Mgmt.)
SFL#Z - Fingerprint Specialist (FS)
Chairperson:
SFS Program Manager for Equipment
Advisory:
SFL Fingerprint Program Manager
Other SFL Program Manager(s), as appropriate

C. The rotation schedule will be as follows:

YEAR	"X" (FC)	"Y" (Mgmt.)	"Z" (FS)
FY-06	8	5	3
FY-07	2	6	4
FY-08	3	7	5
FY-09	4	8	6
FY-10	5	1	7
FY-11	6	2	8
FY-12	7	3	2
FY-13	8	4	3

7805 REVIEW AND APPROVAL

The Operating Program Plan and the Financial Plan will be reviewed by SF to assure the plans are consistent with the policies and goals of the Laboratory System and DEA. SF will notify the respective Laboratory Directors if clarification or justification to the plans is necessary, or of the approval of the plans.

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OFFICE OF FORENSIC SCIENCES
DOCUMENT CONTROL CENTER

Laboratory System Orders

LS - 05 - 002 Reporting Methamphetamine Enantiomers

LS - 05 - 007 Noncompetitive Career Ladder Promotion

LS - 05 - 010 Laboratory Results Reporting Form

LS - 05 - 012 Tracking Unrecoverable Fingerprints

LS-06-004 Tracking of Fentanyl Exemplars

LS-06-007 Medical Accommodations and Limited Duty

LS-07-001 Submitting Latent Fingerprints for Search with DHS

LS-07-005 Policy Revision - Increase in Maximum Storage Quantities of Stock Training Materials

LS-07-006 Utilization of "DGF' LEMS Code when Fingerprint and Drug Evidence are Sealed within the Same Container

LS-07-008 Reconciliation of NIDA Samples

LS-08-001 Validation of Quantitative NMR Methods

LS-08-002 Disclosure Policy

LS-08-003 Clarification Regarding the Reporting of Small Amounts of Base in Heroin and Cocaine Samples

LS-08-004 Electronic Dissemination of Analytical and Evidence Destruction Reports

LS-08-005 Revised Heroin Signature Program Sampling Procedures

LS-08-006 Policy for the Return of Drug Evidence to Its Owner

LS-08-007 Discontinued Use of DEA-307 Cards

LS-08-008 Giglio Disclosure Policy

LS-08-009 Revised Methamphetamine Profiling Program Sampling Procedures

LS-08-010 Policy Revision - (b)(7)(E)

LS-08-011 Policy Revision - Analysis of Evidence

LS-08-012 Customer Satisfaction Survey

LS-08-013 Revised Heroin Signature Program Sampling Selection

LS-09-001 Analysis of Marijuana Seeds

LS-09-002 Instrument Performance Verification Procedures and Acceptance Criteria

LS-09-003 Determination of Special Program Quantitative Analytical Inconsistencies

LS-09-004 Estimate of Uncertainty of Measurement for the Purity of Controlled Substances

LS-09-005 Determination of Net Weight and Uncertainty of Measurement Estimates

LS-09-005 Attachment 1 Uncertainty Calculator with Instructions

LS-09-005 Attachment 2 Examples

LS-09-005 Validation of Uncertainty Calculator Electronic Spreadsheet

LS-09-006 Facilities and Environmental Conditions

LS-09-007 Immigration and Customs Enforcement Latent Print Evidence

LS-09-008 Adulterations to Substances at Clandestine Laboratory Seizures

LS-09-009 Receiving Evidence

LS-09-010 Payment for Professional Certification

LS-09-011 Procedures for Reporting Weights and Unit Counts on the Forensic Chemist Worksheet (DEA 86 form)

LS-09-012 Evidence Destruction Operational Plan

LS-10-001 Transferring Laboratory Funds for the Procurement of Accountable Administrative Furniture and Equipment

LS-10-002 Retention of Case-Related Correspondence

LS-10-003 Guiding Principles of Professional Responsibility

LS-10-004 Internal Audits and Management Reviews

LS-10-005 Administrative and Technical Review Procedures for the Analysis of Controlled and

LS-10-006 Monitoring Storage Conditions

LS-10-007 Verification of Drug Reference Materials

LS-10-008 Laboratory Monthly Report

LS-10-009 Discontinued Use of Laboratory Index Book

LS-10-010 Policy Revision - Canine Training Materials Program

LS-10-011 Definition of Laboratory Number

LS-10-012 Receiving Evidence II

LS-10-013 Laboratory Case File

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-10-002**

ORDER

Classification Code
7302.57.A

Issue Date: 02/22/2010

SUBJECT: Retention of Case-Related Correspondence

PURPOSE:
This laboratory system order (LSO) establishes policy for the selection and retention of case-related correspondence in laboratory case files. This requirement is effective immediately and will be incorporated into the next version of the Laboratory Operations Manual (LOM).

BACKGROUND:
Under the Federal Records Act, 44 U.S.C. 3301, all government employees are required by law to make and preserve records containing adequate and proper documentation of the organization; its functions, policies, decisions, procedures; and essential agency transactions. In order to meet the government's obligation for discovery, DEA laboratories are required to maintain substantive case-related information for disclosure.

In response to recent civil litigation regarding the disclosure of e-mail, the Deputy Chief Counsel, Operational Law, has advised that e-mail correspondence regarding chain of custody and all case-related communications with the case agent or prosecutor qualify as 'substantive' and must be retained in laboratory case files. This LSO also applies to case-related notes resulting from telephonic or in-person conversations.

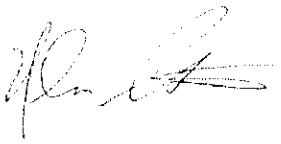
POLICY:
To ensure compliance and conformity in the retention of case-related correspondence, DEA laboratories will include hard copies of all documentation concerning chain of custody and communications with the case agent or prosecutor in the case file. In accordance with LOM § 7302.57.A.18, all retained correspondence will bear a unique identifier.

7302.57 Laboratory: Case File

A. The laboratory case file for DEA cases consists of:

1. The original DEA-307 after disposition is completed.
2. The original DEA-48.
3. For exhibits whose net weight exceeds threshold amounts specified in LOH, Appendix HA-1, transmittals from the SAC notifying the appropriate United States Attorney or the responsible state/local prosecutor of destruction procedures, as well as any additional response or appeals of same.
4. DEA-12 or documentation of delivery to U.S. Postal Service or other official carrier (see**LOM** 7303.5).
5. A copy of the DEA-7 and other laboratory reporting forms, where appropriate.

6. DEA-86, original, and DEA-86a (if applicable).
7. DEA-7a copy five (5).
8. Any required source determination reports.
9. Pertinent analytical material, e.g., charts, graphs, etc.
10. Any investigative photographs and/or negatives.
11. The DEA-466.
12. A copy of the Fingerprint Report.
13. Digital records.
14. **A copy of the DEA-500 and DEA-6 from clandestine laboratory investigations.
15. All documentation, including but not limited to, handwritten notes and observations, hardcopies of computer generated notes, photographs, sketches, or diagrams generated by laboratory personnel from an investigation outside of the laboratory including crime scenes.
16. Copies of clandestine laboratory investigation documents such as defendant personal notes and synthesis notes, where applicable.
17. **Printed copies of any communication (e.g., e-mails) regarding chain of custody or case-related communications with case agents or prosecutors.**
18. Administrative documentation identified with a unique identifier. If bound, the unique identifier should only be on the front page.**



Nelson A. Santos
Acting Deputy Assistant Administrator
Office of Forensic Sciences

02/05/2010
Date

Laboratory System

ORDER

LS-09-007

Classification Code
73

Issue Date: September 21, 2009

SUBJECT: Immigration and Customs Enforcement Latent Print Evidence

---

OBJECTIVE:
To establish policy and procedures for forwarding U.S. Immigration and Customs Enforcement (ICE) latent print evidence to the ICE Forensic Document Laboratory (FDL).

BACKGROUND:
DEA Laboratories receive a significant number of exhibits from ICE which require both drug and latent print examination. In order to more effectively utilize the latent print resources available to both agencies, ICE latent print evidence submitted to a DEA Laboratory as part of the drug evidence will be separated from the drug evidence and mailed to the ICE FDL for examination. In addition, ICE evidence submitted only for latent print analysis is not to be accepted by the laboratory.

POLICY:
ICE latent print evidence submitted to DEA Laboratories as part of the drug evidence will be forwarded to the FDL for latent print examination. Exceptions to this policy will be made to recognize that drug evidence will not be submitted to FDL and that ICE latent print/drug evidence may be impractical to separate or send to the FDL. In these situations, laboratory management will use its discretion to determine if and how the latent print evidence will be separated from the drug evidence to be sent to the FDL for processing, or whether the ICE latent print evidence will be examined at the DEA laboratory.

The following procedures will be followed when sending ICE latent print evidence to the FDL.

1. The Forensic Chemist analyzing the exhibits will separate the non-drug physical evidence (packaging) from the alleged controlled drug substance in accordance with LOM 7302.71.

2. The Forensic Chemist will seal the non-drug evidence in a heat sealed evidence envelope, one exhibit per envelope, and return the exhibit to the evidence vault. The forensic chemist will annotate box 6 of the DEA-86 with the statement "Original packaging submitted to ICE FDL for latent print examination"

3. ICE latent print evidence will be sent to FDL once every two weeks.

4. When forwarding the ICE latent print evidence to the FDL, the following documentation must be attached to the respective evidence:

    a. A copy of the DEA-7 (or other receipt documentation) that was submitted with the exhibits in the case.

    b. A copy of the ICE Form 73-003, if it was received with the evidence.

    c. Either the original or a copy of any ~~latent~~ fingerprints or palmprint cards that were submitted for comparison.

    d. A DEA-12 completed in accordance with the LOM.

5. ICE latent print evidence and associated documentation will be sent from the DEA Laboratory to FDL utilizing the standard ICE memorandum (copy attached).

6. Prior to forwarding exhibits to FDL, an e-mail must be sent to FDL at (b)(6) notifying the latent print section that latent print exhibits are being forwarded. The subject line of the e-mail must be listed as: *DEA Submission of ICE Latent Print Exhibits*. The body of the e-mail must contain a scanned copy of the signed standard ICE memorandum for each case submitted.

Any questions or concerns should be directed to the FDL latent print section by calling (b)(6) and asking to speak to a Latent Print Specialist. Questions can also be e-mailed to the latent print section at (b)(6) When e-mailing a question, please make sure that the subject line of the e-mail indicates that the question relates to the DEA submission of ICE latent print exhibits.

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

9/18/2009
Date

U.S. Department of Justice
Drug Enforcement Administration
DEA Laboratory
xxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxx
(xxx) xxx-xxxx

www.dea.gov

OI FDL STOP 5116
IMMIGRATION AND CUSTOMS
ENFORCEMENT
8000 WESTPARK DR STE 200
MCLEAN, VA 20598-5116

ATTN: CHIEF FORENSIC DOCUMENT EXAMINER

Reference: Case No. _____
Exhibit Number(s) _____
DEA Lab Number(s) _____
ICE Case Identifier (name of subject) _____

This is a request for latent print examination of the above referenced exhibit. The original containers and/or packaging materials to be examined are enclosed.

In addition to the physical evidence, also enclosed are copies of the following documents:

____ ICE transmittal letter submitted with the physical evidence
____ DEA 7 Form(s)
____ DEA 12 Form
____ ICE Form 73-003 (if received with the evidence)

Please sign and return the DEA 12 to the xxxxxxxx Laboratory to acknowledge receipt of the evidence. Upon completion of the examination, please send the original report of examination and the sealed physical evidence to the submitting ICE office. Also forward a copy of the report of examination to the xxxxxxxxxxxx Laboratory at the above address.

Sincerely,

xxxxxxxxxxxxxx
Laboratory Director

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United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System

ORDER

LS-05-002

Classification Code
7002.2

Date: March 3, 2005

SUBJECT: Reporting Enantiomeric Forms of Methamphetamine Hydrochloride

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OBJECTIVE:
This Laboratory System Order establishes policy for reporting the enantiomeric forms of methamphetamine hydrochloride.

BACKGROUND:
The United State Sentencing Commission Guidelines define "ice" for the purposes of the guideline to mean a mixture or substance containing d-methamphetamine hydrochloride of at least 80% purity. In order to establish a consistent policy for reporting the enantiomeric form(s) of methamphetamine hydrochloride, the following policy is established:

POLICY:

1. Because of the conventions used throughout DEA for many years and the verbiage used in the United States Sentencing Commission Guidelines, the d- and l- designations will be used where enantiomeric designations are required.

2. If the methamphetamine HCl concentration is less than 80%, report the total methamphetamine HCl concentration with no isomeric determination.

3. If the methamphetamine HCl concentration is greater than or equal to 80%, and contains a mixture of d- and l- isomers, report total methamphetamine HCl concentrations with no isomeric determination.

4. If the methamphetamine HCl concentration is greater than or equal to 80%, and contains only the d- isomer, report d-methamphetamine HCl and the concentration.

Thomas J. Jankovsky
Deputy Assistant Administrator
Office of Forensic Sciences

Date

Distribution: SFD, SFE, SFL, SFS, SFQ, All Laboratory Directors

Initialed by:

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United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System

ORDER

LS-05-007

Classification Code

Date: March 15, 2007

SUBJECT: Noncompetitive Career Ladder Promotion/Review Procedures for GS-13 Senior Forensic Chemist

---

OBJECTIVE:

To provide revised procedures for the promotion of forensic chemists to the GS-13 level.

BACKGROUND:

Section 2250.37 of the Personnel Manual (PM) describes procedures for the promotion of nonsupervisory chemists to the GS-13 level. These procedures have been revised, in consultation with the Human Resources Division Policy Staff, to ensure that they are consistent with those recently developed for the promotion of fingerprint specialists within the laboratory system.

PROCEDURE:

A. General. This section addresses the noncompetitive promotion criteria, recommendation and review process for the GS-13 Senior Forensic Chemist, GS-1320 series, within the DEA Laboratory System. A GS-12 Forensic Chemist may be considered for promotion to the GS-13 level only after s/he has been in grade at least one year and has demonstrated evidence of possessing the appropriate specialized experience (at the GS-12 level) and competencies needed to perform the GS-13 higher graded duties as described in the position description. Promotions to GS-13 are not automatic nor are they an employee entitlement. They are contingent upon several criteria: 1) the continued availability of sufficient higher-graded work (as described in a GS-13 Senior Forensic Chemist position description; Generalist or Impact), 2) authorized funding, 3) the employee's demonstrated ability to satisfactorily perform the *higher graded* duties, 4) the supervisor's recommendation and the laboratory director's certification that the above is evident and, 5) documentation that the employee's overall performance is at an acceptable level. Active participation by the employee in a recognized professional organization is highly desirable.

B. Senior Forensic Chemist Career Ladder GS-13 Promotion Criteria

1. The employee's supervisor must recommend him/her for promotion to the GS-13 level.

2. The employee must have completed at least one year in grade as a GS-12.

3. The employee must have demonstrated the ability to independently assist law enforcement officers with the processing of seized clandestine laboratories and with trace evidence collections (Generalist).

4. The employee must have received an overall rating of "successful" or higher on their most recent performance appraisal.

5. The employee must possess qualifying specialized experience and demonstrate the ability to successfully perform the duties at the GS-13 full performance level, as described in the Senior Forensic Chemist position description.

6. The Laboratory Director must personally concur with the first line supervisor's recommendation and certify that the forensic chemist's performance meets the GS-13 criteria. This responsibility cannot be delegated.

7. A candidate for promotion must not have been the subject of any disciplinary action within the past three years that, in the opinion of the Deputy Assistant Administrator, Office of Forensic Sciences (SF) would warrant denial of promotion to the GS-13 level.

C. Senior Forensic Chemist Career Ladder GS-13 Promotion Procedures

1. Recommendations for promotion will be initiated by the immediate supervisor and forwarded through the laboratory system chain of command to SF. The package submitted to SF must contain the following: a) a copy of the GS-13 Senior Forensic Chemist position description; b) a narrative prepared by the immediate supervisor, which justifies the promotion by describing the individual's accomplishments, attesting to the breadth of his/her experience, and includes examples of higher level duties performed by the employee as stated in the position description; c) a copy of the SF-50, Notification of Personnel Action, showing the employee's promotion or appointment to the GS-12 level; d) a copy of the employee's most recent Performance Appraisal Record (DEA Form-460, note - overall rating must be "successful" or higher); e) an SF-52, Request for Personnel Action, signed by the Laboratory Director; f) a statement, signed by the Laboratory Director, certifying that the employee has the required time in grade and has the necessary breadth of experience by demonstrating the ability to perform at the GS-13 level as described in the position description accompanying the promotion request.

2. SF will review the package for completeness and sufficiency of documentation. A decision will be made based upon review of the submitted documentation and an assessment of the degree to which the employee's accomplishments correspond with the higher level duties described in the GS-13 position description.

3. SF will also initiate name checks to determine if there has been any disciplinary action within the past three years, which would warrant denial of promotion.

4. If the package is approved by SF, it will be forwarded to the Recruitment and

Placement Section (HRR) of the Human Resources Division for review, approval and processing.

5. After review, if the package is satisfactory, HRR will notify SF of the Section's approval of the promotion before processing the final action. SF will notify the Laboratory Director who will notify the employee.

6. If the promotion is denied, the package will be returned to the Laboratory Director with a written explanation. The Laboratory Director will forward the explanation to the employee.

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

March 15, 2007
Date

United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System

ORDER

LS-05-010

Classification Code

Issue Date: November 13, 2009

SUBJECT: Laboratory Results Reporting Form

This Laboratory System order (LSO) replaces LS-05-010, dated February 13, 2009. This LSO was revised to clarify the manner of reporting net weight, concentration or purity, amount of actual drug, reserve weight, and remarks. In addition, the Sample Laboratory Report (Attachment 1) was revised to demonstrate these clarifications.

OBJECTIVE:

Provide guidelines and procedures for the use of an analytical report form so that all laboratories report drug analysis results in a consistent manner. Effective September 23, 2005, Form LS-05-010 will be used temporarily pending finalization in Jet Forms. A new heading is necessary on Form LS-05-010 to comply with ASCLD/LAB *International* AL-PD-3034: ISO/IEC 17025:2005 / 5.10.5 Opinions and Interpretations. All reports generated on or after February 17, 2009, must use the revised format.

BACKGROUND:

The current version of the DEA-7 eliminates space for the reporting of laboratory results. A number of different formats for reporting results were in use within the laboratory system. There was wide disparity in the substitute reporting formats.

POLICY:

A. Form LS-05-010 must be used by all laboratories (except the Special Testing and Research Laboratory (SFL1) and the Digital Evidence Laboratory (SFL9)) to report chemical analysis results in place of the DEA-7, DEA-113, or any other substitute reporting form. SFL1 will report the results of analysis from foreign operations in accordance with Laboratory Operations Manual Section 7302.6A. SFL9 will utilize the DEA-6 to report results of analysis. Form LS-05-010 will be controlled on the Share Drive by the Office of Forensic Sciences pending final creation in Jet Forms. Under no circumstances should the basic layout and setup of Form LS-05-010 be altered.

B. The Laboratory Operations Manual (LOM) and Laboratory Operations Handbook (LOH) will be revised in the next edition to accommodate this change in the reporting format. Specific revisions that will be necessary for this change will occur in the following Sections:

LOM: 7001.33 7302.54 7305.61J

7006.1	7302.6A	7307.41
7009.12G	7303.5B	7307.42
7301.6G3	7305.31A	7308.3
7302.53 Item 6	7305.31B	7313.2A3
7302.53 Back of Worksheet	7305.41	

LOH: H7102.24B
H7309.3D

C. The following general procedures detail how the form shall be used:

1. After completion of the analysis and technical review, the results will be typed using Form LS-05-010 in accordance with the instructions (see D. below). Multiple exhibits can be reported on this form.

2. The analyst will review for accuracy, sign and date the report once it is printed and will submit it for administrative review.

3. The laboratory director or designee will sign the form upon successful completion of the administrative review, including any required editing.

4. The accompanying DEA-7 will be annotated with "See Laboratory Report" and will be signed by the laboratory director. Note that the current version of the DEA-7 does not need to be annotated and does not require the laboratory director's signature.

D. The following instructions are to be followed for completing Form LS-05-010.

1. To ensure every data space in the report has been evaluated, all empty data spaces must be annotated with four dashes (see Attachment #1).

2. "TO": Enter the Division name and the submitting office for DEA submissions or the appropriate name for other agency submissions.

3. "FROM": Enter the laboratory's name and the laboratory's location (i.e.: Northeast Laboratory, New York, New York; Mid-Atlantic Laboratory, Largo, Maryland; Southwest Laboratory, Vista, California, etc.).

4. "RESULTS AND CONCLUSIONS": This heading was added to satisfy ASCLD/LAB - *International* AL-PD-3034: ISO/IEC 17025:2005 / 5.10.5 Opinions and Interpretations.

5. "CASE NUMBER": Enter the exhibit's case number from the DEA-7 or block #4 of the DEA-86.

6. "Exh. No." (Exhibit Number): Enter the information from block #7 of the DEA-86.

7. "Lab No." (Laboratory Number): Enter the information from block #8 of the DEA-86.

8. "Active Drug Ingredient": Enter the information from block #9 of the DEA-86.

9. "Gross Weight": Enter the information from block #6 of the DEA-86. For sub-exhibits, the gross weight will be entered in the appropriate space for the first split.

10. "Net Weight": Enter the information from block #6 of the DEA-86. Enter all values as grams or kilograms; include uncertainty values when appropriate.

11. "Conc. or Purity": Enter the information from block #10 of the DEA-86. Enter all values as percentages; include uncertainty values when appropriate.

12. "Amount of Actual Drug": Enter the information from block #11 of the DEA-86. Enter all values as grams or kilograms; include uncertainty values when appropriate.

13. "Reserve Weight": Enter the information from block #12 of the DEA-86. Enter all values as grams or kilograms.

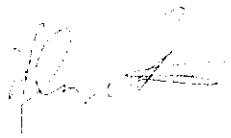
14. "Remarks": Enter all additional information concerning the sample analysis such as other identifications, special programs, etc. Information such as bulk statements, certificate of compliance statements (Mid-Atlantic Laboratory), and explanations of abbreviations used will be placed in this section. In addition, when samples are in a form other than powder, include the net unit count, the reserve unit count and the concentration in amount/unit. The laboratory director can approve the inclusion of more information, on a case by case basis, as necessary.

15. "Analyzed By": Print the analyst's name and title. The analyst will sign and date upon completion of the report.

16. "Approved By": Print the name of the laboratory director and title. The laboratory director will sign and date after the administrative review of the report.

17. "Page __ of __": Enter Page 1 of 1, unless additional copies of the form are required to report results.

E. Attachment #1 provides examples on how to fill out Form LS-05-010.



11/13/2009
Date

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

U.S. Department of Justice

Drug Enforcement Administration

LABORATORY REPORT

TO: **San Diego Field Division** **CASE NUMBER: XX-YY-ZZZZ**

FROM: Southwest Laboratory (SFL8)
Vista, California

RESULTS AND CONCLUSIONS:

Exh. No.	Lab. No.	Active Drug Ingredient (Established or Common Name)	Gross Weight	Net Weight	Conc. or Purity	Amount of Actual Drug	Reserve Weight
1a-k	123455	Marijuana	1200 g	1150 g	----	----	1123 g
2	123456	Cocaine Hydrochloride	65.32 kg	49.78 kg (± 0.90 kg)	88.5% (± 3.3%)	44.05 kg (± 1.80 kg)	49.77 kg
3.01	123457	Oxycodone Hydrochloride	153.8 g	56.7 g (± 0.1 g)	16.0% (± 1.2%)	9.0 g (± 0.7 g)	55.2 g
3.02	123457	No Controlled Substance	----	50.1 g (± 0.1 g)	----	----	45.0 g
4	123458	Methamphetamine (Calculated as the Hydrochloride)	672.4 g	446.8 g (± 0.3 g)	8.6% (± 0.7%)	38.4 g (± 3.3 g)	441.5 g
5	123459	Cocaine Base	35.2 g	9.3 g (± 0.003 g)	35.6% (± 2.0%)	3.3 g (± 0.2 g)	7.9 g

Remarks:
The reported uncertainty values represent expanded uncertainty estimates at the 95% confidence level.
Exhibit 1a-k: 25.0 g removed for Special Program.
Exhibit 2: Also contains caffeine and procaine.
Exhibit 2: 39.77 kg held for destruction pending written notification.
Exhibit 2: 3.0 g removed for Special Program.
Exhibit 3.01: Total unit count = 227 tablets (net); 200 tablets (reserve); active drug concentration: 40.2 mg/tablet.
Exhibit 3.01: Also contains acetaminophen.
Exhibit 4: Total volume = 447 mL (net); 435 mL (reserve); active drug concentration: 86.7 mg/mL.

Analyzed By: Jane Doe, Senior Forensic Chemist **Date:** _____
(Signature, Printed Name, Title)

Approved By: John Smith, Laboratory Director **Date:** _____
(Signature, Printed Name, Title)

United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System

ORDER

LS-05-012

Classification Code

Date: March 15, 2007

SUBJECT: Tracking Unrecoverable Fingerprints

OBJECTIVE:

To establish a procedure for tracking unrecoverable fingerprints in the System To Retrieve Information from Drug Evidence (STRIDE) and the Laboratory Evidence Management System (LEMS).

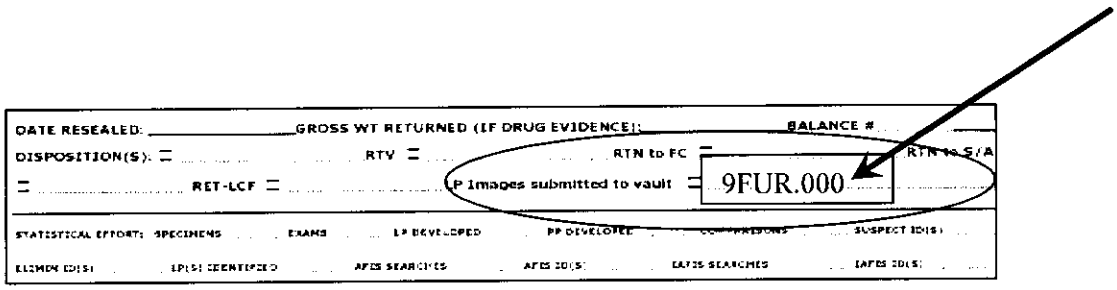
BACKGROUND:

During the examination for latent prints, there are certain types of situations where the detected print cannot be preserved on its substrate and retained as evidence. In these cases, the image of the recovered print used in the identification process becomes the best evidence in the case and is labeled as an "unrecoverable fingerprint." In order to track unrecoverable fingerprints, a new STRIDE code (9FUR.000) and a new "type" code (FUR) in LEMS has been created.

PROCEDURE:

"Read-only" media containing images of unrecoverable fingerprints will be sealed by the Fingerprint Specialist in a new heat sealed evidence envelope and submitted to the vault. This will require an increase in fingerprint units ("63" transaction) in LEMS. For the unrecoverable fingerprints, the "type" field extension must be changed from FIN to FUR. Also, the DEA-307 card must be annotated to update the increase in the fingerprint unit "FUR" so as to accurately reflect the total number of units for that exhibit.

In order for STRIDE to correlate with LEMS, the Fingerprint Specialist will also annotate the STRIDE code, 9FUR.000, on the "LP Images submitted to vault" line on the back of their worksheet (see below) which will be entered into the secondary drug code field of the corresponding fingerprint LP record in STRIDE.



All LEMS "FUR" units generated from drug exhibits (DRG) will be maintained in the laboratory's vault. All LEMS "FUR" units generated from non-drug (NDE) exhibits will be returned to the submitting agent along with the original evidence and annotated on a DEA-12. All LEMS "FUR" units generated from other agency (non-DEA) exhibits will be returned to the submitting agent along with the original evidence and annotated on a DEA-12.

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

March 15, 2007
Date

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United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System
ORDER

LS-06-007

Classification Code

Date: October 4, 2006

SUBJECT: Medical Accommodations and Limited Duty

INTRODUCTION

Medical accommodations and limited duty status determinations for chemists were subjects of discussion during the September 4-6, 2003, Laboratory Directors' Conference. The purpose of this laboratory system order is to formalize a June 1, 2004, memorandum issued to clarify the procedures to be followed when an employee requests an accommodation due to a medical condition.

BACKGROUND

Laboratory System employees sometimes present their supervisors with requests for restricted work activities or accommodations due to their medical conditions. In order to ensure consistency in granting medical accommodations for laboratory employees, all accommodation requests which will exceed 30 days based on an employee's medical condition, must be submitted to the Human Resources Division, Health Services Unit (HREH) for review and concurrence prior to formal approval.

According to the DEA Personnel Manual, Section 2735.17, [Medical] "Limited Duty can be defined as removing some or all of the normal duties of the assigned position from the employee for a specific amount of time." For any employee who cannot perform the functions of his/her job description, medical information should be submitted to HREH for review. The Chief Medical Officer will review the information and advise the respective supervisor whether the employee requires a limited duty accommodation or can return to full duty.

POLICY

Laboratory Directors may place employees in limited duty status for periods of 30 days or less without HREH concurrence. Employees who are placed on limited duty will normally be assigned duties within the scope of the position, in conjunction with medical restrictions. Any Laboratory Director who initially places an employee on limited duty will notify HREH within three business days of this action. This notification will help to guarantee that employees will not be performing duties that my exacerbate their medical conditions or endanger others. All such notifications will be in writing, and include

notification to the affected employees. HREH is the approving authority to place employees in limited duty status for periods in excess of 30 days.

According to the DEA Personnel Manual, Section 2735.18, when a determination is made by the DEA Medical Officer that an employee has a medical condition, the Deputy Assistant Administrator for Human Resources will send a medical advisory notification memorandum to the Laboratory Director with a copy to the employee. The memorandum will state that the employee has a medical condition and identify any limitations this condition may entail. Once the employee recovers, the Chief Medical Officer must clear the employee to return to full unrestricted duty. In some cases a Medical Fitness for Duty Examination (MFFDE) or Suitability Review Protocol examination (SRP) may subsequently be ordered. In this case, the employee will be examined by a DEA-appointed physician. The physician will be provided with a list of questions, a copy of the employee's performance work plan, and the current position description. This process allows the assessment of the employee's ability to perform specifically assigned duties. If, based on the results of a Medical Fitness for Duty Examination, no reasonable accommodation can be provided, DEA may offer reassignment within the Agency, or may take other appropriate administrative action.

In cases of "Job-Related Injury or Illness," Section 2810 of the Personnel Manual provides guidance for handling federal employees' compensation for temporary and permanent disabilities. Additional information on work related injury can be found in Section 2792 of the Personnel Manual, and Chapter 77 of the Laboratory Operations Manual.

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

10/4/2006
Date

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United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System
ORDER

Classification Code
LS-07-006

SUBJECT: Utilization of 'DGF' LEMS Code when Fingerprint and Drug Evidence are Sealed within the Same Container

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OBJECTIVE:
This Laboratory System Order establishes a mechanism via the Laboratory Evidence Management System (LEMS) to signify when both fingerprint and drug evidence are sealed within the same container.

BACKGROUND:
There are occasions in which it is necessary for a forensic chemist to provide drug evidence *directly* to a fingerprint specialist for the purposes of latent print examination. In these situations, the forensic chemist and fingerprint specialist follow the procedures outlined in Laboratory Operations Manual (LOM) 7302.52 B1a for intralaboratory transfers of evidence. Pursuant to this procedure, the drug and fingerprint evidence are often enclosed within the same evidence container and returned to the vault. This type of evidence, whereby both drug material and fingerprint media are sealed in the same container, is not easily recognizable upon visual inspection of the evidence or review of electronic records.

In addition to intralaboratory transfers, there may be other occasions which result in this type of evidence. For instance, consider those occasions in which it is necessary for a fingerprint specialist to receive drug evidence directly from the vault (i.e., evidence technician) prior to chemical analysis for latent print examination. As noted in LOM 7302.42 H, the fingerprint specialist will handle the evidence in the same manner as a forensic chemist; however, substituting the DEA-466 for DEA-86. Once again, this may result in fingerprint and drug evidence sealed into a single container.

To more effectively handle the above situations, a new type code, **DGF**, has been created in LEMS to provide a means to easily identify evidence which contains both drug material and fingerprint packaging within the same unit. DGF evidence is only to be created in those unique circumstances where it is not possible or impractical to separate the packaging and create an additional unit (e.g., trace evidence on a particular object such as a pocket scale, LSD-impregnated paper, or a bulk kilo brick seizure). On most occasions, the fingerprint packaging can be separated from the drug material. This LSO is designed only for the exception.

PROCEDURE:

Analysts are required to separate fingerprint packaging whenever possible in accordance with LOH 7302.7. All efforts should be made to separate evidence, however, when not possible or impractical, the following procedure should be followed utilizing the new type code, DGF, in LEMS.

1. Once determined that the latent print examination should be conducted while the evidence is in the forensic chemist's possession, the established LOM procedures (LOM 7302.52 B1a) for intralaboratory transfers of evidence will be followed.
2. Upon completion of the fingerprint and chemical analysis, the forensic chemist will reseal both the drug and fingerprint evidence in the same container, as appropriate. The forensic chemist shall annotate "Drug/FP" under the LEMS label on the sealed container.
3. The forensic chemist will return the completed drug/fingerprint unit to the vault and inform the evidence technician that an intralaboratory transfer for fingerprint examination was completed.
4. The evidence technician will amend the type code in LEMS to a drug/fingerprint unit (**DGF**). A new bar code label will be printed and affixed directly over the existing label.

RESPONSIBILITIES:

A. The forensic chemist and fingerprint specialist will ensure that all transfers of evidence for purposes of a latent print examination are documented and transferred via a DEA-12 in accordance with LOM 7302.52 B1a.
B. The forensic chemist will ensure the evidence technician has been informed of the latent print examination completed on the exhibit(s) while in their possession (i.e., intralaboratory transfer) when returning it to the vault as well as annotate under the LEMS label "Drug/FP."
C. The evidence technician will ensure that LEMS and the barcode labels are updated and changed to **"DGF"** for all evidence returned to the vault containing both drug and fingerprint evidence.
D. Likewise, any additional occurrences which may result in one unit which contains both drug and fingerprint evidence must be designated as a DGF in LEMS. Personnel handling the evidence will be responsible to ensure the proper designation is assigned. Under some conditions, the fingerprint specialist is the responsible party for marking the evidence appropriately by annotating "Drug/FP" on the container, as well as, notifying the evidence technician to change the LEMS code to DGF.

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

April 5, 2007
Date

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United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System
ORDER

LS-08-001

Classification Code
ADM

Date: March 7, 2008

SUBJECT: Validation of Quantitative NMR Methods

Introduction

Method validation is the process of demonstrating that an analytical method has acceptable accuracy and precision for its intended purpose. For method validation to be successful, the critical instrumental parameters must be fixed and evaluated to show that they do not adversely affect the methodology over a set operational range.

This validation procedure was developed to address the unique factors inherent in quantitative NMR methods. All previously developed methods must be updated and validated using this protocol.

In the quantitative NMR method, the integral of the peak (or peaks) is proportional to the number of nuclei being observed regardless of the compound. In this way, an internal standard of known weight and purity can be added to a weighed sample containing a compound to be quantitated. The integrals of the internal standard and the analyte can be used to determine the percent by weight of the compound in a sample using the following equation:

% compound in sample = (MW_a/MW_{is}) x (WT_{is}/WT_{samp}) x (H_{is}/H_a) x (INT_a/INT_{is}) x 100

MW_a = molecular weight of analyte

MW_{is} = molecular weight of internal standard

WT_{is} = internal standard weight

WT_{samp} = sample weight

H_{is} = number of protons integrated of the internal standard

H_a = number of protons integrated of the analyte being quantitated

INT_a = integral of the analyte peak

INT_{is} = integral of the internal standard peak

The requirements for a successful quantitation are that:

- The NMR experiment utilizes parameters that ensure quantitative results,
- The compound(s) and internal standard are soluble in the solvent, and
- The integrated spectral peaks are clear of interferences (other compounds or solvent peaks).

NMR does not need a reference standard of the analyte to be run to determine the quantitation of the sample, as do separation techniques; the internal standard in the sample solution is the reference standard[1].

This validation procedure outlines which factors must be considered and which instrumental parameters can be adjusted to obtain accurate and precise quantitative measurements on any compound using a given solvent and internal standard. Once these parameters have been adjusted to produce accurate integrals throughout the spectrum being integrated (normally 0.0-10.0 ppm for proton), then this NMR experiment can be saved as the quantitative method to be used for the quantitation of any compound.

As with all quantitative methods (i.e., spectroscopic, electrophoretic, or chromatographic), one must ensure that the compounds in the sample and the internal standard are fully soluble. Furthermore, the signals integrated (sample and internal standard) must be free of interfering signals (impurity or other compound signals), the compounds and the internal standard must not react or decompose in the solvent at a rate that would influence accurate quantitation, and the internal standard must not be a compound found in the sample.

Quantitative NMR methods are not instrument dependent (once NMR parameter tests are done), and methods developed and validated at one laboratory can be transferred to any other DEA laboratory with one exception; methods developed with NMR instruments of higher magnetic field strength should not be conveyed to those whose magnets have a lower field strength (i.e., do not convey a 600 MHz NMR method to a 400 MHz NMR). This is because the spectral resolution will be less for the lower magnetic field strength NMR. However, methods can be conveyed going from a lower field magnet to a higher field magnet (i.e., a method developed at 400 MHz can be used on a 600 MHz NMR).

[1] There are other ways to quantitate by NMR, such as standard addition, which do not use an internal standard compound. They would follow the same steps as described here for validation.

Tests to Validate a NMR Quantitation Method

The following tests will be performed to show that the quantitative NMR experiment uses parameters for accurate and precise quantitation of compounds. There are two sections to the validation process: the parameter tests and the analyte tests.

The parameter tests verify that a quantitative spectrum can be acquired using a set of NMR parameters. These tests are compound and solvent independent and need only be done once for a specific instrument and its probe.

The analyte tests demonstrate how well a compound behaves using a specific internal standard/solvent combination, which assists the chemist in determining which peaks are appropriate for quantitation. The analyte tests are not instrument dependent; that is to say, the test run at one laboratory is conveyable to all other laboratories and need not be repeated on every instrument.

I. NMR parameter tests (based on specific instrument). Done once for a given spectrometer and probe.

A. Test #1: 90 degree pulse width and spectral width.

1. Determine the 90 degree pulse width using normal calibration procedures.

2. The maximum pulse width (PWmax) for proton quantitation will be $\leq$10 microseconds, or the 90 degree pulse width, whichever is smaller.

3. Obtain a full spectrum of the quantitative NMR experiment illustrating that it includes at least the spectral width of -1 to 11 ppm.

Acceptance Criteria:

The quantitative experiment parameters are such that the spectral width at least covers -1 to 11 ppm and the pulse width is $\leq$90 degrees and $\leq$10 microseconds.

B. Test #2: Illustrating uniformity over the quantitative spectral region.

1. Set up the quantitative NMR experiment. Place in the magnet a solution containing a compound with one prominent peak, such as dimethylsulfone in chloroform or "doped" D_2O. Adjust the NMR parameters as follows:
   a. Set the delay (D1) to 5 times the spin-lattice relaxation time (T1) of the prominent peak or set the delay to 45 seconds.
   b. Set the number of transients to 1 or more.
   c. Array transmitter offset (TOF) to move the prominent peak throughout the spectral width with at least 5 equally spaced positions in the region where quantitation will occur (0-10 ppm). Acquire the spectrum.

d. Individually phase, drift, and baseline correct each spectrum, and with the display set to absolute intensity (ai), determine the peak height of the prominent peak for each spectrum. Calculate the relative standard deviation of these peak heights in the range 0-10 ppm.

Acceptance Criteria:

Peak height relative standard deviation (RSD) must be less than 3% (Figures 1 and 2).

C. Test #3: Linearity and sensitivity over varying concentrations.

A linearity study verifies that the response of a signal is linear with regard to the population of observable nuclei present (i.e., its concentration). NMR is unique for quantitative instruments because the area beneath a peak is proportional to the population of nuclei producing the signal, regardless of the analyte. Because of this, the linearity study is performed on only one substance to ensure the spectrometer and probe function linearly over a wide range of concentrations. If it is linear for that compound, it will be linear for any compound and it will be linear for signals above 10:1 signal-to-noise and below the probe's analog-to-digital converter overload level (ADC overflow or saturation limit).

Choose a common, pure analyte. Prepare at least 5 different solutions ranging in concentration from 0.1% - 200% containing the same concentration of internal standard. Set up the quantitative NMR experiment and acquire one spectrum for each concentration.

Acceptance Criteria:

Integrate all peak groups of the analyte and determine the integral values for each of the concentrations relative to the integral of the internal standard. Plot the results, concentration versus integral, and calculate the correlation coefficient. The plot should be a straight line and the correlation coefficient should be greater than 0.998 for the concentrations of 1% - 200%. Calculate the purity of the analyte for each concentration. These values should be within 5% of the purity of the standard. The 0.1% solution will assist the chemist in recognizing the detection limits of the quantitation experiment parameters used.

Signals above 10:1 signal-to-noise ratio are needed for best accuracy.

D. Test #4: Precision.

Precision is the measure of the degree to which independent test results using the same experimental parameters on a given system agree with each other.

Select two concentrations representing the upper and lower limit of the linearity study and perform a total of five quantitative experiments on these samples. Calculate the quantitation values (percent purity) for all peak groups of the analyte.

Acceptance Criteria:

The RSD of the quantitative results for all integrals in the individual experiment must be less than 3%. Quantitative results for the same integral in the spectrum (e.g., the NCH_3 of methamphetamine), from one experiment to the next for the same sample must have an RSD less than 3%.

II. Analyte specific tests.

A. Test #1: Nuclei relaxation.

Demonstrate sufficient delay between transients to allow full nuclei relaxation. ***Only required if delay is set below 45 seconds for proton quantitation.***

If a delay of less than 45 seconds is to be used, run the manufacturer's T1 experiment or perform a simple ***180-delay-90-acquire*** experiment[2] to determine the maximum T1 value of the internal standard and analyte signals. From the results of this experiment, set the delay prior to the pulse to at least five times the largest T1 value. T1 values are influenced by many factors. Provided the conditions for analysis (including magnetic field strength) remain the same, data from reference standard samples (these would have the longest T1 values) by one laboratory can be used by other labs (an example is found in Supplemental Section).

Acceptance Criteria:

The quantitative method must use a delay before the pulse (D1) of at least of 45 seconds or $\geq$5 times the longest T1 value. If the latter is used, either a T1 experiment must be performed or reference to a T1 table must be made.

B. Test #2: Accuracy, solubility, and stability of analyte.

Accuracy is defined as the closeness of the obtained value to the purity value determined by other means (e.g., actual weighings of reference standard compounds or comparison of results from other authenticated quantitative analytical methods). This test determines the solubility and stability of the compound in the internal standard solution, which protons exchange with the

[2] ***180-delay-90-acquire*** experiment: a 60 second delay prior to a 180 degree pulse followed by a delay and a 90 degree pulse followed by acquisition. Vary the delay to find the time where all peaks are nulled or positive. T1 is the delay time when a peak is nulled divided by 0.693.

solvent deuteriums, and identifies those analytes that have multiple forms present (e.g., keto-enol tautamers, amide rotamers, etc.).

Run a quantitative experiment on a reference standard. Integrate all peak groups and calculate the purity of the standard at each integral. Compare these values to values obtained by authentication data or from purity values from other accepted and validated methods. Low quantitative values for all integrals can indicate that the analyte was not fully soluble at that concentration and rerunning the analyte at lower concentrations is in order. In the event that there is no reference drug standard available for this test, go to section D below.

Acceptance Criteria:

True versus experimental NMR values should agree within 5%. Be aware that some compounds absorb moisture from the air making them less pure than when they were dry.

C. Test #3: Repeatability and analyte stability with solvent and internal standard.

Repeatability expresses precision under the same operating condition, over a short period of time. This study will also determine the compatibility of the analyte in the solution with the internal standard.

Rerun a quantitative NMR experiment on the standard solution used for accuracy (Test #2) after two hours or longer and compare quantitative results. If results increase or decrease over time, determine the rate of change. Decreasing signals could be due to an exchangeable proton.

Acceptance criteria:

Only integrals whose change in quantitative values is less than 1% per hour in solution will be used.

D. What to do if no reference drug standard is available.

In the event that a drug is discovered in an exhibit for which there is not an authenticated reference standard, quantitation can still be accomplished by NMR using the following guidelines. All analyses must comply with the requirements of the Analytical Sufficiency Document. Only chemists with specific training to deal with these samples should be allowed to work on them. The molecular weight of the substance and the number of protons at each integral must be known.

i. Determine solubility. The homogeneous sample is quantitated at two different concentrations using all available "clean" signals. If the results are within one half of the PTP criteria, then the solubility limit

in both concentrations was not exceeded. Proceed to the next step. If the results exceed these criteria, then perform a third quantitation at a more dilute concentration and compare the lower two concentration results. If solubility is so restrictive that the compound's signals do not achieve a signal-to-noise ratio of 10:1 or greater, other solvents (and possibly internal standard) will need to be investigated.

ii. Determine stability. Rerun the sample from the first step at least two hours later and compare results for all available "clean" signals. Acceptable signals will have a change of less than 1% (relative) per hour.

TABLE 1— *Standards in a few solvents. Concentration of approximately 5 mg/mL used for measurements.*

Drugs/Compounds	solvent	max. T1 value	5 x T1max
Heroin HCl	D_2O	2.2	11.0
Heroin HCl	DMSO	2.2	11.0
Cocaine HCl	D_2O	2.3	11.5
Cocaine base	$CDCl_3$	2.9	14.5
Methamphetamine HCl	D_2O	3.6	18.0
Methamphetamine HCl	DMSO	1.6	8.0
Dimethyl sulfone	D_2O	<5.8	<29.0
Internal Standards			
Dioxane	D_2O	4.3	21.5
Maleic acid	D_2O	4.9	24.5
Maleic acid	DMSO	1.9	9.5
Methenamine	D_2O [a]	0.9	4.5
Methenamine	CD_3OD [a]	1.4	7.0
Methenamine	$CDCl_3$	1.2	6.0
Malonic acid	D_2O	7.9	39.5
Malonic acid	DMSO	0.9	4.5
Sodium acetate	D_2O	4.3	21.5
Iodoform	$CDCl_3$	6.2	31.0
TSP	D_2O	3.5	17.5
TMS	$CDCl_3$	4.8	24.0

[a] The methenamine peak is very near the HDO or CD_3OH solvent peak at 4.8 ppm, which can be a problem. Ensure that this peak is baseline resolved and does not interfere with integration of methenamine.

TABLE 2—*Common Internal Standards*

Internal Standard	MW	#H	PPM	Weight [a]	Solvents [b]
Maleic acid	116.07	2	6.4	5.8	1,3,4,5
Dimethylfumarate	144.13	2	6.8	7.2	2, 3
		6	3.8		
Methenamine [c]	140.19	12	4.7	1.2	1,2,3
1,4-dioxane	88.11	8	3.7	2.2	1
Dimethyl sulfone	94.33	6	2.9	1.6	1,2,3,4
3-(Trimethylsilyl)propionic-2,2,3,3-d4 acid, sodium salt (TSP)	172.28	9	0.0	(0.05 wt. %)[d]	1

[a] Milligram weight of internal standard based on 30 mg drug (MW = 300) to get equivalent integral between drug and internal standard. These are approximate weights.
[b] Solvent code: 1=water, 2=chloroform, 3=methanol, 4=DMSO, 5=acetone
[c] Warning: Methenamine that comes in contact with a free acid can become insoluble in $CDCl_3$, precipitate out, and result in higher than actual quantitative results. Checking the ratio of methenamine to TMS can determine if this has occurred.
[d] TSP can come premixed in D_2O. Determine the actual weight per milliliter of TSP using appropriate high purity reference standards such as dimethylsulfone.

Appendix

Significant Parameters, Spectrum Processing, and Good Laboratory Practices

Quantitative NMR is greatly affected by several parameters in the method. This is a list of those parameters and procedures to adjust them for quantitative results.

a. Pulse width.

i. Issue: Fourier Transform (FT) NMR relies on a square radio frequency pulse of a very short duration (microseconds) and specific frequency to cause the observed nuclei to tip away from the axis of the magnetic field. After the pulse, the receiver is turned on and the tipped precessing nuclei produce a decaying signal called a free-induction decay curve (FID) as they return to the axis of the magnetic field. This FID contains the frequencies of all the tipped nuclei. The shorter the pulse width, the greater the spectral width containing nuclei equally tipped. The maximum pulse width (PWmax) to accomplish the same tip angle on all observed nuclei is determined by the expression:

$$PWmax << 1/(4*SW)$$

where PWmax is in seconds and SW (spectral width of observable peaks) is in Hertz.

Another consideration is that the pulse width used in quantitative experiments should be no greater than the calibrated 90 degree pulse width to minimize the delay needed for the nuclei to return to equilibrium.

ii. Solution: Use a pulse width which is less than or equal to 10 microseconds and is less than or equal to 90^{o}. Pulse widths greater than 10 microseconds, if they are less than 90^{o}, can be confirmed to be appropriate using the Test #2: "Illustrating uniformity over the quantitative spectral region".

b. Spectral width (SW) and transmitter offset (TOF).

i. Issue: The width of the spectrum and the transmitter offset determine where the NMR spectrum is focused and which signals can be detected for the purposes of quantitation. If the spectral width is not wide enough to include all signals from the sample (analytes, internal standard and

solvent) then some signals will be missing or the signals will "fold in"; showing up on the other side of the spectrum which can lead to problems if the folded peak is in an area being integrated.

ii. Solution: Ensure the spectral width is at least from -3 ppm to 13 ppm and the transmitter offset is in the middle of this region. If a smaller spectral width is desired, it must first be shown that no peaks lie outside the new spectral width and NMR parameter test #2 (Illustrating uniformity over the quantitative spectral region) will need to be performed with these new parameters.

c. Delay prior to pulse (D1).

i. Issue: Once a nucleus is "tipped" by the NMR pulse, the magnetization vector begins the process of relaxing back to its original alignment with the magnetic field. This relaxation (i.e., spin-lattice relaxation time or T1) occurs at a rate that depends on a number of factors including molecular size and rigidity, temperature, sample solution composition, presence of paramagnetic contaminants such as molecular oxygen, and magnetic field strength. In general, the smaller the molecule, the longer it takes to return to equilibrium. If not allowed to fully relax prior to the next pulse, the signal received after the pulse will be less for that signal and thus affect the integral of that signal.

ii. Solution: Determine the spin-lattice relaxation time (T1) for the individual quantitation signals of the internal standard and any smaller compounds being quantitated in the solvent of choice. Set the delay between pulses to at least 5 times the largest T1 value (see Table 1). The longest T1 is usually associated with the signal of the smallest molecule; usually the internal standard. Be aware that changing the solvent does affect the T1 values of a compound. Use of a 45 second delay has been experimentally shown to be sufficient for all commonly seen organic compounds of interest to DEA and exceeds the "5 times T1" requirement for proton quantitation. [Note: This is not the case for quantitative carbon-13 experiments where T1 values can exceed 60 seconds.]

d. Acquisition time (AT).

i. Issue: After the pulse tips the nuclei, the receiver is turned on and an FID is acquired. Ideally, one wants the acquisition time long enough to collect only the FID and nothing additional. If a longer acquisition time is used, then noise is added to the spectrum, reducing signal-to-noise (S/N). If the FID is truncated, then a ringing wave appears in the spectrum, especially

near the longer T1 signals. Neither of these effects will alter the integrals of peaks, but they can affect appearance of the spectrum and possibly the precision due to lowered S/N.

ii. Solution: Determine the time where the FID becomes noise and use approximately this time as the acquisition time (a default of 2-5 seconds is acceptable).

e. Receiver gain.

i. Issue: If the receiver gain is set too high, the signal overloads the analog-to-digital converter (ADC) resulting in distortion of the baseline of the spectrum and adversely affecting the integrals. If the receiver gain is too low, then signal-to-noise is lowered.

ii. Solutions:

1. Let the NMR automatically determine the receiver gain or
2. Find the receiver gain that would be used on a sample of the maximum concentration encountered and set the receiver gain to a value just lower than this (i.e., 1-4 db) or
3. If ADC overflow error occurs and receiver gain is at zero, reduce pulse width until you no longer have the ADC overflow error.

The advantage of automatic adjustment is optimal S/N is achieved; the disadvantage is that the experiment will take longer to acquire.

f. Fourier number.

i. Issue: This parameter determines the number of points to be Fourier transformed. If the Fourier number is less than the number of points acquired then the spectral peaks will be defined by fewer points creating the potential for error in the integration of that peak.

ii. Solution: Set the Fourier number at 2 or more times the number of points acquired. This is called zero-filling and adds to the accuracy of the integration by defining a peak with more data points.

g. Weighting functions.

i. Issue: There are a number of weighting functions that can be used to change the post-run spectral appearance. Extreme care needs to be exercised in the use of these functions since they affect spectral line shape,

resolution, signal-to-noise, and integration. Weighting functions whose maximum is at the first point of the FID (i.e., line broadening and Traf functions), do not affect integration. However, other functions (i.e., sinebell) should not be used because they will drastically affect integration because their maximum is not at the first point of the FID. Line broadening is an exponential window function which improves signal-to-noise, but also broadens the peaks. The disadvantage of line broadening is that it produces broader peaks which decreases resolution between adjacent peaks and requires wider integrals. The Traf function improves signal-to-noise, but does not affect resolution.

ii. Solution: With the exception of line broadening and the Traf function, do not use weighting functions on the Fourier transform of the FID.

h. Phasing, drift correction, and baseline correction.

i. Issue: NMR spectra can be out of phase (left side of a single peak is not in line with the right side of the peak), can have a general tilt or slope (drift) or can have bowing (baseline distortion) which will cause integrals to be distorted and integral values to be incorrect.

ii. Solution: Perform phasing, drift correction, and baseline correction on the spectrum as needed to correct for these issues and result in integrals that are flat in the noise regions of the spectrum.

i. Integration: When to start and stop an integral.

i. Issue: Starting and stopping the integral for a given peak or set of peaks is important. NMR peaks are Lorenzian in shape and they taper off at each side. An integral set too narrow will produce a quantitative result that will be lower than it should be. Proton peaks also contain carbon-13 satellite peaks on either side of them.

ii. Solution: Whenever possible, integrals should be started and stopped away from the peak(s) into the baseline region to include the entire peak(s) area. The integrals should be small enough not to include the carbon-13 satellite peaks.

j. Interference with other compounds.

i. Issue: Samples rarely contain a single component. However, most

compounds encountered have more than one signal to be integrated and their signals will not always be at the same frequencies as the other compounds present, even when they are structurally similar (such as amphetamine and methamphetamine). Visual inspection of the peaks of interest and their integral values will assist in determining if other compounds are affecting these integrals.

ii. Solution: Integrate all the clean signals of the compound being quantitated and report the lowest quantitative value. The second lowest quantitative value (if available) must agree with the reported value (less than ½ of the PTP criteria). Because a multiple compound solution will represent the sum of all the spectra of the compounds present, you can determine the integral of a compound's signal mixed with another compound by calculating the integral of the interfering compound and subtracting it from the mixture integral. For example, in D_2O, acetaminophen has doublets at 7.2 and 6.9 ppm, both representing 2 protons. The doublet at 6.9 ppm interferes with peaks for one of heroin's protons. By taking the integral of acetaminophen's 7.2 ppm peaks and subtracting it from the combined heroin-acetaminophen 6.9 ppm integral, an accurate integral for heroin can be derived. Even so, the reported result must be from a clean integral.

k. Internal standards.

Table 2 contains some common compounds used as internal standards. This is not an exhaustive list. In fact, any pure compound can be used so long as it is fully soluble in the NMR solvent, is pure with a known molecular weight, is not found in the sample, is compatible with the sample (not reactive), and its integrated peak(s) are free of other signals. Compounds such as caffeine and nicotinamide could be used in some cases, such as verifying the purity of a primary reference drug standard, but should not be used in the quantitation of illicit drug exhibits since these are common adulterants.

i. Issue: Internal standards need to be pure, which includes accurate knowledge of whether it is a hydrate or anhydrous so that an accurate molecular weight is known.

Solution: Determine the purity of the internal standard using a quantitative NMR experiment using a different compound of known purity as the internal standard. For example, maleic acid can be tested using dried, high purity dimethylsulfone (manufacturer's purity of 99+%) or by quantitating an authenticated reference drug standard of known purity with the maleic acid (e.g., methamphetamine HCl, 100.0% pure). A quantitative result of 98-102% is satisfactory for the maleic acid's purity. By performing purity experiments on a large number of internal standards, it is possible to determine which standard is the purest and then determine the other standards' purities relative to it.

Other techniques can be used to determine the purity of internal standards, such as differential scanning calorimetry (DSC), and/or GC-FID to determine the percent area of the largest peak of all the peaks (except for the solvent front peak).

l. Internal standard to reference (0 ppm) standard integral ratio.

For non-volatile reference (0 ppm) standards such as DSS and TSP, the ratio of the internal standard to the reference standard integrals is a good way to verify that the internal standard peak is pure. This ratio should be within 5% of the ratio obtained from the blank of the internal standard solution or from the purity test solution of the internal standard.

m. Recovery study (Optional).

i. A recovery study may be performed, but is not necessary. Because NMR spectra are the sum of the spectra of the compounds in solution, integrals containing multiple compound signals are the sum of the integrals of the individual compounds. It is possible to derive quantitation results from a multi-compound integral by subtracting the contributions of the individual compounds. This is done by integrating clean signals of the compound at other places in the spectrum and multiplying this integral by the ratio of the number of protons for the compound in the multi-compound integral and the number of protons in the clean integral.

When multiple integrals for a compound are present, at least 2 of the lowest quantitative values for the analyte must be within one half of the PTP criteria.

ii. If a recovery study is to be performed, it may be done in the following ways:
   a. Comparing NMR results against preparations of different mixtures containing a measured amount of test drug appropriate to an actual illicit sample with appropriate matrices or
   b. Comparing results from another validated quantitative method (i.e., GC, HPLC, CE) on real exhibits.

Results should be within one half of the PTP criteria, using one of the following equations:

(Measured (NMR) – Actual Value)/Actual Value X 100

(Measured (NMR) – Measured (other method))/measured (other method) X 100

Study results from other laboratories can be used by all other laboratories.

n. Sample weight and concentration.

Balances used in the weighing of samples for NMR quantitation must be calibrated to ensure an accurate weight. Concentration of the sample solution (sample in deuterated solvent) should be high enough to have signals being quantitated at ≥10:1 signal-to-noise and low enough to prevent exceeding the solubility limit of the analyte. High concentrations can cause an analog-to-digital overflow error (ADC overflow), but this can be dealt with by lowering the pulse width until the error goes away (automated sample analysis does this automatically). Sample limited exhibits or those with very low levels of analyte can increase the signal-to-noise ratio of analyte signals by increasing the number of scans.

o. Internal Standard Volume Accuracy.

If the internal standard is made in bulk at a known concentration (not weighed directly to the sample and then solvent added), then a correct, known volume of the internal standard solution is critical for an accurate NMR quantitation. For this reason, pipettes should be calibrated routinely to ensure they dispense the exact volume of internal standard solution to the sample.

Beware: autopipettes often have variable pick-up speeds. Also, some types of autopipette tips are appropriate for only certain solvents. Testing the accuracy of the pipette volume at different speeds for a specific internal standard solution is mandatory. Autopipettes should be calibrated on a regular basis to ensure delivery of the desired volumes.

p. Is the NMR functioning?

The NMR calibrations performed monthly determine how well the spectrometer is functioning overall. Each sample spectrum tells the chemist that the experiment was a success and that the NMR functioned properly. The internal standard and 0 ppm reference peaks must be a single peak (not jagged) with a width-at-half-height of <2 Hz. If the peak is jagged or its line width is ≥2 Hz, then there may be something in the sample that is causing short T2 relaxation or that is hampering gradient shimming or the instrument is malfunctioning. In this case, run an internal standard blank or another sample. If the condition persists, it is a spectrometer problem and will need to be addressed by the instrument monitor. If the problem does not appear in the subsequent spectrum, it is a sample problem which can sometimes be corrected via dilution. The sample is diluted with deuterated solvent (usually 3:1 dilution using the same solvent, but not containing internal or reference standards), remixed, filtered, put in a new NMR tube, and rerun (sample and internal standard weights remain unchanged). If no improvement is observed, then a different instrument will need to be used for quantitation.

q. General expiration date for internal standard solutions.

All internal standard solutions should be properly sealed to prevent evaporation. Tetramethylsilane (TMS, the 0 ppm reference for organic solvents) is particularly volatile, as are chloroform and methanol.

Maleic acid in D_2O is quite stable and will last well over a month, while maleic acid in methanol-d_4 will begin to show changes in the maleic acid signal (from a singlet to 2 peaks) in a few days. In general, all internal standard solutions, except maleic acid in D_2O, should be used within 2 days of preparation.

Supplemental Section

Example of Analyte Specific Test #1: Nuclei relaxation

Figure 3 shows heroin HCl with maleic acid (internal standard) in D_2O. The delay time between the 180 and 90 degree pulses was set to 1 second. Positive peaks have a T1 of less than 1.4 seconds (T1 <1 sec/0.693=1.4 seconds); however, there are some peaks, notably the maleic acid at 6.4 ppm and the heroin aromatic peaks, that are negative, requiring a longer delay time between the 180 and 90 degree pulses. Figure 4 shows the same sample with the delay set to 4 seconds (T1=4/0.693=5.8 seconds). All peaks are positive with the exception of the water peak at 4.7 ppm which is unimportant since it is not integrated. Five times T1max in this case is 5 x 5.8 or 29 seconds.

Figures

Figure 1. *Arrayed transmitter offset test results showing very poor uniform response throughout the spectral window, especially at the spectrum ends. This can be due to the effect of filters, lack of digital sample processing (dsp off), or a long pulse width.*

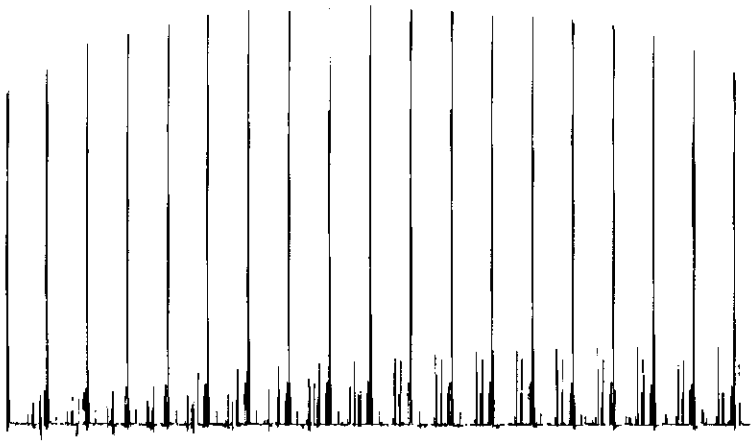


Figure 2. *Arrayed transmitter offset test showing good uniform response throughout the spectral window.*

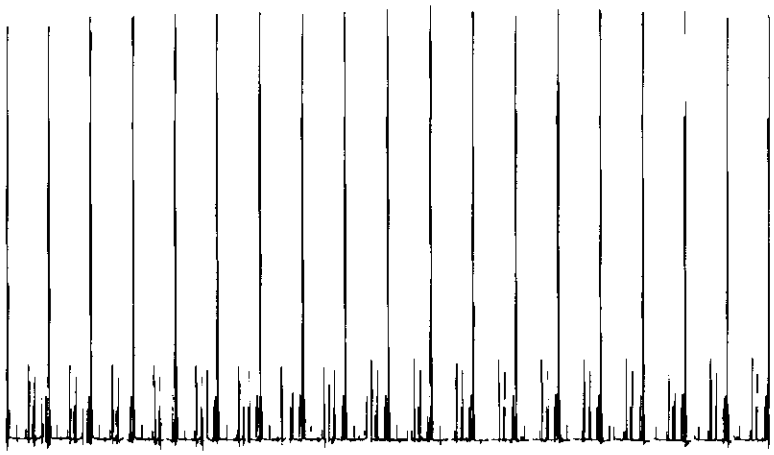


Figure 3. *Determination of maximum T1 using 180-delay-90-acquire pulse experiment. Delay between pulses was set to 1 second. Positive peaks have T1 values <1.4 seconds (delay/0.693). Negative peaks have T1 >1.4 seconds.*

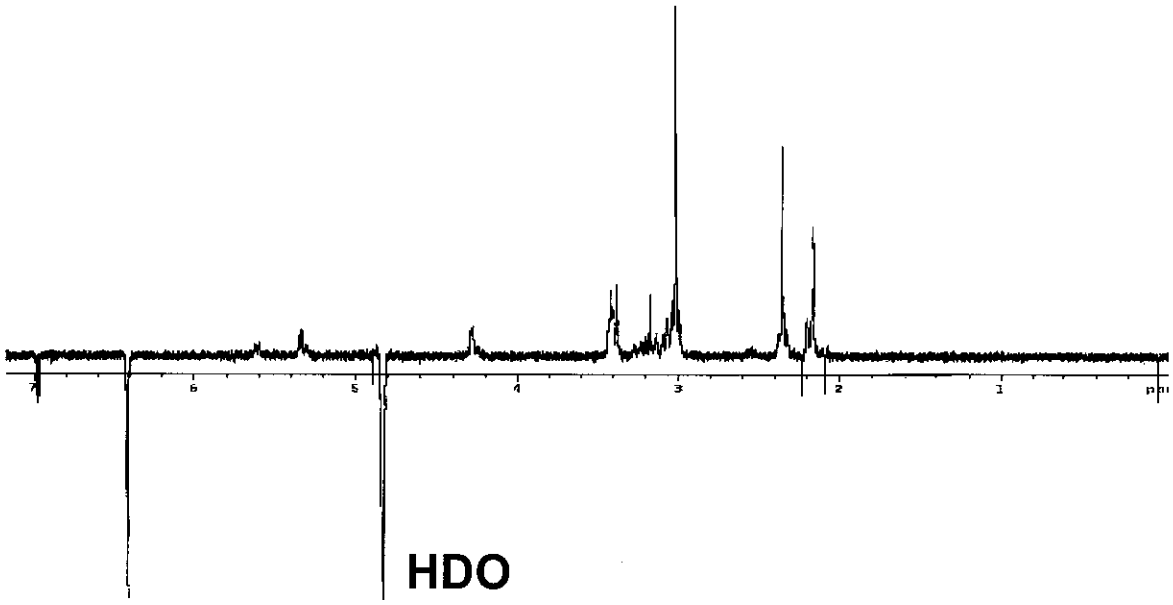
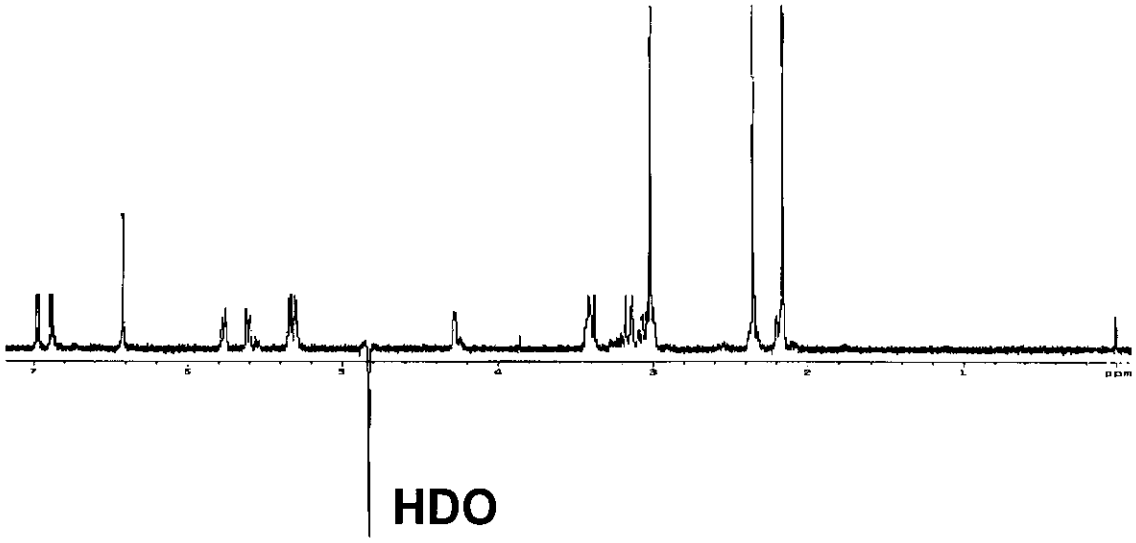


Figure 4. *Determination of maximum T1 using 180-delay-90-acquire pulse experiment. Delay was set to 4 seconds. At a delay time of 4 seconds, all of the non-solvent peaks are positive. This means that the T1max is about 4/0.693 or 5.8 seconds. A quantitative experiment with a 29 second delay before the pulse (5 times T1max) would be sufficient.*



Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

03/07/2008
Date

United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System
ORDER

LS-08-002

Classification Code
7005

05/30/2008

SUBJECT: Disclosure Policy

OBJECTIVE:

To provide a procedure for disclosing case file information to prosecuting attorneys and to specify those items which may be disclosed on a routine basis.

PROCEDURE:

The following supplements Laboratory Operations Manual Section 7005. The analyst will ensure that a signed copy of the disclosure notification (attachment #1) is forwarded to the case agent when the analyst is notified that a trial date has been scheduled for a given case. The disclosure notification must be signed by the laboratory director (or designee). The signed disclosure and confirmation that it was forwarded to the case agent will be kept in the laboratory's case file.

The case agent will supply the disclosure notification to the prosecuting attorney. The disclosure notification specifies the items that are available, upon request, and allows a reasonable period of time for their delivery. The items will only be provided to the prosecuting attorney upon request. In addition to the DEA laboratory report, which is routinely forwarded to the case agent, the available items are as follows:

Front and back of the analyst's worksheet (i.e. DEA-86, DEA-466, etc.)
All instrumental data attached to the analyst's worksheet
Summary of testimony
Curriculum vitae

Should the prosecuting attorney request any other document, record, or item not listed above, the laboratory director must consult with the Office of Chief Counsel (CC) and SF prior to providing the requested information. Any request received in the form of a subpoena, a court order, or letter will be forwarded to CC (with a copy to the Office of Forensic Sciences) to determine the agency's position on the release of additional information. Before this information is released to the prosecutor, it must be approved by the Office of Forensic Sciences.

Under no circumstances shall laboratory personnel directly release material of any type to the defense unless approval is provided in writing by the Office of Forensic

Sciences. As stated previously, with the exception of the items specifically listed above, no additional material will be released without the Office of Forensic Sciences' approval.

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

5/30/08
Date

Attachment #1

Notification of Disclosure Materials

(Date)

(Analyst Name)

(Case number, laboratory number, and exhibit number(s))

This notification is being provided to advise the prosecuting attorney of the documents associated with the DEA laboratory report. It must be forwarded to the prosecuting attorney along with the laboratory results. If the prosecuting attorney requires additional information beyond the DEA Laboratory Report, the following four items are available upon request:

1. The analysts worksheet, which lists the procedures used to reach the conclusions contained in the DEA Laboratory Report
2. All instrumental data from instrumentation used in the analysis
3. The analyst's summary of testimony
4. The analyst's curriculum vitae

Since these materials could be voluminous, please allow a reasonable period of time for the laboratory to copy and deliver the information to the prosecuting attorney.

Any request for additional information not described in this notification should be faxed to the laboratory at (fax number) clearly describing the additional information requested. Upon receipt, the laboratory will consult with the Office of Chief Counsel and the Office of Forensic Sciences to determine the agency's position on the release of the additional information.

Sincerely,

(Name and title)
Laboratory Director

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-08-003**

ORDER

Classification Code
70, 73

Date: June 16, 2008

SUBJECT: Clarification regarding the reporting of small amounts of base in heroin and cocaine samples.

OBJECTIVE:

The purpose of this order is to clarify the requirements for the determination of a small amount of base in heroin and cocaine samples.

BACKGROUND:

Results recently reported in the Proficiency Testing Program demonstrate the need to clarify laboratory system policy regarding this issue. Studies have demonstrated that the conversion of the free base form of heroin and cocaine to a salt form may not be 100% efficient. For example, a recent survey of Cocaine Signature Program samples indicated that cocaine HCl samples may contain 0-22% cocaine base after the conversion process has taken place. Additional factors such as residual processing solvents, moisture, and other substances present in the sample, e.g., sodium bicarbonate, may also contribute to the presence of the free base in heroin and cocaine samples that are predominantly the salt form.

POLICY:

Laboratory Operations Manual (LOM) Section 7002.2.B.2, states, "The form (e.g., salt, free base, free acid, etc.) of controlled substances will be routinely identified unless it is impossible or inappropriate to do so. For example, if the identification of the salt form would involve an inordinate amount of time or require the use of an inordinate amount of evidence, the forensic chemist must consult with the supervisory chemist and obtain approval to forego the identification of the form of the controlled substance."

CLARIFICATION:

To avoid any misunderstanding, the current policy, noted above, should be applied within the discretion stated. As a practical matter, this means that there is no blanket requirement to screen heroin or cocaine samples specifically for the free base form to verify the presence or absence of a small amount of base in samples present predominantly as a salt form. The presence of heroin or cocaine base should only be pursued and reported, in samples present predominantly as a salt form, if determined to be present incidental to the normal analytical process, e.g., base form noted in an infrared spectra.

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

6/25/08
Date

Distribution: SFD, SFE, SFL, SFS, SFQ, All Laboratory Directors **Initiated By:** SF

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Withheld pursuant to exemption

(b)(7)(E)

of the Freedom of Information and Privacy Act

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-08-012**

ORDER

Classification Code

Date: October 6, 2008

SUBJECT: Customer Satisfaction Survey

This laboratory system order replaces LS-06-011 dated July 24, 2007.

BACKGROUND:

This laboratory system order addresses the ASCLD/LAB-*International* (ISO/IEC 17025:2005) requirement identified in clause 4.7.2:

> "The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management system, testing and calibration activities and customer service.
>
> NOTE Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers."

In order to ensure consistent feedback from all laboratory system customers, a customer satisfaction survey (Form LS-08-012) was developed by the Office of Forensic Sciences and added to the SF Document Control Website Blank Forms tab.

POLICY:

At least once each year, laboratory directors will distribute the Customer Satisfaction Survey, Form LS-08-012, to each DEA field office and other law enforcement organization (e.g., FBI, ATF, ICE) that uses laboratory services. The form should be edited so that the name of each laboratory appears at the top of the form and the laboratory director's information is at the end of the form. The laboratory directors will use appropriate follow-up procedures to ensure that the surveys are returned. The feedback, both positive and negative, from the surveys must be used to improve the laboratory's management system through corrective or preventive actions, as applicable.

The surveys will be maintained in the records control list. Each laboratory director must review each survey during the annual management review process.

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

October 6, 2008
Date

Distribution: SFD, SFE, SFL, SFS, SFQ, All Laboratory Directors

Initiated By: SF

Laboratory System **Office of Forensic Sciences** **LS-09-002**

ORDER

Classification Code
7503

Issue Date: 08/30/2010

SUBJECT: Instrument Performance Verification Procedures and Acceptance Criteria

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OBJECTIVE:

This laboratory system order establishes minimum system-wide requirements and guidelines for instrument performance verification procedures. Acceptance criteria are also provided.

BACKGROUND:

In compliance with ISO/IEC 17025:2005, Section 5.5, this laboratory system order establishes a system-wide program with procedures and minimum requirements for evaluating the performance of instrumentation and equipment throughout the DEA laboratory system. Successful completion of the performance verification procedures ensures that laboratory instrument performance is adequate for the intended work.

For instruments such as NMR, IR and Raman, specific procedures are listed below, some of which are adapted from international measurement standards and shall be adopted and implemented by all laboratories. For other instrumentation, such as separation components, procedures and acceptance criteria have not been specified. For these systems, general system requirements that will allow for individualization at the laboratory level are listed below. For these types of instruments, each laboratory is responsible for establishing specific performance verification procedures and acceptance criteria which meet the general system requirements and are consistent with the methods utilized on those instruments. Before implementation, these procedures must be reviewed and approved by the quality assurance specialist, associate laboratory director, and laboratory director.

Performance verification templates are included at the end of this laboratory system order to aid in the consistent implementation of the following performance verification procedures throughout the laboratory system. These templates must contain specific performance verification procedures to be completed by instrument monitors, or their delegates, on a routine basis. Completed templates shall be included in each instrument logbook and shall be made available to auditors upon request.

INSTRUMENT PERFORMANCE VERIFICATION PROCEDURES AND ACCEPTANCE CRITERIA:

A. Infrared Spectrophotometer (IR)

1. Transmission Wavelength and Resolution Check

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Polystyrene

iii. Procedure: Collect polystyrene transmittance spectrum (8 scans; 4 cm^{-1} resolution). Report the peak positions measured for the following three bands: 3060, 1601, and 1028 cm^{-1}.
iv. Acceptance Criteria: Measured peak positions shall be within 4 cm^{-1} of above referenced values.

2. Reflectance Wavelength and Resolution Check (ATR)

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Caffeine
iii. Procedure: Collect caffeine spectrum (8 scans; 4 cm^{-1} resolution). Report the peak positions measured for the following three bands: 3111, 1644, and 743 cm^{-1}.
iv. Acceptance Criteria: Measured peak positions shall be within 4 cm^{-1} of above referenced values.

B. Raman Spectrophotometer

1. Wavelength and Resolution Check (A)

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Polystyrene
iii. Procedure: Maximize signal for polystyrene spectrum by adjusting the laser power. Collect spectrum of polystyrene (8 scans; 4 cm^{-1} resolution). Report the peak positions measured for the following three bands: 3054, 1602, and 1001 cm^{-1}.
iv. Acceptance Criteria: Measured peak positions shall be within 4 cm^{-1} of above referenced values.

2. Wavelength and Resolution Check (B)

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Caffeine
iii. Procedure: Collect caffeine spectrum (8 scans; 4 cm^{-1} resolution). Report the peak positions measured for the following three bands: 2957, 1328, and 555 cm^{-1}.
iv. Acceptance Criteria: Measured peak positions shall be within 4 cm^{-1} of above referenced values.

C. Nuclear Magnetic Resonance Spectrometer (400 MHz NMR)

1. Proton Line Shape

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Chloroform in acetone-*d6* (non-spinning sample)
iii. Procedure: Obtain ^{1}H NMR spectrum of performance sample (1 scan, 500 Hz spectral width, acquisition time $\geq$ 8 seconds).
iv. Acceptance Criteria: Peak width for chloroform proton signal shall be equal to or less than 1.0 Hz, 12.0 Hz and 24.0 Hz at 50%, 0.55%, and 0.11% peak height, respectively.

2. Probe File Update

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Methyliodide (^{13}C-enriched)
iii. Procedure: Perform these automatic calibrations: 90° pulse calibrations for proton observed (pw90), proton decouple (pp90), carbon observe (pw90), and carbon decouple (pwx90), and gradient G/cm/dac and C/H gradient ratio calibrations.
iv. Acceptance Criteria: All 90° pulse widths for proton and carbon shall be less than 20 microseconds. The instrument's probe file will be updated automatically.

3. Proton Sensitivity (Only for indirect detection probes)

i. Frequency: Every 6 months (or after substantial maintenance)
ii. Performance Sample: Ethyl benzene in chloroform-*d*

iii. Procedure: Obtain ^{1}H NMR spectra of performance sample (90° pulse, dl ≥ 60, 1 scan, lb = 1.0). Record signal-to-noise (S/N) level for the 2.5-7.0 ppm region containing the quartet at 2.65 ppm.
iv. Acceptance Criteria: Measured S/N value shall be greater than 400.

D. Polarimeter

1. Specific Rotation

i. Frequency: Every six months (or after substantial maintenance)
ii. Performance Sample: Quartz wave plate filter
iii. Procedure: Measure the optical rotation of the quartz wave plate at 589.3 nm (sodium D line).
iv. Acceptance Criteria: The experimentally measured rotation for the quartz wave plate shall be within the uncertainty measurement specified in the calibration certificate.

E. UV/Vis Spectrophotometer

1. Wavelength Accuracy

i. Frequency: Every six months (or after substantial maintenance)
ii. Performance Sample: UV region - holmium oxide filter or solution; Visible region - didymium filter or solution.
iii. Procedure: Collect at least one spectrum over the entire UV-Visible range.
iv. Acceptance Criteria: The measured absorption or emission peaks shall be within ±1 nm in the UV range (200-380 nm) and within ±3 nm in the visible range (380-800 nm) of the value(s) listed in the reference standard certificate.

2. Photometric Accuracy (UV)

i. Frequency: Every six months (or after substantial maintenance)
ii. Performance Sample: 0.006% (w/v) solution of potassium dichromate (60.06 mg/L) in 0.001 N perchloric acid.
iii. Procedure: Collect a spectrum of the performance solution by scanning from 210 to 450 nm (using 0.001 N perchloric acid as the reference standard).
iv. Acceptance Criteria: The measured absorbance values at 235, 257, 313, and 350 nm shall be within ± 0.01 AU of 0.741, 0.862, 0.289, and 0.642, respectively.

3. Photometric Accuracy (Vis)

i. Frequency: Every six months (or after substantial maintenance)
ii. Performance Sample: Neutral density filters (SRM 930e or SRM 1930)
iii. Procedure: Measure the absorbance of the filters at each of the wavelengths specified in the calibration certificate (440, 465, 546, 590, or 635 nm).
iv. Acceptance Criteria: The measured absorbance values at the specified wavelengths shall be consistent with the values listed in the filter calibration certificate.

F. Ion Mobility Spectrometer (IMS)

1. Verification

i. Frequency: Monthly and before use at off-site location
ii. Reference Sample: Manufacturer-recommended reference material
iii. Procedure: Analyze the reference material following manufacturer's instructions.
iv. Acceptance Criteria: All calibration tests shall pass indicating that all components in the reference sample have been detected and are within manufacturer's specifications.

G. Balances

1. Calibration Check

i. Frequency: Monthly (or after substantial maintenance)

ii. Performance Sample: NIST-traceable weights[1]

iii. Procedure: (1) Following manufacturer's instructions, check the linearity of the balance by using the internal balance adjustment or calibration function. (2) Check the repeatability of the balance by performing three measurements on each of two different NIST-traceable weights. Weights must ~~differ by at least a factor of ten~~ represent 5-15% and 50-75% of the balance load capacity. (3) Check the accuracy of the balance by evaluating each of the three repeatability measurements and by calculating the average weight measured for each of the NIST-traceable weights.

iv. Acceptance Criteria: (1) Linearity: verify that the check is successful. (2) Repeatability: the relative standard deviation for each set of three measurements shall be $\leq 0.5\%$. (3) Accuracy: for each NIST-traceable weight used, verify that the measured averaged weight and at least two of the individual weights are within the following acceptance ranges:

Readability:	Acceptance Range:
0.000001 g	± 0.000020 g
0.00001 g	± 0.00040 g
0.0001 g	± 0.0005 g
0.001 g	± 0.004 g
0.01 g	± 0.10 g
0.1 g	± 0.4 g
1 g	± 4 g
10 g	± 40 g
100 g	± 400 g

H. Gas Chromatography System (GC)[2,5]

1. Chromatography

i. Frequency: Monthly (or after substantial maintenance)

ii. Performance Sample: Mixture containing a minimum of three commonly encountered compounds at known concentrations. Sample must contain a critical resolution pair and at least one low-response compound.

iii. Procedure: Analyze the performance sample a minimum of three times using a routine analysis method.

iv. Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For the replicate measurements, the calculated relative standard deviation (RSD) for the relative area and relative retention times for each compound in the mixture shall not exceed 5%. In addition, for at least three compounds in the mixture, the average relative area (b)(7)(E) and the average relative retention times shall be within 5% of the values measured during the previous month.

I. High Performance Liquid Chromatography System (HPLC)[3,5]

1. Chromatography

i. Frequency: Monthly (or after substantial maintenance)

ii. Performance Sample: Mixture containing a minimum of three commonly encountered compounds at known concentrations. Sample must contain a critical resolution pair.

iii. Procedure: Analyze the performance sample a minimum of three times using a routine analysis method.
iv. Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For the replicate measurements, the calculated RSD for the relative area and relative retention times for each compound in the mixture shall not exceed 5%. In addition, for at least three compounds in the mixture, the average relative area and average relative retention times shall be within 5% of the values measured during the previous month.

2. Diode Array Detector (DAD)

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: N/A
iii. Procedure: Perform detector tests and calibrations as recommended by manufacturer.
iv. Acceptance Criteria: Test and calibration results shall be within manufacturer's specifications.

J. Capillary Electrophoresis System (CE)[4,5]

1. Electrophoresis

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Mixture containing a minimum of three commonly encountered compounds at known concentrations. Sample must contain a critical resolution pair.
iii. Procedure: Analyze the performance sample a minimum of three times using a routine analysis method.
iv. Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For the replicate measurements, the calculated RSD for the relative area and relative migration times for each compound in the mixture shall not exceed 5%. In addition, for at least three compounds in the mixture, the average relative migration times shall be within 5% of the values measured during the previous month.

2. Diode Array Detector (DAD)

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: N/A
iii. Procedure: Perform detector tests and calibrations as recommended by manufacturer.
iv. Acceptance Criteria: Test and calibration results shall be within manufacturer's specifications.

K. Gas Chromatography - Mass Spectrometry System (GC-MS)[2,5,6]

1. Chromatography and Mass Spectrometer Response

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Mixture containing a minimum of three commonly encountered compounds at known concentrations. Sample must contain a critical resolution pair and at least one low-response compound.
iii. Procedure: Analyze the performance sample using a routine analysis method.
iv. Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For at least three compounds in the mixture, the relative retention times shall be within 5% of the values measured during the previous month. In addition, for each compound in the mixture, the mass spectrum obtained shall be consistent with the substance being analyzed.

2. Mass Spectrometer Calibration

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: PFTBA
iii. Procedure: Tune the mass analyzer following manufacturer's instructions.
iv. Acceptance Criteria: Tune results shall be within manufacturer's specifications.

L. Gas Chromatography - Infrared Spectrophotometer (GC-IR)[2,5,6]

1. Gas Chromatography

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Mixture containing a minimum of three commonly encountered compounds at known concentrations.
iii. Procedure: Analyze the performance sample using a routine analysis method.
iv. Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For at least three compounds in the mixture, the relative retention times shall be within 5% of the values measured during the previous month. In addition, for each compound in the mixture, the vapor-phase IR obtained shall be consistent with the substance being analyzed.

2. IR Detector

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: A solution containing a semi-volatile substance with a documented (reference) vapor-phase IR spectrum
iii. Procedure: Analyze the performance sample using an instrument method that collects the infrared spectrum at the flow cell temperature and spectral resolution cited in the reference.
iv. Acceptance Criteria: Measured peak positions of three high intensity absorption bands shall be within the experimental resolution of the cited reference values.

M. Liquid Chromatography – Mass Spectrometry System (LC-MS)[3,5,6]

1. Liquid Chromatography

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Mixture containing a minimum of three commonly encountered compounds at known concentrations. Sample must contain a critical resolution pair.
iii. Procedure: Analyze the performance sample using a routine analysis method.
iv. Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For at least three compounds in the mixture, the relative retention times shall be within 5% of the values measured during the previous month. In addition, for each compound in the mixture, the mass spectrum obtained shall be consistent with the substance being analyzed.

2. Diode Array Detector (DAD) (if available)

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: N/A
iii. Procedure: Perform detector tests and calibrations as recommended by manufacturer.
iv. Acceptance Criteria: Test and calibration results shall be within manufacturer's specifications.

3. Mass Spectrometer Tune

i. Frequency: Monthly (or after substantial maintenance)
ii. Performance Sample: Laboratory-customized or manufacturer-recommended reference material.

iii. Procedure: Tune the mass analyzer following manufacturer's instructions.
iv. Acceptance Criteria: Tune results shall be within manufacturer's specifications.

4. **Mass Spectrometer Calibration**
   i. Frequency: Every three months (or after substantial maintenance)
   ii. Performance Sample: Manufacturer-recommended reference material.
   iii. Procedure: Calibrate the mass analyzer following manufacturer's instructions.
   iv. Acceptance Criteria: Calibration results shall be within manufacturer's specifications.

DOCUMENTATION REQUIREMENTS:
All instrument performance verification procedures and acceptance criteria must be clearly stated and documented in the instrument logbook. For those components for which specific verification procedures have not been stated in this laboratory system order (e.g. gas and liquid chromatographs, etc.), the instrument logbook (template) must contain the specific procedures and criteria necessary to fulfill the general requirements of this laboratory system order and in addition, the specific requirements established by the laboratory or instrument manufacturer. When manufacturer-recommended procedures are to be followed, the reference citation must be clearly noted in the performance verification template. All performance verification samples (chemicals, filters, solutions) shall be traceable to a certified source.

For instrumentation not covered by this laboratory system order (ICP-MS, EA-IRMS, CD detectors, XRD, research NMR, signature analysis instruments, etc.), specific performance verification procedures must be established, reviewed and approved by the applicable laboratory management. All procedures must be clearly stated and documented in the corresponding instrument logbook.

For seldom-used instrumentation, the frequency of performance verification procedures stated in this laboratory system order shall be revised at the laboratory level. Procedures shall comply with ASCLD/LAB-*International* supplemental requirements stating that "*In general, calibration check intervals shall not be less stringent than manufacturers' recommendations*" (Section 5.6.1.1).

Upon completion of the verification procedures, the results will be documented in the instrument logbook by including copies of the data or report generated. All instrumental data must contain the corresponding DEA identification number, and must be initialed and dated by the analyst performing the verification. The completion of the performance verification tasks, as well as any problems encountered during the procedures, must be clearly noted and dated in the instrument logbook. An electronic copy of the performance verification results should also be available.

If an instrument does not meet the acceptance criteria for the performance checks, the instrument monitor must document the problem in the instrument logbook, investigate the nature and cause of the failure, and make the necessary adjustments and repairs to bring the instrument back to operation. If a service call is to be initiated, the instrument will be clearly identified as *out of service* until the problem has been resolved and the instrument can meet the specified acceptance criteria.

NOTES:

1. Balances shall be calibrated annually by an ISO/IEC 17025:2005 accredited calibration laboratory and NIST-traceable weights shall be recertified every five years by an ISO/IEC 17025:2005 accredited calibration laboratory.
2. Monthly GC performance verifications procedures are to be completed using a routine application method. For example, columns routinely used for screening analysis should be evaluated using a routine screening method. Columns routinely used for isomer analysis should be verified using a routine isomer method. Changes in the temperature program or injection conditions do not require prior verification of the system performance. For situations when a column is used for both screening and isomer analyses, the laboratory may choose to perform two separate monthly checks or one check using the more rigorous conditions of isomer analysis.
3. Monthly HPLC performance verification procedures are to be completed using a routine application method. For non-routine analyses requiring the use of a different column or buffer, the performance of the system must also be evaluated immediately prior to use by utilizing a performance verification procedure appropriate for the new experimental conditions. Changes in the buffer ratios or injection conditions do not require prior verification of the system performance.
4. Monthly CE performance verification procedures are to be completed using a routine application method. For non-routine analyses requiring the use of a different capillary or buffer, the performance of the system must also be evaluated immediately prior to use by utilizing a performance verification procedure appropriate for the new experimental conditions.
5. Significant maintenance and repair events might result in monthly verification parameters that do not comply with the above acceptance criteria. For example, clipping of the column or preparation of a new performance sample solution or capillary might result in relative retention times and peak areas that are not within 5% of the values measured during the previous month. For those cases, the cause(s) for the discrepancies should be clearly stated in the instrument logbook.
6. For GC-MS, GC-IR and LC-MS systems, the performance verification (tune, etc.) of the detector (MS or IR) must be successfully completed prior to evaluation of the separation component (GC or LC). Also for these systems, it is not necessary to generate hard copies of the mass or infrared spectra collected.

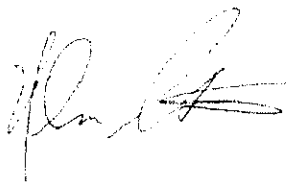
DEFINITIONS:

1. Low-response compound – Compound that produces a low-intensity signal under routine experimental conditions (e.g. quinine, hydroxyzine, noscapine, etc.).
2. Relative area – The ratio of the peak area of one compound relative to the peak area of a reference compound. The selected reference compound can be one of the performance mixture components or a routinely-used internal standard (tetracosane, resorcinol, etc.), and must demonstrate good chromatographic behavior and high peak symmetry.
3. Relative retention/migration time – The ratio of the elution (retention/migration time) of one compound relative to the elution (retention/migration time) of a reference compound. The selected reference compound can be one of the performance mixture components or a routinely-used internal standard (tetracosane, resorcinol, etc.), and must demonstrate good chromatographic behavior and high peak symmetry.
4. Relative standard deviation (RSD) – For replicate measurements, the measured sample standard deviation divided by the mean.

5. Substantial maintenance – Any instrument repairs that require the replacement of serviceable parts or components and that is expected to affect the instrument performance. Substantial maintenance includes all maintenance performed by non-DEA personnel.
6. Critical resolution pair – For separation analyses, a pair of compounds eluting or migrating with a resolution between 1.5 and 5.0.

REFERENCES:

1. Chan CC, Lee YC, Lam H, Zhang XM, editors. Analytical Method Validation and Instrument Performance Verification. New Jersey: John Wiley & Sons, Inc., 2004; Chapter 10, 153-172.
2. Prichard E, Barwick V. Quality Assurance in Analytical Chemistry. United Kingdom: John Wiley & Sons, Ltd., 2007.
3. ASTM E 1421-99, "Standard Practice for Describing and Measuring Performance of Fourier Tranform Mid-Infrared (FT-MIR) Spectrometers: Level Zero and Level One Tests," ASTM International.
4. ASTM E 1840-96 (Reapproved 2002), "Standard Guide for Raman Shift Standards for Spectrometer Calibration," ASTM International.



Nelson A. Santos
Deputy Assistant Administrator
Office of Forensic Sciences

08/30/2010
Date

Performance Verification Templates

- Laboratory shall specify revision date.
- Laboratory shall specify SFL# identification.
- Laboratory shall specify instrument name, manufacturer and model.
- Laboratory shall specify DEA# identification.
- Laboratory shall specify all *[italicized]* entries.
- Complete, reviewed and approved template shall be kept in instrument logbook.
- A detailed example of a GC-MS template (applicable to Agilent instrument) is included as the last template.

IR		
Performance Verification Procedures	**Revised** MM/DD/YYYY	**SFL#**

Instrument: *[Instrument name, manufacturer, model]*
DEA #:

Transmission Wavelength and Resolution Check

Frequency: Monthly (or after substantial maintenance)
Performance Sample: Polystyrene
Procedure: Collect polystyrene transmittance spectrum (8 scans; 4 cm^{-1} resolution). Report the peak positions measured for the following three bands: 3060, 1601 and 1028 cm^{-1}.
Acceptance Criteria: Measured peak positions shall be within 4 cm^{-1} of above referenced values.

Reflectance Wavelength and Resolution Check (ATR)

Frequency: Monthly (or after substantial maintenance)
Performance Sample: Caffeine
Procedure: Collect caffeine spectrum (8 scans; 4 cm^{-1} resolution). Report the peak positions measured for the following three bands: 3111, 1644 and 743 cm^{-1}.
Acceptance Criteria: Measured peak positions shall be within 4 cm^{-1} of above referenced values.

Reviewed by: Quality Assurance Specialist: _____
Name and Date

Reviewed by: Associate Laboratory Director: _____
Name and Date

Approved by: Laboratory Director: _____
Name and Date

Raman

Performance Verification Procedures	Revised MM/DD/YYYY	SFL#

Instrument: *[Instrument name, manufacturer, model]*
DEA #:

Wavelength and Resolution Check (A)

Frequency: Monthly (or after substantial maintenance)
Performance Sample: Polystyrene
Procedure: Maximize signal for polystyrene spectrum by adjusting the laser power.
Collect spectrum of polystyrene (8 scans; 4 cm^{-1} resolution).
Report the peak positions measured for the following three bands:
3054, 1602 and 1000 cm^{-1}.
Acceptance Criteria: Measured peak positions shall be within 4 cm^{-1} of above referenced values.

Wavelength and Resolution Check (B)

Frequency: Monthly (or after substantial maintenance)
Performance Sample: Caffeine
Procedure: Collect caffeine spectrum (8 scans; 4 cm^{-1} resolution).
Report the peak positions measured for the following three bands:
2957, 1328 and 555 cm^{-1}.
Acceptance Criteria: Measured peak positions shall be within 4 cm^{-1} of above referenced values.

Reviewed by: Quality Assurance Specialist: _____
Name and Date

Reviewed by: Assoc. Laboratory Director: _____
Name and Date

Approved by: Laboratory Director: _____
Name and Date

NMR (400 MHz)

Performance Verification Procedures | Revised MM/DD/YYYY | **SFL#**

Instrument: *[Instrument name, manufacturer, model]*
DEA #:

Proton Line Shape

Frequency: Monthly (or after substantial maintenance)
Performance Sample: Chloroform in acetone-*d6* (non-spinning sample)
Procedure: Obtain ^{1}H NMR spectrum of performance sample (1 scan, 500 Hz spectral width, acquisition time ≥ 8 seconds)
Acceptance Criteria: Peak width for chloroform proton signal shall be equal or less than 1.0 Hz, 12.0 Hz and 24.0 Hz at 50%, 0.55%, and 0.11% peak height, respectively.

Probe File Update

Frequency: Monthly (or after substantial maintenance)
Performance Sample: Methyliodide (^{13}C-enriched)
Procedure: Perform these automatic calibrations: 90° pulse calibrations for proton observed (pw90), proton decouple (pp90), carbon observe (pw90), and carbon decouple (pwx90), and gradient G/cm/dac and C/H gradient ratio calibrations.
Acceptance Criteria: All 90° pulse widths for proton and carbon shall be less than 20 microseconds. The instrument's probe file will be updated automatically.

Proton Sensitivity (Only for indirect detection probes)

Frequency: Every 6 months (or after substantial maintenance)
Performance Sample: Ethyl benzene in chloroform-*d*
Procedure: Obtain ^{1}H NMR spectra of performance sample (90° pulse, dl ≥ 60, 1 scan, lb = 1.0). Record signal-to-noise (S/N) level for the 2.5-7.0 ppm region containing the quartet at 2.65 ppm.
Acceptance Criteria: Measured S/N value shall be greater than 400.

Reviewed by: Quality Assurance Specialist: _____ Name and Date

Reviewed by: Assoc. Laboratory Director: _____ Name and Date

Approved by: Laboratory Director: _____ Name and Date

Polarimeter

Performance Verification Procedures	Revised MM/DD/YYYY	SFL#

Instrument: *[Instrument name, manufacturer, model]*

DEA #:

Specific Rotation

Frequency: Every six months (or after substantial maintenance)

Performance Sample: Quartz wave plate filter

Procedure: Measure the optical rotation of the quartz wave plate at 589.3 nm (sodium D line).

Acceptance Criteria: The experimentally measured rotation for the quartz wave plate shall be within the uncertainty measurement specified in the calibration certificate.

Reviewed by: Quality Assurance Specialist: _____
Name and Date

Reviewed by: Assoc. Laboratory Director: _____
Name and Date

Approved by: Laboratory Director: _____
Name and Date

UV/Vis

Performance Verification Procedures	Revised MM/DD/YYYY	SFL#

Instrument: *[Instrument name, manufacturer, model]*
DEA #:

Wavelength Accuracy

Frequency:	Every six months (or after substantial maintenance)
Performance Sample:	Holmium oxide (UV) and didymium filter (Vis)
Procedure:	Collect at least one spectrum over the entire UV-Visible range.
Acceptance Criteria:	The measured absorption or emission peaks shall be within ±1 nm in the UV range (200-380 nm) and within ±3 nm in the visible range (380-800 nm) of the value(s) listed in the reference standard certificate.

Photometric Accuracy (UV)

Frequency:	Every six months (or after substantial maintenance)
Performance Sample:	0.006% (w/v) solution of potassium dichromate (60.06 mg/L) in 0.005 M sulfuric acid.
Procedure:	Collect a spectrum of the performance solution by scanning from 210 to 450 nm (using 0.005 M sulfuric acid solution as the reference standard).
Acceptance Criteria:	The measured absorbance values at 235, 257, 313 and 350 nm shall be within ± 0.01 AU of 0.748, 0.865, 0.292 and 0.640, respectively.

Photometric Accuracy (Vis)

Frequency:	Every six months (or after substantial maintenance)
Performance Sample:	Neutral density filters (SRM 930e or SRM 1930)
Procedure:	Collect a spectrum of the filter by scanning from 380 to 800 nm.
Acceptance Criteria:	The measured absorbance values at 440, 465, 546, 590 and 635 nm shall be consistent with the values listed in the filter calibration certificate.

Reviewed by: Quality Assurance Specialist: _____
Name and Date

Reviewed by: Assoc. Laboratory Director: _____
Name and Date

Approved by: Laboratory Director: _____
Name and Date

Ion Mobility Spectrometer

Performance Verification Procedures	Revised MM/DD/YYYY	SFL#

Instrument: *[Instrument name, manufacturer, model]*

DEA #:

Signal and Performance Optimization

Frequency: Monthly and before use at off-site location

Performance Sample: *[Specify manufacturer-recommended reference material (e.g. Verific®)]*

Procedure: *[Specify manufacturer's instructions for analysis of reference material]*

Acceptance Criteria: *[Specify manufacturer-recommended acceptance criteria and specifications.]*

Reference: *[Include specific reference (instrument manual or scientific literature) to manufacturer's procedures utilized above.]*

Reviewed by: Quality Assurance Specialist: _____
Name and Date

Reviewed by: Assoc. Laboratory Director: _____
Name and Date

Approved by: Laboratory Director: _____
Name and Date

Balances

Performance Verification Procedures | **Revised** MM/DD/YYYY | **SFL#**

Instrument: *[Instrument name, manufacturer, model]*

DEA #:

Calibration Check

Frequency: Monthly (or after substantial maintenance)

Performance Sample: NIST-traceable weights

Procedure: (1) Following manufacturer's instructions, check the linearity of the balance by using the internal balance adjustment or calibration function.
(2) Check the repeatability of the balance by performing three measurements on each of two different NIST-traceable weights. Weights must represent 5-15% and 50-75% of the balance load capacity.
(3) Check the accuracy of the balance by evaluating each of the three repeatability measurements and by calculating the average weight measured for each of the NIST-traceable weights.

Acceptance Criteria: (1) Linearity: verify the check is successful.
(2) Repeatability: the relative standard deviation for each set of three measurements shall be ≤ 0.5%.
(3) Accuracy: for each NIST-traceable weight used, verify that the measured averaged weight and at least two of the individual weights are within the following acceptance ranges:

Readability:	Range:
0.000001 g	± 0.000020 g
0.00001 g	± 0.00040 g
0.0001 g	± 0.0005 g
0.001 g	± 0.004 g
0.01 g	± 0.10 g
0.1 g	± 0.4 g
1 g	± 4 g
10 g	± 40 g
100 g	± 400 g

Reviewed by: Quality Assurance Specialist: _____ Name and Date

Reviewed by: Assoc. Laboratory Director: _____ Name and Date

Approved by: Laboratory Director: _____ Name and Date

GC-FID

Performance Verification Procedures	Revised MM/DD/YYYY	SFL#

Instrument: *[Instrument name, manufacturer, model]*
DEA #:
Column 1: *[Column parameters]* (front)
Column 2: *[Column parameters]* (back)

Gas Chromatography

Frequency: Monthly (or after substantial maintenance)

Performance Sample: **Column 1:** *[Specify mixture components (a minimum of three), their concentration and solvent. Sample must contain a critical resolution pair and at least one low-response compound.]*
Column 2: *[Specify mixture components (a minimum of three), their concentration and solvent. Sample must contain a critical resolution pair and at least one low-response compound (if applicable).]*

Procedure: **Column 1:** Analyze the performance sample a minimum of three times using the *[specify routine method name]* method.
Column 2: Analyze the performance sample a minimum of three times using the *[specify routine method name]* method.

Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For the replicate measurements, the calculated relative standard deviation (RSD) for the relative area and relative retention times for each compound in the mixture shall not exceed 5%. In addition, for at least three compounds in the mixture, the average relative area [redacted] the average relative retention times shall be within 5% of the values measured during the previous month.

(b)(7)(E)

Reviewed by: Quality Assurance Specialist: _____
Name and Date

Reviewed by: Assoc. Laboratory Director: _____
Name and Date

Approved by: Laboratory Director: _____
Name and Date

HPLC-UV

Performance Verification Procedures | **Revised** MM/DD/YYYY | **SFL#**

Instrument: *[Instrument name, manufacturer, model]*
DEA #:
Column 1: *[Column parameters]*
Buffer 1: *[Buffer description]*
Column 2: *[Column parameters]*
Buffer 2: *[Buffer description]*

Liquid Chromatography

Frequency: Monthly (or after substantial maintenance)

Performance Sample: **Column/Buffer 1:** *[Specify mixture components (a minimum of three), their concentration and solvent. Sample must contain a critical resolution pair.]*
Column/Buffer 2: *[Specify mixture components (a minimum of three), their concentration and solvent. Sample must contain a critical resolution pair.]*

Procedure: **Column/Buffer 1:** Analyze the performance sample a minimum of three times using the *[specify routine method name]* method.
Column/Buffer 2: Analyze the performance sample a minimum of three times using the *[specify routine method name]* method.

Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For the replicate measurements, the calculated relative standard deviation (RSD) for the relative area and relative retention times for each compound in the mixture shall not exceed 5%. In addition, for at least three compounds in the mixture, the average relative area and average relative retention times shall be within 5% of the values measured during the previous month.

Diode Array Detector

Frequency: Monthly (or after substantial maintenance)

Performance Sample: N/A

Procedure: *[Specify detector tests and calibrations recommended by manufacturer.]*

Acceptance Criteria: *[Specify manufacturer-recommended acceptance criteria.]*

Reference: *[Include specific reference (instrument manual or scientific literature) to manufacturer's procedures utilized above.]*

Reviewed by: Quality Assurance Specialist: _____ Name and Date

Reviewed by: Assoc. Laboratory Director: _____ Name and Date

Approved by: Laboratory Director: _____ Name and Date

CE-UV

Performance Verification Procedures	Revised MM/DD/YYYY	SFL#

Instrument: *[Instrument name, manufacturer, model]*
DEA #:

Electrophoresis

Frequency: Monthly (or after substantial maintenance)

Performance Sample: *[Specify mixture components (a minimum of three), their concentration and solvent. Sample must contain a critical resolution pair.]*

Procedure: Analyze the performance sample a minimum of three times using the *[specify routine method name]* method.

Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For the replicate measurements, the calculated relative standard deviation (RSD) relative migration times for each compound in the mixture shall not exceed 5%. In addition, for at least three compounds in the mixture, the average relative migration times shall be within 5% of the values measured during the previous month.

Diode Array Detector

Frequency: Monthly (or after substantial maintenance)

Performance Sample: N/A

Procedure: *[Specify detector tests and calibrations recommended by manufacturer.]*

Acceptance Criteria: *[Specify manufacturer-recommended acceptance criteria.]*

Reference: *[Include specific reference (instrument manual or scientific literature) to manufacturer's procedures utilized above.]*

Reviewed by: Quality Assurance Specialist: _____
Name and Date

Reviewed by: Assoc. Laboratory Director: _____
Name and Date

Approved by: Laboratory Director: _____
Name and Date

GC-MS

Performance Verification Procedures	Revised MM/DD/YYYY	SFL#

Instrument: *[Instrument name, manufacturer, model]*
DEA #:

Chromatography and Mass Spectrometry Response

Frequency: Monthly (or after substantial maintenance)

Performance Sample: *[Specify mixture components (a minimum of three), their concentration and solvent. Sample must contain a critical resolution pair and at least one low-response compound.]*

Procedure: Analyze the performance sample using the *[specify routine method name]* method.

Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For at least three compounds in the mixture, the relative retention times shall be within 5% of the values measured during the previous month. In addition, for each compound in the mixture, the mass spectrum obtained shall be consistent with the substance being analyzed.

Mass Spectrometer Calibration

Frequency: Monthly (or after substantial maintenance)

Performance Sample: PFTBA

Procedure: *[Specify tune procedure(s) recommended by manufacturer.]*

Acceptance Criteria: *[Specify manufacturer-recommended acceptance criteria.]*

Reference: *[Include specific reference (instrument manual or scientific literature) to manufacturer's procedures utilized above.]*

Reviewed by: Quality Assurance Specialist: _____
Name and Date

Reviewed by: Assoc. Laboratory Director: _____
Name and Date

Approved by: Laboratory Director: _____
Name and Date

GC-IR

Performance Verification Procedures	Revised MM/DD/YYYY	SFL#

Instrument: *[Instrument name, manufacturer, model]*
DEA #:

Gas Chromatography

Frequency: Monthly (or after substantial maintenance)

Performance Sample: *[Specify mixture components (a minimum of three), their concentration and solvent.]*

Procedure: Analyze the performance sample using the *[specify routine method name]* method.

Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For at least three compounds in the mixture, the relative retention times shall be within 5% of the values measured during the previous month. In addition, for each compound in the mixture, the vapor-phase IR obtained shall be consistent with the substance being analyzed.

IR Detector

Frequency: Monthly (or after substantial maintenance)

Performance Sample: *[Specify solution or component with a documented (reference) vapor-phase IR spectrum.]*

Procedure: Analyze the performance sample using the *[specify method name]* method. Method shall collect the infrared spectrum at the flow cell temperature and spectral resolution cited in the reference.

Acceptance Criteria: The measured peak positions for the *[0000]*, *[0000]*, and *[0000]* cm^{-1} bands shall be within the experimental resolution of the cited reference values.

Reference: *[Include specific reference (instrument manual or scientific literature) to manufacturer's procedures utilized above.]*

Reviewed by: Quality Assurance Specialist: _____
Name and Date

Reviewed by: Assoc. Laboratory Director: _____
Name and Date

Approved by: Laboratory Director: _____
Name and Date

LC–MS

Performance Verification Procedures | **Revised** MM/DD/YYYY | **SFL#**

Instrument: *[Instrument name, manufacturer, model]*
DEA #:

Liquid Chromatography

Frequency: Monthly (or after substantial maintenance)
Performance Sample: *[Specify mixture components (a minimum of three), their concentration and solvent. Sample must contain a critical resolution pair.]*
Procedure: Analyze the performance sample using the *[specify routine method name]* method.
Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For at least three compounds in the mixture, the relative retention times shall be within 5% of the values measured during the previous month. In addition, for each compound in the mixture, the mass spectrum obtained shall be consistent with the substance being analyzed.

Diode Array Detector (if available)

Frequency: Monthly (or after substantial maintenance)
Performance Sample: N/A
Procedure: *[Specify detector tests and calibrations recommended by manufacturer.]*
Acceptance Criteria: *[Specify manufacturer-recommended acceptance criteria.]*
Reference: *[Include specific reference (instrument manual or scientific literature) to manufacturer's procedures utilized above.]*

Mass Spectrometer Tune

Frequency: Monthly (or after substantial maintenance)
Performance Sample: *[Specify sample component(s), concentration and solvent.]*
Procedure: *[Specify tune procedure(s) recommended by manufacturer.]*
Acceptance Criteria: *[Specify manufacturer-recommended acceptance criteria.]*
Reference: *[Include specific reference (instrument manual or scientific literature) to manufacturer's procedures utilized above.]*

Mass Spectrometer Calibration

Frequency: Every 3 months (or after substantial maintenance)
Performance Sample: *[Specify sample component(s), concentration and solvent.]*
Procedure: *[Specify calibration procedure(s) recommended by manufacturer.]*
Acceptance Criteria: *[Specify manufacturer-recommended acceptance criteria.]*
Reference: *[Include specific reference (instrument manual or scientific literature) to manufacturer's procedures utilized above.]*

Reviewed by: Quality Assurance Specialist: _____ Name and Date

Reviewed by: Assoc. Laboratory Director: _____ Name and Date

Approved by: Laboratory Director: _____ Name and Date

GC-MS

Performance Verification Procedures	Revised MM/DD/YYYY	SFL#

Instrument: *[Instrument name, manufacturer, model]*

DEA #: 123456

Chromatography and Mass Spectrometry Response

Frequency: Monthly (or after substantial maintenance)

Performance Sample: Solution containing methamphetamine, caffeine, cocaine, tetracaine and hydroxyzine in methanol. Concentration of each component is 0.1 mg/mL.

Procedure: Analyze the performance sample using the Drug1 method.

Acceptance Criteria: All compounds should be baseline resolved (resolution > 1.5). For at least three compounds in the mixture, the relative retention times shall be within 5% of the values measured during the previous month. In addition, for each compound in the mixture, the mass spectrum obtained shall be consistent with the substance being analyzed.

Mass Spectrometer Calibration

Frequency: Monthly (or after substantial maintenance)

Performance Sample: PFTBA

Procedure: Perform a standard tune following manufacturer's instructions.

Acceptance Criteria:

- Mass peaks should be +/- 0.2 amu
- Peak widths (Pw50) should fall between 0.50 – 0.63
- Dominant peaks should be smooth and symmetrical, and isotopes should be resolved
- Mass 69 abundance: >200,000 but <400,000
- There should be <200 total peaks
- Peaks at 18, 28, and 32 amu with abundances >10% of the base peak (69amu) there may be an air leak in the system
- Diffusion Pump equipped instruments should indicate 40 – 65.
- Turbo Pump equipped instruments should indicate 100.
- Isotope ratios shall be:
  1. 70/69 >0.5 but <1.6
  2. 220/219 >3.2 but <5.4
  3. 503/502 >7.9 but <12.3
- Relative abundance ratios shall be:
  1. m/z 69 100% (base peak)
  2. 219/69 >40% but <85%
  3. 502/69 >2.5% but <5%

Reference: Agilent 5973 GC-MSD Troubleshooting & Maintenance (H2294A) Student Manual, Part Number H2294-90000, Printed April, 2000.

Agilent MSD Example Agilent MSD Example Agilent MSD Example

Reviewed by: Quality Assurance Specialist: _____ Name and Date

Reviewed by: Assoc. Laboratory Director: _____ Name and Date

Approved by: Laboratory Director: _____ Name and Date

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Withheld pursuant to exemption

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of the Freedom of Information and Privacy Act

Page 174 of 287

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of the Freedom of Information and Privacy Act

Laboratory System

ORDER

Office of Forensic Sciences

LS-09-004

Classification Code
LOM 7002.2C

Issue Date: November 13, 2009

SUBJECT: Estimation of Uncertainty of Measurement for the Purity of Controlled Substances

This laboratory system order replaces LS-09-004 issued on September 21, 2009. The LSO has been revised to clarify reporting requirements.

PURPOSE:
This laboratory system order describes the methodology and procedures for determining and reporting the uncertainty of measurement associated with the quantitation of controlled substances.

BACKGROUND:
In order to meet the estimation of uncertainty of measurement requirement described in ISO/IEC 17025:2005 section 5.4.6.2, and the requirements of the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB)-*International* Program, the Office of Forensic Sciences (SF) has established policy for determining the uncertainty of measurement associated with the purity of controlled substances. Re-evaluation of past collaborative studies and investigation of six years (2003-2008) of proficiency testing program (PTP) samples have resulted in a revision of the uncertainty model previously utilized. This laboratory system order revises previous DEA policy and describes a top-down approach for the determination of uncertainty of measurement associated with purity analyses (quantitation) for *all controlled substances*.

POLICY:
For all quantitative analyses, the uncertainty of measurement estimate (UME) associated with the purity result is to be obtained using equation 1:

$$U = \%P \cdot RSD \cdot k_{95\%} \qquad \text{Equation 1}$$

Where, $\%P$ is the empirically-determined purity of the analyte

RSD is the concentration-dependent relative standard deviation (or coefficient of variation) obtained from the statistical analysis of historical data

$k_{95\%}$ is the coverage factor for a 95% confidence level ($k = 2$).

Evaluation of historical system-wide laboratory data indicates that the relative standard deviation (RSD) obtained for quantitative analyses is a natural log function of concentration (% Purity), with higher RSD values observed as the concentration of the analyte decreases. This behavior is similar to that previously characterized and documented by Horwitz and collaborators (1,2)

during the evaluation of more than 100 years of inter-laboratory studies. Horwitz observed that an approximately 2-fold increase in RSD occurs for each 100-fold decrease in analyte concentration. These studies also demonstrated that the RSD associated with purity determinations is independent of analyte, matrix, or analytical technique used.

Figure 1 shows results from DEA PTP samples analyzed during the years 2003-2008 and also results from collaborative studies involving samples of methamphetamine, amphetamine, phencyclidine, and oxycodone. Each data point represents the RSD obtained from multiple analyses of one sample within the DEA laboratory system. Figure 1 also illustrates the best-fit curve (solid line) characterizing the dependence of RSD on concentration, mathematically illustrated by equation 2. The dashed line represents the 95% confidence interval for the RSD values.

$$RSD = 0.0655 - 0.0104\,ln(\%P) \qquad \text{Equation 2}$$

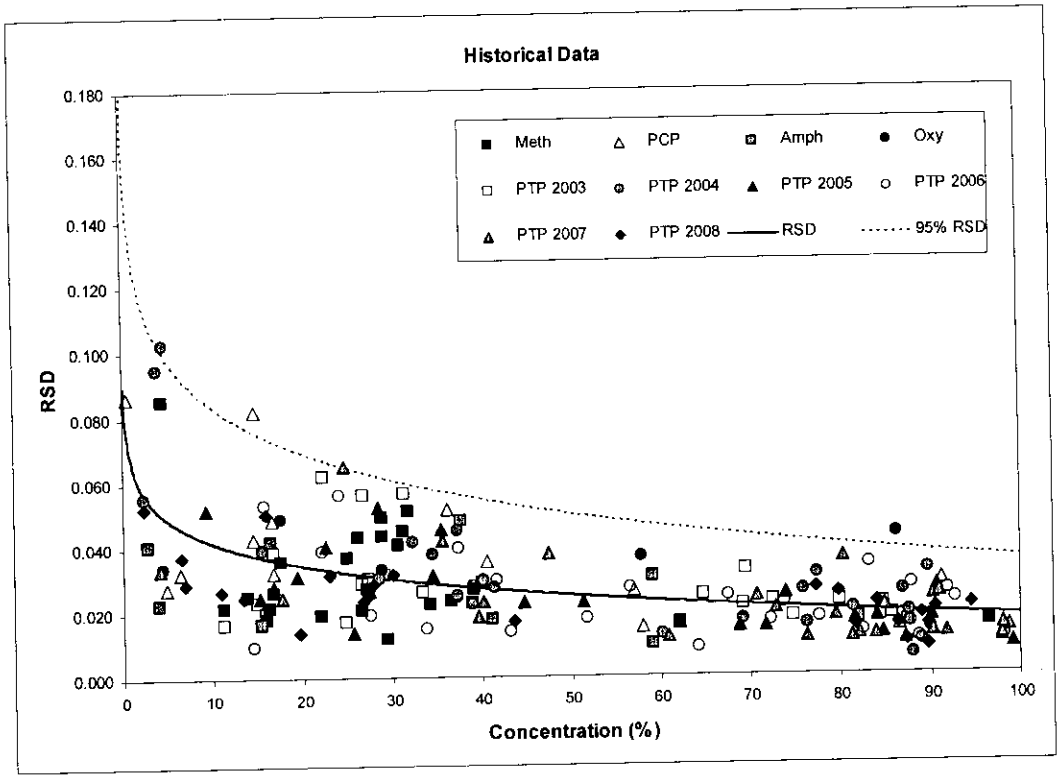


Figure 1: Dependence of RSD values on concentration for PTP samples (2003-2008) and collaborative studies of methamphetamine, phencyclidine (PCP), amphetamine, and oxycodone.

Relative standard deviations can be used to provide reasonable estimates of uncertainty for concentration-dependent systems like the one illustrated above (3). Therefore, RSD values obtained from equation 2 can be used to determine the uncertainty of purity measurements performed by analysts throughout the DEA laboratory system. The resulting uncertainty values will be applicable to all purity analyses, regardless of analyte, laboratory, matrix or analytical methodology used.

Table 1 lists approximate UMEs at different analyte purity levels representing expanded uncertainties at the 95% confidence level. These UMEs were obtained using equation 1 and the concentration-dependent RSD values defined by equation 2.

REPORTING UNCERTAINTY OF MEASUREMENT ESTIMATES:
After completing the quantitation of a substance, DEA chemists shall report the final purity result in percentage (%), truncated to one decimal place, for all purity results equal or greater than 1.0%. For dosage units or liquid exhibits, where the percentage purity (%P) may be below 1.0%, analysts shall truncate the final purity result to 2 significant figures. All UMEs shall be calculated from the % purity value (prior to truncation) using equations 1 and 2. ~~All~~ Final expanded uncertainties shall be rounded to match the number of decimal places reported for the purity. Conventional rounding rules will be followed. That is, a digit will be rounded down if followed by 0, 1, 2, 3 or 4; it will be rounded up if followed by 5, 6, 7, 8, or 9. For example, a powder sample with a purity of 68.652% and a measurement uncertainty of 2.95449% shall be reported as (68.6 ± 3.0) %. A tablet exhibit with a purity of 0.756% and a measurement uncertainty of 0.103434% shall be reported as (0.75 ± 0.10) %. It is recommended that analysts use the Uncertainty Calculator (LS-09-005 Attachment 1) to determine UMEs for all purity analyses.

For tablet, capsule, and liquid samples, the active drug concentration (mg/tablet, mg/capsule, or mg/mL), shall be included in the "Remarks" section of the laboratory report. An example is shown in LS-05-010 Attachment 1.

Uncertainty of measurement estimates must be recorded on the front of the DEA-86 form and the laboratory report. The following statement must also be included in the "Remarks" section of the laboratory report:

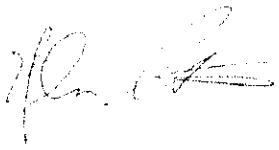
"The reported uncertainty values represent expanded uncertainty estimates at the 95% confidence level."

All UME calculations not performed using the Uncertainty Calculator must be documented on the back of the DEA-86 (or DEA-86a) form. For STRIDE entries, only purity results shall be reported, not their uncertainties.

REVISING UNCERTAINTY OF MEASUREMENT ESTIMATES:
The uncertainty of measurement estimate for controlled substances will be reviewed every five years using cumulative system-wide PTP results or other collaborative data.

REFERENCES:

1. Horwitz W. Evaluation of analytical methods used for regulation of foods and drugs. Anal Chem 1982;54(1):67A-76A.
2. Boyer KW, Horwitz W, Albert R. Interlaboratory variability in trace element analysis. Anal Chem 1985;57(2):454-459.
3. EURACHEM/CITAC Guide CG 4. Quantifying Uncertainty in Analytical Measurement, 2nd Edition, 2000, Appendix E, 108-111.



Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

11/13/2009
Date

Table 1

DEA LABORATORY SYSTEM UNCERTAINTY FOR PURITY MEASUREMENTS

Uncertainty of Measurement Estimates (UME) at the 95% Confidence Level for All DEA Laboratory Quantitations*

$$UME = \%P \times RSD \times k_{95\%}$$

Where,

%P = Drug purity from quantitative analysis

$RSD = 0.0655 - 0.0104 \ln (\%P)$

$k_{95\%}$ = Coverage factor at the 95% confidence level

Purity (%):	UME (%):
0.10-0.14	0.02
0.15-0.21	0.03
0.22-0.28	0.04
0.29-0.36	0.05
0.37-0.43	0.06
0.44-0.51	0.07
0.52-0.60	0.08
0.61-0.68	0.09
0.69-1.1	0.1
1.2-2.1	0.2
2.2-3.2	0.3
3.3-4.5	0.4
4.6-5.8	0.5
5.9-7.2	0.6
7.3-8.7	0.7
8.8-10.3	0.8
10.4-11.9	0.9
12.0-13.7	1.0
13.8-15.5	1.1
15.6-17.4	1.2
17.5-19.5	1.3
19.6-21.6	1.4

Purity (%):	UME (%):
21.7-23.8	1.5
23.9-26.1	1.6
26.2-28.5	1.7
28.6-31.0	1.8
31.1-33.7	1.9
33.8-36.4	2.0
36.5-39.3	2.1
39.4-42.4	2.2
42.5-45.5	2.3
45.6-49.0	2.4
49.1-52.4	2.5
52.5-56.1	2.6
56.2-59.9	2.7
60.0-64.0	2.8
64.1-68.4	2.9
68.5-73.0	3.0
73.1-78.0	3.1
78.1-83.3	3.2
83.4-89.0	3.3
89.1-95.2	3.4
95.3-100.0	3.5

* Uncertainty values listed are *approximations* and may be slightly lower than those calculated using more significant figures and the Uncertainty Calculator.

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System

ORDER

Office of Forensic Sciences

LS-09-005

Classification Code
HA-01

Issue Date: November 13, 2009

SUBJECT: Determination of Net Weight and Uncertainty of Measurement Estimates

This laboratory system order (LSO) has been revised to delete Attachment 3 and direct the analyst to LS-05-010 for the sample laboratory report.

PURPOSE:

This laboratory system order updates the DEA Evidence Sampling Plan and revises procedures for determining the net weight, volume, and total solid dosage count of drug evidence. This laboratory system order also establishes procedures for determining and reporting the uncertainty of measurement estimates (UME) associated with net weight and amount of pure drug calculations.

BACKGROUND AND POLICY:

This laboratory system order establishes criteria and procedures for the consistent determination and extrapolation of these quantities throughout the DEA laboratory system. These policies and procedures are only applicable to the determination and extrapolation of total net weight, volume and unit count. They are not to be applied for the purpose of screening or composite formation. Policy and guidelines for the latter procedures are found in the DEA Evidence Sampling Plan (Appendix HA-01) and the Analytical Sufficiency Document.

For all laboratory exhibits, analysts are to determine the net weight, volume or unit count by direct measurement of all units in the exhibit. If weighing or counting of all units is not practical, then the total net weight, volume and unit count shall be obtained by extrapolation, provided that some or all units in the exhibit contain uniform amounts of material or uniform packaging. For the purpose of weight, volume and unit count determinations, if all units in an exhibit are not uniform but can be divided into subgroups of uniform size or packaging (for example, an exhibit containing 150 10-mL vials and 50 20-mL vials), then the net weight, volume, and unit count shall be obtained for each one of the subgroups. The total net weight, volume or unit count for the exhibit will be obtained from the sum of all the subgroup measurements.

Section I provides procedures for the determination of net weight, volume and unit count for exhibits containing units with uniform amounts of material (uniform weight or volume). Section II provides procedures for the determination of net weight and volume for exhibits containing units with uniform packaging but variable amounts of material (variable weight or volume) per unit. With the exception of hazardous exhibits, the net weight and volume for exhibits containing *fewer than ten* units shall be determined by measuring all units. For exhibits containing *ten or more* units, the net weight and volume shall be obtained *either* by measuring all units *or* by extrapolation of the average weight of material per unit, *or* by extrapolation of the

average weight of each empty container. For solid dosage units, the total number of units shall be determined *either* by counting *or* by extrapolation using the average weight per dosage unit.

Section III establishes methods for calculating the UME for situations where the total net weight of an exhibit is determined by direct weighing(s). For these cases, all weighing events performed and the mass uncertainty (u_{mass}) associated with the balance(s) used must be considered. From a conservative approach, all weight measurements will be treated as correlated quantities and the total UME will be calculated using the *linear* combination of individual standard uncertainties and a coverage factor corresponding to a 95% confidence level. Section IV establishes procedures for calculating the UME when the total net weight of an exhibit has been obtained by extrapolation. For these cases, the total UME shall be determined at the 95% confidence level, by considering the weighing events, the mass uncertainty (u_{mass}) of the balance, and the uncertainty associated with the average weight per unit. Section V establishes procedures for determining the amount of pure drug uncertainty, which will be obtained by combination of the individual uncertainties associated with net weight and purity determinations.

For all weight determinations, analysts must ensure the readability of the balance used is appropriate for the measurements. The uncertainty associated with this equipment will have a direct effect on the final weight and uncertainty calculations. System-wide mass uncertainty (u_{mass}) values have been established for each type of balance that is appropriate for net weight measurements. The established values were calculated by combining the uncertainty from annual balance calibrations (u_{bal}) and the uncertainty associated with the weighing process ($u_{process}$). The latter values were obtained from the statistical evaluation of laboratory-wide monthly calibration-check data (see Note 1).

Balance Readability (g):	u_{mass} (g):
0.1	0.3581
0.01	0.02936
0.001	0.001851
0.0001	0.0005535
0.00001	0.0001698

When performing net weight measurements, analysts must ensure the following minimum weight thresholds are observed. These minimum values will ensure (95% confidence) that all net weight measurements are recorded with a relative uncertainty no greater than 1% (see Note 2). Minimum weight thresholds are applicable to the net weight of the actual substance being measured; they are not applicable to tare containers (paper, weighing boats, original or substitute packaging, glassware, etc.).

Balance Readability (g):	Minimum Weight (g):
0.1	40.0
0.01	3.00
0.001	0.300
0.0001	0.0400
0.00001	0.01000

For situations not covered in this laboratory system order (non-uniform units, two-layer liquids, mixtures of solids and liquids, etc.), net weight, volume and total unit count determinations are left to the discretion of the analyst and supervisory personnel. Signature analyses and other non-enforcement programs performed at the Special Testing and Research Laboratory are exempt from the procedures stated in this laboratory system order.

The traceability of weight measurements will be documented by recording the DEA property inventory number of the balance on the back of the DEA-86 (or DEA-86a) form. In accordance with LOM 7302.53, all net weight, volume, unit count and uncertainty calculations shall be noted on the back of the DEA-86 (or DEA-86a) form or recorded on the attached Uncertainty Calculator spreadsheet (Attachment 1).

CALCULATING NET WEIGHT, VOLUME, SOLID DOSAGE COUNT AND UNCERTAINTY OF MEASUREMENT:

I. Units with uniform amounts of material (net weight or volume):

A. For powders (mixtures of powders and materials), gummy samples and plant material, the total net weight for the exhibit shall be determined as follows:

1. *Fewer than ten units* – Determine the total net weight of the exhibit by direct measurement of the contents of all units, either collectively or in subgroups.
2. *Ten or more units*:
   a. Determine the total net weight of the exhibit by direct measurement of the contents of all units, either collectively or in subgroups; OR
   b. Determine the total net weight by extrapolation as follows:
      i. Determine the net weight of nine randomly selected units (from each subgroup, if applicable) by direct measurement of the contents of each individual unit.
      ii. Determine the average net weight per unit.
      iii. Obtain the total net weight for the exhibit by multiplying the average weight per unit by the total number of units in the exhibit.

B. For solid dosage forms, the total number of units in the exhibit shall be determined as follows:

1. *Fewer than ten units* – Count and weigh all units, either collectively or in subgroups.
2. *Ten or more units*:
   a. Count and weigh all units, either collectively or in subgroups; OR
   b. Determine total unit count by extrapolation as follows:
      i. Determine the total net weight for the entire exhibit by direct measurement of all dosage units.
      ii. Determine the net weight of nine randomly selected dosage units (from each subgroup, if applicable) by direct measurement of each individual unit.
      iii. Determine the average weight per dosage unit.
      iv. Obtain the total number of dosage units in the exhibit by dividing the total net weight by the average weight per dosage unit.

C. For homogeneous liquids, the total net weight and volume for the exhibit shall be determined as follows:

1. *Fewer than ten units:*
   a. Determine the total net weight of the exhibit by direct measurement of the contents of all units, either collectively or in subgroups.
   b. Determine the density of the homogeneous liquid (after screening) by accurately weighing a minimum of 1.0 mL of the composite using class A volumetric glassware and an analytical balance.
   c. Determine the total net volume of the exhibit using the total net weight and density measurements.
2. *Ten or more units*:
   a. Determine the total net weight of the exhibit by direct measurement of the contents of all units, either collectively or in subgroups. Determine the total net volume for the exhibit using the density of the composite as directed in section I.C.1.b and c; OR
   b. Determine the total net weight and volume by extrapolation as follows:
      i. Determine the net weight of nine randomly selected units (from each subgroup, if applicable) by direct measurement of the contents of each individual unit.
      ii. Determine the average net weight per unit.
      iii. Obtain the total net weight for the exhibit by multiplying the average weight per unit by the total number of units in the exhibit.
      iv. Determine the total net volume for the exhibit using the density of the composite as directed in section I.C.1.b and c.

D. For biohazard exhibits, the determination of total net weight shall be performed as follows:

1. *One or two units* – Determine the total net weight of the exhibit by direct measurement of the contents of all units.
2. *More than two units*:
   a. Determine the total net weight by extrapolation as follows:
      i. Determine the net weight of *two* randomly selected units (from each subgroup, if applicable) by direct measurement of the contents of each individual unit. [Selection of two containers minimizes exposure to bio-hazardous material.]
      ii. Determine the average net weight per unit.
      iii. Obtain the total net weight for the exhibit by multiplying the average net weight per unit by the total number of units in the exhibit.

II. Units with uniform containers (packaging) but variable amounts of material (for example, uniform zip-lock bags containing variable amounts of solid, uniform vials containing variable amounts of liquid, and uniform envelopes containing variable amounts of powder):

A. For powders (mixtures of powders and materials), gummy samples, plant material and homogeneous liquids, the total net weight or volume for the exhibit shall be determined as follows:

1. *Fewer than ten units*:

a. For powders (mixtures of powders and materials), gummy samples and plant material, determine the total net weight of the exhibit as directed in section I.A.1.
b. For liquids, determine the total net weight and volume of the exhibit as directed in section I.C.1.

2. *Ten or more units*:
   a. Determine the total net weight of the exhibit by direct measurement of the contents of all units, either collectively or in subgroups. For liquids, determine the total net volume for the exhibit using the density of the composite as directed in section I.C.1.b and c. OR
   b. Determine the total net weight or volume by extrapolation as follows:
      i. Determine the total gross weight of the units by direct measurement of all units, either collectively or in subgroups.
      ii. Randomly select nine units (from each subgroup, if applicable), empty the contents, and determine the weight of each individual empty container or packaging material.
      iii. Determine the average weight per empty container or package.
      iv. Obtain the total weight of the empty containers or packaging materials by multiplying the average weight per container by the total number of units in the exhibit.
      v. Determine the total net weight of the exhibit by subtracting the total weight of the packaging material from the total gross weight for all units.
      vi. For liquids, the total net volume for the exhibit shall be determined using the density of the composite as directed in section I.C.1.b and c.

III. Uncertainty of measurement estimate (UME) determination for direct weighing cases.

A. When the net weight of an exhibit is obtained by direct measurement(s), the uncertainty associated with the total net weight (U_{NW}) shall be obtained by multiplying the combined weighing uncertainty (u_w) and a coverage factor (k) corresponding to a 95% confidence level (Equation 1). As a conservative estimate, all weighing quantities are to be treated as correlated measurements, and all combined net weight uncertainties will be calculated by linear addition of the standard uncertainties associated with each individual weighing event (Equation 2).

$$U_{NW} = u_w \times k \qquad \text{Equation 1}$$

where, $$u_w = u_1 + u_2 + u_3 + \ldots + u_n \qquad \text{Equation 2}$$

u_n = individual uncertainty of weighing event n

k = 2, for a 95% confidence level

1. Net weight determinations will, in most cases, require two weighing operations – the weighing of the container and the weighing of the container plus material. The uncertainty associated with each of these two weighing events must be considered. For example, for an exhibit containing one zip-lock plastic bag (ZPB) containing green plant material, the following measurements were obtained.

ZPB + material: 29.37 g

ZPB:	-1.56 g	Mass uncertainty (u_{mass})	0.02936 g
Total material:	27.81 g		

Based on two weighing events, the total net weight and uncertainty for the exhibit are:

Net weight $\pm U_{NW}$ $= 27.81 \pm (u_w \times k)$
$= 27.81 \text{ g} \pm (u_1 + u_2)(k)$
$= 27.81 \text{ g} \pm (0.02936 + 0.02936)(2) \text{ g}$
$= 27.81 \text{ g} \pm (0.11744) \text{ g}$
$= (27.8 \pm 0.1)$ g (see REPORTING UNCERTAINTY)

** Additional examples are included in Attachment 2.

IV. Uncertainty of measurement estimate (UME) determination for extrapolation cases.

A. When the total net weight of an exhibit is obtained by extrapolation, two sources of uncertainty must be considered, the uncertainty associated with the calculated average weight per unit (u_{avg}) and the uncertainty associated with all the weighing events (u_w) performed. The uncertainty contribution from the weighing events is determined using Equation 2 and the uncertainty associated with the calculated average weight per unit is determined using Equation 3.

$$u_{avg} = \frac{s}{\sqrt{n}} \qquad \text{Equation 3}$$

Where, s = sample standard deviation from individual weight measurements
n = number of units individually weighed

1. For example, for an exhibit containing 50 kilo-packages of suspected cocaine, the following 9 net weight measurements were obtained.

ZPB + material (g)	**ZPB** (g)	**Material** (g)	u_{mass} (g)
1011.4	19.1	992.3	
1018.2	19.0	999.2	
1007.6	19.6	988.0	
1015.9	20.2	995.7	
1019.0	20.0	999.0	0.3581
1016.4	19.4	997.0	
1012.5	18.3	994.2	
1019.6	18.4	1001.2	
1013.1	18.4	994.7	
Average weight per unit, $\bar{x}$		995.7 g	
Standard deviation, s		4.018 g	

Based on 18 correlated measurements, the uncertainty associated with the weighing events is:

$$u_w = (18)(0.3581\ \text{g}) = 6.4458\ \text{g}$$

The uncertainty associated with the average weight per unit is:

$$u_{avg} = \frac{s}{\sqrt{n}} = \frac{4.018\ g}{\sqrt{9}} = 1.3394\ \text{g}$$

The average net weight and combined uncertainty per unit are:

$$\text{Average NW} \pm u_c = 995.7\ \text{g} \pm (u_w + u_{avg})$$

$$= 995.7\ \text{g} \pm (6.4458 + 1.3394)\ \text{g}$$
$$= 995.7\ \text{g} \pm 7.7852\ \text{g}$$

The total extrapolated net weight and uncertainty for the exhibit are:

$$\text{Net weight} \pm U_{NW} = (50\ \text{units})(\text{Avg. NW} \pm u_c \cdot t_{95\%})$$
$$= (50\ \text{units})(995.7\ \text{g}) \pm (50\ \text{units})(7.7852\ \text{g})(2.306)$$
$$= (50\ \text{units})(995.7\ \text{g}) \pm (50\ \text{units})(17.9526\ \text{g})$$
$$= (49{,}785 \pm 897.63)\ \text{g}$$
$$= \mathbf{(49.78 \pm 0.90)\ kg} \quad \text{(see REPORTING UNCERTAINTY)}$$

(Coverage factor used is $t_{95\%} = 2.306$, corresponding to the Student's-t value for 8 (9-1) degrees of freedom at 95% confidence level)

** Additional examples are included in Attachment 2.

Acceptance criteria: For extrapolation cases, exhibit units are considered uniform (based on contents or container) if the relative standard deviation (RSD) obtained from the nine individual measurements performed is 10% or less. Final uncertainty values associated with net weight determinations are considered acceptable if the calculated relative uncertainty (U/NW) is 25% or less. If higher RSD or relative uncertainty values are obtained, alternative approaches to net weight determination should be pursued. For example, use of a higher precision balance, extrapolation by container instead of contents, weighing of units by groups of higher uniformity, etc. Analysts and supervisory personnel should evaluate these situations on a case by case basis.

V. Uncertainty of measurement estimate (UME) determination for the amount of pure drug.

A. The uncertainty associated with the amount of pure drug will be calculated by combining the standard relative uncertainties associated with net weight and purity using the root-sum-of-square (RSS) method for uncorrelated quantities. The total amount of pure drug (APD) and uncertainty will be obtained as follows:

$$\begin{aligned}
\text{APD} \pm U_{APD} &= \text{APD} \pm (u_{APD})(k) \\
&= \text{APD} \pm (\text{APD})\left(\frac{u_{APD}}{APD}\right)(k) \\
&= \text{APD} \pm (\text{APD})\left(u'_{APD}\right)(k) \\
&= \text{APD} \pm (\text{APD})\left(\sqrt{\left(u'_{NW}\right)^2 + \left(u'_{P}\right)^2}\right)(k)
\end{aligned}$$

Where u'_{APD}, u'_{NW}, and u'_{P} are the relative uncertainties associated with amount of pure drug, net weight, and purity, respectively.

1. For the 50 kilo-packages example above, the purity was determined to be 88.5%. An expanded uncertainty (U_P) of 3.3% is assigned using the DEA Laboratory System Uncertainty table for purity measurements (LS-09-004). The total amount of pure drug (APD) and uncertainty for the exhibit will be calculated as follows:

$$u'_{NW} = \left(\frac{u_{NW}}{NW}\right) = \left(\frac{(50\ units)(7.7852\ g)}{49785\ g}\right) = 0.007818821$$

$$u'_{P} = \left(\frac{u_P}{P}\right) = \left(\frac{(3.3\ \%)}{(2)(88.5\ \%)}\right) = 0.018644068$$

$$\begin{aligned}
\text{APD} \pm U_{APD} &= \text{APD} \pm (\text{APD})\left(\sqrt{\left(u'_{NW}\right)^2 + \left(u'_{P}\right)^2}\right)(k) \\
&= (49.785\ \text{kg})(88.5\%) \\
&\quad \pm (49.785\ \text{kg})(88.5\%)\left(\sqrt{(0.007818821)^2 + (0.018644068)^2}\right)(2) \\
&= 44.0597\ \text{kg} \pm (44.0597\ \text{kg})(0.020217201)(2) \\
&= 44.0597\ \text{kg} \pm 1.7815\ \text{kg} \\
&= \mathbf{(44.05 \pm 1.78)\ kg} \qquad \text{(see REPORTING UNCERTAINTY)}
\end{aligned}$$

** Attachment 1 (Uncertainty Calculator) provides a Microsoft® Excel worksheet that can be used for the calculation of all uncertainties associated with net weight, purity and amount of pure drug determinations.

REPORTING UNCERTAINTY:

All final net weight and uncertainty results must be reported on the front of the DEA-86 form and on the laboratory report. All final net weights will be truncated following DEA significant figure requirements (LOM 7302.53.B.7), and all final expanded uncertainty values will be rounded to at least one significant figure using conventional rounding rules. That is, a digit will be rounded down if followed by 0, 1, 2, 3 or 4; it will be rounded up if followed by 5, 6, 7, 8, or 9. Final net weights and uncertainties shall be reported to the same precision (same number of decimal places). For example, for the situation illustrated in section III.A.1 (ZPB containing green plant material), the total net weight and uncertainty obtained were (27.81 ± 0.11744) g.

Application of the DEA significant figure rules would result in a final reported value of (27.8 ± 0.1) g. For the example in section IV.A.1 (50 kilo-packages of suspected cocaine), the total net weight and uncertainty obtained were (49,785 ± 897.63) g. When reporting to 4 significant figures, the final result of (49.78 ± 0.90) kg is obtained.

When reporting uncertainty values, the following statement must be included in the "Remarks" section of the laboratory report (See LS-05-010 Attachment 1).

"The reported uncertainty values represent expanded uncertainty estimates at the 95% confidence level."

Final uncertainty estimates will be included in the laboratory report (or front of DEA-86) even if the final calculated value does not impact the reported net weight. For example, for the green plant material discussed above, if a higher-precision balance (0.001 g readability) is used and the measured values are (27.813 ± 0.0074) g, the result would be reported as (27.8 ± 0.007) g. In these situations, final uncertainty values shall be rounded to one significant figure and will result in the reporting of net weights and the uncertainties to different degrees of precision (different number of decimal places).

Total solid dosage unit counts and total volumes will be reported under the "Remarks" section of the laboratory report. Measurement uncertainty values associated with these quantities do not need to be reported on the front of the DEA-86 or included on the laboratory report. However, such values shall be made available if requested by law enforcement officials or attorneys. Examples of the calculation of uncertainties associated with total dosage unit count and total volume are included in Attachment 2.

NOTES:

1. System-wide mass uncertainty (u_{mass}) values were obtained using Equation 4, where u_{bal} is the maximum system-wide balance calibration uncertainty, and $u_{process}$ is the maximum system-wide process uncertainty obtained from the statistical evaluation of one year of monthly-calibration-check data.

$$u_{mass} = \sqrt{u_{bal}^2 + u_{process}^2} \qquad \text{Equation 4}$$

2. Minimum weight thresholds were obtained using Equation 5, where $k = 2$ corresponds to a 95% confidence level and u_{rel} is the relative uncertainty requirement of 1%, and u_{bal} is the maximum system-wide balance calibration uncertainty.

$$Min.\ weight = \frac{k}{u_{rel}}(u_{bal}) \qquad \text{Equation 5}$$

3. Procedures that deviate from the stated criteria shall be approved in advance by a supervisor.
4. The determination of individual weights is only necessary when the total net weight, volume or solid dosage unit count is to be determined by extrapolation.
5. Policy exception #1 – For 1B-K samples, the net weight may be obtained by weighing all samples and subtracting the extrapolated weight of *one* empty container.
6. Policy exception #2 – When extrapolating and combining the net weights of *two or more* subgroups of an exhibit, the opening and weighing of nine individual units per subgroup is not

necessary. With supervisory approval, analysts can obtain an extrapolated net weight for the subgroup using less than nine units. For these cases, it is recommended that the total number of units opened for net weight determination does not exceed the total number of units to be opened for screening.

7. Policy exception #3 – Uncertainty estimates are not required for laboratory submissions for which the net weight is not a relevant quantity. For example, signature analyses submitted to the Special Testing and Research Laboratory, 1A-K samples, etc.
8. When individual net weights from various subgroups (or exhibits) are combined to obtain a total net weight for an exhibit (or case), the total combined uncertainty will be determined by linear addition of the individual standard uncertainties associated with each individual net weight amount. Linear addition will also be used when determining the total combined uncertainty associated with the addition of amount of pure drug results from multiple exhibits.

DEFINITIONS:

Measurement uncertainty – Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand (1).

Standard uncertainty – measurement uncertainty expressed as a standard deviation (1).

Combined standard uncertainty, *u* – standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model. In case of correlations of input quantities in a measurement model, covariances must also be taken into account when calculating the combined standard measurement uncertainty (1).

Expanded uncertainty, *U* – product of a combined standard measurement uncertainty and a factor larger than the number one. The factor depends upon the type of probability distribution of the output quantity in a measurement model and on the selected coverage probability. The term 'factor' in this definition refers to a coverage factor (1).

Coverage factor – number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty. A coverage factor is usually symbolized *k* (1).

Uncorrelated measurements – independent measurements that are subject only to random sources of uncertainties. The uncertainty associated with the combination of uncorrelated measurements is obtained by the quadratic sum of the individual uncertainties (2,3).

Correlated measurements – measurements that are not independent of each other or that are dependent on a common third quantity. The uncertainty associated with the combination of correlated uncertainties is obtained by the linear sum of the individual uncertainties (2,3).

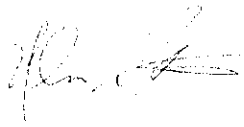
REFERENCES:

1. ISO/IEC Guide 99 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM), ISO/IEC, Geneva, 2007.
2. Drosg M. Dealing with Uncertainties – A Guide to Error Analysis. Berlin: Springer, 2007, Chapter 7, 91-104.
3. Taylor JR. An Introduction to Error Analysis – The Study of Uncertainties in Physical Measurements. Second Edition; Sausalito: University Science Books, 1997, Chapter 3, 57-62.

ADDITIONAL RESOURCES:

1. Uncertainty Monograph, DEA Basic Forensic Chemist Training Program.
2. Guideline on Representative Drug Sampling, European Network of Forensic Science Institutes (ENFSI) Drugs Working Group, 2003.

3. EURACHEM/CITAC Guide Quantifying Uncertainty In Analytical Measurement (Second Edition), EURACHEM Secretariat, BAM, Berlin, 2000.
4. Kirkup L, Frenkel B. An Introduction to Uncertainty in Measurement. Cambridge: Cambridge University Press, 2006.



Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

11/13/2009
Date

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-09-006**

ORDER

Classification Code
71, 7303, 7502, 7503

Date: May 14, 2009

SUBJECT: Facilities and Environmental Conditions

PURPOSE:
This laboratory system order establishes policy to ensure that appropriate environmental conditions are maintained to ensure correct performance of analytical testing.

BACKGROUND:
Environmental conditions, such as temperature and humidity, are recognized as factors that may negatively impact laboratory examinations. Maintenance of normal laboratory environmental conditions will minimize the influence these conditions can have on the quality of results. In general, the methods utilized to conduct forensic analysis in DEA laboratories are sufficiently rugged to withstand all but the most extreme variations in environmental conditions without affecting the quality of analytical results.

POLICY:
DEA laboratories will maintain environmental conditions that will provide for the correct performance of forensic analyses. If an analytical method is utilized that requires specific environmental conditions, appropriate documentation and monitoring will be maintained. Examinations will be stopped when environmental conditions compromise the quality of the results. Extreme care will be taken when sampling or examinations are undertaken at sites other than permanent laboratory facilities.

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

5/14/09
Date

Page 192 of 287

Withheld pursuant to exemption

(b)(7)(E)

of the Freedom of Information and Privacy Act

Page 193 of 287

Withheld pursuant to exemption

(b)(7)(E)

of the Freedom of Information and Privacy Act

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-09-009**

ORDER

Classification Code 7302.2

Date: 8/19/2009

SUBJECT: Receiving Evidence

PURPOSE:

This laboratory system order revises the "receiving evidence" procedures to ensure consistent acceptance criteria across the laboratory system for evidence submitted in the self-sealing plastic evidence bags.

BACKGROUND:

The change from heat-sealed evidence envelopes to self-sealed evidence envelopes (SSEE), and the associated changes in the Agents Manual (AM), have resulted in inconsistent interpretation and enforcement of the AM requirements among the laboratories. This has caused some confusion among the enforcement personnel when submitting evidence for analysis in the new SSEEs.

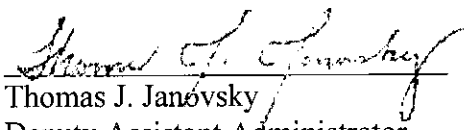
In order to ensure consistent acceptance criteria, LOM Section 7302.2 has been revised to define a proper seal and to delineate the minimum requirements for documentation on the evidence seal.

7302.2 RECEIVING EVIDENCE

Evidence technicians (ET), laboratory managers, or other personnel designated in writing by the laboratory director will process for receipt all evidence exhibits delivered to the laboratory. Only trash receptacles with self-closing lids will be placed in evidence receipt and processing areas. No trash receptacles of any type may be kept in the main vault. All shipping containers and wrapping paper must be carefully examined to ensure that all evidence has been removed prior to discarding the material.

A. All evidence must be properly sealed by the submitting SA, TFO or DI. **A proper seal prevents the loss, cross-transfer, or contamination while ensuring that attempted entry into the container is detectable. ~~in accordance with~~ Subchapter 666 ~~of the Agents Manual.~~ The evidence seal must contain, at a minimum, the initials of the submitting SA, TFO or DI under the seal.** Identifying labels must be affixed to all exhibits, with the following information provided:

1. Case number.
2. Exhibit number.
3. Date of acquisition (by seizure, purchase, taken into DEA custody, etc.).
4. Sealing official (sealing SA's, TFO's or DI's signature).
5. Witnessing official (witnessing SA's, TFO's or DI's signature).



Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

8/19/09
Date

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System | **Office of Forensic Sciences** | **LS-09-011**

ORDER

Classification Code
7305.53

Issue Date: November 13, 2009

SUBJECT: Procedures for Recording Weights and Unit Counts on the Forensic Chemist Worksheet (DEA 86 form)

PURPOSE:
This laboratory system order clarifies the format for recording "Net Weight" (Item 6), "Quantitative Results" (Item 10), and "Amount of Pure Drug" (Item 11) on the Forensic Chemist Worksheet to be consistent with the reporting requirements of LS-09-004, LS-09-005, and LS-05-010.

POLICY:
7302.53 Forensic Chemist Worksheet, DEA-86, and Continuation Worksheet, DEA-86a

A. Front of the Worksheet

The forensic chemist *must* write or print legibly in ink of permanent nature all required entries on the worksheet. This worksheet is used to record all raw data, observations, and calculations and *must* be written to permit adequate reconstruction of the analysis or examination performed (see LOH, Exhibit H-19). All observations, data, and calculations must be recorded at the time they are made and must be identifiable to the specific task. **All weights and quantitation results will be reported to the appropriate number of significant figures and in no case should a number be rounded up.** **For information on reporting of uncertainty of weights, review *LS-09-005 Determination of Net Weight and Uncertainty Measurement Estimates*.** No stamps are allowed on the form with the exception of those used to indicate the removal of material for a special program or the entry of data into STRIDE. Any corrections to the DEA-86 and or associated data must be in ink and made by an initialed single straight line strikeout. Any additions to examination documentation must be initialed by the person making the addition. Record information on the DEA-86 as follows:

1. Page _____ of _____. Complete as appropriate.

2. Item 1. From. Name of individual from whom the evidence is physically received by the examining forensic chemist.

3. Item 2. Date. The date the forensic chemist receives the evidence for analysis.

4. Item 3. Seals. Indicate the condition of seals as received.

5. Item 4. File No./Exhibit No./Lab No. As supplied by submitting *SA, TFO or DI* on the DEA-7 or from other transmittal documents, and Lab Number as assigned by the ET.

6. Item 5. Description of Evidence. A detailed description of the physical evidence, including containers, markings and other information. This should be written so that the evidence may be readily visualized by reading the description. The description should begin with the number and type of container(s) submitted, e.g., three (3) heat- sealed evidence envelopes, one (1) cardboard box, suitcase, etc., and end with the substance to be analyzed, e.g., powder, liquid, residue, etc.

7. Item 6. Summary of Findings. This space should contain a conclusion of laboratory analysis. Information necessary to complete the *appropriate reporting form* appears in this space, along with information in Items 7-12 (below). The placement of information should be as illustrated in LOH, Exhibit H-19. The net amount must be reported in units of weight, *followed by* any other appropriate units, e.g., volume, number of dosages units, etc.*, reported in parentheses*. If a portion of the evidence was removed for a special program, enter the notation, "__ grams (or __ tablets, etc.) removed for special program" into this block, accurately reflecting the amount of material removed. For bulk exhibits, in which the exhibit exceeds the threshold amount, a statement will be placed on the DEA-86 and *appropriate reporting form* indicating the amount pending destruction. (See LOM 7301.6G3). For bulk exhibits, in which the exhibit is from a non-DEA case and exceeds the threshold amount, a statement will be placed on the DEA-86 and *appropriate reporting form* indicating the amount separated in excess of threshold where applicable.

8. Item 7. Exhibit Number. Enter the exhibit number assigned by the submitting *SA, TFO or DI* or split exhibit number(s), as necessary.

9. Item 8. Laboratory Number. Same as found in Item 4.

10. Item 9. Active Drug Ingredient. *List controlled substance(s) identified. Also, list other substances(s) identified when quantitation is performed.* Include isomer and salt form, if identified.

11. Item 10. Quantitative Results. Strength, as determined *as a percent*, along with *amount per* unit (milligrams per tablet, etc.) *in parentheses, when appropriate*. For those exhibits not quantified (marijuana, *opium*, etc.) enter N/A.

12. Item 11. Amt. (Amount) of Pure Drug. Total amount of controlled substance in Item 9 (quantitative result*, as a percent.* (Item 10) multiplied by Net Weight (Item 6)). ** For those exhibits not quantified, enter N/A**.

13. Item 12. Reserve. Net weight of exhibit remaining after completion of analysis. The amount should be reported in the same units as in Item 6. For those exhibits over the threshold amount, the reserve is the entire remaining amount including the amount pending destruction.

14. Item 13. Reserve Evidence. A description of the reserve portion of the evidence, from the sample analyzed to the final container. Specifically address any major change that was

made to packaging (substitute container, etc.). For exhibits with multiple containers, indicate what identifying marks were placed on the containers, e.g., containers numbered X of X; containers(s) X marked for destruction above threshold, box(es) marked as representative sample, etc.

15. Item 14. Forensic Chemist's Signature. Self-explanatory.

16. Item 15. Date Reported. Date completed worksheet is forwarded for review.

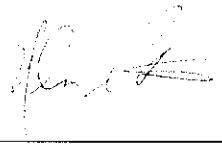
17. Item 16. Reviewed by (initials) and date. Supervisory review for completeness and scientific accuracy. Enter initials and date reviewed.

The technical reviewer in a forensic drug analysis is required to initial the DEA-86 or other worksheets. The initials of the technical reviewer on a DEA-86 or other worksheet will be interpreted as follows: After evaluating all reviewable data submitted with the DEA-86 or other worksheets, the technical reviewer agrees with the conclusions to include the identification of the controlled substance or other drugs as reported by the analyst.

The technical reviewer in a Digital Evidence analysis is required to initial the DEA-6 or alternate worksheets. The initials of the technical reviewer on a DEA-6 will be interpreted as follows: After evaluating all reviewable data submitted with the DEA-6 or other worksheets, the technical reviewer agrees with the conclusions as reported by the original examiner.

In those cases where a latent print identification has been made, the verifying examiner in the Fingerprint Program will evaluate all latent prints that were identified and the corresponding conclusions. The initials of the "verifier" on the reporting documents will be interpreted as follows: After evaluating all identified latent prints of the examination, the "verifying examiner" agrees with the conclusions as reported by the original examiner.

18. Item 17. Remarks. All other comments, including STRIDE codes for all substances identified.



Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

11/13/2009
Date

United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System

ORDER

LS-10-001

Classification Code
7400

Issue Date: January 19, 2010

SUBJECT: Transferring Laboratory Funds for the Procurement of Accountable Administrative Furniture and Equipment

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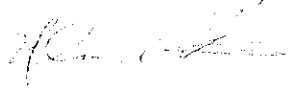
OBJECTIVE:
This laboratory system order (LSO) provides a threshold amount for funds that a laboratory may transfer from its operational account to an equipment account for the procurement of accountable administrative furniture and equipment.

BACKGROUND:
The prior federal financial management system used by the Drug Enforcement Administration (DEA) did not permit the transfer of funds from one office account to another office account without the assistance of the Office of Resource Management (FR). The new federal financial management system, Unified Financial Management System (UFMS), used by DEA, permits each laboratory to transfer funds from one account to another account without the assistance of FR. In order to ensure consistency, the Office of Forensic Sciences (SF) has set a threshold on the amount of funds which a laboratory may transfer from their operational account to an equipment account for the procurement of accountable administrative furniture and equipment in a fiscal year.

POLICY:
Laboratories may transfer funds from their operational account to an equipment account for the procurement of accountable administrative furniture and equipment. Laboratories must receive all approvals and concurrences from the Office of Administration, Property Management Unit (SAOP) and the Office of Information Systems (SI), as stated in the Property Management Handbook, before funds may be transferred to an equipment account. The maximum amount that a laboratory may transfer in one fiscal year is $10,000. Any amount over the $10,000 threshold must have the written authorization of the Associate Deputy Assistant Administrator or Deputy Assistant Administrator, Office of Forensic Sciences.



Nelson A. Santos
Acting Deputy Assistant Administrator
Office of Forensic Sciences

01/5/2010
Date

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-10-003**

ORDER

Classification Code
LOM 70

Issue Date: 06/04/2010

SUBJECT: Guiding Principles of Professional Responsibility

PURPOSE:

This laboratory system order provides guiding principles of ethical and professional responsibilities for the Drug Enforcement Administration (DEA) laboratory analysts and managers. While not all inclusive, the Guiding Principles of Professional Responsibility describe desired characteristics of expected behavior and shall supplement the DEA Standards of Conduct (Personnel Manual 2735).

RESPONSIBILITY:

The quality assurance manager or designee shall ensure that all laboratory analysts and managers (including technical support personnel who undergo proficiency testing) read and sign the Form LS-10-003, *Guiding Principles of Professional Responsibility*. This form shall be signed upon starting employment with DEA and during the annual performance appraisal process.

DISCUSSION:

These guiding principles are designed to promote integrity among practitioners and to increase public confidence in the quality of DEA laboratory services. They are intended to create a culture of ethical behavior and professional responsibility within the laboratory. The concepts presented in Form LS-10-003 have been drawn from other professional codes and suggestions made by leaders in the forensic community. It is important that all laboratory analysts and managers are aware of these guiding principles and support each other by incorporating the principles into their daily work.

GUIDING PRINCIPLES OF PROFESSIONAL RESPONSIBILITY

Professionalism

The ethical and professionally responsible forensic scientist and laboratory manager . . .

1. Are independent, impartial, detached, and objective, approaching all examinations with due diligence and an open mind.
2. Conduct full and fair examinations. Conclusions are based on the evidence and reference material relevant to the evidence, not on extraneous information, political pressure, or other outside influences.

3. Are aware of their limitations and only render conclusions that are within their area of expertise and about matters which they have given formal consideration.

4. Honestly communicate with all parties (the investigator, prosecutor, defense, and other expert witnesses) about all information relating to their analyses, when communications are permitted by law and agency practice.

5. Report to the appropriate legal or administrative authorities unethical, illegal, or scientifically questionable conduct of other laboratory employees or managers. Laboratory management will take appropriate action if there is potential for, or there has been, a miscarriage of justice due to circumstances that have come to light, incompetent practice or malpractice.

6. Report conflicts between their ethical/professional responsibilities and applicable agency policy, law, regulation, or other legal authority, and attempt to resolve them.

7. Do not accept or participate in any case on a contingency fee basis or in which they have any other personal or financial conflict of interest or an appearance of such a conflict.

Competency and Proficiency

The ethical and professionally responsible forensic scientist and laboratory manager . . .

8. Are committed to career-long learning in the forensic disciplines which they practice and stay abreast of new equipment and techniques while guarding against the misuse of methods that have not been validated. Conclusions and opinions are based on generally accepted tests and procedures.

9. Are properly trained and determined to be competent through testing prior to undertaking the examination of the evidence.

10. Honestly, fairly and objectively administer and complete regularly scheduled:
    - relevant proficiency tests;
    - comprehensive technical reviews of examiners' work;
    - verifications of conclusions.

11. Give utmost care to the treatment of any samples or items of potential evidentiary value to avoid tampering, adulteration, loss or unnecessary consumption.

12. Use appropriate controls and standards when conducting examinations and analyses.

Clear Communications

The ethical and professionally responsible forensic scientist and laboratory manager . . .

13. Accurately represent their education, training, experience, and area of expertise.

14. Present accurate and complete data in reports, testimony, publications and oral presentations.

15. Make and retain full, contemporaneous, clear and accurate records of all examinations and tests conducted, and conclusions drawn, in sufficient detail to allow meaningful review and assessment of the conclusions by an independent person competent in the field. Reports are prepared in which facts, opinions and interpretations are clearly distinguishable, and which clearly describe limitations on the methods, interpretations and opinions presented.

16. Do not alter reports or other records, or withhold information from reports for strategic or tactical litigation advantage.

17. Support sound scientific techniques and practices and do not use their positions to pressure an examiner or technician to arrive at conclusions or results that are not supported by data.

18. Testify to results obtained and conclusions reached only when they have confidence that the opinions are based on good scientific principles and methods. Opinions are to be stated so as to be clear in their meaning. Wording should not be such that inferences may be drawn which are not valid, or that slant the opinion to a particular direction.

19. Attempt to qualify their responses while testifying when asked a question with the requirement that a simple "yes" or "no" answer be given, if answering "yes" or "no" would be misleading to the judge or the jury.

REFERENCE:

ASCLD/LAB Guiding Principles of Professional Responsibility for Crime for Laboratories and Forensic Scientists. http://ascld-lab.org/about_us/guidingprinciples.html.

Nelson A. Santos
Deputy Assistant Administrator
Office of Forensic Sciences

06/04/2010
Date

Laboratory System **Office of Forensic Sciences** **LS-10-004**

ORDER

Classification Code
LOM 71

Issue Date: 06/04/2010

SUBJECT: Internal Audits and Management Reviews

PURPOSE:

This laboratory system order provides instructions for performing internal audits and management reviews.

RESPONSIBILITY:

The quality assurance manager (QAM) is responsible for all aspects of the laboratory's quality system. The QAM (or designee) shall conduct all internal system audits, and provide the laboratory director with the necessary documentation to conduct the management reviews.

INTERNAL AUDIT:

This procedure shall be utilized within the laboratory to annually audit and review all aspects of the quality system. It provides instructions to ensure compliance of all documented system requirements and the initiation of corrective and preventive actions as required.

The QAM (or designee) shall conduct an internal audit annually in accordance with ISO/IEC 17025 requirements using the DEA Assessment Checklist (Master List A Blank Forms). Internal quality audits are scheduled by the QAM, unless otherwise indicated. The audits include random samplings of records and documents, as well as observations of actual activities and functions ensuring compliance with laboratory policies and procedures. A written report of audit findings shall be maintained for ten years. Below is the procedure for conducting internal quality audits.

A. The management system shall be audited annually to ensure compliance with documented requirements. The QAM schedules these audits between January and December each year unless otherwise specified by the Office of Forensic Sciences. These audits shall be carried out by trained and qualified* personnel who are independent of the activity to be audited.

B. Annual audits shall be conducted on each section of the DEA Assessment Checklist and include a review of all requirements, procedures, and supplemental instructions. Audits should involve a random sampling of records and documents as well as a review of witnessed activities.

C. The observations of each audit or review shall be compared to documented policies and procedures to verify compliance. Results of the internal audit or review, and corrective

actions taken will be summarized and recorded in a written report as determined by the QAM and forwarded to the Office of Forensic Sciences.

D. When audit findings cast doubt on the effectiveness of the operations or on the correctness of validity of the laboratory's test results, the laboratory shall take timely corrective action in accordance with the laboratory's quality assurance laboratory order, and shall notify customers in writing if investigations show that the laboratory results have been affected.

E. The QAM shall verify and record the implementation and effectiveness of the corrective action taken.

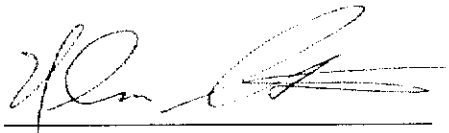
*Qualified personnel are employees that have participated in conducting management visits, inspections with the Office of Inspections, external evidence inventories or completed the ASCLD/LAB assessor training course. The Office of Forensic Sciences maintains a list of qualified personnel at: S:\Lab System\Information Exchange\General System Information\ASCLD-LAB Assessors & Management Activities

MANAGEMENT REVIEW:

The laboratory director (LD) shall conduct a management review annually in accordance with ISO/IEC 17025 requirements using the DEA Assessment Checklist. The purpose of this review is to ensure compliance with policies and procedures, the continuing suitability and effectiveness of the laboratory's management system and analytical processes, and to introduce necessary changes or improvements. A summary of such reviews must be documented in a written report as determined by the LD and forwarded to the Office of Forensic Sciences. The management review shall take into account the following:

- The suitability of policies and procedures
- Reports from managerial and supervisory personnel
- The outcome of recent internal audits
- Corrective and preventive actions
- Assessments by external bodies
- The results of proficiency tests
- Changes in the volume and type of the work
- Customer feedback
- Complaints
- Recommendations for improvement
- Other relevant factors, such as quality control activities, resources and staff training

All internal audit and management review documents shall be retained for a period of ten years and stored under DFN: 170-02.



Nelson A. Santos
Deputy Assistant Administrator
Office of Forensic Sciences

06/04/2010
Date

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System | **Office of Forensic Sciences** | **LS-10-005**

ORDER

Classification Code
7104, 7202, 7302.53

Issue Date: 06/04/2010

SUBJECT: Administrative and Technical Review Procedures for the Analysis of Controlled and Non-Controlled Substances

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PURPOSE:

This laboratory system order (LSO) establishes guidelines for the technical and administrative reviews of laboratory reports and supporting documentation pertaining to the analysis of controlled and non-controlled substances.

POLICY:

1. Technical Review

Every laboratory report, chemist worksheet, and supporting documentation submitted by a forensic chemist shall be technically reviewed by a supervisory chemist or designee prior to the administrative review. The technical review shall be in accordance with the following:

- Evidence descriptions and gross weight are complete and consistent with DEA-7 form or equivalent
- Observations and analyses are clearly and completely documented in accordance with laboratory policy
- Analytical techniques are appropriate and in accordance with the laboratory policy;
- Appropriate data and attachments are included (e.g., spectra, chromatograms, bulk photos, uncertainty calculations)
- All conclusions are supported by analytical data
- Mathematical calculations are accurate
- All documents are free of administrative or transfer errors and improper use of abbreviations

If a discrepancy is observed by the technical reviewer, the reviewer shall clearly communicate the discrepancy to the analyst and return the laboratory report and supporting documentation to the analyst for resolution. The analyst shall document any changes, as appropriate, per LOM 7302.53.

Once the technical review is complete, the reviewer shall document concurrence by initialing and dating the DEA-86 worksheet or equivalent (LOM 7302.53.A.17). After completion of the technical review, the laboratory report and all supporting documentation shall be forwarded for an administrative review.

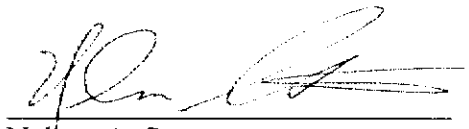
2. Administrative Review

Every laboratory report, chemist worksheet, and supporting documentation submitted by a forensic chemist shall be administratively reviewed by the laboratory director, associate laboratory director, or designee before the official report is released outside the laboratory. This review shall be in accordance with the following parameters:

- The technical review is complete and documented according to laboratory policy
- Case, exhibit, and laboratory number are properly documented
- The report is free of administrative or transfer errors and improper use of abbreviations

If a discrepancy is observed by the administrative reviewer, the reviewer shall clearly communicate the discrepancy to the technical reviewer and return the laboratory report and supporting documentation to the technical reviewer for resolution.

Once the administrative review is complete, the reviewer shall document concurrence by signing and dating the laboratory report (LS-05-010.D.16).



Nelson A. Santos
Deputy Assistant Administrator
Office of Forensic Sciences

06/04/2010
Date

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(b)(7)(E)

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-10-007**

ORDER

Classification Code
7314.12 C

Issue Date: 06/25/2010

SUBJECT: Verification of Drug Reference Materials

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1 **PURPOSE:** This laboratory system order establishes procedures for the verification of drug reference materials.

2 **INTRODUCTION:** Drug reference materials are pure substances that have been authenticated in accordance with the Special Testing and Research Laboratory's (SFL1) authentication procedures or purchased from reputable commercial sources. Verified reference materials are suitable for evidence analysis. While most drug reference materials are stable and their purity will not change over many years, verification of these materials must be performed on a scheduled basis to ensure that the reference materials' compositions and purities have not significantly changed from the authentication data generated by the SFL1 or the data of an approved reference materials source. This verification procedure may result in a revised purity value for the drug reference material.

3 **POLICY:**

3.1 Stock Drug Reference Material: Upon receipt and every three years, verification will be performed to ensure the material's composition and purity have not changed significantly from the most recent verification or authentication data.

3.2 Working Drug Reference Material: Shall be made available to analysts in amounts below 1.0 grams and shall be dispensed from a Stock Drug Reference Material source (lot) that has been verified within the previous three years. Working Drug Reference Materials used for quantitation shall be clearly labeled and distinguished from those used for qualitative analyses. Available working drug reference materials shall be restricted to those drugs which are commonly depleted within three years.

3.3 Exemption: Drug reference materials that are used infrequently, very expensive, or present in small amounts, are exempt from the three-year verification requirement. However, these reference materials shall be verified prior to use.

4 **SCOPE:** This policy includes all controlled substances, listed chemicals, and any other substances for which standards are used to verify identification or quantitation in a DEA laboratory report.

5 **STOCK DRUG REFERENCE MATERIALS:** Stock drug reference materials are the laboratory's authenticated and inventoried stock of drug substances which are not readily

available to the chemist staff (LOM 7314.12 D). Working drug reference materials are dispensed from this inventory.

5.1 Stock drug reference materials shall be obtained from commercial sources, SFL1's Authenticated Drug Reference Material Stockpile, or from another DEA laboratory.

5.2 Verification must be performed on stock drug reference materials prior to being dispensed as a working drug reference material for the purpose of qualitative or quantitative analysis.

5.3 Reference materials known to degrade, absorb water in their storage environment, or become otherwise unstable will be listed on the LS-10-007a form in the "Drug Reference Materials Known to Degrade" section (see example). The materials will be controlled by the reference materials monitor and not placed in the working drug reference materials inventory.

6 WORKING DRUG REFERENCE MATERIALS: Working drug reference materials are dispensed from stock drug reference materials that have been authenticated or verified within the last three years. Typically these materials are stored within the laboratory in-process vault and are made readily available to analysts.

6.1 Working drug reference materials shall be classified and clearly labeled as *quantitative* or *qualitative* materials. Working drug reference materials with purity values between 98.0% and 100.0% are acceptable for use in *quantitative* analyses. Reference materials with verified purities outside this range shall be used only for *qualitative* analyses, unless specifically authorized by the laboratory director (e.g., for rare or limited supply materials).

6.2 A list of working reference materials shall be maintained on the LS-10-007a form in the "Working Drug Reference Materials" section (see example).

7 PROCEDURES FOR THE VERIFICATION OF STOCK DRUG REFERENCE MATERIALS

7.1 QUALITATIVE VERIFICATION: The procedure for verifying identification of drug reference materials requires one confirmatory (i.e., MS, NMR, or IR) and one separation technique (i.e., CE, HPLC, UPLC, or GC). The verification data obtained must match the literature, most recent verification, or original authentication data. All unexpected reference material components present must be identified and explained.

7.1.1 SEPARATION TECHNIQUES: Separation techniques provide an indication of sample composition by providing a means to evaluate for possible multiple components. These tests must be appropriate for the sample and may include TLC, GC, LC, and CE. Some separation techniques may be interfaced with non-selective (presumptive) or selective (identification) detectors.

7.1.2 CONFIRMATION TECHNIQUES: Confirmation techniques provide distinctive structural information to identify a substance. A confirmation technique must be

appropriate for the sample and may include the following: IR, MS, Raman, or NMR spectroscopy. A confirmation technique can be interfaced with a separation technique (i.e., GC-MS, GC-IRD, or LC-MS). In addition, NMR, ESI/MS/MS or DESI/MS/MS may be used to evaluate samples for possible multi-component mixtures.

7.2 **QUANTITATIVE VERIFICATION:** The procedure for verifying quantitative values of drug reference materials used to report quantitative values requires one quantitative proton NMR experiment (unless the substance cannot be accurately quantitated by this method), and one separation area percent purity experiment. The separation technique shall include an instrument that is normally used to quantitate this compound. All unexpected reference material components present must be identified and explained.

7.2.1 **SEPARATION AREA PERCENT PURITY (SAPP):** To determine if any degradation products are present, a SAPP experiment using a quantitative separation technique (GC-FID, CE, HPLC, or UPLC) appropriate for this drug shall be performed. Area percent results will be compared to the original authentication or most recent verification data for that technique.

7.2.1.1 **GC-FID:** All peak areas in the chromatogram (not including the solvent front) are measured and the compound peak area is divided by the total area of all peaks to obtain an "area percent." This technique assumes that detected impurity peaks have the same response factors to those of the drug reference material. This technique does not detect some substances that could be present in the drug reference material (such as water, solvents, inorganic materials, or thermally labile compounds). This technique assumes that injection port artifacts are not produced.

7.2.1.2 **HPLC-UV or UPLC-UV or CE-UV:** The UV spectra of all peaks in the chromatogram are compared to the main analyte peak UV spectrum. If all the peaks' UV spectra are similar, then the "area percent" purity is determined using the most sensitive UV wavelength (i.e., the analyte UV wavelength maximum). If the UV spectra of all sample components are not similar, "area percent" purity cannot be calculated and only a note mentioning the number of peaks present in the chromatogram can be made. This technique does not detect substances such as water, solvents, inorganic materials, or compounds with very weak or no chromophores.

7.2.2 **QUANTITATIVE PROTON NMR (qHNMR):** Purity is verified by analyzing three (if sample quantity allows) accurately weighed samples of the reference material using a validated qHNMR method. The following will be performed:

7.2.2.1 The quantitative solutions must be visually inspected to ensure the absence of any insolubles. If the sample is not completely soluble, the solubility will be calculated and concentrations at 70% or below the solubility limit will be prepared and used for verifying purity.

7.2.2.2 The spectra are acquired and processed using a validated qNMR method. All acceptable analyte peak groups[1] and the internal standard peak are integrated and used to calculate purity values. Outlier purity results are identified. All non-outlier results will be averaged for the experimental purity. Normally, all integral results are used for high purity drug reference materials. At least one usable integral must be present in order to obtain an accurate quantitative value. The molecular weight used in the purity calculations must be that of the formula of the material, which includes its salt form and hydrate form, if any.

7.2.2.3 The average of all experimental purities is used for the final qHNMR purity.

7.2.3 ACCEPTABLE PURITIES: The SAPP and qHNMR purities obtained must be between 98.0-100.0%. If the SAPP purity falls outside of this range, the reasons must be explained. If the qHNMR purity is outside this range, then one of the following must be performed:

7.2.3.1 Additional qHNMR (7.2.2) experiments shall be performed to establish that earlier results were outliers (e.g., error from balance, pipette, or solubility). Average the three qHNMR purity results to establish a new purity value.

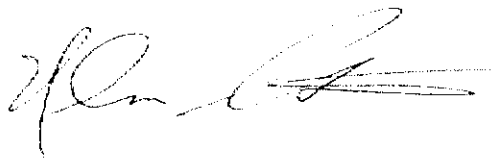
7.2.3.2 If the new purity value is outside of the 98-100% range then the laboratory director may authorize the use of the reference material at this new purity level.

7.2.3.3 If the purity value is not in the accepted range, the reference material is removed and dried or purified. If this is done then the entire verification process shall be performed again.

8 DOCUMENTATION: The laboratory must maintain all authentication and verification data for each Drug Reference Material for a minimum of three years from the date of consumption.

Such data shall include:

- Completed Form LS-10-007 (b)(7)(E)
- Authentication data provided by SFL1, if applicable
- Authentication data provided by commercial source, if applicable
- All laboratory generated verification data to include: SAPP and purification data



06/25/2010

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Office of Forensic Sciences

Date

[1] Acceptable peak groups are those whose integral values do not change over time due to decomposition or chemical exchange, whose integral is not too wide, and whose integral does not contain known impurity or solvent signals.

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System | **Office of Forensic Sciences** | **LS-10-008**

ORDER

Classification Code
7006.2, Exhibit H-01

Issue Date: 07/12/2010

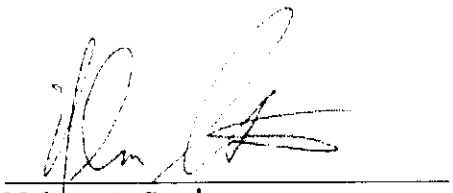
SUBJECT: Laboratory Monthly Report

PURPOSE:
This laboratory system order (LSO) revises the reporting requirements of the Laboratory Monthly Report. This LSO is effective immediately and will be incorporated into the next version of the Laboratory Operations Manual (LOM).

BACKGROUND:
Previous submissions of the Laboratory Monthly Report contained incremental changes that affected standardized reporting to the Office of Forensic Sciences (SF). In accordance with LOM 7006.2, SF is responsible for the establishment and dissemination of reporting formats. To restore consistency and ensure relevancy in the reporting of laboratory accomplishments, SF has revised the format of the Laboratory Monthly Report (H-01A (SFL1) and H-01B (SFL2-SFL9)) and Attachment 1, Bulk Drug Seizures by Division.

POLICY:
7006.2 LABORATORY MONTHLY REPORT. This report summarizes accomplishments of the DEA laboratories in important areas. Laboratory Directors are responsible for preparing reports for their facilities **according to the format approved by SF.** SF is responsible for establishing and disseminating the format for these reports and for reviewing submissions (Laboratory Operations Handbook, Exhibit H-01A and H-01B). The report is due by the 7th of each month following the month of the laboratories' accomplishments. If the 7th falls on a Saturday or Sunday the report is due on the next business day. **Deviations from these formats must be approved by the deputy assistant administrator, SF**

These changes will result in the discontinuation of § 7307.43 and Exhibit H-24.



Nelson A. Santos
Deputy Assistant Administrator
Office of Forensic Sciences

07/12/2010
Date

Distribution: SFD, SFE, SFL, SFS, SFQ, All Laboratory Directors

Initiated By: SFL

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-10-010**

ORDER

Classification Code
7312

Issue Date: 7/26/2010

SUBJECT: Policy Revision – Canine Training Materials Program

PURPOSE:
This laboratory system order revises section 7312 of the Laboratory Operations Manual (LOM) and provides policy regarding the handling of controlled substances for the Canine Training Materials Program. These changes are effective immediately and will be included in the next edition of the LOM.

POLICY:
The following revisions, marked in red, supersede the current policy and procedures in section 7312 of the LOM.

7312.1 THE CANINE TRAINING MATERIAL PROGRAM

7312.11 Responsibilities

The *laboratory* director of the Special Testing and Research Laboratory (SFL1) must designate canine training material officers, in writing, who will have the responsibility to maintain the controlled substances utilized by the laboratory for canine training. The laboratory director will designate, in writing, one canine training material officer as the program lead. The canine training material officers will be responsible for the following:

A. Receipt, storage, and distribution of canine training materials.

B. Originating requests for disposal of canine training materials.

C. Originating and maintaining detailed records of transactions.

D. Maintaining an accurate balance of each controlled substance in the canine training material stockpile.

(b)(7)(E)

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(b)(7)(E)

7312.14 Storage of Stock Canine Training Materials

(b)(7)(E)

All stored items must be identified and maintained in a sealed condition. Any transfer of materials to or from the stockpile, including creating individual training samples, must be witnessed. The canine stockpile will be maintained separately from all other stockpiles (reference materials, etc.).

7312.15 Preparation of Samples for Distribution

Canine samples will be prepared from the stock supply. These samples will be placed into suitable containers, uniquely labeled (e.g., K9CH-03-001, K9MH-03-001, etc.), and placed into a plastic sealed evidence envelope (PSEE). (b)(7)(E)

7312.16 Processing Requests for Canine Training Material

A. Canine training materials will only be provided to law enforcement agencies. The request must be in writing on agency letterhead from a public law enforcement agency and be signed with an original signature by the sheriff, chief of police or person with an equivalent rank. Under no circumstances will requests directly from commercial dog handlers be accommodated. Commercial dog handlers may request canine training materials from their local law enforcement agencies.

B. The requestor must be a DEA Registrant.

C. The request must be made using a DEA-222 and in accordance with DEA regulations. The request may be accompanied by a copy of the registrant's current registration form, DEA-223, Certificate of Registration. If the DEA-223 is not received, the canine training materials officer(s) will verify registration using the Office of Diversion Control's Registrant Information Consolidation System (RICS) database.

D. For all requests for canine training materials, the original letter of request, the DEA-222 and a memorandum from SFL1 requesting concurrence must be forwarded to the SAC or his or her designee of the DEA division office from where the request originated (with a copy to the division's Diversion Program Manager) for review and concurrence. SFL1's request for concurrence must specifically ask that the request be reviewed to ensure that:

1. the requestor's Registration Number is valid.

2. the registrant is authorized to handle the specific drugs and amounts requested.
3. the individual who signed the DEA-222 is authorized to do so.

E. Not more than 28 grams of any one drug may be provided to a law enforcement agency unless the agency is redistributing the controlled substances to agency sub-units located at different addresses. Requests for up to 400 grams require approval in writing from the laboratory director of SFL1. These requests may be approved if the law enforcement entity is to redistribute the supply to agency subunits or other law enforcement agencies within the state. Requests for greater amounts may be approved by the deputy assistant administrator, Office of Forensic Sciences (SF), on a case by case basis, when accompanied by a signed Memorandum of Agreement (MOA) between the requesting agency and their division office. The laboratory director, SFL1, will evaluate such requests and forward them to SF for concurrence along with his or her recommendation and appropriate justification.

F. Requests for replacement material will be considered only if 12 months have elapsed since the preceding request was filled.

G. The laboratory director will not authorize subsequent requests unless appropriate documentation indicating destruction or permanent relinquishment of custody is received for materials previously provided.

H. Should a request be received that cannot be satisfied, the laboratory director will notify the requestor that the material is not available. If requested materials are not available at the time the request is received but are expected to become available in the near future, the requesting agency may be advised that the request will be held until it can be filled. Alternatively, the request may be returned to the agency for resubmission at a later date.

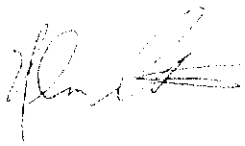
I. Requests for canine training material from foreign countries will not be honored.

(b)(7)(E)

7312.18 Inventory and Disposal of Canine Training Materials

During January of each year, or after changes in personnel responsible for administering the program, a supervisor and one other individual without access to the canine training materials will inventory all contents of the canine training material stockpile and reconcile the inventory against the program records. A memorandum stating the inventory has been completed will be

forwarded to SF no later than the last day of January of each year (or as needed). Any discrepancies must be immediately investigated. If the discrepancy cannot be immediately resolved, OPR and SF must be notified. During the inventory and at other times during the year, any materials that are no longer needed for the program will be identified and destroyed in accordance with LOM 7317. Transfer of canine training materials for destruction from the canine training material officer(s) to the destruction officer will be documented on a DEA-12, with copies maintained in the stockpile file.



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07/26/2010
Date

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-10-012**

ORDER

Classification Code
LOM 7302.2, 7302.5

Issue Date: 08/13/2010

SUBJECT: Receiving Evidence II

PURPOSE:
To replace and supersede procedures detailed in Laboratory Operations Manual 7302.2.B and 7302.51.

POLICY:
7302.2 RECEIVING EVIDENCE

B. Evidence received will be carefully checked against the DEA-7 for accuracy and completeness. Evidence received with problems will not be routinely returned to the submitting office. Efforts must be made to resolve the problems through e-mail or memoranda to the submitting SA, TFO, DI or group supervisor. Entries should not be made in Laboratory Evidence Management System (LEMS) or System To Retrieve Information from Drug Evidence (STRIDE) until the problems are resolved. The evidence must be stored in the vault, segregated from other evidence and documented in a special bound logbook for this purpose. Entries in the logbook must contain dates, identifying information, a description of the evidence, gross weight, and notes documenting communication with the submitting office or agency. Once the problems are resolved, the evidence should be officially received into the laboratory (see LOM 7302.51), and the bound logbook should be annotated to indicate resolution of the problem. If a particular problem is not resolved within 14 days the evidence must be returned to the submitting office or agency with an explanatory memorandum.

7302.5 PREPARING AND MAINTAINING LABORATORY RECORDS

7302.51 Laboratory Evidence Management System (LEMS) and Laboratory Index Book

Within one (1) business day of receipt in the laboratory or within one day of resolving problems with submitted evidence (see LOM 7302.2.B), the ET or other personnel designated in writing by the Laboratory Director will create a record of evidence in LEMS. LEMS will be maintained in such a manner as to accurately reflect the exact location and the correct number of units for each exhibit received by the laboratory. Only one (1) LEMS unit label may be used per evidence container. Multiple LEMS unit labels may not be placed on a single piece of evidence. LEMS will also be utilized to account for special program exemplars and proficiency test samples. LEMS will not be used to account for other non-evidentiary accountable controlled substances stored by the laboratory.

Nelson A. Santos
Deputy Assistant Administrator
Office of Forensic Sciences

08/13/2010
Date

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-10-013**

ORDER

Classification Code
7302.57

Issue Date: 08/30/2010

SUBJECT: Laboratory Case File

PURPOSE:
This laboratory system order revises LOM 7302.57 in order to clarify the requirements for maintaining documents in laboratory case files.

POLICY:

7302.57 Laboratory: Case File

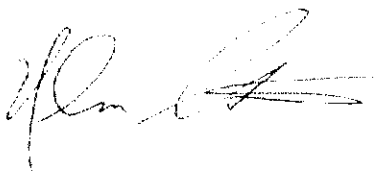
A. The following documents shall be maintained in the laboratory case file for DEA cases, as applicable:

1. The original DEA-48
2. For exhibits whose net weight exceeds threshold amounts specified in LOH, Appendix HA-1, transmittals from the SAC notifying the appropriate United States Attorney or the responsible state/local prosecutor of destruction procedures, as well as any additional response or appeals of same.
3. DEA-12 or documentation of delivery to U.S. Postal Service or other official carrier (see LOM 7303.5).
4. A copy of the DEA-7
5. Laboratory Report
6. DEA-86, original, and DEA-86a
7. DEA-7a and DEA-7b
8. Any required source determination reports
9. Pertinent analytical material, e.g., charts, graphs, etc.
10. Any investigative photographs and/or negatives
11. The DEA-466
12. A copy of the *Latent Print* Report
13. Digital records
14. A copy of the DEA-500 and DEA-6 from clandestine laboratory investigations
15. All documentation, including but not limited to, handwritten notes and observations, hardcopies of computer generated notes, photographs, sketches, or diagrams generated by laboratory personnel from an investigation outside of the laboratory including crime scenes.
16. Copies of clandestine laboratory investigation documents such as defendant personal notes and synthesis notes.
17. **Printed copies of any communication (e.g., e-mails) regarding chain of custody or case-related communications with case agents or prosecutors.**

18. Administrative documentation identified with a unique identifier. If bound, the unique identifier should only be on the front page.

B. The following documents shall be maintained in the laboratory case file for other enforcement agency cases, as applicable:

1. DEA-12, one copy or documentation of delivery to U.S. Postal Service or other official carrier (see LOM 7303.5).
2. DEA-7 or letter requesting analysis
3. Laboratory Report, one copy
4. DEA-86, and DEA-86a
5. Any required source determination reports
6. Pertinent analytical material, e.g., charts, graphs, etc.
7. The DEA-466
8. A copy of the *Latent Print* Report
9. **Printed copies of any communication (e.g., e-mails) regarding chain of custody or case-related communications with case agents or prosecutors.**



08/30/2010

Nelson A. Santos
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Date

United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System
ORDER

LS-08-004

Classification Code

Date: August 12, 2008

SUBJECT: Electronic Dissemination of Analytical and Evidence Destruction Reports

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OBJECTIVE:
This laboratory system order establishes policy for the electronic dissemination of analytical results (e.g., LS-05-010) and evidence destruction reports (DEA-48s) for DEA evidence. This order applies to the Regional Laboratories (SFL 2-8) and Sub-Regional Laboratories. This order does not apply to the Special Testing and Research Laboratory (SFL1) or the Digital Evidence Laboratory (SFL9).

BACKGROUND:
The DEA Laboratory System is responsible for ensuring that Special Agents, Task Force Officers and Diversion Investigators receive analytical results and evidence destruction documentation in a timely manner. By utilizing the technology available through Firebird, the Laboratory System is able to provide electronic documentation to customers in a manner that is more efficient and effective than routinely issuing hard copies of the reports.

POLICY:
In accordance with existing policy, analytical results and evidence destruction reports must be reviewed and authorized prior to dissemination. The following procedure describes the process of electronically scanning, disseminating and maintaining analytical results and evidence destruction documentation. At this time, the policy only applies to DEA evidence.

1) To ensure that reports are disseminated to the appropriate individual, the case agent of record must be identified/verified (b)(7)(E)

2) Reports will be scanned as Adobe PDF documents, ensuring scan settings are set to minimize file size (e.g., approximately 50 Kb per page). Files will be saved with case and exhibit notation (e.g., MN-08-0022_1-3 and MN-08-0022_1-3FP for fingerprint evidence) and stored in a temporary location on the laboratory's share drive pending email dissemination via Firebird.

3) The electronic version of the report will be disseminated via Firebird email to the case agent of record. The following statement, indicating the purpose of the communication, will be included in the body of the message:

> "In an effort to provide completed reports in a more efficient manner, the Laboratory System has established a program wherein the results of analysis and evidence destruction reports are scanned and disseminated via email. You are receiving this message because you are the case agent on record. **Please print a copy of the report for your case file and forward the message to your respective investigative assistant or other personnel as appropriate.** Note that no other copy will be mailed separately and the original report will be maintained at the laboratory."

4) A "sent" copy of the reporting email must be printed and filed with the original laboratory report in the corresponding case file. Once the "sent" copy has been filed, the electronic copy may be deleted. Laboratories are not required to maintain archived PDF copies of the reports.

5) If the original report is requested by the case agent, a copy will be made for the case file and the original report disseminated to the requesting customer.

6) Laboratories will continue to send hard copies of analytical reports and DEA-48s to the Investigative Records Unit (SARI) in accordance with LOM 7302.54 and 7304.23.B.

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8/19/08
Date

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-08-007**

ORDER

Classification Code
73

Date: August 12, 2008

SUBJECT: Discontinued Use of DEA-307 Cards

OBJECTIVE:

This laboratory system order (LSO) revises current policy by removing redundancies from the evidence accountability process through the elimination of the use of DEA-307 cards. The revisions documented in this LSO are effective immediately and will be included in the next edition of the Laboratory Operations Manual (LOM), the Fingerprint/Photography Program Handbook (FPH), and the System to Retrieve Information from Drug Evidence (STRIDE) Handbook.

BACKGROUND:

The South Central Laboratory (SFL6) conducted a six-month pilot study to determine whether the elimination of DEA-307 cards would adversely affect the accountability of evidence. The pilot study commenced on August 13, 2007, and concluded on March 24, 2008. During this period, routine daily evidence transactions, evidence destructions, and an external evidence inventory were conducted at SFL6 without the use of DEA-307 cards. No evidence accountability issues arose during this time period. Additionally, all evidence was accounted for during the external evidence inventory performed January 6 – 11, 2008.

POLICY:

As a result of the study's findings, DEA-307 cards will no longer be used in the laboratory to document evidence transactions. The laboratories will continue to use the Laboratory Index Book, LEMS, STRIDE, and all other evidence accountability forms in accordance with current policy. As noted above, all references to the DEA-307 card will be removed from existing policy in upcoming revisions.

In the event that LEMS is non-operational, evidence transactions will be recorded in a bound logbook, dedicated for this purpose. The following information must be recorded in the logbook:
1. Date of the transaction
2. Case number, exhibit number, laboratory number (including the unit number)
3. Initials of the individuals involved in the evidence transfer in the appropriate "To" and "From" columns (If the evidence is transferred "To" or "From" another agency, the name of the agency will be recorded in the appropriate column.)
4. The type of transaction (i.e., out to chemist, out to court, etc.)
5. Date the transaction was recorded in LEMS

The transactions recorded in the logbook will be recorded in LEMS within two business days of LEMS returning to an operational status.

Immediately upon implementation of this policy, all existing DEA-307 cards must be stamped with the following annotation:

"As of _____, this document is obsolete. Refer
(Date)
to LEMS for a complete evidence transaction history."

The DEA-307 cards will be placed in their corresponding case files either immediately following annotation, or during the destruction process.

Thomas J. Janovsky
Deputy Assistant Administrator
Office of Forensic Sciences

8/25/04
Date

United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System

ORDER

LS-08-008

Classification Code

Date: August 12, 2008

SUBJECT: Giglio Disclosure Policy

OBJECTIVE:
This laboratory system order establishes policy and provides guidance for disclosing potential impeachment information regarding witnesses expected to testify on behalf of the Government. This order applies only to those witnesses that have been notified as having information that must be disclosed.

BACKGROUND:
The Government has an obligation pursuant to *Brady v. Maryland*, 373 U.S. 83, 87 (1963), *Giglio v. the United States*, 405 U.S. 150 (1972), and its progeny, to disclose potential impeachment information regarding witnesses expected to testify on behalf of the Government. This obligation exists with respect to criminal proceedings occurring in both State and Federal courts. See *Strickler v. Greene*, 527 U.S. 263, 280 (1999) (setting forth the requirements for Brady violation and observing that a prosecutor has a duty to obtain favorable evidence from law enforcement entities acting on behalf of the Government, relying on case law arising from both State and Federal criminal proceedings).

POLICY:
To fulfill this disclosure obligation, employees identified as having potential impeachment information are hereby directed as follows:

1. Immediately upon formal or informal notification that you will be called to testify in any State or Federal criminal proceeding, you must advise your supervisor in writing (an electronic mail message is sufficient) of the name of the court case, the name and office telephone number of the responsible prosecutor, and the anticipated date, time and location of the requested testimony. Additionally, if you have been asked to provide an affidavit or declaration for a State or Federal criminal proceeding, you will notify your supervisor in writing when the affidavit/declaration is due to the responsible prosecutor.

2. Immediately upon formal or informal notification that you will be called to testify or provide an affidavit or declaration in any State or Federal criminal proceeding, you must advise the responsible State or Federal prosecutor:

   a. of any potential impeachment information concerning you.

   b. that he/she may request that the Drug Enforcement Administration disclose to him/her any potential impeachment information concerning you, by forwarding a written request to:

      Chief
      Domestic Criminal Law Section
      Office of Chief Counsel
      Drug Enforcement Administration
      Washington, D.C. 20537
      Phone: 202-307-8030
      Fax: 202-307-8046

Witnesses must comply with the above directives unless notified in writing that their compliance is no longer required. Any questions regarding the above information should be directed to your immediate supervisor.

Thomas J. Jonnasky

Thomas J. Jonnasky
Deputy Assistant Administrator
Office of Forensic Sciences

8/13/08
Date

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United States Department of Justice
Drug Enforcement Administration
Office of Forensic Sciences

Laboratory System

ORDER

LS-10-009

Classification Code
73

Issue Date: 07/12/2010

SUBJECT: Discontinued Use of the Laboratory Index Book

PURPOSE:
This laboratory system order (LSO) removes redundancies from the evidence receipt process by eliminating the requirement to maintain a record of evidence in an index book. The revisions documented in this LSO are effective immediately and will be included in the next edition of the Laboratory Operations Manual (LOM), the Fingerprint/Photography Program Handbook (FPH), and the System to Retrieve Information from Drug Evidence (STRIDE) Handbook.

POLICY:
Laboratory index books will no longer be used as an official record of evidence received by the laboratory. Laboratories will continue to use the Laboratory Evidence Management System (LEMS), STRIDE, and all evidence accountability forms (e.g. Form DEA-7) as official records of evidence received, in accordance with current policy. As noted above, all references to the laboratory index book will be removed from existing policy in upcoming revisions.

Laboratory index books currently in use will be retained in accordance with LOM 7302.59C.

Nelson A. Santos
Deputy Assistant Administrator
Office of Forensic Sciences

July 12, 2010
Date

Distribution: SFD, SFE, SFL, SFS, SFQ, All Laboratory Directors
Initiated by: SF

FORM DEA -42 (7-00)

LS-10-009

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Laboratory System **Office of Forensic Sciences** **LS-09-010**

ORDER

Classification Code

Issue Date: 01/19/2010

SUBJECT: Payment of Expenses for Professional Certification

PURPOSE:

This laboratory system order (LSO) establishes policy for payment of expenses associated with individual certification for forensic chemists, fingerprint specialists, and forensic information technology (IT) specialists. The policy documented in this LSO is effective immediately and will be reviewed and revised with updated cost estimates each fiscal year.

BACKGROUND:

The Drug Enforcement Administration (DEA) recognizes the importance of technical competence in laboratory analyses and supports laboratory accreditation and individual certification for forensic chemists, fingerprint specialists, and forensic IT specialists. The scientific community likewise acknowledges the importance of quality and credibility within the forensic science discipline. A recommendation cited in the February 2009 National Academy of Sciences (NAS) report, "Strengthening Forensic Science in the United States: A Path Forward," calls for the mandatory certification of all forensic science professionals. Although not currently mandatory, individual certification is encouraged as providing a means of acknowledging professional competency and reinforcing expert witness qualifications. In addition, DEA recognizes the significance of certification as it pertains to the continuing education and professional growth of its employees. In order to further these goals, DEA has made funding available in accordance with the Department of Justice (DOJ) Human Resources Order 1200.1, Chapter 5-2 and United States Code, 5 U.S.C. § 5757(a) to finance the certification of forensic chemists, fingerprint specialists, and forensic IT specialists.

POLICY:

The following procedure describes the requirements for payment of expenses associated with individual certification.

1. All forensic chemists who meet the following criteria may request payment of expenses for certification:
    a. possess at least two years of full time experience in the practice of forensic drug analysis
    b. are actively working in the area of forensic drug analysis
    c. possess, at a minimum, a baccalaureate degree, or equivalent, in a natural science or appropriately related field from an accredited institution

2. All fingerprint specialists who meet the following criteria may request payment of expenses for certification:
    a. possess at least two years of full time experience in the practice of latent fingerprint examinations
    b. are actively working in the area of latent fingerprint examination
    c. possess, at a minimum, a baccalaureate degree plus two years of full time experience, or an associate degree plus three years of full time experience, or four years of full time experience
    d. have completed a minimum 80 hours of certification board approved training in latent fingerprint matters

3. All digital evidence examiners who meet the following criteria may request for payment of expenses for certification:
    a. possess at least five years of full time experience in the practice of digital evidence examinations
    b. are actively working in the area of digital evidence examination

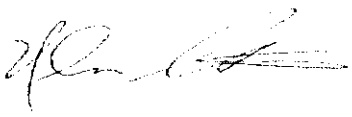
4. Certification may only be obtained from a recognized certification body, such as the American Board of Criminalistics (ABC), the International Association for Identification (IAI), or the Digital Forensics Certification Board (DFCB). No internal federal government entity exists that can provide equivalent certification.

5. Employees wishing to obtain payment for certification must submit a memorandum to their supervisor, outlining the specific certification and provider, application and examination fee, location and date of examination, and estimated cost of travel to and from the examination location (if applicable). A Requisition for Equipment, Supplies, or Services (DEA-19) and Official Travel Request (DOJ-501), if applicable, must be attached to the memorandum. Final approval will be granted by the laboratory director or designee.

6. Laboratory directors will use operational funds to pay for application fees, examination fees, costs associated with employee travel to and from the testing location, and annual ~~proficiency test~~ maintenance fees, if applicable. Every effort must be made to ensure that employees attend examination offerings in their regional area.

7. If an employee fails the certification examination, they will not be eligible for payment of expenses for any subsequent certification examinations unless they have completed a mandatory six month study period following the most recent failed examination.

Laboratory directors are advised that the certification cost estimate for fiscal year (FY) 2010 is approximately $300 per chemist, $150 per fingerprint specialist, and ~~$350~~ $450 per digital examiner for the examination/application/maintenance fees. Additional travel costs will depend upon test availability and proximity to the DEA laboratories. Based on a 75% participation rate for forensic chemists and forensic IT specialists and a 25% participation rate for fingerprint specialists, it is estimated that the laboratory system will spend approximately $85,000 for the certification of forensic professionals in FY 2010.



Nelson A. Santos
Acting Deputy Assistant Administrator
Office of Forensic Sciences

01/15/2010
Date

Diversion Investigators Manual

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DEA SENSITIVE
This manual is the property of the Drug Enforcement Administration. Neither it nor its contents may be disseminated outside the DEA without the express permission of the Office of Chief Counsel.

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

DIVERSION INVESTIGATORS MANUAL

SUPPLEMENTAL TRANSMITTAL

DATE: 9/20/2011
TRANSMITTAL NUMBER: FY11-1

TABLE OF CHANGES

Remove	Identification Date	Insert	Explanation of Changes
Subchapters 511-512	4/28/2010	Table of Contents	Subchapter 517 is reserved.
Subchapter 513	1/22/2010	Subchapters 511-516	Circulation for Subchapters 519 and 520 is now complete.
Subchapters 514-516	5/17/2010	Subchapter 518-520	
Subchapter 517	4/16/1996		
Subchapter 518	5/17/2010		Chapter 51, in its entirety, embraces the new policies and procedures following the passage of new laws and regulations.
Subchapters 519-520	4/16/1996		
			This is the first transmittal for FY 2011. The last transmittal was TR-10-4.

(b)(6)

Chief of Operations

DISTRIBUTION: H-1, 2, 3C.3D, 4, 5
F-1 THROUGH 7

DIVERSION INVESTIGATORS MANUAL

SUPPLEMENTAL TRANSMITTAL

DATE: 10/03/2011
TRANSMITTAL NUMBER: TR-12-1

TABLE OF CHANGES

Remove	Identification Date	Insert	Explanation of Changes
Subchapter 521	4/16/96	Table of Contents	Subchapters 521, 522 and 523 are updated to bring them into compliance with the various changes made in the Federal rules and regulations. This is the first transmittal for FY 2012. The last transmittal was TR-11-1.
Subchapter 522	4/16/96	Subchapter 521	
Subchapter 523	2/7/00	Subchapter 522	
		Subchapter 523	
		Appendix 5231A	
		Appendix 5231B	
		Appendix 5231C	
		Appendix 5231D	
		Appendix 5231E	

(b)(6)

Chief of Operations

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U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

DIVERSION INVESTIGATORS MANUAL
SUPPLEMENTAL TRANSMITTAL

DATE: 3/13/2012
TRANSMITTAL NUMBER: TR 12-2

TABLE OF CHANGES

Remove	Identification Date	Insert	Explanation of Changes
Make the following Pen and Ink Change as listed.			
5113.47 Drug Detection Canine Training Program	**9/20/2011**		

Currently Reads:

1.b. Large law enforcement organizations may choose to have a single registration (e.g., at their headquarters) and transfer controlled substances to other locations (e.g., various posts within their jurisdiction). Adequate security measures and record-keeping should be outlined in a **Memorandum of Understanding (MOU)** with the local DEA field office. Normally, DEA registrants are required to have separate registrations for separate locations. The DEA registration for law enforcement canine handlers is only to facilitate the acquisition of training materials from DEA. Thus, it is permissible, since law enforcement has the authority to possess and handle controlled substances without a DEA registration, to transfer the controlled substances obtained from DEA to other posts within their jurisdiction. However, the registered location which receives training aids from DEA and then distributes them to other locations is required to maintain records documenting their receipt, storage, distribution, dispensing, and destruction of controlled substances.

Should Read:

1.b. Large law enforcement organizations may choose to have a single registration (e.g., at their headquarters) and transfer controlled substances to other locations (e.g., various posts within their jurisdiction). Adequate security measures and record-keeping should be outlined in **a Memorandum of Agreement (MOA)** with the local DEA field office. Normally, DEA registrants are required to have separate registrations for separate locations. The DEA registration for law enforcement canine handlers is only to facilitate the acquisition of training materials from DEA. Thus, it is permissible, since law enforcement has the authority to possess and handle controlled substances without a DEA registration, to transfer the controlled substances obtained from DEA to other posts within their jurisdiction. However, the registered location which receives training aids from DEA and then distributes them to other locations is required to maintain records documenting their receipt, storage, distribution, dispensing, and destruction of controlled substances.

(b)(6)

Chief of Operations

DISTRIBUTION: H-1, 2, 3C.3D, 4, 5
F-1 THROUGH 7

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

DIVERSION INVESTIGATORS MANUAL

SUPPLEMENTAL TRANSMITTAL

DATE: 6/11/2012
TRANSMITTAL NUMBER: 12-3

TABLE OF CHANGES

REMOVE	DATE	INSERT	EXPLANATION OF CHANGES
		Table of Contents	The Diversion Investigators Manual is being streamlined. Subchapters 534 (Pre-registrant Investigation) and 535 (Processing Applications) of Chapter 53 have been updated and included in Subchapters 522 and 523.
Subchapter 522	10/03/2011	Subchapter 522	
Subchapter 523	10/03/2011	Subchapter 523	
Appendix 5231A	10/03/2011	Appendix 5231A	
Appendix 5231B	10/03/2011	Appendix 5231B	
Appendix 5231C	10/03/2011	Appendix 5231C	
Appendix 5231D	10/03/2011	Appendix 5231D	
Appendix 5231E	10/03/2011	Appendix 5231E	
Subchapter 534	10/30/1998		
Subchapter 535	10/30/1998		

(b)(6)

Chief of Operations

DISTRIBUTION: H-1, 2, 3C.3D, 4, 5
F-1 THROUGH 7

CHAPTER 50 CONTROL OF LEGALLY MANUFACTURED CONTROLLED SUBSTANCES

SUBCHAPTER 501 MISSION AND GOAL

5011 INTRODUCTION

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5012.1 CYCLIC INVESTIGATIONS OF NONPRACTIONER CSA REGISTRANTS - (b)(7)(E)

5012.2 DOMESTIC CHEMICAL DIVERSION INVESTIGATIONS - (b)(7)(E)

5012.3 DRUG COMPLAINT INVESTIGATIONS - (b)(7)(E)

5012.4 DRUG AND CHEMICAL LIAISON WITH STATE AND INDUSTRY - (b)(7)(E)

5012.5 OPERATIONAL SUPPORT ACTIVITIES - (b)(7)(E)

CHAPTER 50 CONTROL OF LEGALLY MANUFACTURED CONTROLLED SUBSTANCES

SUBCHAPTER 501 MISSION AND GOAL

5011 INTRODUCTION

A. The purpose of the Diversion Control Program is to prevent, detect, and investigate the diversion of controlled substances from legitimate channels, while at the same time ensuring an adequate and uninterrupted supply of controlled substances required to meet legitimate needs.

B. Prevention of diversion from legitimate drug traffic is a cooperative effort between Federal and state governments. DEA has primary responsibility for enforcing the Control Substance Act of 1970 (CSA) with respect to all nonpractitioner registrants. DEA also targets any registrant violator who meets established criteria. Investigative information developed on a violative practitioner registrant not meeting established criteria is generally referred to appropriate state authorities for investigation.

5012 PROGRAM PRIORITIES

A. The Diversion Control Program priorities are designed to ensure that the limited resources available to achieve the mandates of the CSA of 1970 and the Chemical Diversion and Trafficking Act (CDTA) are effectively employed against a variety of competing goals.

B. The major priorities of the Diversion Control Program are:

1. Cyclic investigations of CSA nonpractitioner registrants.

2. Drug diversion complaint investigations.

3. Domestic chemical diversion investigations.

4. Drug and chemical liaison with state/local officials and with industry.

5. Operational support activities essential to the operation of the above priorities such as: Preregistrant investigations, Diversion Investigator recruitment, registration and regulatory support, an organized system of drug destruction, and drug and chemical surveys.

C. There is also an ongoing priority to maintain an overall geographic picture of drug and chemical diversion and abuse problems and to identify new trends or patterns in diversion and abuse.

D. Subsections 5012.1 through 5012.5 reflect the relative priority of the various functions of the Diversion Control Program. In general, field office Diversion Investigator staffing has been allocated consistent with these priorities. The percentages listed after each paragraph heading indicate the average percentage of available Diversion Investigator, investigative work hours to be devoted in each program function on a national basis. (See Sections A and B of DEA-351.)

E. Regional factors, such as size and type of registrant and chemical handler populations, degree of state and local effort, or level of clandestine laboratory activity will require adjustment to the percentage of resources allocated to the various functions on an office by office basis. When a diversion field office determines that significant and ongoing variations in the allocation of resources between the program priorities are required by local circumstances, the adjustments must be documented and justified in the Field Management Plan (FFS: 190-01) and each Quarterly Progress Report submitted by the Division.

CONTENTS

5012.1 CYCLIC INVESTIGATIONS OF NONPRACTITIONER CSA REGISTRANTS - (b)(7)(E)

Cyclic investigations serve as a deterrent to diversion through the continuous evaluation of registrants' record keeping procedures, security, and general adherence to the CSA.

A. Investigations of manufacturers and distributors can vary significantly with the size of the operation affecting personnel allocation.

Full in-depth investigations shall be conducted at least once every three years for non-practitioners including bulk manufacturers and importers in Schedule I and II. Emphasis shall be given to inventory/record keeping, follow-up verification of customers and orders, security, intelligence collection and case support. Responses to requests for support from other Divisions will be handled expeditiously as they occur. Section 303 Investigations of Bulk Manufacturers and Importers shall be completed at the beginning of each calendar year to ensure timely processing of the applications and publication in the Federal Register.

B. Quota review investigations shall be carried as part of regularly scheduled cyclic investigations and completed early for publication in the Federal Register. Independent quota reviews will be directed in response to special circumstances.

C. An established work plan for a fiscal year can be altered if a complex criminal investigation will require significant expenditure of investigative time. Any alteration in the cyclic work plan for the year shall be documented in the Quarterly Progress Plan and included in the next fiscal year work plan.

5012.2 DOMESTIC CHEMICAL DIVERSION INVESTIGATIONS - (b)(7)(E)

The CDTA does not establish a closed system of distribution. However, it does allow for a system of controls over the distribution, import and export of List I chemicals designed to detect and prosecute those who would divert chemicals to clandestine laboratories.

A. The primary focus of the Chemical Program will be:

1. Follow-up to specific clandestine laboratory cases;

2. Local investigation of chemical firms based upon direct intelligence that the firms may be sources of supply to the illicit market;

3. Specific investigations supporting national or regional targeting of chemicals for a certain drug (i.e., national ephedrine tracking), with priority attention to Special Enforcement Operations Special and Enforcement Programs (SEO/SEP) investigation and support.

Investigations in support of cases conducted by Divisions with high concentrations of chemical firms/activity shall be given a high priority.

B. Chemical diversion prevention activities should center on occasional visits with industry aimed at reinforcing compliance with the CDTA and, as resources allow, targeted visits to develop intelligence leads.

C. Other chemical activities include oversight of imports and support of investigative and legislative activities at the state/local level.

D. Domestic support for foreign chemical investigations shall center on monitoring of ports for chemical exports and "in-transit" shipments. In port areas, formal programs of coordination and cooperation with Customs are required. Action requested to support the suspension or denial of a chemical export must be given the highest priority, due to the

limited legal time frame in which DEA can act.

E. Limited investigations of local chemical exporters and verification of DEA-486's shall be utilized to insure continued compliance with the requirements of the CDTA as resources allow.

5012.3 DRUG COMPLAINT INVESTIGATIONS - (b)(7)(E)

Drug complaint investigations are aimed at significant violators dealing in products which are prevalent in the illicit market, or whose activities involve actual diversion, or in which significant diversion is strongly indicated.

A. Investigations, regarding the suspected diversion of controlled substances, are a major investigative priority within the Diversion Program. The greatest emphasis shall be placed on investigations of DEA registrants, who through their position in a criminal or legitimate organization are suspected of diverting quantities of controlled substances at the G-Dep Class 1 or 2 level, followed by individual practitioners suspected of diversion at the same level. Priority shall also be given to cases initiated by the Diversion Groups as primary cases in an approved SEO/SEP, and to cases in support of SEO/SEP's.

B. Following in priority would be those controlled-by-DEA cases which target high level nonregistrant organizations suspected of trafficking in licit drugs. Such cases shall be given priority over non-registrant cases which involve only one targeted individual. Commitment of significant work hours to single target non-registrant investigations must be justified by a substantial amount of diversion or by a relatively sensitive position held by the individual (i.e., a drug company employee with unlimited access to controlled substances).

C. Other areas of priority, are:

1. Civil and/or administrative actions, which either follow a criminal case or stand alone as the action of choice.

2. Public Interest Revocation actions.

3. Providing support to state/local or other Federal agency criminal investigations of both registrants and nonregistrants.

4. Cases initiated by state licensing and regulatory agencies.

D. Occasionally, it may be necessary to adjust priorities to accommodate drug specific trends or problems encountered in a specific geographic area and to expend work hours in identifying the extent of the problem. Also, this might be necessary to address a specific emphasis directed by Headquarters due to a national drug trend. When individual cases are investigated in conjunction with a drug trend, which is significantly affecting an area, the trend may be larger than the individual targets. Consequently, resources may be realigned to accommodate a lower level of target when that target is part of a larger trend. Such realignment of priorities must be reflected in the office's Quarterly Report.

5012.4 DRUG AND CHEMICAL LIAISON WITH STATE AND INDUSTRY - (b)(7)(E)

Upgrading state and local law enforcement and regulatory capabilities is a Federal effort which develops and facilitates state and local action at the practitioner level to complement DEA initiatives and programs.

A. Activities, to increase the effectiveness of the Diversion Control Program, shall include:

1. Maintaining continued liaison with local enforcement/ regulatory agencies to encourage cooperation and exchange of information.

2. Advocating the establishment of prescription monitoring systems; developing joint operations; assisting in developing grant programs.

3. Establishing interagency work groups.

Identification of local training needs and encouragement of state and local personnel to participate in training opportunities -should be stressed, as well as involvement in the presentation or evaluation of training programs administered to non-DEA investigative, regulatory or enforcement personnel.

B. Support shall be provided to the states on pending legislation and initiatives through such means as direct contact with state officials and the use of local and regional conferences.

C. Diversion prevention activities with industry and organizations shall be aimed at upgrading the level of self-enforcement by the drug and chemical industry and the regulated population. Activities should provide national industry associations, state professional associations, professional schools, and medical societies with a conduit to encourage registrants to identify potential diversion and to foster cooperation. Voluntary compliance, registrant inquiries, public presentations, industry meetings, seminars and conferences, and DEA/Industry discussion groups and panels should be stressed.

5012.5 OPERATIONAL SUPPORT ACTIVITIES - (b)(7)(E)

The following activities warrant specific resources to ensure balanced and comprehensive program activities.

A. ***Intelligence Collection and Reporting***. The effective gathering and reporting of intelligence information related to the diversion, abuse, and trafficking of controlled substances, and regulated chemicals is essential to the conduct of a successful Diversion Program. Each Division/Group shall actively solicit information regarding trends, statistics, arrest information, lab seizures (to include commercial sources of any chemicals seized); etc., from crime laboratories, treatment facilities, state and local enforcement and regulatory agencies, etc. The results shall be summarized in the Division's Trends in Traffic submission, and utilized for comparison with other indicators of diversion such as Excessive Purchase Reports and ARCOS Reports.

B. ***Preregistration Investigations***. Preregistrant investigations reduce the possibility of registering unauthorized subjects, ensure that the means to prevent diversion are in place, and determine whether registration is consistent with the public interest.

Preregistrant investigations must be conducted at the earliest possible time following receipt of the application by the Division. However, the desire for timeliness should not compromise the quality of the investigation. Local on-site investigations shall be carried out as soon as possible. The need for timeliness must be given strong consideration when planning TDY investigations.

Special consideration shall be given to expeditious processing of researcher applications based on compassionate Investigational New Drugs (IND), which often have a high degree of public visibility.

Investigations of new or non-traditional activities, such as pharmaceutical disposers, shall be coordinated with the Office of Diversion Control (OD) to insure uniform development of registration policy.

C. ***Registration/Regulatory Support***. Each office must respond to registrant queries, including requests to clarify policy.

D. ***Drug and Chemical Surveys***. Drug and chemical surveys provide important data in the development of programs and initiatives. In general, such surveys are conducted on an ad hoc basis to support drug or chemical control initiatives or to document the extent of a problem for strategically focused initiatives.

E. ***Drug Destructions***. An efficient and cooperative program with local registrants will help prevent potential diversion and avoid problems with all registrants sending their controlled substances to the DEA office for destruction.

F. ***Recruitment of Diversion Investigators***. Recruiting will focus on the development of a core group of high quality applicants.

CHAPTER 51 POLICY AND INTERPRETATION

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*Revision
**Addition

CHAPTER 51 POLICY AND INTERPRETATION

Subchapter 511 Registration

5111 INTRODUCTION This subchapter sets forth established policy and interpretation as it relates to the registration of entities who handle controlled substances. Provisions are set forth in 21 C.F.R. §§ 1301.01 through 1301.52 for registration and renewal of registration with DEA.

5111.1 Renewal of Registration The DEA registration system provides for annual registration of Type "B" registrants (manufacturers, distributors, researchers, analytical laboratories, importers, exporters, and narcotic treatment programs) and for triennial registration of Type "A" registrants (retail pharmacies, hospital/clinics, practitioners, and teaching institutions).

5111.2 Investigative Actions Investigative Actions, formerly known as Administrative Codes, are used to denote a special characteristic of a specific registration or application, and are for internal DEA use only. Listed below is a comparative table that illustrates the current Oracle Controlled Substances Act II Database (CSA2/RICS) Investigative Actions and the corresponding old system of CSA1:

CSA2 INVESTIGATIVE ACTIONS (NEW SYSTEM)	CSA1 ADMIN. CODES (NO LONGER USED)
Administrative Hearing	-
Civil Fine	-
Under Review/Investigation	*6 or N*
Letter of Admonition	-
Order to Show Cause	*0*
Out of Business (*applicable to accounts with DEA Numbers only*)	*7*
Application Withdrawn	-
Immediate Suspension	*9*
Surrender for Cause	*1*
Revoke	*2*
Denied (*new applications only*)	*D*
Renewal Denied	-

The following actions must be entered into CSA2:

NOTE: The Investigative tab in the CSA2 database allows users to enter information about investigative tasks on registrants' accounts.

A. Administrative Hearing - DEA will hold an Administrative Hearing when the severity of the violations and/or the registrant's attitude toward the violations would render the Letter of Admonition (LOA) ineffective. Consideration must be given to the severity of the violations or violative history of the firm in determining the need for an Administrative Hearing. The Administrative Hearing provides the opportunity for both DEA and the registrant to explain their respective views on the violations and to discuss the necessary remedial or corrective actions. A copy of the DEA-6 documenting an Administrative Hearing is to be sent to the Regulatory Section (ODG). A complete copy of the Distribution of Reports can be found on WebSter.

B. Civil Fine - Civil fines are an effective tool in dealing with registrants who have a history of failure to comply with DEA regulations or who, by virtue of the activities, should have familiarized themselves with DEA regulations, but failed to do so. They are just one of a number of sanctions that DEA may apply when circumstances warrant. Field management must make the final determination whether civil prosecution is justified based on all relevant factors in the case. All cases being presented to the United States Attorney's Office should be referred through the Diversion Program Manager or the Assistant Special Agent in Charge (ASAC) with oversight of the Diversion Control Program. Civil fines may be pursued in conjunction with a criminal prosecution and/or administrative action. A copy of the DEA-6 is to be sent to ODG. Upon completion of the investigation copies of all complaints and settlement agreements also need to be forwarded to ODG.

C. Under Review/Investigation - No Automatic Renewal – This action administratively prevents the automatic renewal of a DEA registration and denotes that the registrant has an administrative action on-going by the field office. The registrant may continue to operate until final disposition by DEA. The Diversion Group Supervisor is responsible for monitoring these statuses and removing them when necessary. A copy of the DEA-6 is to be sent to the following offices:

1. ODG (Regulatory Section) if a case involves pharmaceutical controlled substances and is a regulatory matter, and
2. ODP (Pharmaceutical Investigations Section) if the case received a G-DEP, and/or
3. ODS (Synthetic Drugs and Chemicals Section if the case involves chemicals.

D. Letter of Admonition (LOA) - The purpose of a Letter of Admonition (LOA) is to advise the registrant of any violations which are alleged to have occurred and to document these violations in written form. The letter allows for voluntary, corrective action by the registrant and also makes violations a matter of record should the same violations be encountered at a later date. A copy of the DEA-6 is to be sent to ODG.

E. Order to Show Cause (OTSC) - An OTSC may be issued for denial, revocation, or suspension of a DEA registration and administratively prevents the renewal of a DEA registration. The field will enter this status or remove it from the CSA2 database following notification from the Office of Chief Counsel or the Registration and Program Support Section (ODR). This status is found in the Investigative tab in the CSA2 database. A copy of the DEA-6 is to be sent to the following offices:

1. CCD (Office of Chief Counsel's Diversion and Regulatory Litigation Section), and
2. ODG if a case involves pharmaceutical controlled substances and is a regulatory matter, and
3. ODP if the case received a G-DEP, and/or
4. ODS if the case involves chemicals.

F. Out of Business - The appropriate DEA field office will directly input into the CSA2 database when a registrant discontinues business. Supporting documentation must be maintained on file at the field office. A copy of the DEA-6 is to be sent to the following offices:

1. CCD (Office of Chief Counsel's Diversion and Regulatory Litigation Section) and
2. ODG if a case involves pharmaceutical controlled substances and is a regulatory matter.

G. Application Withdrawn - If an applicant requests to withdraw their application for registration for any reason, a copy of the DEA-6 is to be sent to ODG and CCD. An applicant cannot withdraw an application after DEA has issued an OTSC unless OD authorizes the withdrawal.

H. Immediate Suspension (ISO) - This action denotes that a registration has been suspended simultaneously with the issuance of an OTSC. A registrant whose registration has been placed in this status has no controlled substances privileges. This status is entered by the Diversion Group Supervisor, who is responsible for documentation and any necessary follow-up. The status can be selected in the Investigative tab in the CSA2 database. A copy of the DEA-6 is to be sent to the following offices:

1. CCD, and
2. ODG if a case involves pharmaceutical controlled substances and is a regulatory matter, and
3. ODP if the case received a G-DEP, and/or
4. ODS if the case involves chemicals.

I. Surrender for Cause - This action denotes a voluntary surrender of controlled substance privileges by the registrant for alleged violations. The appropriate field office will select the Surrender for Cause status from the drop down menu in the Investigative tab in the CSA2 database, and will maintain a copy of the completed DEA Form 104 (Voluntary Surrender of Controlled Substances Privileges) for their files along with the original voided registration

certificate. Unused order forms (DEA Form 222) must be surrendered to DEA for destruction. A registration that is surrendered following an OTSC action, but prior to the Final Order being issued, is a Surrender for Cause as opposed to Out of Business or Revocation. A copy of the DEA-6 is to be sent to the following offices:

1. ODG if the case involved pharmaceutical controlled substances
2. ODP if the case received a G-DEP and/or
3. ODS if the case involves chemicals.

J. Revoke (Revocation) - This action is taken against the registrant through show cause proceedings as provided for in 21 U.S.C. §§ 823, 824, and 958. The field office is responsible for updating the DEA record with this status upon notification from CCD or ODR. The revocation status can be found in the CSA2 database under the Investigative tab. The field office is responsible for sending a copy of the DEA-6 to the following offices:

1. CCD, and
2. ODG if a case involves pharmaceutical controlled substances and is a regulatory matter, and
3. ODP if the case received a G-DEP, and/or
4. ODS if the case involves chemicals.

K. Denied - This action denotes that a new application for registration has been denied as the result of OTSC proceedings. The field is responsible for entering this status in the CSA2 database. A copy of the DEA-6 is to be sent to the following offices:

1. CCD, and
2. ODG if a case involves pharmaceutical controlled substances and is a regulatory matter, and
3. ODP if the case received a G-DEP, and/or
4. ODS if the case involves chemicals.

L. Renewal Denied - This action is taken following the outcome of an OTSC when a renewal was submitted subsequent to the expiration date.

M. Other Actions - Restriction/Limiting Address or Controlled Substance Schedules of Registrants:

1. Address – This is commonly used for resident practitioners where state law restricts them to only use their controlled substances authority at a university school medical center or a foreign physician in the United States for a specific study or curriculum. This action prevents any automatic change or update of a registrant's address until the flag is removed by the field office in the CSA2 database by opening up Section 1 and 2, and checking the box by the address labeled "Restricted."

2. Schedules – The schedules of a registrant may be either limited or restricted depending on the circumstances of the case by opening Section 3 and 4 on the registrant's CSA2 Master Record, and putting either an "L" or "R" in the box directly under the schedule that is to be restricted or limited. The field office is responsible for entering the proper code. A copy of the DEA-6 is to be sent to ODG.

3. Limited Schedules – This action denotes that a registration is limited to certain schedules and/or to certain activities (e.g., prescribing only) because the state has granted only limited authority. The responsible field office will enter the "Limited Flag" into CSA2.

4. Restricted Schedules – This action denotes that a registration is restricted to certain drug schedules because the registrant has had administrative action imposed by either the state licensing authority or DEA. The responsible field office will enter the "Restricted Flag" and cause a new registration certificate (DEA Form 223) to be issued. Unused order forms (DEA Form 222) must be obtained by the field office if the restriction does not allow the registrant to handle schedule II controlled substances. If the registrant is a CSOS (Controlled Substances Ordering System or electronic order forms) participant, the action of restricting schedule II controlled substances will suspend the registrant from conducting any CSOS ordering.

N. 303 Investigations of Schedule I and II Bulk Manufacturers and Importers - A 303 investigation is required for each new schedule I and II bulk manufacturer and importer registration as well as the renewal of each schedule I and II bulk manufacturer and importer registration. The CSA2 database automatically assigns the 303 investigative action flag to both the assigned field office and ODG workload. The registrant's record will remain in either new or renewal pending status until the 303 investigation workload has been cleared from the CSA2 database. The purpose of this review is to ensure that the requirements of 21 C.F.R. §§ 1301.33 and 1301.34 are satisfied.

O. Obsolete Administrative Codes in CSA2 - The following Administrative Codes are no longer used in CSA2/RICS

1. Code 4 - Refund
2. Code 5 - Delinquent in Renewing Registration
3. Code 8 - Improperly Completed Renewal Application
4. Code K - Referred to Field for Investigation
5. Code U - Uncollectible Fee

5111.3 Renewal Applications

A. A renewal application is automatically sent for each registration which has not been renewed by 45 days prior to the expiration date of the registration. ODR sends a notification to all registrants 65 days prior to the expiration date. This notice explains that their registration will expire and that they are able to go to the DEA website to renew their registration no earlier than 60 days prior to the expiration date. For registrations that have not been renewed by the

expiration date, the CSA2 system automatically changes the registration's status from active to expired the day after the expiration of the registration. The expired status prevents the issuance of order forms. Seven days after a registrant's DEA registration has expired, a delinquency notice is sent to the registrant. At this time, the registrant's record remains in the system and may be renewed for up to 23 days after the delinquency renewal application has been sent to the registrant. The first day of the month following the expiration month the registration will be removed from the Active Master File to the Retired Status File, if a renewal application is not received. The expiration date, delinquency date, and retirement dates of a registration are determined by the first character of the last name of the registrant as follows:

EXPIRATION, DELINQUENT NOTICE, AND RETIREMENT DATES

1st Character of Last Name	Expiration Date	Delinquent Notice (10 days after expiration)	Retirement Date (30 days after expiration)
A, D	06-30-CY	July	August
B	07-31-CY	August	September
C, E	08-31-CY	September	October
F, G	09-30-CY	October	November
H, N	10-31-CY	November	December
I, T	11-30-CY	December	January
J, K, O	12-31-CY	January	February
M	01-31-CY	February	March
S	02-28-CY	March	April
L, P	03-31-CY	April	May
Q, R, 9	04-30-CY	May	June
U, V, W, X, Y, Z	05-31-CY	June	July

NOTE: Bulk manufacturers and schedules I and II importers are an exception to the 45 day advance timeframe, and are sent their renewal applications 120 days prior to the expiration date of the DEA registration

B. A registration is legally invalid the day after it expires. Registrants who are listed in the CSA2 database as having an OTSC must submit the renewal application at least 45 days prior to the date of expiration of their registration for the application to be considered submitted in a timely fashion as required by 21 C.F.R. § 1301.36(i). Furthermore, any record of an OTSC, Suspension or Under Review Investigation will not be purged to the Retired Status File if the registrant has submitted the renewal until the status is changed by the field office. Registrants that have not submitted a renewal application in a timely manner will be purged to the Retired Status file.

C. There are cases where circumstances beyond the control of the registrant may have caused the registration to expire (e.g., renewal application received by ODR but not processed by the

registration's expiration date). In these rare instances, the field office should notify ODR for resolution.

5111.4 Fees and Exemptions DEA is authorized under 21 U.S.C. §§ 821 and 958(f) to charge application fees for registration. Fee schedules are specified in 21 C.F.R. § 1301.13(e)(1). Persons exempt from fees are specified in 21 C.F.R. § 1301.21. In addition, registration exemptions are set forth in 21 C.F.R. §§ 1301.22 through 1301.24.

5111.41 Refund of Application Fees Pursuant to 21 C.F.R. § 1301.13(e), application fees are not refundable except for duplicate applications or agency error.

5111.5 Falsification of Application Willful material falsification of an application is grounds for revocation or denial as well as a violation of 21 U.S.C. § 843(a)(4). An application on which information has been omitted, such as questions pertaining to state registration, felony conviction, suspension, revocation, or denial of application, should be returned to the applicant. An application reaching the field, which does not contain all pertinent information, should not be processed until a signed statement regarding the issue is obtained from the applicant.

5111.6 CSA2 Database Registration Workload

A. Workloads are assigned based on business activity. DEA procedures that result in the issuance of a DEA Registration Certificate are detailed in Reference 5111A.

B. Listed below are DEA personnel whose actions result in the issuance of a DEA Registration Certificate, the responsibilities for whom are outlined in Reference 5111A.

1. Diversion Investigators/Diversion Group Supervisors
2. DEA Headquarters/Registration and Program Support Section (ODR)
3. Registration Program Specialists (RPS)

5111.7 Construction of a DEA Number for Controlled Substance Registrants

A. The DEA number consists of nine characters. The first character is always an alpha character and is an "A", "B", or "F" for Type A registrants; an "M" for Type A – Mid-Level Practitioner registrants, or a "P" or "R" for Type B Registrants. (See Subsection 5111.1 for a definition of Type A and Type B registrants).

Note: Type A registrants include retail pharmacies, hospitals/clinics, practitioners and teaching institutions. Type B registrants include manufacturers, distributors, researchers, analytical laboratories, importers, exporters and narcotic (opioid) treatment programs.

B. The alpha characters "A" and "P" were used in DEA registration numbers issued from May 1, 1971, through September 30, 1985. All DEA registration numbers issued on or after October 1, 1985, begin with the alpha "B" or "R". Due to the large Type A registrant population, the "B"

character has been exhausted. As of November 9, 2006, the alpha letter "F" is the first character for all new Type A registrations (except for Mid-level Practitioners (MLPs) that will remain the alpha letter "M").

C. The second character of a DEA registration number represents the first character in the registrant's last name if the registrant is an individual (e.g., Dr. Jones = BJ1234563) or the first character in the registrant's name if the registrant is a business (e.g., Elm Street Pharmacy = BE1234563).

D. Where the registrant's name is a number, the digit 9 is substituted for the alpha character. For example, "5th Avenue Drug" would have the following type of registration number: A91234563.

E. To check the validity of a number, (b)(7)(E)
(b)(7)(E)

(b)(7)(E)

(b)(7)(E)
(b)(7)(E) This indicates only that the number is structurally valid.

5111.8 Power of Attorney. An applicant may authorize one or more individuals to sign applications on their behalf by executing a power of attorney for each authorized individual. The power of attorney must be signed by a person who is authorized to sign such applications and must also contain the signature of the individual being authorized to sign such applications. The power of attorney is valid until revoked by the applicant. There is no DEA form for the power of attorney to sign applications. The power of attorney document must be kept at the registered location and be available for inspection. An example of the power of attorney format may be found in 21 C.F.R. § 1305.05.

5112 REGISTRATION CATEGORIES

5112.1 General

A. The DEA registration system provides for two general categories of registrants which are designated as practitioner and non-practitioner. These categories are further delineated as follows:

Practitioner	Non-practitioner
Physician	Manufacturer
Retail Pharmacy	Distributor
Hospital Clinic	Reverse Distributor
Teaching Institution	Importer
Researcher	Exporter
Analytical Laboratory	Narcotic Treatment Program
Mid-level Practitioner	

B. The categories of "Researcher" and "Analytical Laboratory" are included with the "practitioner" designation by definition in the CSA (21 U.S.C. § 802(21)). However, these applicants are required to apply for registration using a DEA Form 225 (Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, and Exporter).

All other practitioner registrants must apply using a DEA Form 224. In addition, although DEA considers narcotic treatment programs as non-practitioner registrants, they must apply using a DEA Form 363. DEA has registered other activities as authorized by individual states to handle controlled substances. (See Section 5113 Special Activity Registration)

5112.2 Registration Application Forms All of the DEA registration application forms are available on-line at www.DEADiversion.usdoj.gov, under "Registration Support."

Form	Form Number
New Application for Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institute or Mid-Level Practitioner	224
Renewal Application for Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institute or Mid-Level Practitioner	224A
Retail Pharmacy Registration Affidavit for Chain Renewal	224B
New Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter	225

Form	Form Number
Renewal Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter	225A
New Application for Narcotic Treatment Program	363
Renewal Application for Narcotic Treatment Program	363A
New Application for Chemical Registration	510
Renewal Application for Chemical Registration	510A

5112.3 Coincident Activities Registration in one activity may include authorization to conduct other related coincident activities without a separate registration. Allowable coincident activities are listed in the table at 21 C.F.R. § 1301.13(e)(1). Registrants may only conduct coincident activities related to a primary registration, not coincident activities of a coincident activity. For example, a person registered as an analytical laboratory may conduct manufacturing activities coincident to analytical work and may distribute to other laboratories as a coincident activity. However, they may not, as a general rule, manufacture material for commercial distribution under their analytical laboratory registration as a means to circumvent the requirements of a separate manufacturer registration.

5113 SPECIAL ACTIVITY REGISTRATION

5113.1 Military Activities

5113.11 Military Veterinary Clinic

A. A military veterinary clinic is required to register with DEA only if it purchases controlled substances from commercial sources. A military veterinary clinic that purchases controlled substances exclusively from the Defense Logistics Agency (DLA), formerly the Defense Supply Agency, is exempt and does not require DEA registration.

B. DEA requires military veterinarians to have their own DEA registration number if they expect the civilian pharmacies to fill their prescriptions. Also, a number of states require state licensure of military veterinarians who write prescriptions to be filled outside the military installation at which they practice.

5113.12 Military Canine Training Program

A. Military canine units are considered federal law enforcement and therefore are exempt from the requirement of DEA registration. However, most canine training facilities within the Department of Defense (DOD) are registered with the DEA as research facilities. Canine units may obtain controlled substances used as training aids for detector dogs from DEA registrants

authorized to distribute schedule I through V controlled substances, as outlined in 21 C.F.R. § 1301.24(b), provided the officer procuring is acting in the course of his or her official duties and obtains or distributes the controlled substances only to another official exempted by 21 C.F.R. § 1301.24(b).

B. A canine unit may also obtain controlled substances according to current Military Working Dog Program (MWDP) directives. New directives for procurement of controlled substances are in progress at Lackland Air Force Base, San Antonio, Texas. For further information, contact the Program Manager, DOD MWDP, at (210) 925-5638.

5113.13 Military Hospital A military hospital is required to register with DEA if it purchases controlled substances from commercial sources. A military hospital that purchases controlled substances exclusively from the DLA is exempt and does not require DEA registration.

5113.14 Military Procurement

A. Controlled substances are normally procured for the military from civilian suppliers by procurement officers of the DLA. Civilian wholesalers will supply controlled substances according to terms of a procurement contract, to a military domestic supply depot, or to a domestic U.S. Post Office APO box. In turn, these controlled substances are distributed both domestically and internationally to U.S. military installations for official military use. When the wholesaler is registered as an exporter, controlled substances can be shipped directly to an overseas U.S. defense installation if this procedure is within the terms of the procurement contract. Also refer to 21 C.F.R. § 1305.13(f).

B. Military health installations and hospitals are exempt from DEA registration and order form requirements if controlled substances are ordered through military supply centers and not directly through civilian wholesalers. If a domestic military hospital wishes to obtain controlled substances directly from civilian wholesalers, it must register with DEA as a hospital/clinic.

5113.15 Military Contract Practitioner A contract physician, who is not an official of the military on active duty but is engaged in medical practice at a military installation, must possess a current DEA registration. The individual must also possess a valid state license for the same state in which he or she is registered with the DEA. A contracting physician is not required to obtain a DEA registration in the same state in which the military installation is located if the contracting physician only practices at the military installation and no controlled substance prescriptions are filled at a civilian pharmacy. A check with state regulatory officials should be conducted to verify that the contract physician is not violating any laws or regulations that require the contracting physician to be licensed, or otherwise authorized, in the state in which they are practicing. Military contract practitioners are not exempt from paying the DEA registration fee.

5113.2 Health Care Facilities

5113.21 Emergency Vehicles

A. DEA normally does not register emergency vehicles to procure or dispense controlled substances independently. However, in those states where the services are licensed to handle controlled substances, DEA will consider registering the ambulance service as a Mid Level Practitioner (business activity M1). DEA allows emergency vehicles to obtain controlled substances for dispensing pursuant to required state authority and a physician's instruction through one of three business activities or registrations:

1. Mid-Level Practitioner Registration. A state licensed Emergency Medical Service (EMS) may register as a mid-level practitioner in order to obtain needed controlled substances. A mid-level practitioner registration will enable the EMS to obtain controlled substances, even when a supervising practitioner has changed.

2. Practitioner Registration. Small quantities of controlled substances may be supplied to an emergency vehicle under the control of a consulting practitioner. The practitioner must register with DEA at the EMS central office location.

The practitioner is responsible for the ordering, use, and security of any controlled substance used in an emergency vehicle operated by the EMS. Under this registration, it is required that the practitioner order and maintain a sufficient inventory of drugs to replenish medication dispensed by the emergency vehicle.

3. Hospital/Clinic Registration. There are two ways to supply an emergency vehicle with controlled substances under this business activity or registration. First, the emergency vehicle can be operated by the hospital and supplied by the hospital pharmacy or hospital emergency room as an extension of the hospital. Second, a private emergency medical service may enter into a formal written agreement with one specific hospital to supply the EMS with a prepared emergency kit and replenish the kit as necessary based on adequate records produced showing usage. In this situation, a private EMS must return to its designated supply hospital for drug replenishment even though it may have delivered a patient to another area hospital.

B. To ensure that any current or proposed system for supplying controlled substances to EMS units meets DEA's requirements, it is recommended that the system be reviewed by the Diversion Program Manager in the EMS' geographic area. A written request to the Diversion Program Manager outlining the scope of operations, proposed security measures, and proposed record keeping controls is required. (b)(5)

(b)(5)

(b)(5) A Diversion Program Manager may approve emergency vehicles with a

MOA provided the state authorizes hospital pharmacies or practitioners to supply controlled substances to emergency vehicles.

C. The following requirements apply to all procedures:

1. Record keeping and Security. The hospital pharmacy (hospital registration), physician (practitioner registration), or EMS (mid-level practitioner registration) is responsible for the ordering, use, and security of any controlled substances to be used in an emergency vehicle. The registrant is responsible for developing and implementing record-keeping and security measures which will minimize the potential for diversion. When a hospital pharmacy supplies controlled substances to a private service, no more than one kit per vehicle will be supplied. Subsequent distributions will be made only on a replacement basis.

2. Program Approval. The DEA Diversion Program Manager may provide written approval of an emergency vehicle. A written request outlining the scope of operations, proposed security measures, and proposed record keeping controls is required of the registrant to the SAC. If the SAC determines that these controls provide adequate safeguards against diversion, written approval will be granted.

3. State Approval. Specific state authorization to allow hospital pharmacies or practitioners to supply controlled substances to an emergency vehicle is required prior to the issuance of a DEA registration unless specified in state legislation that DEA approval must be granted before state licensure will be granted. A person making inquiry regarding this requirement should also be referred to the proper state agency. If the state agency disapproves an emergency vehicle request, DEA approval will not be granted.

4. Withdrawal of Authorization. When diversion occurs, appropriate action is to be initiated. The SAC will determine if additional record keeping or security measures are required or if the DEA registration is to be revoked/surrendered or withdrawn. When the SAC decides to cancel the authorization, the registrant must be notified in writing.

5113.22 Long Term Care Facility (LTCF)

A. Federal regulations define a Long Term Care Facility (LTCF) as a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients. Adult care homes, family care homes, group homes for the developmentally disabled, and in-patient hospice facilities are also considered LTCFs under the DEA definition. Two common features shared by these facilities are that each has medical staff on-site, 7 days per week, and that patients reside at these facilities.

B. A restorative treatment facility for adolescents that the state has also licensed as a mental health care hospital, and which is registered with DEA as a hospital, is considered a hospital by DEA and not a LTCF.

C. LTCFs may possess controlled drugs under the following options:

1. A LTCF provides custodial care for the controlled substances prescribed to its residents. As a result, no DEA registration is required where the facility separately maintains each patient's controlled substances. DEA considers these controlled substances the property of the patient instead of the LTCF.

2. A LTCF can obtain a DEA registration as a hospital/clinic if the state registers the facility as either a hospital or a clinic. The LTCF then orders and dispenses all controlled substances pursuant to that DEA registration. Such dispensing takes place in response to a medication order.

3. A LTCF may apply for a DEA registration as a retail pharmacy if the state registers the facility as a retail pharmacy. All regulations pertaining to a pharmacy apply, including that the requirement to fill only prescriptions, not medication orders.

D. A pharmacy located outside the LTCF which, in response to a prescription, dispenses controlled substances to patients within the facility may not maintain a common stock of controlled substances at the LTCF, with the exception of an emergency kit, as permitted by the state.

E. Pursuant to 21 C.F.R. § 1301.27, a retail pharmacy may install an Automated Dispensing System (ADS) containing controlled substances in a LTCF if state law and regulation allow. The retail pharmacy must first obtain a separate DEA pharmacy registration at the location of each LTCF where it places an ADS. The ADS allows the retail pharmacy to dispense small quantities of controlled substances to patients of the LTCF pursuant to a prescription. DEA allows the use of an ADS as an option, not a requirement, and recognizes that an ADS may not work in all circumstances. An ADS machine is a viable solution for preventing the accumulation of excess controlled substances.

F. A LTCF may acquire the services of a practitioner that would register with DEA at the address of the LTCF. The practitioner could then order controlled substances for general stocking and dispensing at the LTCF. The DEA registered practitioner would be responsible for controlled substances at the facility concerning their use, security, and recordkeeping including 21 C.F.R. § 1304.22(c).

G. An emergency kit containing controlled substances is permitted at the LTCF for emergency purposes without requiring a separate DEA registration as permitted by the state. DEA differentiates between regular dispensing at a LTCF and emergency dispensing and relies on the respective state authority to set specific rules and procedures. While registration is required by 21 C.F.R. § 1301.17 and 1301.27, the requirement only pertains to those pharmacies which install or operate an ADS at a LTCF for the regular dispensing of controlled substances. See the Federal Register publication covering Emergency Kits in LTCFs in the DEA Reference Book (5113B).

H. Narcotic Drug Treatment: Although most LTCFs are not DEA registrants and therefore lack the authority to independently acquire or dispense narcotics, they do provide custodial care of controlled substances dispensed via prescription to individual patients. The Drug Addiction Treatment Act (DATA) allows for physicians who are properly certified by the Center for Substance Abuse Treatment (CSAT) and DEA to prescribe schedule III-V controlled substances, such as Suboxone and Subutex, approved by the FDA for opioid addiction treatment. The physicians are known as DATA-waived physicians because the Act waives the requirement of registering as an NTP. Title 21 C.F.R. § 1306.07(a) prohibits the prescribing of schedule II narcotics, such as methadone, approved by the FDA for the purpose of maintenance and detoxification. LTCFs may provide controlled substances for addiction treatment in the following circumstances:

1. To patients enrolled in a registered NTP that supplies patient-specific controlled substances for dispensing to individual patients.

2. To patients that receive a prescription for Suboxone or Subutex from a DATA-waived physician for dispensing to individual patients.

3. Pursuant to a separate NTP registration obtained by the LTCF.

4. Pursuant to an institutional practitioner registration (hospital) obtained by the LTCF. The LTCF could dispense narcotics to their patients as a registered hospital treating an individual's addiction as an incidental adjunct medical condition.

5113.23 Poly-Drug Abuse Treatment Program Federal regulations pertaining to maintenance or detoxification treatment pertain only to addiction to narcotic drugs. DEA registered practitioners associated with poly-drug abuse treatment programs may administer, dispense, or prescribe controlled drugs only when the course of treatment falls within the approved medical use of the controlled substances.

5113.24 Group Practices/Medical Clinics

A. When a group practice is licensed by a state as a hospital/clinic to practice medicine, DEA may also register the practice as a hospital/clinic. In group practice situations, one primary practitioner may register with DEA and the others in the practice may act as agents of the registrant when they administer or dispense controlled substances from a common stock. However, all practitioners who prescribe controlled substances must register with DEA. A secondary physician may also register at the business location to serve as a back-up in the event the primary practitioner discontinues his/her professional practice or dies. When multiple practitioners dispense from a common stock, the primary registered practitioner should impose additional inventory requirements as a means of ensuring that the practice is maintaining adequate records and security. State requirements may be more restrictive.

B. In a state that does not license group practices to handle controlled substances, each physician needs to be separately registered at his or her principal place of business to order, store, and dispense controlled substances.

5113.25 Retail Hospital Pharmacy A hospital pharmacy operated by a DEA registered hospital/clinic is authorized to dispense out-patient prescriptions without obtaining a DEA retail pharmacy registration provided this practice is allowed by the state. A hospital pharmacy operating in this manner is required to maintain controlled substance prescription records in the same manner as a regular retail pharmacy.

5113.26 Hospital Analytical Laboratory

A. A hospital analytical laboratory conducting chemical analysis for the hospital is not required to have a separate registration as an analytical laboratory unless conducting chemical analysis for other institutions.

B. Ancillary analysis that requires separate registration includes urinalysis for NTPs, chemical analysis for a coroner, or any other work that is independent of the hospital or outside the existing DEA registration of the facility, e.g., involving schedule I controlled substances.

5113.27 Mobile Clinics A mobile clinic may operate under an individual practitioner's registration or be included under the registration of the hospital. Where a practitioner's registration is utilized, practitioner may prescribe, but not administer or dispense controlled substances from the vehicle. The CSA requires that a separate registration be obtained for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed (21 U.S.C. § 822(e)). Under 21 C.F.R. § 1301.12(b)(3), DEA has provided a limited exception to this requirement. Practitioners who register at one location, but practice at others within the same State, are not required to register for any other location in that State at which they only prescribe controlled substances. If they maintain supplies of controlled substances, administer, or directly dispense controlled substances at a location, they must register for that location (21 U.S.C. § 823(f)). (See Final Rule published on December 12, 2006, titled Clarification of Registration Requirements for Individuals Practitioners and Subsection 5113.21 regarding Emergency Vehicles.)

5113.28 Department of Veterans Affairs (VA) Multiple Locations Each VA hospital is required to register as a hospital/clinic. A VA hospital that has more than one dispensing site or building within the same physical complex need only have one hospital/clinic registration for the entire complex. Each VA facility registered as a hospital/clinic may act as a distributor to other VA registered facilities, provided it complies with the security requirements for a distributor. Transfer of schedule II controlled substances may be made only on DEA Form 222, official order forms issued under the hospital/clinic registration, this procedure is established through an agreement with VA Headquarters.

****5113.29 Online Pharmacy**

A. DEA registered retail pharmacies that wish to dispense controlled substances by means of the internet and whose business practices do not meet one of the exemptions provided under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, must request a modification of their DEA registration to Online Pharmacy on the DEA Office of Diversion Control Website, www.deadiversion.usdoj.gov. The term "online pharmacy" and the exemptions are listed in 21 U.S.C. § 802(52). Registrants must provide additional information, such as applicable websites and state licenses during the application process. (See Section 5223.8 for additional information) This request must be sent at least 30 days prior to offering a controlled substance for sale, delivery, distribution, or dispensing by means of the internet. There is no fee to apply for modification of an existing registration. Although the regulations stipulate that the registrant must notify DEA at least 30 days prior to offering a controlled substance, no sales, deliveries, distributions or dispensing may take place until the registrant is properly registered.

B. The modification is entered into the workload in the Registration Information Consolidated Systems (RICS) for the local DEA field office as well as the workload for DEA Headquarters Regulatory Section (ODG). The local DEA field office will be required to conduct an on-site pre-registration investigation (See Section 5223.8). **

5113.3 Registration Modification

5113.31 Modifications Within the Same State

A physician may change the address on their DEA registration from one business location to another within the same state by requesting a modification of registration on the DEA Diversion website. The Registration Program Specialist (RPS) in the area where the physician is relocating is responsible for ensuring that the physician's current medical license is valid and for conducting background checks as needed.

When a state issues a new license, permit, or authorization to a retail pharmacy, hospital/clinic, teaching institution, researcher, or analytical laboratory, a new DEA registration application is not necessarily required (See Section 5222 Requirements for Registration for guidance). If the state does not issue a new permit, but merely modifies an existing license by means of changing the name or address, then the registrant only needs to submit a letter requesting modification of the registration or by modifying the address on the website.

The RPS, Diversion Investigator, or Special Agent must input modifications of physician registrations into the Registrant Information Consolidated System (RICS). Absolutely no modifications will be made without a written request signed by the registrant. DEA will maintain all appropriate documentation at the field office where the modification was made. A registrant may request a modification of the controlled substance schedules they are authorized

**Addition

to handle either in writing or on the website. The registrant's state authorization to handle the additional schedules must be confirmed by the RPS prior to modifying the registration.

5113.32 Modifications from One State to Another

A physician may transfer their DEA registration from one state to another. The physician must send their modification request to the Registration Unit of the local field division into which the physician is moving or they can change their address on the website and the RICS will automatically put the change of address to the proposed new office. The RPS in the area where the physician is relocating is responsible for verifying state licensure and conducting background checks. If the receiving field office grants approval, the RPS will input the necessary modifications into RICS or approve the RICS workload. Physician modifications are not to be considered routine and will always include a NADDIS query and a background check in the state from which the physician moved.

A researcher registered in schedules II-V relocating to a new state may retain their registration as long as they have appropriate authorization to handle controlled substances in that new state. The field office in the area into which the registrant is relocating should use discretion in determining the need for an on-site inspection of security at the researcher's facility prior to modifying the registration. If the receiving field office grants approval, a Diversion Investigator or Group Supervisor will input the necessary modification into RICS. Researchers in schedule I must apply for a new registration since approval in this activity requires separate review and approval by the Drug and Chemical Evaluation Section (ODE) and the Food and Drug Administration of a new protocol.

Information for Modification of Pharmacy Registrations, see Section 5113.34.

5113.33 Modifications for Non-Practitioners Requests for registration modification by non-practitioners (e.g., manufacturers and distributors) require an on-site investigation by the local DEA office prior to taking any action. Address changes across state lines require the submission of a new application. The appropriate field office will send copies of the DEA Report of Investigation (DEA-6) to the Regulatory Section (ODG). All information pertaining to approvals for modification of non-practitioner registrations not requiring a Section 303 analysis will be input into RICS by the appropriate field office. The appropriate field office will send reports pertaining to modifications of registration for firms requiring a Section 303 analysis to the Registration and Program Support Section (ODR) for input into RICS. The appropriate field office will send a copy of the DEA-6 to ODG.

5113.34 Change of Ownership Title 21 C.F.R. § 1301.52 provides requirements for termination and transfer of registration. When a registrant undergoes a change of ownership, the DEA will permit the existing registration to continue or will require a new application for registration depending upon the following:

A. **Sole Proprietorship** A change of ownership will require a new application since there will also be a change of the person legally responsible for the registrant's activities. A new application will be required even if the state does not require a new state license or permit.

B. **Partnership** A change of partners legally constitutes a change of ownership. DEA's policy is to permit the existing registration to continue in force provided the following conditions are met:

1. The business continues to operate under the same name.
2. The partner who signed the application for registration remains as a partner in the business
3. The new partner(s) has not been convicted of a felony in connection with controlled substances under state or federal law.
4. The new partner(s) has never had a previous DEA registration revoked, suspended or denied.

C. **Corporation** Unlike a sole proprietorship and a partnership, a corporation is a separate legal entity having its own rights, privileges, and liabilities distinct from its owners. The sale of stock in a corporation does not require the acquisition of a new registration. If a corporation is purchased in its entirety to become a wholly owned subsidiary of another corporation and there is no change in the subsidiary corporation, a new registration is not required, unless the subsidiary corporation ceases to exist. If a corporation/registrant is merged with another, and the corporation is changed or ceases to exist, the new corporation must obtain a new registration in accordance with 21 C.F.R. § 1301.11.

D. **Pharmacy** If a pharmacy relocates within the same state without a change in ownership, a new registration is not necessarily required by the DEA, even if the state licensing authority requires that the pharmacy obtain a new license (memorandum dated April 19, 2010, by Joseph T. Rannazzisi, Deputy Assistant Administrator, OD). Any registrant wishing to discontinue business activities should be instructed to return its registration certificate and any unused order forms to their local DEA office. The registrant must notify DEA of the discontinuance of registration at least 14 calendar days in advance of the date of the proposed transfer. Any controlled substances or List I chemicals on hand at the time of discontinuance of business must be inventoried by the registrant and either transferred or disposed of in accordance with 21 C.F.R. §§ 1301.52(e), 1307.21, or 1309.62.

In situations where the sale of a DEA-registered facility requires the purchaser to obtain a new DEA registration but the application will not be approved prior to the finalization of the sale, the DEA may allow the new owner to temporarily use the seller's DEA registration. The primary condition for this allowance is that the new owner expeditiously applies for a DEA registration and appropriate state licensure, and both the purchaser and seller enter into a power-of-attorney that specifically sets forth the following:

1. The seller agrees to allow the purchaser, as an agent of the seller, to continue the

controlled substance or List I chemical activities of the registrant, including the ordering of these products, to be carried out under the seller's DEA registration.

2. The seller acknowledges that, as the registrant, they will be held accountable for any violations of law or regulation regarding controlled substances and List I chemicals which may occur.

3. The purchaser agrees that the controlled substance or List I chemical activities of the registrant may be carried out under the seller's registration and the power-of-attorney must remain in effect for no more than 45 days after the purchase date, which must be recorded in the agreement.

Additionally, the purchaser must notify the appropriate local DEA office of the proposed use of the seller's DEA registration and, if requested, furnish a copy of the agreement. The local DEA office may withhold permission for the purchaser to use the seller's registration if circumstances warrant. These circumstances could include an investigation on the purchaser or seller, a history of compliance or diversion problems with either party, or questions regarding whether the purchaser will be able to obtain the necessary state permits in time. If it becomes necessary to extend the power-of-attorney beyond 45 days, a written request for an extension must be furnished to the local DEA office by the seller. Reasons for the extension must be cited and will be reviewed by DEA on a case-by-case basis.

The Diversion Investigator should make every effort to determine whether derogatory information exists before advising a registrant that no new application need be filed. Furthermore, the criteria contained in this section should not be made generally available to registrants since it is only intended to provide guidance to the Diversion Investigator.

5113.35 Narcotic Treatment Program (NTP) Relocation

Relocation of a Narcotic Treatment Program (NTP) within a state requires only a letter of request from the registrant to modify its registration. DEA will grant the modification subsequent to approval by both the Center for Substance Abuse Treatment (CSAT) and the state. DEA may grant approval of a proposed site on the basis of adequate security and record keeping; however, the program should be instructed not to begin operation at the new location until the approvals by CSAT and the state are received.

When an NTP meets security and record keeping requirements, (b)(7)(E) (b)(7)(E) The Registration Unit will issue an amended certificate only when all required approvals are obtained. In some instances, state approvals may be contingent upon DEA approval.

5113.36 Exemption from Registration

A. **Physician** There are situations where a physician may *administer or dispense* a controlled substance without the physician obtaining a separate registration with the DEA. An individual physician who is an agent or employee of another physician (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of a prescription) controlled substances, if and to the extent that such individual physician is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principle physician in lieu of being registered himself/herself (21 C.F.R. § 1301.22(b)).

An individual physician who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, *administer, dispense, or prescribe* controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered himself/herself, provided that all parties to the arrangement meet the six conditions outlined in 21 C.F.R. § 1301.22(c).

The Diversion Investigator should be aware that some physicians might attempt to use this hospital registration in private practice in an effort to avoid having to pay for a separate DEA registration. The physician is then acting outside the normal course of business or employment and must obtain a separate DEA registration to administer, dispense, or prescribe controlled substances in this private practice.

B. **Military NTP** Activity by the military using controlled substances inside the military system is outside DEA's closed system of distribution. If the military NTP needs to obtain methadone or buprenorphine from a DEA registrant, the military makes such purchases through one central location, and the DEA registration number of that location issues a DEA Form 222. The supplier can then ship the methadone, buprenorphine or any other controlled substances to any location identified by the military (21 C.F.R. § 1301.13(f)).

C. **Penal Institution NTP** A Penal Institution NTP must obtain a DEA registration as a Narcotic Treatment Program if it plans to provide maintenance or detoxification treatment to inmates.

A physician, registered at a penal institution, can administer methadone for the purpose of treating withdrawal symptoms, to an inmate for up to three days (21 C.F.R. § 1306.07(b)) while the physician works to get the patient enrolled in an NTP.

A penal institution may serve as a custodian for an inmate that is enrolled in a NTP and can receive and store methadone specific to that inmate. The penal institution can also return the methadone to the NTP if the inmate is released.

D. **Ocean-Going Vessel** 21 C.F.R. § 1301.25 provides for exemption from registration for ocean-going vessels and certain aircraft, to store controlled substances, provided these controlled substances are carried on the vessel under the auspices of a medical officer.

E. **Federal Physician** The following refers to three different categories of physicians employed by the Federal Government.

1. **Military Physicians in United States**: An application for registration submitted by a physician exempt from state licensing of the registered address state and/or registration on the basis of employment with the military will be referred to ODR. ODR will issue a registration to such a physician for official duties only, provided the physician has completed an acknowledgment form indicating that this physician is aware of, and will abide by, the restrictions placed upon the use of that registration.

Documentation is maintained by ODR and the credentialing office of the military base

2. **Military Physician Assigned to a U.S. Military Reservation on Foreign Soil**: DEA and state registrations are waived for a medical physician conducting official duties while in military service. This includes a physician in the military stationed outside the official boundaries of the U.S.

The military physician stationed at a U.S. military installation abroad would use the controlled substance stock procured by that installation.

3. **Physician Assigned to a U.S. Embassy**: A medical care physician employed by the Department of State for embassy personnel, though located overseas, is issued a DEA registration so that they can order controlled substances from U.S. suppliers. Their application for registration must reflect the following address: Physician's Name, U.S. Department of State, M/MED/QI, SA-1, Washington D.C. 20522-0102.

F. **Fee Exemption**: Federal Government physicians (FEDDOC) and other authorized officials are eligible for exemption from DEA registration fees. FEDDOCs considered for fee exemption are as follows (listed in alphabetical order by common acronyms):

BOP – Federal Bureau of Prisons
CDC – Centers for Disease Control
DEA – Drug Enforcement Administration
DoD – All branches of the U.S. Armed Services
DOJ – U.S. Department of Justice
FAA – Federal Aviation Administration
FDA – Food and Drug Administration
HHS – Health and Human Services
ICE – Immigration and Customs Enforcement
IHS – Indian Health Services

NASA – National Aeronautics and Space Administration
NCI – National Cancer Institute
NIH – National Institutes of Health
NIMH – National Institute of Mental Health
PHS – Public Health Services
U.S. Capitol Physician's Office
USDA – U.S. Department of Agriculture
USPS – U.S. Postal Service
VA – U.S. Veterans Affairs
The White House

Physicians that are direct employees (not contract physicians) at the above institutions may obtain a DEA number without being licensed in the state in which they are physically located, so long as they hold state licensure (both a medical license and any additional state registration to handle controlled substances) somewhere in the United States. The official business address must be on the DEA application form and the DEA registration number may only be used for official business.

If a FEDDOC physician wishes to maintain a DEA registration for a private practice, which would include prescribing for private patients, they must be fully licensed to handle controlled substances by the state in which they are located. Under these circumstances, the FEDDOC physicians will not be eligible for the fee exemption and must pay the DEA registration fee as mandated by Congress.

5113.4 Registration Requirements

5113.41 Analytical Testing Laboratory Registration

Reserved

5113.42 Athletic Team Practitioner Registration

A. A DEA registered team practitioner may maintain a stock of controlled substances at the physical address of the team's home stadium. However, the practitioner must register with DEA at that location. The registered team practitioner is accountable for DEA and state compliance with controlled substance recordkeeping and security regulations. The practitioner may dispense or administer controlled substances from this stock; however, the practitioner may only administer or dispense controlled substances at this registered location. The practitioner may prescribe controlled substances anywhere inside a state in which they hold a DEA registration as long as such prescribing complies with Federal, State and local laws and regulations. For further information on this issue, please refer to the Final Rule, titled Clarification of Registration Requirements for Individual Practitioners that DEA published in the Federal Register on December 1, 2006.

B. As part of appropriate security, the practitioner must limit access to these controlled substances. Where state law permits, a registered practitioner may authorize training staff individuals to dispense or administer controlled substances pursuant to the practitioner's instructions and direct supervision.

C. Many sports organizations have established procedures to audit controlled substance activities to safeguard against potential abuse. Individuals, who learn of the abuse of controlled substances or the violation of regulations pertaining to controlled substances, should promptly report this information to DEA or the appropriate state or local authorities.

D. The Diversion Investigator should be aware that the team practitioner, or another practitioner, might have legitimately prescribed controlled substances to a specific team member. These controlled substances, which are now in the possession of those team members, are not the responsibility of the team practitioner.

5113.43 College-Affiliated Researcher Registration An application for registration as a college-affiliated researcher may be made by either an individual or a department. The registration must be in accordance with existing state registration requirements. Research protocols are required for schedule I controlled substances as outlined in 21 C.F.R. § 1301.18. In addition, the DEA Diversion Investigator may also request research protocols for schedule II-V controlled substances if that information is
critical to the processing of an application.

5113.44 Opium Poppy Cultivation United States policy prohibits the commercial cultivation of opium poppies. Limited cultivation for opium poppy research (i.e. botanical or chemical) is allowed in accordance with existing state registration requirements and the DEA research protocols in 21 C.F.R. § 1301.18.

5113.45 Animal Shelter Registration

A. To be consistent with the activities involved and the amount of controlled substances used, DEA may register animal shelters as mid-level practitioners if also consistent with
state law. In states that register animal shelters as independent entities, the personnel managing the shelters are the responsible individuals. Employees and agents of the shelter performing duties in their usual course of employment may administer substances as allowed by state law and directed by shelter management.

B. In states that do not register shelters as separate entities, shelters must follow the rules established by each state and DEA for individual practitioners. In this case, veterinarians at animal shelters may maintain a limited quantity of controlled substances if the veterinarian has a valid DEA registration at that location. The practitioner holding the registration is responsible for all of the shelter's controlled substance activity. Employees or agents of the shelter may administer the controlled substances (usually for euthanasia purposes) only under the direct supervision of the practitioner.

DEA Form 222 or placing an order via the Controlled Substance Ordering System (CSOS), which is only available to DEA registrants. Thus, if a law enforcement canine program wants to obtain controlled substance training aids from DEA, it must register as a researcher, business activity G-1. All federal, state, and local law enforcement canine training programs are exempt from the registration fee. If a local law enforcement organization does not want to obtain a DEA registration, yet still wants to have a canine training program, it may do so by utilizing its own, adjudicated supply of controlled substances seized during arrests, or controlled substances scheduled to be destroyed, if allowed by state law and regulation. A law enforcement organization that does not have a DEA registration may not obtain controlled substances from DEA.

b. Large law enforcement organizations may choose to have a single registration (e.g., at their headquarters) and transfer controlled substances to other locations (e.g., various posts within their jurisdiction). Adequate security measures and record-keeping should be outlined in a *Memorandum of Agreement (MOA) with the local DEA field office. Normally, DEA registrants are required to have separate registrations for separate locations. The DEA registration for law enforcement canine handlers is only to facilitate the acquisition of training materials from DEA. Thus, it is permissible, since law enforcement has the authority to possess and handle controlled substances without a DEA registration, to transfer the controlled substances obtained from DEA to other posts within their jurisdiction. However, the registered location which receives training aids from DEA and then distributes them to other locations is required to maintain records documenting their receipt, storage, distribution, dispensing, and destruction of controlled substances.

c. DEA field laboratories will not be a source of supply for law enforcement canine handlers. Rather, DEA provides controlled substances as training aids to law enforcement canine handlers through the Special Testing and Research Laboratory (STRL), Office of Forensic Sciences, Operational Support Division. The STRL will only provide these training aids to state and local law enforcement entities registered with DEA. Pursuant to this policy, state and local law enforcement organizations may not subsequently provide private canine handlers with controlled substances obtained from DEA. DEA will discontinue supplying controlled substances to any state or local law enforcement entity found to be engaged in this practice.

d. The STRL is responsible for dispensing controlled substances to registered law enforcement entities with drug detection canine handler programs. Field offices that receive requests for controlled substances from law enforcement organizations should forward those requests to:

Laboratory Director (or designate)
DEA Special Testing and Research Laboratory
22624 Dulles Summit Court
Dulles, Virginia 20166-9509
(703) 668-3300

5113.46 Registration to Use Carfentanil, Etorphine HCL, and Diprenorphine for Exotic Animals, Wildlife, and Deer Farms

NOTE: All three drugs are schedule II substances. Due to the extreme potency of etorphine HCL and carfentanil, special security and record keeping provisions are required for their use. Registrants should refer to 21 C.F.R. §§ 1301.74(g), 1301.75(d), and 1305.07 for details concerning these provisions.

A. **Exotic Animals and Wildlife** Etorphine HCL (also known as M-99) has been approved for the immobilization of exotic animals and wildlife. Carfentanil has been approved specifically for immobilizing the ranging or confined members of the Cervidae family (deer, elk, and moose). Diprenorphine (also known as M50-50) is used as the antagonist for both etorphine HCL and carfentanil. The Food, Drug, and Cosmetic Act restricts the use of these three drugs to licensed veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers whose work includes
some wildlife specialty.

B. **Deer Farm Herds** A practitioner may provide controlled substances to a deer farm in two ways. A practitioner could obtain a DEA registration at a deer farm. Under this registration, the veterinarian can then obtain controlled substances. The individuals working at the deer farm can then administer these controlled substances, as needed, to members of the herd, while operating under the direct supervision of the practitioner. As an alternative, a veterinarian with a valid vet-client-patient relationship may issue a prescription for the controlled substance to the deer farm owner. Under Food and Drug Administration (FDA) veterinarian guidelines, the deer herd is the patient.

5113.47 Drug Detection Canine Training Programs

A. DEA recognizes two categories of drug detection canine handlers: civilian and law enforcement. To acquire controlled substances for training purposes, DEA requires a civilian canine handler to register as a researcher. The civilian canine handler must obtain its training materials from other DEA registrants. Law enforcement canine handlers are specifically exempt by regulation from registering with DEA to handle controlled substances. However, if a law enforcement canine handler wishes to obtain controlled substance training aids from the DEA Special Testing and Research Laboratory, then the law enforcement canine handler must first obtain a DEA registration as a researcher. Diversion Investigators must be aware of the distinction between the two types of canine handlers and know the following policy and procedures for both.

1. Law Enforcement Canine Training Programs.

a. Title 21 C.F.R. § 1301.24 exempts federal, state, and local law enforcement entities and their canine drug detection programs from registration. However, DEA's policy is that these entities may only obtain controlled substances from DEA by submitting a properly executed

Requests must be in writing on the letterhead of the law enforcement organization making the request and signed with an original signature by the Sheriff, Chief of Police, or equivalent rank. For complete instructions on the information that these requests must contain, field offices should contact the STRL at the address/telephone number indicated above. Controlled substance materials requested for this purpose will be provided free of charge to the requester.

2. Private Canine Training Programs

a. Private canine training programs that handle controlled substances are required to register as researchers, business activity G-1, and are not exempt from the registration fee.

b. Private canine handlers may obtain controlled substances from a private source (manufacturer) or from a local law enforcement organization's adjudicated supply of controlled substance material scheduled for destruction. A private canine handler may not obtain controlled substance from a law enforcement organization who has obtained those same materials from DEA. In addition, private canine handlers are prohibited from obtaining controlled substance material from a local law enforcement organization that is contraband, that is, material that has not been adjudicated, for use in training canines.

c. If a state or local law enforcement organization wishes to distribute controlled substances from its own seized, adjudicated supply of controlled substances to a private canine handler, then the Controlled Substances Act and DEA regulations require that both the law enforcement organization and the private canine handler register with DEA as researchers. Once registered, the law enforcement organization can distribute controlled substances to a private canine handler as a coincident activity under 21 C.F.R. § 1301.13(e)(1)(v). It is at the law enforcement organization's discretion whether it wishes to provide controlled substances to a private canine handler. The law enforcement organization may choose not to provide controlled substances to a private canine handler for a variety of reasons, such as inadequacy of the canine training program, security concerns, or lack of need for drug detection services.

d. If a law enforcement organization registered with DEA decides to distribute controlled substances to a private canine handler, and that private canine handler has registered with DEA, then the participants must document this distribution on a DEA Form 222 or placing an order via CSOS. DEA also advises, but cannot require, that there be a MOU between the law enforcement organization and the private canine handler regarding the responsibilities of each participant. Again, because the STRL provides controlled substances to law enforcement organizations at no charge, the same organizations are barred from providing them to non-law enforcement/private companies, even if they hold a DEA registration.

e. Private canine handlers do not have the authority to take into custody any of the material the canine may find. Their authorization does not extend to seizing and handling contraband drugs. Only law enforcement authorities may seize and possess such contraband.

5113.48 Veterinary Hospitals and Affiliated Practitioners Registration

A. Veterinary Hospitals

1. DEA does not register veterinary clinics or hospitals under a hospital/clinic business activity. An exception to this rule is made when a veterinary institution is clearly an animal hospital for a large regional area and not just a group practice. This veterinary hospital must employ an extensive number of veterinarians, with a large staff operating 24 hours, seven days per week. The hospital must contain a multitude of inpatient kennels or beds, its own inpatient pharmacy, and be registered by the state as a veterinary hospital.

2. A veterinary hospital which is operating under the authority of a college should be registered as a teaching institution if its primary purpose is to teach interns, residents, and students regarding veterinary medicine. However, a veterinarian treating private animal patients while employed at a teaching institution is engaged in private practice and must be separately registered with DEA as a practitioner

B. **Affiliated Practitioners** Individual veterinarians must register with DEA to order, administer, dispense, and prescribe controlled substances. If a group of affiliated veterinarians are practicing together at one location, the principal veterinarian may register with DEA in lieu of each individual veterinarian becoming registered as a practitioner. The principal veterinarian, under whose DEA registration number the controlled substances are ordered, would be responsible for recordkeeping and security for the controlled substances.

5113.49 Locum Tenens Practitioner

A. There are no DEA regulations governing locum tenens practice by DEA registered practitioners. If and when regulations are promulgated on locum tenens, this manual will be updated accordingly.

B. The practice of locum tenens, whereby a DEA registered practitioner substitutes for another practitioner on a temporary or sporadic basis at that other practitioner's DEA or registered place of business, is considered by the DEA to be a "principal place of business professional practice" for purposes of DEA registration (see 21 C.F.R. § 1301.12(a)). The Controlled Substances Act (CSA) requires that a separate registration be obtained for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed. Title 21 U.S.C. § 802(10) defines "dispensed" as meaning "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance..."

C. The DEA regulations provide an exception that a practitioner who is registered at one location, but also practices at other locations, is not required to register separately for any other location at which controlled substances are only prescribed (21 C.F.R. § 1301.12(b)(3)). The exception applies only to a secondary location within the same state in which the practitioner

maintains his or her registration. If the practitioner maintains supplies of controlled substances, administers, or directly dispenses controlled substances at the separate location the practitioner must register for that location. Thus, if the locum tenens practice is within the state in which the practitioner is DEA registered, a second DEA registration is not required if the above parameters are met.

D. Since DEA practitioner registrations are based on state authority to practice medicine and prescribe controlled substances, a practitioner is not authorized to dispense controlled substances outside the state in which he or she is registered. Therefore, any locum tenens practice that is conducted in a state other than the state in which a practitioner maintains his or her DEA registration is subject to a separate DEA registration for that state.

E. As an alternative to obtaining a second DEA registration in another state to accommodate locum tenens practice, if a practitioner is licensed in the other state to practice medicine and handle controlled substances, he or she may submit an address change for their current DEA registration for the temporary practice location. There is no cost to change a DEA address, even temporarily. At the end of the locum tenens practice, the practitioner may then submit a request to change their address back to their primary place of business. Address changes should be made using the Office of Diversion Control website (www.DEAdiversion.usdoj.gov).

F. If the practitioner's locum tenens service is with a hospital, and the hospital agrees, the practitioner may use the registration of that hospital. The DEA regulations provide an exemption for an individual practitioner who is an agent or employee of a hospital. This exemption places the controlled substance registration and recordkeeping responsibility with the hospital or other institution; therefore, there is no need for individual DEA registration. The term "institution" in this context is not defined in the Controlled Substances Act or C.F.R. However, for purposes of clarification, an "institution" refers to any entity registered with the DEA as a hospital/clinic. Additional institutions may fall under this category as circumstances warrant. Consult with the Diversion Program Manager, the Assistant Special Agent in Charge (ASAC) with oversight of the Diversion Control Program, or Liaison and Policy Section, Office of Diversion Control, for additional guidance if necessary.

5114 REGISTRATION NUMBER VERIFICATION

Prior to distributing a controlled substance, a DEA registrant is required under 21 C.F.R. §1301.74(a) to make a good faith inquiry to ensure that any customer to whom they propose to supply controlled substances is properly registered with the DEA and/or the appropriate state controlled substances registration agency. Verification is necessary to determine that the customer's DEA registration number is valid and the customer is ordering a controlled substance which is permitted by its registration, including the proper drug codes for researchers, if those researchers are required to list drug codes on the registration applications. An online registration validation tool is available at DEA's diversion website www.DEAdiversion.usdoj.gov to assist the DEA registered supplier to verify a customer's DEA registration number. In order to utilize the validation tool on the DEA website, the requesting entity must be a DEA registrant.

DEA sends a weekly update of registration information to the Department of Commerce, National Technical Information Service (NTIS); NTIS, which in turn, sells the information to commercial sources. Customers (credentialing offices, insurance companies, etc.) may subsequently subscribe to a commercial website for a fee in order to validate DEA registrations.

Subchapter 512 Security

5121 GENERAL All applicants and registrants are required to provide effective controls and procedures to guard against the theft and diversion of controlled substances. Regulations regarding security requirements, although specific and needing little in the way of further interpretation are outlined in 21 C.F.R. Parts 1300 to End. This subchapter will attempt to clarify and explain certain aspects of the security requirements of controlled substances. The Investigator must have a thorough knowledge of the regulations pertaining to security. When evaluating any security system, it is important for the Investigator to consider all aspects of a registrant's security system. 21 C.F.R. § 1301.71 sets forth the general guidelines for conducting the security investigation.

5122 STORAGE ENCLOSURES 21 C.F.R. § 1301.72 identifies several permitted methods for storing controlled substances and should be reviewed prior to approving specific storage containers or areas.

5122.1 Safes

A. Requirements for safes or steel cabinets used to store controlled substances are set forth in 21 C.F.R. § 1301.72(a)(1). Most safes are rated by Underwriters Laboratories, Inc. (UL), an independent, nonprofit, testing laboratory. The UL ratings can be used to determine if the safe meets the requirements spelled out in the regulations. A safe used to store controlled substances must meet the following specifications or the equivalent: 30 man-minutes against surreptitious entry; 10 man-minutes against forced entry; 20 man-hours against lock manipulation; and 20 man-hours against radiological techniques.

The GSA Class 5 safe is an approved storage container and is rated for 30 man-minutes against surreptitious entry and 10 man-minutes against forced entry. In the event a registrant cannot locate a Class 5 safe, they should locate and obtain a UL rated TL-15 safe. The letters "TL" indicate the safe is rated to resist forced entry by most common hand tools. The number, "15," represents the amount of time in minutes UL has rated this type of safe to resist forced entry.

The 15 minutes exceeds the regulation's 10 minute requirement for forced entry. As an alternative, a registrant could also use a higher rated safe: a TL-30 or TL-60.

In order to identify and/or verify that a safe/container meets regulatory requirements, the registrant should provide the paperwork or specifications sheet on the safe. The documentation should have all the identifying information and there should be an identification label affixed to the safe. On file cabinet style safes, the label should be affixed to the external side of the drawer

containing the lock. The identification label should show the manufacturer, make, model and serial number. On GSA rated safes there should also be a "certification label." The label will bear the following certification:

For the Class 5 –

"This is a U.S. Government Class 5 cabinet which has been approved by GSA under Fed. Spec. AA-F-358H. It affords the following protection:

30 man-minutes against covert entry
10 man-minutes against forced entry
20 man-hours against surreptitious entry"

For the Class 6 –

"This is a U.S. Government Class 6 cabinet which has been approved by GSA under Fed. Spec. AA-F-358H. It affords the following protection:

30 man-minutes against covert entry
20 man-hours against surreptitious entry
No forced entry requirement"

(NOTE: Class 6 containers are not authorized for use in storing schedule I & II controlled substances.)

On other style safes and containers, the labels should be located on the inside face of the door and should be clearly visible when the door is open.

If for some reason the registrant does not have paperwork for the safe and/or the labels are missing, a licensed locksmith must certify the type of safe and protection level it affords its contents.

B. UL Safe Ratings:

TL-15: Combination locked safe, 750 pounds minimum weight, resists forced entry for a minimum of 15 minutes using any common hand tools, picking tools, mechanical or portable electric tools, grinding points, carbide drills, and pressure applying devices or mechanisms. TL-30: Combination locked safe, 750 pounds minimum weight, resists forced entry for a minimum of 30 minutes using any tools specified under TL-15 and may also include abrasive cutting tools and power saws.

TRTL-30 and TRTL-60: Combination locked safe, 750 pounds minimum weight, resists forced entry for a minimum of 30 and 60 minutes respectively using any tools specified under TL-30 and may also include impact tools and a gas cutting or welding torch. TXTL-60: Combination

locked safe, 1000 pounds minimum weight, resists forced entry for a minimum of 60 minutes using all the tools under TRTL-30 and additional may include nitroglycerine and other high explosives.

C. Any safe used to store schedule I and II controlled substances should weigh at least 750 pounds. A safe weighing less than 750 pounds should be bolted or otherwise affixed to the floor or wall to prevent removal from the area. In addition, Investigators should not approve any safe, regardless of weight, that is equipped with wheels or casters unless the safe is anchored to the floor or wall. Finally, safes must be alarmed in accordance with the regulations (see 21 C.F.R. § 1301.72(a)(1)(iii)).

5122.2 Vaults

Requirements for vaults used to store schedule I and II controlled substances are set forth in 21 C.F.R. § 1301.72(a)(2) and 21 C.F.R. § 1301.72(a)(3). The regulations require a vault meet the following specifications or the equivalent: 30 man-minutes against surreptitious entry; 10 man-minutes against forced entry; 20 man-hours against lock manipulation; and 20 man-hours against radiological techniques.

An alternative to the traditional monolithic, poured-in-place, reinforced concrete vault described in the regulations is the modular vault. Modular vaults are light weight and structurally equivalent to the traditional vault. Modular vaults allow the registrant the flexibility to move or expand the vault as needed to meet security needs.

UL approved modular vault panels comply with the regulations for storage of controlled substances. The modular vault should utilize a GSA approved Class V vault door and frame. UL classifies modular vaults according to tests that determine the amount of time it takes to breach the vault. The four UL classifications are:

Class M - 15 minutes resistance against forced entry
Class 1 - 30 minutes resistance against forced entry
Class 2 - 60 minutes resistance against forced entry
Class 3 - 120 minutes resistance against forced entry

Although the Class M Modular Vault meets the minimum requirements for resistance against forced entry as spelled out in the regulations, it is recommended that registrants install a Class 1 vault.

Although the regulations require all vault floors to be constructed of "at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½ inch steel rods tied 6 inches on center, or the structural equivalent...," it has been determined that registrants may vary from these strict requirements if they meet certain conditions. The following conditions, as outlined in Security Notice 95-1 dated March 30, 1995, if implemented, permit a registrant to vary from the regulations:

1. The proposed vault floor is cored/drilled to determine consistency (minimum 3000 psi) and thickness (minimum six inches).
2. The location of the proposed vault (monolithic or modular) is constructed on a slab on grade with no basement or crawl space within 15 feet of the proposed site.
3. The proposed vault is constructed within the building's interior. It should be no closer than 15 feet from an exterior wall.
4. The proposed vault has adequate protection, utilizing physical barriers and an intrusion alarm system, which affords perimeter and volumetric protection.
5. Consideration is given to the fifteen standards set forth in 21 C.F.R. §1301.71(b).

In order to avoid the above five qualifiers, a registrant should be encouraged to build a six-sided vault (four sides, roof and floor) when conditions allow.

5122.3 Locks Combination locks for safes and vaults are classified according to the degree of protection afforded against manipulation:

A. **MECHANICAL LOCKS**

Group 1 combination locks are highly resistant to expert or professional manipulation. The protection against expert manipulation includes closed cams, notched tumblers, extra levers, or other advanced design features not found in conventional designs.

Group 1R combination locks afford the same protection against expert or professional manipulation as a Group 1 lock and in addition include resistance against radiological methods of attack.

Group 2 combination locks are resistant to semiskilled manipulation.

Group 2M combination locks are moderately resistant to skilled manipulation.

B. **ELECTRONIC LOCKS**

Type 1 high security electronic locks are highly resistant to expert or professional manipulation or to surreptitious attacks.

Type 1F high security electronic locks afford the same protection against expert or professional manipulation or surreptitious entry as a Type 1 lock, and in addition, have been evaluated in accordance with U.S. Federal Specification FF-L-2740, except for security tests. Type 1F locks are considered suitable on safes, security files, and vaults where the highest degree of protection is required.

There are two categories of locks approved for use by DEA registrants for securing schedule I and II controlled substances in safes or vaults: Group 1R and Type 1 (or Type 1-F) locks. The UL rated Group 1R lock is a mechanical lock and the UL rated Type 1 (1F) is a high security electronic lock.

21 C.F.R. § 1301.72(a)(1)(i) states, "Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques."

The "20 man-hours against lock manipulation and 20 man-hours against radiological techniques" are the only references in the regulations relating specifically to the lock. Both the Group 1R and Type 1 high security electronic locks meet these requirements.

In order to properly identify a lock, the registrant should provide information, (sales receipt, purchase order, data sheet, or specification sheet) as to what type of lock is installed. Most locks will have identifying labels affixed to the lock body. The paperwork should be compared to the identifying label on the lock to verify that the correct lock has been installed. If the registrant does not have paperwork on the lock or the labels are missing, a licensed locksmith must inspect the lock and provide certification on its type.

Group 1 locks (mechanical) can be identified by the type of dial. It should have a "spy-proof" dial and dial ring. The "spy-proof" dial restricts the reading of the combination to those around the safe. In order to dial the combination, you must be looking down, onto the dial. This prevents unauthorized individuals from witnessing the combination while it is being dialed. Dials prior to the "spy-proof" dial (i.e. front reading dials) allowed anyone interested the opportunity to watch the combination being dialed.

The Group 1 locks are designed to resist opening by manual and electro-mechanical lock manipulation techniques. Some models are equipped with a special cam that prevents opening until either an external turn knob (located in the center of the dial) is engaged or the dial is pushed inward. The differences between the Group 1 and 1R locks are the type of combination wheels used. Group 1 locks usually feature brass and aluminum combination wheels. Acetal resin wheels (Nylon, Lexan, Delron or plastic) are used in the 1R version for radiological attack resistance.

NOTE: Investigators should not remove the back cover or try to disassemble any lock. Removing the cover should only be done by a qualified individual. Improperly removing the cover can damage the lock.

Type 1 electronic locks (electro-mechanical) come in a variety of makes and models from a variety of manufacturers. They can either come with a traditional "spy-proof" dial (similar to mechanical locks) or with a push button key pad. Although the push button style of the Type 1

electronic lock is approved for use, registrants should be discouraged from using them. If the lock is already installed on a safe or vault door then the registrant should be cautioned when using this style of lock. The numbered buttons on the key pad can become worn, soiled or faded over time revealing the combination numbers, although not necessarily in the correct order. Another potential problem with the push button style locks is the lack of the "spy-proof" dial. Without a "spy-proof" dial unauthorized persons could potentially witness the combination being entered on the key pad while standing behind the individual entering the numbers. Some makes and models of the push button locks can be ordered with an optional spy-proof cover. Registrants should be encouraged to employ this option. Regardless of which type of lock used (traditional dial or push button), the Investigator is required to verify the lock is a UL approved Type 1 lock.

Schedule III, IV and V controlled substances can be stored in containers equipped with any of the categories of locks: Group 1, Group1R, Group 2, Group 2M, Type 1 and Type 1F.

5122.4 Cages and Other Storage Enclosures

Regardless of the type of storage enclosure used, it should provide adequate security to prevent the theft and/or diversion of the controlled substances stored within. The storage enclosure should meet the minimum specifications as outlined in 21 C.F.R. § 1301.71 through § 1301.76. Access to the controlled substances should be limited to the minimum number of authorized employees necessary.

Controlled substances in schedules III, IV and V can be stored in a variety of storage areas. They can be stored in a safe or vault with schedule I and II controlled substances or in a building, cage or any other substantially constructed enclosure deemed to provide adequate security and approved by the Investigator.

If a registrant chooses to utilize an entire building to store controlled substances, the registrant needs to ensure the building has adequate security. The number of entrances and exits should be limited to as few as possible. The doors should be self-closing and self-locking, substantially constructed and alarmed. If allowed by code, the exterior hardware (door knobs and handles) should be removed from all doors not used as primary entrances/exits. Emergency exits should be equipped with alarmed crash bars and be alarmed at all times. Any and all exterior door hinges should be welded, sealed, pinned or otherwise constructed to prevent the removal of the hinge pin. All windows should be alarmed and have security bars installed or be covered with a security mesh if allowed by code.

Cages used to store schedule III, IV and V controlled substances should meet the minimum standards outlined in 21 C.F.R. §1301.72(b)(4). The regulations require a cage be constructed of, "not less than No. 10 gauge steel wire...." It should be noted that the "gauge" of wire is the rating given the wire based on its thickness and is inverse to the number assigned. For example, No. 9 gauge wire is thicker than No. 10 gauge and No. 8 gauge is thicker than No. 9 gauge. Thus, the smaller the rating number, the thicker the wire. A registrant with a cage constructed of

No. 9 or No. 8 gauge wire would exceed the minimum requirements but a registrant with a cage constructed of No. 11 or No. 12 gauge wire would not meet the requirements.

The regulations require that a controlled substances cage be constructed with a mesh manufactured with, "openings of not more than two and one-half inches across the square." The term "across the square" has been interpreted as the greatest point of separation in the mesh configuration in any direction (vertically, diagonally, and horizontally). In order to help further define "across the square," the Investigator must first review the purpose of a cage. The cage must segregate schedule III, IV and V controlled substances from non-controlled substances and afford adequate physical protection against theft and diversion. The intent of the mesh configuration is to prevent pilferage by removing items through the openings. Investigators need to take a "common sense" approach when determining the adequacy of the wire mesh to protect the controlled substances. There are mesh configurations currently being used that are the exception to the rule. For example, if the cage is constructed of security fencing that has a mesh opening with a ½ inch vertical measurement and a three-inch horizontal measurement, by the definition of "across the square," this cage would not meet the standard because it has a three-inch long horizontal opening. However, the mesh opening is so small that the average person would be unable to get their fingers between the mesh.

Schedule III, IV and V controlled substances can be stored in virtually any type of enclosure provided it adequately prevents the theft or diversion of the substances. The regulations allow the Investigator, with approval of the Group Supervisor, the flexibility to approve an enclosure constructed of almost any material after carefully considering the 15 factors listed in 21 C.F.R. § 1301.71(b). In addition to considering the 15 factors, the Investigator needs to consider the totality of the situation. For example, what is the applicant's experience with controlled substances; does the registrant have a violative history with DEA; is there a history of diversion, theft or unexplained losses. The Investigator should thoroughly evaluate the security afforded the controlled substance before approving any storage area or enclosure.

5122.5 "Knox-Box®" Rapid Entry Systems

A "Knox-Box®" Rapid Entry System is a high security, heavy duty key box which is mounted on the exterior of a building. The boxes are constructed of ¼ inch solid steel with a ½ inch steel door and reinforced locking mechanism and are UL listed against physical attack. The Medeco security lock is patented and UL listed for drill, pick and pull resistance. Further, the boxes store a key which provides firefighters and other emergency personnel non-destructive emergency access to buildings. One "master key" provides firefighters immediate building entry day or night, access to all properties within its jurisdiction, time-saving response to false alarms, and safe entry without force or potential injury.

Municipalities across the country are increasingly passing ordinances requiring that commercial properties and buildings to be equipped with fire alarm and/or sprinkler systems utilizing these key boxes. By utilizing the lock box and allowing firefighters to get in early, they can keep a

small fire from spreading, thereby limiting damage to a facility. In the event the alarm turns out to be a "false alarm" the building can be secured by simply re-locking the undamaged door. Most Knox-Box® models offer optional tamper switches which allow the box to be connected to the buildings alarm system. Any registrant or facility storing controlled substances that are required by municipal fire codes/ordinance to install a "Knox-Box®," must utilize the tamper switch option and must connect the box to the alarm system. Also, it is highly recommended that the registrant use a recessed mounted box equipped with a hinged door instead of a surface mounted model or lift-off door.

NOTE: Knox-Box® is one brand of key box that is manufactured and sold by the Knox Company, Irvine, CA. It appears to be the most popular brand Rapid Entry System key box in use.

5123 GRANDFATHER CLAUSE PROVISION

A. Title 21 C.F.R. § 1301.72(a)(2) states that, "schedule II controlled substances may be stored in a vault which was constructed or under construction before September 1, 1971, that is of substantial construction with a steel door, combination or key lock, and alarm system." In addition, 21 C.F.R. § 1301.71(e) states that, "physical security controls of locations registered under the Harrison Narcotics Act or the Narcotics Manufacturing Act of 1960, shall be deemed to comply substantially with the standards set forth in 21 C.F.R. §§ 1301.72, 1301.73, and 1301.75."

B. Substantial construction and compliance is determined on a case-by-case basis with consideration of the type and quantity of controlled substances handled and the overall security afforded by the firm. Situations such as rescheduling of drugs, increases in stock, and history of theft are grounds for requiring additional security measures for schedule II vaults, as well as for schedules III through V storage areas. (See DEA Reference Book 5123A for DEA policy on Grandfather Clause.) The "Grandfather" provision facilitated the implementation of the Controlled Substances Act (CSA). Any firm beginning business after the effective date of the CSA is not entitled to the Grandfather provision. In addition, should a firm whose security was approved under the Grandfather provision be sold to another firm, the Grandfather Clause does not transfer to the new firm. The new firm is required to meet security regulations in effect at the time it applied for DEA registration.

C. Schedules III through V security areas approved under 21 C.F.R. § 1301.72(b) prior to the implementation of the CSA were not covered by the Grandfather Clause.

5124 ALARM SYSTEMS

A. Title 21 C.F.R. §§ 1301.72(a)(1)(iii), 1301.72(a)(3)(iv), 1301.72(b)(3)(i), and 1301.72(b)(4)(v), require registrants and applicants for registration to have an alarm system to protect controlled substances from theft and robbery. The alarm system, upon unauthorized entry, must transmit a signal via supervised transmission lines directly to a central station

protection company operating continuously, a local or state police agency that has a legal duty to respond, or to a 24-hour central supervising station operated by the registrant.

B. Further, 21 C.F.R. § 1301.71(b)(9) establishes criteria for determining substantial compliance with the security regulations in part by an evaluation of the adequacy of the "electronic detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources."

C. Alarm systems consist of sensors, control units, and transmitters to send signals off the protected property, and have three major characteristics:

Zone – a protected area, item, or facility
Display and Control Panel – a visual or audible status indication
Communications Link – a path for transmitting signals between the Zone and the Display/Control Panel and a path from the Display/Control Panel to the monitoring station

For its part, the Zone contains three major components:

Sensor(s) – detects changes in the area
Processor – processes the signal received from the sensor(s)
Communications Link – an electrical path for transmitting signals between the Sensor and the Processor and a path from the Processor to the Display/Control Panel

D. Underwriters Laboratories has established alarm system standards and lists those companies that comply with these standards. Underwriters Laboratories (UL) has developed standards on most aspects of the electronic security industry, including equipment, installation and maintenance procedures, central station record keeping, and alarm response. UL lists those companies that comply with these standards, and to be listed by UL, a company must demonstrate that it meets the standards for each category.

E. The National Burglar and Fire Alarm Association (NBFAA), founded in 1948, was organized to pursue the common interests of the alarm industry. NBFAA is a federation of state associations and is governed by a board of directors from each state. The NBFAA is a leading resource on the subject of alarm systems and related fields. The organization has played an active role in fashioning alarm industry licensing and standards. The DEA relies upon UL and NBFAA standards for burglar alarm systems that may be used by DEA registrants. Although not required, DEA highly recommends that UL listed *burglar alarm* equipment be installed and the system be monitored by an UL listed monitoring station. UL's Alarm System Certificate Program provides a convenient and reliable way to identify alarm systems that are tested, monitored, and maintained to meet all nationally recognized codes and standards.

F. UL issues, through authorized UL listed alarm service companies, four types of Burglar Alarm System Certificates: Central Station Service; Mercantile Burglar Alarms; Bank Burglar

Alarms; and Proprietary Alarm Systems. Each certificate identifies the type of alarm system, the name and address of the property protected by the system, and the name and address of the alarm service company responsible for issuing the certificate. A description of the equipment installed, its coverage and other protection details are included. Every certificate has a unique serial number, issue date and expiration date. Certificates are issued for any period up to five years, can be renewed upon request, and can be revoked or cancelled before the stated expiration date. The certificated installations are subject to random physical audits by UL's alarm system auditors. As part of the annual audit process, the UL representatives also scrutinize the required documentation for maintenance, service, and monitoring that is required to be maintained with a certified alarm system. If noncompliance with recognized codes and/or standards is found, the alarm company must rectify the problem or face cancellation of the certificate. It is important to note that not all alarm systems receive a certificate.

G. The two Alarm System Certificates, though not the only, that meet the requirements of 21 C.F.R. § 1300, and which the DEA finds acceptable, are the Central Station Burglar Alarm System and the Mercantile Burglar Alarms.

1. Central Station Service - Service in this category is based on the concept that the alarm service company is fully responsible for the system, that is, the installation, maintenance and monitoring of the system. A certificate may not be issued if the central station is only monitoring the system. A central station system is one in which the arming and disarming (opening and closing) of the system is supervised in the central station. In addition, alarm signals are recorded and runner teams are dispatched to investigate the cause of such signals. The maximum runner response time (five to 45 minutes) to an individual system is identified on the certificate. The certificate also identifies the number of runners and if a representative of law enforcement is dispatched. Central stations have a defined service territory that is based on a maximum travel time by the runner of one hour. Systems that are located beyond this range are not eligible for a certificate unless a listed service center is established by the central station. Runners must be on duty at the central station, a runner station, or a listed service center.

Repairs are initiated no later than one hour after the scheduled closing of the system plus the runner response time stated on the certificate.

2. Mercantile Burglar Alarms - A Mercantile Burglar Alarm System differs from the Central Station Service in that the alarm service company is responsible for the installation and maintenance, but the monitoring station may be an independent entity. Also, the arming and disarming of the system is not required to be monitored. A sounding device is required on both monitored and non-monitored systems. This certificate service does not require investigation of alarm activations (can be added/required). Lastly, repairs are initiated within 18 hours of the request for service.

H. Security systems are completely dependent on a continuous power supply; an interruption of power can jeopardize an entire facility. Normal power sources fail occasionally, so an emergency back-up power system must be part of the system design. The standby or back-up

power source should be capable of maintaining full operation of the alarm system for not less than 24 hours and DEA recommends 48. The switch-over from either back-up power or primary power source should be instantaneous and automatic upon failure/restoration and should not create alarms. The system should also send a signal to the monitoring station indicating "low battery" when necessary.

I. It is important to note that just about any alarm system will work and should be approved by DEA if the following conditions are met:

1. upon unauthorized entry, the system transmits a signal directly to a monitoring station staffed 24 hours per day
2. the signal is transmitted via supervised transmission lines

New applicants and those registrants upgrading their alarm systems should be encouraged to incorporate an alarm system that meets the UL standards for certification.

5124.1 Alarm Categories There are four basic categories of alarm systems: the perimeter or boundary protection; the area/space protection; the object/spot protection; and the duress or panic alarm:

A. The perimeter or boundary protection alarm system is the first line in the defense to detect an intruder. The most common points which are equipped with sensing devices for perimeter protection are doors, windows, vents, skylights or any opening to a facility. Perimeter protection can also be pushed to the exterior of a facility with sensing devices installed on fences or walls.

B. The area or space protection alarm system protects the facility against intrusion whether or not the perimeter is breached. It is effective against the stay-behind intruder or one who cuts through the roof or breaks through a wall.

C. The object or spot detection alarm system provides direct security for an object and is used to detect the activity or presence of an intruder at a single location. The objects which are most frequently protected include safes, vaults or cabinets.

D. The duress or panic alarm system is also known as a hold-up alarm. This is a device which signals a hold-up and is usually surreptitious and manually activated. It can be a fixed mechanical switch/button or portable and worn on the person.

5124.2 Alarm Line Supervision

A. Title 21 C.F.R. § 1301.71(b)(9) contains the criteria for use in determining substantial compliance with the federal regulations of the "electronic detection and alarm systems, if any, including use of supervised transmittal lines...."

B. The communication path between the protected property (i.e., the registered location), and the monitoring facility is required to be supervised with a technique known as "line security" (or line supervision or signal authentication). Line security exists when the communication path is supervised against compromise. Compromising ranges from simple attempts to cut or short the transmission line to more sophisticated clandestine attempts to deceive or spoof the monitoring system. Spoofing is the act of defeating or compromising an alarm system by substituting a fraudulent signaling device for a real transmitter or line supervision device located in the protected area. Line security is characterized by a two-way communication path in which the equipment in the monitoring station sends a coded check-in signal that is uniquely matched to the equipment in the protected property. The check-in signaling occurs pseudo-randomly within a fixed period of time. Line security can be described as Standard or Encrypted. Encrypted Line Security utilizes a 128-bit encryption algorithm to encrypt the check-in signal. Line security was formally referred to by UL as Grade AA. However, UL retired the A, AA, B, BB, C, and CC grading system in 1996. There are web/internet based transmission systems available that meet the line security requirements and can be approved for use by DEA registrants provided they are certified by, and installed in accordance with, UL and NBFAA standards.

C. Registrants and applicants must install alarm systems with supervised transmission lines or communications paths. They should be cautioned to ensure that, in whatever system they choose to employ, the line security/line supervision initiates a check-in inquiry between the monitoring station and the protected premises as frequently as possible, or at least once every five minutes. However, shorter supervision cycles are preferred. Anytime a system fails to initiate a check-in signal within the prescribed time frame, then an alarm signal is transmitted to the monitoring station. Also, registrants and applicants need to be cautioned that "trouble" alarms or signals should be treated as actual alarms. There have been incidents wherein the monitoring station received a "failed time check" signal or other such signal which was treated as a trouble call to be scheduled for maintenance the next business day. In reality the alarm lines were cut and the registrant was burglarized.

D. The transmission line(s) between the protected area and the monitoring station is usually the most vulnerable if it can be identified or isolated. Measures should be taken to make the lines as inaccessible and unidentifiable as possible. Whenever and wherever possible, registrants should request that all wiring and cables associated with the alarm system be installed in conduit. Antennas associated with cellular and radio frequency alarm transmission should be installed within the protected zone or installed in such a way as to prevent damage and/or tampering. Registrants should not allow either alarm installers or telephone repair technicians to mark or tag (or otherwise identify or single out) terminals associated with the alarm system in the telephone junction boxes inside or outside the protected area. They often do this for maintenance convenience, but in doing so, allow potential intruders to easily identify and circumvent the alarm transmission line.

5124.3 Alarm Transmission Methods There are several methods for transmitting alarm signals from the protected area to the central monitoring station. Below are a few of the most common methods.

A. **Dedicated Line** – The Dedicated Line is "supervised," in that it is a dedicated telephone circuit between the premises and the monitoring station. Loss of this line, for whatever reason, alerts the monitoring station to an "off-line condition." This line is polled on a regular basis by the monitoring station for loss of continuity. Loss of continuity alerts the monitoring station of an off-line condition. The operator can then take appropriate action. Disadvantages to the dedicated line are that the dedicated line is very expensive and rarely seen except in proprietary systems, and an off-line condition only indicates to the station operator that the circuit between the premises and the monitoring station has opened. There is no way of knowing where the opening has occurred, be it at the premises or somewhere in-between. Signals cannot be transmitted to the monitoring station over the line until continuity has been re-established.

B. **McCullough Loop** - The McCullough Loop operates on the same principal as the dedicated line, but utilizes a dedicated pair of wires in an area and allows multiple premises to wire-in a series with the main feeder wire. The main feeder wire is run to the monitoring station. Each premise has a unique identifier and the monitoring station has equipment that can decipher and decode the signals from the different protected premises. The McCullough Loop is more cost effective than the dedicated line because the cost is equally shared by all the protected premises on the loop. The disadvantage to the McCullough Loop is that the system is easy to compromise. If an intruder cuts the line to one premise it effectively disables all the units on that feed. Also, if more than one unit is "tripped" (goes into alarm) at the same time, it causes a conflict and the identifying pulses become difficult to decipher or decode. **The McCullough Loop is not approved for use by registrants.**

C. **Digital Dialer** - Digital Dialers are programmed to seize an available phone line and call a designated receiver at a monitoring center. The Digital Dialer digitally transmits its unique identification number that identifies the protected premise. This is by far the most common method of monitoring in the marketplace today. The Digital Dialer reports events to the monitoring station over regular phone lines. The alarm panel is connected to the phone line through an "8 pin CA38A jack." This configuration allows the alarm panel to seize the phone line when activated, dial out to the monitoring station, and download the information. From line seizure to re-establishment, the line takes between three to seven seconds or up to 35 seconds, depending on the specific dialer. There is cost savings in that the alarm panel, depending on the age, already has a dialer built-in and there are no additional phone company charges since it utilizes an existing phone line. The disadvantage of using a digital dialer is that the line is not supervised. If the line is cut, the alarm panel Digital Dialer cannot communicate with the monitoring station. **Thus, the digital dialer is not approved as a standalone system. If used by registrants, it must have an approved back-up system that is capable of being supervised.**

D. **Cellular** – The Cellular method of monitoring utilizes a cellular telephone network to transmit signals to the monitoring station. It is primarily a back-up system and is usually associated with the Digital Dialer. The cellular signal is supervised, in that it is polled on a regular basis through the control center. The cellular transceiver is self contained, has its own power supply, and a back-up battery. It interconnects to the alarm panel (virtually any alarm panel) and has a number of zone inputs. This unit constantly monitors the system. Should the telephone line tied to the Digital Dialer go dead for whatever reason, this unit will report "phone line trouble" to the monitoring station over the cellular network. As long as the phone line is down, the cellular transceiver will monitor the alarm panel for other signals, e.g., fire, intrusion, panic. Cellular systems can be used for monitoring alarms in remote areas where there are no telephone lines available. A major disadvantage to the cellular system is that the cellular transceiver is only able to communicate with properly equipped monitoring stations. *Long Range Radio Communications* - Another option available to transmit alarm signals is the Long Range Radio Frequency (LRRF). LRRF uses a powerful radio transmitter located at the protected premise and, when activated, transmits a signal to the nearest tower where it is repeated to the next tower until it reaches the monitoring center. There are typically two types of LRRF systems - one-way and two-way. One-way radios check in at regular intervals. Two-way radios are polled by the network. LRRF is recommended as a back-up system if cellular is unavailable, provided the two-way type is utilized.

E. **Internet** - Internet monitoring eliminates the need for the expensive dedicated line and provides a high level of line security (formerly UL "AA" high line security). It provides alarm communication over the internet using a standard web browser and any "always-on" internet connection. When transmitting an alarm signal, it sends an encrypted message through the internet to a control center. The control center checks that the unit is properly authenticated and once authenticated send the message into the central monitoring station. This typically takes place in under six seconds. The system employs high security encryption and two-way authentication. This assures that both the protected premise and the central station are who they say they are. Internet systems can be approved by DEA for use by registrants provided the registrants implement the "high line security," encryption and the two-way authentication.

F. **Voice over Internet Protocol (VoIP)** - Sometimes when new technologies are released before they can be thoroughly engineered, it causes side effects that can jeopardize what were previously thought to be secure conditions. One such new development that causes concern is Voice over Internet Protocol (VoIP). VoIP, by which voice signals are transmitted over a data network, attracts many residential and business consumers with offers of extensive and unlimited local and long-distant calling minutes at a single monthly rate. The appeal of VoIP is that it can be packaged with cable or satellite television and internet service to lock in all communication accounts of residential and business customers. VoIP is also used as a method to transmit alarm signals. VoIP has its controversies. Of primary concern to the DEA is if used as a method to transmit alarm signals, VoIP has difficulties interfacing with intrusion detection systems, that is, alarm systems. When conducting a test of the alarm systems during a pre-registration or an on-site scheduled regulatory investigation, Investigators need to determine if the registrant subscribes to a VoIP system and should consider some of the difficulties VoIP subscribers

have encountered. Specifically, new subscribers to some VoIP services are often finding their alarm service inoperable or unreliable for one or more of the following reasons:

1. Digital alarm communication transmissions (DACTs) and other alarm transmitter initiate tones designed for transmission over old telephone service (POTS). The specific tones intended for receivers do not reliably propagate over some VoIP channels. Sometimes this transmission failure is the result of protocol conflicts, and other times it results from distortion of signals on the VoIP lines.

2. Connection of VoIP service to the line side of an existing telephone service will prevent the line seizure that is required for an alarm transmitter to send its message. With this type of installation, there is no direct connection of the alarm system to the VoIP channel. Correcting this problem requires the installer to acknowledge the installation error and correct the wiring.

3. The alarm panels are required to supervise the operability of the telephone line that connects the panel to its central monitoring station. With some forms of VoIP, the loss of an active transmission line can no longer be verified by the on-site equipment. Supervision of a loss of the connecting signal can only be performed by the central monitoring station. Providers should give subscribers some form of equivalent of on-site supervision for loss of line.

4. Depending upon the configuration and type of VoIP equipment installed, a loss of the electric utility power can make the VoIP connection inoperative. The secondary power source (battery back-up) in the alarm panel does not provide operating power to the VoIP equipment. A separate VoIP secondary/emergency source of power must be provided for any equipment essential for the operation of the VoIP channel.

5. The affects of VoIP conversion on alarm systems can vary with each VoIP vendor or configuration. Registrants should be discouraged from using VoIP systems to transmit alarm signals. However, for those who are already utilizing a VoIP system, there are steps Investigators should follow in testing the systems. Specifically, Investigators should obtain necessary information about the reliability of the system by requesting detailed information. VoIP service providers and alarm central station monitoring services must be asked to demonstrate transmission of alarm conditions not only under normal circumstances, but also when there is a failure of the primary electrical power source. Specifically, they must provide documented evidence that upon loss of VoIP service or failure of VoIP conversion, equipment, computers, cable services or other essential emergency communications or other transmitting components, will continue to function. Subscribers should insist upon receiving direct affirmative responses to these concerns, observing the transmission of these conditions.

5124.4 Alarm Sensors

A. Sensors detect events and are the eyes and ears of any alarm system. Their function is to detect change, and devices that respond to human intrusion. They are the "input" devices to the alarm system. There are two major types - perimeter and interior. Perimeter sensors detect entry through windows, doors, and other openings. Interior sensors are designed to detect movement inside a facility. The systems are further defined by the type of sensors they employ - active or passive.

1. Active Sensors introduce energy into an area which is interpreted by a receiver. When the receiver senses a change in energy, it registers an alarm. A photoelectric beam or break-beam is a good example of this type of sensor. Here, a transmitter focuses light, which is energy, into a receiver. When the receiver notes a change in light, such as when someone passes by and "breaks the beam," it triggers an alarm

2. Passive Sensors measure changes in an environment over time. Although not alarm related a good example of this type of sensor is a thermostat, which, when the temperature drops, triggers a furnace.

B. No matter what input device is in use, it behaves exactly like a simple on-off switch. Some mechanical detectors actually contain a switch that changes state when the unit is violated. Other electronic detectors, such as motion detectors and glass-break sensors, may switch states electronically or use a miniature relay. In either case, it is the opening or closing of the sensor's internal circuit that triggers the alarm. Sensors of all types should be designed to initiate alarms under any of the following conditions:

1. occurrence of the event or condition being monitored (penetration of protected area)
2. loss of electrical power opening
3. shorting or grounding of the device circuitry
4. failure of the sensor itself tampering with the sensor's enclosure or distributed control panels.

C. There are a number of differing types of sensors which are described below:

1. **Passive Infrared (PIR) Sensors** - Commonly referred to as PIRs, they are the most widely used intrusion detectors today because they are highly versatile. PIRs "see" the invisible, bold colors of thermal or infrared (IR) energy. Because there is no beam, they are called passive. This energy, like heat from the sun, has no visible color or light. Just as a camera takes a picture in light, a PIR sees warm, infrared images against a cooler background. It must distinguish between heat from a heating vent, office space-heater, lights and others sources and the infrared image of a human intruder. Temperature operating ranges are from -40° Celsius to +50° Celsius (-40° Fahrenheit to + 120° Fahrenheit), with some units able to discriminate to within 1° Celsius.

PIRs are able to detect objects that are either warmer or cooler against, or when compared to, background temperature. Effectiveness diminishes as background temperature approaches that of the intruder. Since human intruders in temperate climates are usually warmer than the background, the requirement is for a PIR to detect warmer objects. This perspective changes in warmer climates, where room temperatures may be hotter than intruders. The cooler temperature of a human (98.6° Fahrenheit) is what the PIR should see. In environments where temperatures are not artificially regulated, such as unheated, non-air conditioned warehouses or vacant vacation homes, or where the ability of the PIR to discern temperature variations is particularly critical, automatic temperature compensation is an essential feature. A unit is needed that expands the temperature range at which it can see an intruder. Design and installation of PIRs are key to avoiding sources of false alarms.

2. **Glass Break Sensors** – These sensors are installed directly to the glass and have largely replaced foil in most applications. They offer the advantage of sounding an alarm while an intruder is still outside. Breaking glass produces unique sound wave frequencies (3 to 5 kHz), that glass break sensors "hear," and seismic shock frequencies (200 Hz) that they "feel." Built-in microprocessors enable the devices to react to these sounds and ignore others that cause false alarms.

3. **Acoustic Glass Break Sensors** – These sensors are installed on the walls or ceilings, to the side or above the glass. Detection is best when installed on a wall *opposite* protected glass, since sound waves need not then reflect off an opposing wall before reaching the detector. Range depends on the room being protected; rooms with bare floors and few furnishings reflect sound better than those filled with furniture, partitions and draperies. Acoustic glass sensors are designed to respond to the higher frequency energies generated by breaking glass and not low frequency structural vibrations (e.g., building noises). A registrant should assume the worst case scenario when installing sensors, and when selecting and installing glass break sensors, should consider its susceptibility to false alarms from radio frequency interference. In addition, sound waves from glass breakage have specific characteristics. Amplitude, frequency, and duration will vary according to the size and type of glass.

4. **Shock Sensors** – As the name implies, these sensors "feel" the shock wave generated by breaking glass and signal an alarm. Attached directly to a protected pane of glass or adjoining window frame, they are an appropriate choice for protecting glass in loud, occupied rooms where acoustic sensors may be prone to false alarms. Designs vary, but devices are approximately one to two inches square and are mounted with adhesive tape in the corner of the protected pane of glass. This installation also provides a visible deterrent to intruders. Corner mounting is optimal because shock waves are concentrated in that location, improving detection. Shock sensors are most effective when used to protect a single pane of glass, but the technology permits protection of more than one pane of glass in some applications.

Shock sensors operate by one of two methods. The most common design can be compared to a disc-like mechanism that sits on two electrical-contacts completing a circuit. The shock of breaking glass causes the disc to move (jump) off the contacts, breaking the circuit and initiating

an alarm. This principle permits sensors of this type to detect shock waves traveling into adjoining window frames, allowing for protection of several panes. Another method utilizes an electrical element called a piezo, which operates like a bias switch. The piezo creates its own electrical current as it bends or flexes to the frequency of breaking glass. This feature virtually eliminates false alarms since the device cannot alarm without generating its own electricity. The greatest limitation of piezo technology is the fact that devices utilizing it can only assuredly protect one pane of glass, leading to higher equipment and installation costs.

5. **Dual Technology Sensors** - Dual technology PIR/Microwave detectors initiate an alarm upon simultaneous activation of two alarm technologies working in concert (communicating) with one another. Both technologies must process and signal to initiate an alarm. Internal microprocessors require a specific signature and timing of signals. Modern pattern recognition technology is capable of identifying and ignoring repetitive false alarm sources. Dual technology sensors are better able to distinguish between signals caused by human intruders and those of small animals, such as cats or rodents, than the best single technology detectors. Units with supervised circuitry provide continuing protection from the PIR alone if the microwave fails.

6. **Electromechanical Sensors** - These devices are relatively simple and provide stable, reliable service. Included in this category are such items as foil, wire and screen detectors, pressure mats and mechanical or magnetic contacts. Foil, wire and screen detectors, and pressure mats have been largely replaced in many applications by PIR, glass break and dual-technology sensors. Wired electromechanical devices may be costly to install and because of their simplicity, easily circumvented by a knowledgeable intruder. This type of sensor is designed to place a current-carrying conductor between an intruder and an area to be protected. The current keeps a holding relay (switch) in an open position. A cessation of the electrical current releases the relay allowing contacts to close, activating an alarm circuit.

7. **Foil** - This type of detector was formerly widely used on glass windows. Breaking the glass would presumably cause foil to be severed, interrupting the electrical current and initiating an alarm. Foil is a thin, current-carrying metallic tape typically applied with adhesive to the secure side of the surface being protected. Use of foil is considered obsolete by most installers and has been replaced by glass break sensors.

8. **Magnetic and Mechanical Switches** - Accessible openings such as doors, windows and skylights may be protected with either mechanical or magnetic intrusion switches. This type of sensor is composed of a two-part electrical contact. One is installed on the opening surface, the other installed on the fixed surface. When the opening surface (typically a door), is in a closed position, the two contacts provide a closed circuit and a continuity of electrical current. When the opening surface is moved, separating the contacts, the circuit is broken and the interruption in the current activates an alarm. The switch is usually installed so that it operates when the leading edge of the moveable surface is opened.

Switches may be either mechanical or magnetic, recessed or surface mounted, wired or wireless. They should always be installed on the protected or secure side. While surface mounted switches are cheaper to install than those that are recessed, they may be more susceptible to damage and compromise. Surface mounted switches may not be aesthetically suitable for office or residential applications.

Two examples of mechanical switches are the plunger and the lever, which are activated by the movement of the surface upon which they are mounted. The plunger switch may be recessed mounted, while the lever switch is usually surface mounted. Plunger switches are often mounted in doors and windows and detect the opening and closing of these entrances. Lever switches are mounted outside a structure. A light switch is a simple example of a lever switch. Mechanical switches are prone to malfunction when exposed to freezing or wet weather and heavy, repeated use. They also accumulate dirt from the environment, and, without regular maintenance, will often stick.

A magnetic switch has two parts. One part is the magnet, generally mounted in a nonferrous housing or bracket. The other part is the switch assembly consisting of a ferrous lever attached to an actuator. When the magnet is properly oriented and mounted on the opening surface adjacent to the switch, metal reeds within the switch are opened. When the alarmed door is opened, moving the magnet, the reed switches close, energizing an electrical circuit and activating an alarm. For higher security, a bias switch should be used. Biased, or dual magnet switches, are designed with a small magnet on the reed switch. If exposed to an increase or decrease in the magnetic field, or if substitution of an external magnet is attempted, the polarity of the switch is quickly reversed. The switch should also be electrically protected so that a sudden surge of voltage from lightening or other source does not cause an alarm.

9. **Wire and Screen Detectors** - Fine, hard-drawn break wire may be utilized in various configurations to fabricate window screens, grids and lacing for installation on openings and barriers to detect forcible penetration. Prefabricated screens are commercially available. Such an installation should be designed so that an alarm is initiated if the current-carrying wire is cut, broken, grounded or spread enough to allow an opening of 96 square inches or more. This method of protecting building openings is not as widely used today as other technologies.

Wire "strain gauges" may also be used on fencing. For example, a single strand of wire may be installed along a barrier, such as a chain link fence. If the tension of the wire is disturbed by an intruder attempting to climb the fence, an alarm is initiated. In newer systems utilizing optical fiber, flexing or stress on the fence modifies the light path through the fiber to cause an alarm.

10. **Ultrasonic Sensors** - The operation of ultrasonic sensors is much like that of more technologically advanced and popular passive infrared detectors. Based on the "Doppler Effect," microwaves or sound waves are disturbed when movement changes signal frequency between transmission and receipt. As long as the return pattern being received is the same as that being transmitted, a stable condition exists. When a distortion of the wave pattern caused by movement is detected, an alarm is initiated.

Discriminator logic (intelligence) can be designed into sensors so that the amplitude of the disturbance can be determined. The discriminator can be adjusted so that the movement of a bird or small animal would be disregarded, while movement of a human would signal an alarm. Discriminators should be set so an alarm is initiated when an intruder walks through a wave pattern at the rate of one step per second. For area coverage, a sensor should initiate an alarm as the result of an intruder walking not more than four consecutive steps, at a rate of one step per second. The ultrasonic sensor employs sound waves at a frequency higher than the human ear can detect. The waves travel between transmitter and receiver at about 1,130 feet per second, and at a frequency of about 19.2 kHz. Transmitted sound waves are integrated with other sound waves in the area and are returned to the receiver. Samples of the transmitted and received signals are fed to a microprocessor for comparison. When there is no movement in the protected area, the signals received directly from the transmitter and those reflected from stationary objects remain unchanged. Because signal frequencies reflected from a moving object differ, a comparison of the two patterns causes initiation of an alarm. This type of sensor is usually limited to indoor applications where types of movement are less varied than those found in typical exterior environments.

Like PIRs, the range of an ultrasonic detector is limited. In larger rooms, it may be necessary to use more than one transmitter and receiver. Construction and contents of a room also affect the size of an area that a single unit is capable of filling with sound waves. Empty rooms without structural obstructions attenuate sound waves far less than do rooms with heavy drapes, soft furniture, or rugs, which absorb or muffle sound.

An ultrasonic sensor is not influenced by exterior audio noise. Because it reacts only to movement within a protected area, movement beyond walls of the protected area will not cause an alarm. Sensors can be adjusted so that movement of air caused by a fire will activate an alarm, but other air currents, such as those from air conditioning, will not trigger false alarms. As with a PIR, an ultrasonic detector would detect a "lock in," or concealed intruder by that person's movement. It does not alarm if cabinets or containers placed flush against a wall are penetrated through the wall because there is no movement in the path of the sound waves.

11. **Microwave Sensors** - These sensors operate on generally the same principle as the ultrasonic sensor. The difference lies in the type of wave or signal used. The ultrasonic sensor uses a high frequency sound wave, whereas the microwave sensor utilizes much higher frequency electromagnetic energy. The microwave transmitter sends a signal that is reflected back to an antenna. A comparison circuit compares the transmitted and reflected signals. If there is no movement in the area, the wave form remains constant; when the signal is reflected from a moving object, the wave form changes, initiating an alarm.

Microwave sensors may be utilized in outdoor applications as well as indoors because they are not generally affected by heavy fog, rain, snow, sleet, air turbulence, drafts, noise, temperature extremes, or atmospheric disturbances. When utilized for area protection, the wave pattern is designed to flood a room or area being protected. When used for perimeter protection, a narrow beam is directed around the area or zone to be protected. An interruption of this beam causes an

alarm. Installed in this way, the sensors are identifiable by a thick, round, disc-like device mounted on a short pole.

A microwave beam can be blocked or diverted by metal objects, so any movement behind metal objects in a room or area will not be detected. The waves penetrate common nonmetallic construction material, such as plaster walls, and detect movement outside the protected area. False alarms may result if this factor is not considered when planning a microwave installation.

12. **Capacitance Sensors** – These sensors are large electrical condensers that radiate energy and detect change in the capacitive coupling between an antenna and the ground. In a typical installation, a capacitance sensor wire is connected to an object to be protected, such as a safe or file cabinet. An intruder who touches the object absorbs some of the electrical energy, disturbing the circuit and causing an alarm. Newer technologies, such as PIRs, detect an intruder long before he or she reaches a protected object, and have replaced many capacitance type devices. However, if it is critical to limit the field of detection just to the protected object (safe or file cabinet for example), the capacitance device may still be the preferred protection.

13. **Shock and Vibration Sensors** - Utilizing the same technology as glass break shock sensors for object protection; these alarms detect vibrations caused by an intruder's attempt to penetrate the wall of a room, enclosure, vault, control panel, safe or filing cabinet. An alarm discriminator may be included in the sensor and adjusted so that vibration outside the protected space or surface is disregarded.

14. **Audio Sensors** – With this type of sensor, microphones capable of receiving sound in the audible range (from 20 to about 20,000 Hz) are inconspicuously installed inside the protected area. An amplifier is also part of the installation so that intrusion sounds can be transmitted and activate an alarm. As audio sensors have become more sophisticated, their use has increased in specialized applications. For example, a typical use may be inside a specialty retail store in a busy shopping mall. Central station operators monitoring sensor output can actually listen in on the protected space, recording sounds and voices of intruders, later to be used as evidence. Fences may also be protected by audio sensors that "listen" to the sound of cutting or climbing as it travels through fencing material. Audio sensors may allow for greater discrimination between genuine forced entry or climbing attempts and false alarm sources such as wind or accidental impact.

15. **Photoelectric Sensors** - Photoelectric sensors operate based on modification of a light level or interruption of a light beam protecting an area. In the first application, an ambient light threshold is established in a protected area. When an intrusion alters this light level, the sensor initiates an alarm. A basic concept of beam interruption is that the wave length of light being transmitted is compatible with receivable frequencies. Most light sources cover essentially the entire visible spectrum and are richer in infrared rays of lower frequency. The receiver operates by receiving light and converting it with a photoelectric cell into electrical energy. This energy is used to establish a reference value from which variations can be measured. Variation in the amount of light received by the photoelectric cell when the light beam is interrupted changes the

reference value and triggers an alarm. If the light beam is visible, this can be avoided. For this reason, infrared filters are usually placed over the light source so that only invisible light is transmitted. Since photoelectric cells are sensitive to infrared light, no modification to the receiver is necessary. Over distances longer than 500 to 1,000 feet operating ranges, light sources or receiver strength may need to be amplified. To counteract the possibility of circumventing the device by introducing an outside light source such as a flashlight, receiver frequencies may be designed to modulate, thereby being unpredictable. In a typical application protecting multiple doors, such as at a loading dock, a single straight beam of light may be zigzagged using mirrors, or multiple beams may be tiered, making avoidance difficult.

16. **Wireless Sensors** - As the name implies, these sensors are not connected to the alarm control panel with wires. Wireless sensors contain a battery and a small transmitter. When compromised, these sensors transmit a signal to the control panel using radio frequency. Although the wireless sensor is easier to install and is used in many residential and commercial settings, wireless sensors are not recommended for use in security systems protecting controlled substances. This is because the signal transmitted with wireless sensors can be easily compromised with metal wall studs, steel beams, reinforced concrete, and electronic equipment such as computers, which can interfere with or block transmissions. There are methods to counter this signal deflection, however, there is not a method to entirely overcome the problem and ensure 100 percent signal transmission. Thus, registrants should be discouraged from using wireless sensors.

5124.5 Testing Alarms When conducting an on-site investigation of a registrant's security system, the Investigator is required to test the alarm (b)(7)(E)

(b)(7)(E)

(b)(7)(E)

Registrants should be encouraged to test and inspect their alarm systems at least weekly. They too should look for sensors that may have been tampered with, damaged or that are blocked by merchandise and/or equipment.

5124.6 Hospital Security Guidelines Title 21 C.F.R. § 1301.75 and § 1306.76 provide the security regulations for practitioners; however, more stringent security guidelines have been established by the American Society of Hospital Pharmacists. The guideline is in the DEA Reference Book (5124A).

5124.7 Perishable Schedule II Security A perishable schedule II controlled substance should be stored under the required schedule II security when possible. A small quantity may be stored in a refrigerator equipped with a locking mechanism located within a schedules III through V

secured area, provided such security meets the requirements outlined in 21 C.F.R. § 1301.71(a) and (b).

5124.8 Hospital Drug Destruction Many hospitals have a misconception that they may dispose of controlled substances if witnessed by two nurses or pharmacists. However, if a hospital desires to destroy controlled drugs in lieu of surrendering them to an approved reverse distributor, it must be granted authority to do so by the local Special Agent in Charge pursuant to 21 C.F.R. § 1307.21.

5124.9 Employee Hiring Practice DEA recommends that a non-practitioner registrant screen prospective employees pursuant to 21 C.F.R. § 1301.90.

5124.10 Theft or Loss of Controlled Substances

A. Theft or Significant Loss. A registrant is required under 21 C.F.R. § 1301.74(c) and 1301.76(b) to report any theft or significant loss of controlled substances within one business day of discovery of the theft or loss. Definite quantitative limits cannot be placed upon the word "significant," primarily because it is relative to other factors that may exist, such as frequency, volume, or type of controlled substance. Routine anticipated losses occurring during manufacturing processes are not significant losses and, therefore, are not subject to the reporting procedure. The purpose of the theft report (DEA Form 106, Report of Theft or Loss of Controlled Substances) is for actual thefts or losses, not as an inventory adjustment for the drug industry. At the non-practitioner level, any discovered shortage which the firm fails to convincingly establish not to have been diverted after reasonable review/investigation should generally be considered as a reportable loss.

B. Reporting In-Transit Loss. 21 C.F.R. § 1301.74(c) and 1301.76(d) provide the following procedures for reporting an in-transit loss:

1. The supplier is responsible for reporting an in-transit loss of controlled substances by the common or contract carrier.

2. When it is determined that a loss or theft occurred while in the possession of the receiving registrant, the receiving registrant is required to file the theft report.

3. If the receipt of a shipment is accepted by the receiving registrant who subsequently discovers the loss, the receiving registrant is required to file the report.

4. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss.

C. Salvage Companies: Occasionally, a freight salvage company which is not entitled to a DEA registration comes into possession of controlled substances from common carriers. Usually these controlled substances were previously reported as lost in transit by controlled substance suppliers and subsequently recovered by their common carriers. In these instances, the salvage company does not have the legal authority to possess the controlled substances. Consequently, the salvage company must contact the local DEA field office for instructions on the proper method of controlled substance disposal, pursuant to 21 C.F.R. § 1307.21. Consistent with this section, the Special Agent in Charge (SAC) may instruct the salvage company to:

1. Contact the supplier, if known, and request that the controlled substances be returned to the supplier. The supplier, in turn, will document the receipt of these controlled substances in accordance with 21 C.F.R. § 1304.21(a), whether or not this supplier has previously reported the loss or has been compensated for the loss by an insurance company. The SAC must require that documentation of the return be submitted to the DEA field office having jurisdiction over the salvage company.

2. If the supplier is unknown or refuses the return of the controlled substances, the SAC has the option of instructing the salvage company to surrender the controlled substances to DEA for destruction or to establish a time and place where DEA destruction can occur.

D. FBI Responsibility for Controlled Substance Thefts: The Controlled Substance Registrant Protection Act of 1984 (CSRPA), Public Law 98-305, (18 U.S.C. 2118) makes it a felony under federal law to take controlled substances by burglary, force, violence, or intimidation from a DEA registrant when any of the following criteria exist:

1. The value of controlled substances is not less than $500.00
2. The subject uses interstate or foreign commerce to facilitate the crime
3. A person is killed or seriously injured as a result of the crime

The FBI is responsible for actions under CSRPA. If DEA receives information of a registrant theft which appears to meet the above criteria, DEA must immediately notify the FBI office having jurisdiction. Additionally, the registrant will be reminded to immediately contact and inform the local police agency of the theft. Not every theft or loss will meet these criteria. (b)(7)(E)

(b)(7)(E)

E. Report Requirement: Notification to the local DEA field office that a theft or significant loss has occurred must be received in writing within one business day of discovery of the theft or loss. If the actual date of the theft is not known, the discovery date must be used. If the theft(s) occurred over a substantial time period without discovery, as in the case of employee pilferage, the date range should be indicated on an attached sheet. The notification must be

signed and should be titled by a responsible representative of the registrant. Due to the possibility of further investigation and to establish exactly which controlled substances are

missing, a DEA Form 106 is not required to be submitted until the circumstances surrounding the theft or significant loss are clear; however, an update must be given to DEA within 60 days of initial notification. Upon completion of the investigation a DEA Form 106 must be submitted. Barring these circumstances the DEA Form 106 must be submitted one business day after discovery.

If an investigation continues and the original DEA Form 106 is found to be incorrect, an amended copy must be submitted. The registrant should print "**Amended"** on the form preferably above the theft date on the face of the form The registrant can also submit an electronic version of the DEA Form 106 (Report of Theft or Significant Loss of Controlled Substances) or an amended DEA Form 106. The electronic format is available for DEA registrants at www.DEAdiversion.usdoj.gov. The form is completed online and electronically submitted via the internet to DEA Headquarters. If the DEA Form 106 is amended online, the number of the amendment(s) is/are documented in the block that states "Date of Theft/Loss." DEA clarifies the regulations and provides guidance to registrants regarding the theft, significant loss, and unexplained loss of controlled substances, in the Final Rule published August 12, 2005 title "Reports by Registrants of Theft or Significant Loss of Controlled Substances."

F. Accidental Spillage: A DEA Form 106 is not required for accidental breakage or spillage of a controlled substance since the circumstances of the incident are known to the registrant. However, registrants must salvage as much of the contents as possible and document the dosage form and amount lost. Registrants are required to report the incident verbally to the local DEA field office. The local field office will instruct the registrant as to which method of disposal is required (e.g. send to a registered reverse distributor, destruction by DEA or locally approved regulatory agency for permission to destroy with at least two witnesses). The registrant also will be informed if DEA wishes to observe the remnants of the container before destruction. If permission is granted to the registrant to destroy the controlled substance(s), a DEA Form 41 must be submitted to DEA.

G. Reconciliations: Miscounts and adjustments to inventory involving clerical errors on the part of the registrant, should not be reported on a DEA Form 106, but should be noted in a separate log maintained by the registrant. If small quantities are missing from inventories on a monthly basis which establishes a pattern, pilferage may be occurring. In these instances, the amounts should be reported with an explanation to the local DEA field office.

H. Multiple Thefts: If multiple thefts or unexplainable losses occur from a registrant on the same date (e.g., mail order pharmacies), each instance must be reported upon discovery on a separate DEA Form 106 within the one business day.

5125 COMPLIMENTARY SAMPLES

A. DEA encourages drug manufacturers not to distribute controlled substance samples through sales representatives but to substitute other, more secure, methods of promoting their products. 5125

These methods could include sending samples to physicians directly and not through sales representatives, or instituting complimentary prescriptions that the practitioners can then provide to their patients, where not prohibited by state laws.

B. Request for controlled substance samples by practitioners (dispensers). Pursuant to Title 21, U.S.C. Chapter 9, Subchapter V, Part A, Section 353(d) (2) (A), a manufacturer or authorized distributor may distribute drug samples in response to a written request from physicians. The written request must contain the following:

1. The name, address, professional designation, and signature of the practitioner making the request,
2. The name of the manufacturer of the drug sample requested, and
3. The date of the request.

Upon receipt of the sample, the practitioner must complete a written receipt and return the receipt to the manufacturer or authorized distributor.

5125.1 Schedule II Controlled Substance Samples To acquire schedule II controlled substances, including samples, a DEA Form 222 or its electronic equivalent (21 C.F.R. § 1305) is required. The health care practitioner and the manufacturer respectively, must preserve his or her copy of the written or electronic DEA Form 222 for a minimum of two years.

5125.2 Storage of Controlled Substance Samples Samples of schedule II through V controlled substances must be stored in a securely locked substantially constructed cabinet (21 C.F.R. § 1301.75(b).

5125.3 Persons Handling Controlled Substance Samples Practitioners must not employ as an agent or employee with access to samples of controlled substances, any person convicted of a felony relating to controlled substances (21 C.F. R. § 1301.76(a)).

5125.4 Reporting the Loss or Theft of Controlled Substance Samples Practitioners must notify the DEA Field Division Office in their area, in writing, of any theft or significant loss of samples of controlled substances within one business day of the discovery of the loss or theft. In addition, the practitioner must complete and submit to the DEA Field Division Office in their area a DEA Form 106 regarding the loss or theft of controlled substances. When determining whether a loss is significant, the practitioner should consider the factors listed in Section 5124.10.

5125.5 Recordkeeping for Controlled Substance Samples by Practitioners (Dispensers) Practitioners must maintain records of receipt of controlled substance samples from the manufacturer for two years. The records must contain the following information: name, address,

and registration number of the manufacturer and the name, finished form (e.g. 10-mg. tablet or 10-mg concentration per fluid ounce or milliliter), number of units or volume per sample (4 tablet sample or 1 milliliter vial), and quantity of control substance samples received (21 C.F.R. § 1304.22(c)).

5125.6 Recordkeeping for Controlled Substance Samples by Manufacturers

A. The manufacturer is required to preserve the written request that it has received from the practitioner, or its electronic equivalent, for all schedule II – V controlled substances that it samples. The manufacturer is required to keep these records for a minimum of two years. The request must contain the name, address, signature, and registration number of the practitioner and the name, finished form, number of units or volume per sample (4 tablet sample or 1 milliliter vial), and the quantity of controlled substance samples that the practitioner requested (21 C.F.R. § 1304.22(a)(2)).

B. The Diversion Investigator should note that the sample request form may be in addition to any required records the manufacturer must maintain for its distribution of a controlled substance. However, for controlled substances in schedule II, the sample request can also be the required executed DEA Form 222. For controlled substances in schedules III – V, a copy of the sample request form may also be used by the manufacturer as the company's required record of distribution; if so, it must meet all corresponding recordkeeping requirements. The manufacturer may instead choose to generate and maintain a separate record for documenting this distribution, in addition to the sample request form.

5126 REQUIREMENT TO REPORT SUSPICIOUS ORDERS

A. Title 21 U.S.C. § 823 requires manufacturers and distributors to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, or industrial channels. 21 C.F.R. §1301.74(b) further requires registrants to design and operate a system to disclose to the registrant suspicious orders, and report such orders to their local field office. By its very nature, an order is a request to purchase controlled substances and has not yet been filled. Reporting a filled order is potentially allowing controlled substances to be diverted. Therefore, suspicious orders will not be filled.

B. Registrants may fill an order that was previously deemed suspicious only after such time as a thorough review has been conducted and findings appropriately documented, as outlined in the Dear Registrant Letter, dated September 27, 2006.

C. DEA field offices will not approve or disapprove a registrant's shipment of controlled substances, nor their procedures for detecting suspicious orders. The responsibility for detecting

suspicious orders and making the decision to ship rests solely with the registrant. An exception to this occurs when a registrant complies with a DEA field office's request to initiate a controlled delivery of controlled substances. Controlled deliveries require HQ's approval via Sensitive Activity Review Committee (SARC) in accordance with 6602 of the Agents Manual.
5126

D. Registrants can verify the current status and accuracy of a customer's registration via the official Diversion Website in making an independent decision on whether to ship controlled substances. The web site is: https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp and is a free service provided to the registrant.

E. Upon receipt of a suspicious order report, the DEA Field Office will complete a DEA Form 6, Report of Investigation, under general file number GFXX-00-(b)(7)(E) Suspicious Orders. If the customer is not within the area of responsibility of the field office authoring the Report of Investigation, a copy will be forwarded to the office having responsibility.

F. Some registrants, either by Memorandum of Agreement or as compelled by other administrative actions, are reporting all suspicious orders directly to HQ's via the Suspicious Order Reporting Systems (SORS). In such case, those suspicious orders reported via SORS will be forwarded to the responsible field office(s) the next business day. Upon receipt of a SORS notification, the field office will document the suspicious order via DEA Form 6.

Subchapter 513 Labeling and Packaging

5131 INTRODUCTION Title 21 U.S.C. 825 establishes labeling and packaging requirements for controlled substances. These requirements are further defined in 21 C.F.R. §1302. Primary labeling and packaging provisions, however, are the responsibility of the Food and Drug Administration (FDA) and may be found in the FDA's Good Manufacturing Practices regulations in 21 C.F.R. §211.122.

5131.1 Warning Label Requirement The containers in which controlled substances in schedules II, III and IV are dispensed to the ultimate user are required by 21 U.S.C. 825(c), and FDA regulations to have the following clear, concise warning statement: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Although each state has different requirements for the information that pharmacists must include on the label of the prescription bottle, common requirements include:

1. pharmacy name and phone number
2. name of the drug dispensed
3. drug strength
4. "use by" date
5. serial (prescription) number
6. date of dispensing

7. name of patient
8. name of prescribing practitioner
9. directions for use
10. cautionary statements, if any, required by law

5131.2 Tamper Resistant Container Controlled substances for outpatient use must be dispensed in child-resistant packaging, in accordance with 16 C.F.R. § 1700.15, unless the patient or his/her practitioner request standard (non-special) packaging. The commercial container of any controlled substance in Schedule I or II and any narcotic controlled substance in Schedule III or IV must be tamper resistant. Each bottle, multiple dose vial, or other commercial container must have a seal securely fixed to the stopper, cap, lid, covering or wrapper of such container, to disclose upon inspection any tampering or opening of the container. Title 21 C.F.R. § 1302.06. The term "commercial container" means any bottle, jar, tube, ampule, or other receptacle in which a controlled substance is held for distribution or dispensing to the ultimate user, and any box or package in which the receptacle is held. A commercial container should not be confused with a prescription container for dispensing.

5131.3 Labeling of Shipping Container

A. Title 21 C.F.R. §1301.74(e) requires a registrant who ships a controlled substance to guard against diversion by ensuring that the shipping container does not easily identify or reveal the contents. DEA does not allow the words "controlled substances" or a recognized brand name on the exterior of the shipping container. The use of National Drug Code (NDC) numbers, company code, etc., is left to the discretion of the registrant.

B. When DOT regulations require, the outside container must be labeled with the technical name or generic chemical description of the substance. DOT requirements relating to hazardous substances are contained in the DOT Hazardous Materials Regulations, 49 C.F.R. Parts 171-80.

C. When necessary to comply with DOT regulations, DEA allows shippers to label the outside container with the technical name or generic chemical description and to place a label with the brand name of the controlled substance inside the shipping container. This method of labeling substantially complies with the intent of 21 C.F.R. §1301.74(e) due to the relative obscurity of the chemical names of the products.

Subchapter 514 Quotas

5141 TYPE OF QUOTA

5141.1 Aggregate Production Quota The requirement regarding production quotas is found in Title 21 United States Code (21 U.S.C.) § 826 (a).

5141.2 Manufacturing Quota The requirement regarding manufacturing quotas is found in 21 U.S.C. § 826 (c). Manufacturing quotas are issued to bulk manufacturers who manufacturer

either from synthetic routes (e.g., hydrocodone from codeine, controlled substances from non-controlled chemicals), or extraction from narcotic raw material (e.g., coca leaves, opium and poppy straw concentrate).

5141.3

5141.3 Procurement Quota Procurement quotas are typically issued to dosage form manufacturers and repackagers or relabelers for manufacturing activities. Examples of required procurement quotas are:

A. A procurement quota is required to receive bulk Active Pharmaceutical Ingredients (API) to be manufactured into dosage units.

B. A procurement quota is required for a company to receive bulk finished dosage units for relabeling or repackaging.

C. A manufacturer who buys/acquires codeine to manufacture hydrocodone would require a procurement quota for codeine and a manufacturing quota for hydrocodone. A manufacturing quota for hydrocodone is required because the substance manufactured is in a different basic drug class than the starting material.

D. A manufacturer that acquires fentanyl base, converts it into fentanyl citrate, and then manufacturers fentanyl patches, would only require a procurement quota for fentanyl. A manufacturing quota for fentanyl would not be required because only the salt form changed; the end product is still in the same basic drug class.

Procurement quotas are issued annually by the "share-of-the-market theory" to the various procurement quota applicants. "Share-of-the-market" is determined by calculating the percentage of business a firm did in a particular basic class the previous year as compared to the total disposals of all the firms utilizing that same basic class.

A registrant's year-end inventory will be considered when assessing a registrant's need for quota. A registrant may request, with the Drug and Chemical Evaluation Section, an increase or decrease in quota at any time.

5142 LEGITIMATE MEDICAL NEED

5142.1 Sales of Controlled Substances Legitimate need is based in part upon sales data reported by manufacturers. Any production in excess of demand could accumulate at the distributor and dispenser level as inventory and may be diverted to meet illicit demands.

5142.2 Controlled Substances Prescribed And Dispensed An analysis of the national prescribing and dispensing patterns is used in determining legitimate medical need. This procedure includes the evaluation of a number of different programs (e.g., Drug Abuse Warning

Network (DAWN) and the Office of National Drug Control Policy) that track the amount of diversion of controlled substances, since all drugs are not prescribed or dispensed for valid medical purposes.

5142.3 Food and Drug Administration (FDA) Estimates of Medical Need

The Food and Drug Administration submits to DEA estimates of legitimate medical and scientific needs of the U.S. for consideration in determining quotas. DEA is not bound by these estimates, but has made it a practice to consider the estimates, as well as the "share of the market theory" and year-end inventory reports as previously mentioned. When the DEA Administrator determines there is enough information, an aggregate production quota is proposed via a Federal Register Notice, and subsequently, a final order is issued.

5143 ADDITIONAL QUOTA FACTORS

5143.1 Inventory Allowances A reserve supply of controlled substances is necessary to meet continuing demand in intervals between manufacturing operations and to provide for emergency stocks. Thus a provision is made for inventories at each level of the drug distribution network. Inventory allowances are assigned to bulk manufacturers as well as procurement firms. Bulk manufacturers are authorized an inventory allowance pursuant to 21 C.F.R. § 1303.24. Dosage form manufacturers are also provided with an inventory allowance. Authorization for procurement inventory allowances is set to ensure an uninterrupted supply throughout the distribution network.

DEA has data sources which monitor prescription and dispensing statistics that indicate the amount necessary to adequately meet the public's need. If inventories build up in excess of this need, action can be taken to reduce inventories.

5143.2 Relationship Between Research And Quota Reference is made to the "Clarification of Coincident Activities for Researchers," published in the Federal Register on October 31, 1995. Research and manufacturing are designated as independent activities for which separate registration is required. However, each type of registration is authorized to conduct certain coincident activities as provided in 21 C.F.R. § 1301.13(e)(1).

Researcher registrants are not required to obtain quotas for their activities. DEA policy permits a researcher to manufacture small amounts of bulk material under a research registration if the following two conditions are met:

A. The quantities are set forth in, and consistent with, the statement filed with the application for registration.

B. If the purpose, as set forth in the statement filed with the application, is to develop synthesis procedures or other research not related to dosage form development.

Manufacturing registrations are issued quotas for schedule I and II controlled substances and for the following list I chemicals: pseudoephedrine, ephedrine, and phenylpropanolamine. Regardless of the reason for the manufacturing activity, i.e., research or commercial, a

manufacturing registration must obtain appropriate quotas for its activities. While a manufacturer registration may conduct coincidental research activities, it is still required to obtain quotas.

The investigator should be mindful not to confuse a researcher registration with coincidental research activities performed under a manufacturing registration. Also note that researcher registrations are not required to obtain a quota. Manufacturing registrations are required to obtain quotas for all their activities, even those considered research.

5143.3 Manufacture of Small Quantities of Controlled Substances by Analytical Laboratories Those persons registered as analytical laboratories, who are also authorized as a coincident activity to manufacture small amounts of controlled substances for use as analytical standards, may perform such manufacture in accordance with 21 C.F.R. § 1303.12(e)(2) upon notification of the appropriate DEA field office. This manufacture may take place without obtaining manufacturing quotas for schedule I and II controlled substances, with the exception of heroin, whose manufacture is specifically prohibited by the Controlled Substances Act. Handling and accountability procedures for legitimate controlled substance pharmaceuticals should be the same as those established for illicit controlled substances. Complete records of such manufacturing and disposition are required. Amounts less than 50 grams may be disposed of if desired by laboratories, in accordance with established procedures. If no such procedures are in effect, the registrant should contact the appropriate DEA field office for assistance. Disposition of quantities in excess of 50 grams may be made only after contacting the appropriate DEA field office.

5143.4 Conversion Factors These factors are employed by the Drug and Chemical Evaluation Section, Quota Unit, in evaluating production. All quotas are issued in terms of anhydrous base by basic class of controlled substance. In reviewing a firm's performance against quota, all manufacture or procurement must be converted (by use of these factors) to base drug. NOTE: The Quota Unit uses a two decimal conversion factor, e.g., oxycodone hydrochloride 0.90 vs. 0.8964. The conversion factor can be found in WebSter in the Conversion Factor Chart.

Subchapter 515 Records and Reports

5151 GENERAL

5151.1 Inventories

A. Title 21 C.F.R. § § 1304.04 and §1304.11 describe the inventory requirements for controlled substances. These requirements are different depending on whether the registrant is handling controlled substances in schedules I and II, or schedules III-V controlled substances. These requirements are also different depending on the type of registrant taking the inventory.

B. An inventory is a complete and accurate record of all stocks and forms of controlled substances "on hand" or in the possession of the registrant as determined by an actual physical

count conducted by the registrant or the registrant's agent. The Controlled Substance Act (CSA) also requires that all inventory records be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection. The registrant must keep inventory records of schedules I and II controlled substances separate from all other controlled substance records. There is no requirement to submit a copy of the inventory to the DEA.

C. DEA considers a controlled substance to be "on hand" if it is in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complementary samples.

5151.12 Initial Inventory When issued a DEA registration a registrant must take an initial inventory. This inventory is an actual physical count of all controlled substances in the registrant's possession at time of registration. If the registrant has no controlled substances on hand, the registrant must still make a record showing a zero inventory.

5151.13 Biennial Inventory Following the initial inventory, DEA requires that the registrant take a physical inventory every two years thereafter. The biennial inventory is an actual physical count of all controlled substances in the registrant's possession. The registrant may take the biennial inventory on any date which is within two years of the previous inventory date.

5151.14 Newly Scheduled Controlled Substances When a drug not previously listed as a controlled substance is scheduled or a controlled substance is moved either to a higher or lower schedule, the registrant must take an actual physical inventory of the controlled substance as of the effective date of the scheduling or change in scheduling.

5151.15 Inventory of Controlled Substances to be Destroyed The registrant must generate a separate inventory for controlled substances that are:

1. damaged, defective, or impure and are awaiting disposal;
2. held for quality control purposes; or
3. maintained for extemporaneous compounding.

5151.16 Inventory at Time of Termination or Transfer On the date of termination or transfer of a DEA registration a complete inventory of all controlled substances being transferred shall be

taken. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee.

5151.17 Inventories and Central Recordkeeping As outlined in 21 C.F.R. § 1304.04, registrants may not request central recordkeeping approval for required physical inventories. Physical inventories must be maintained at the registered location, with the exception of Automated Dispensing Systems.

5151.2

5151.2 Controlled Substances Identification

A. DEA regulations require the information in both inventories and continuing records (i.e., invoices) clearly state the name, strength, and size of commercial containers for all products in finished dosage form. The name and quantity of controlled substances in any other form (bulk, in-process) must be included on all records. In cases where the strength of a product is inherent in the brand name, DEA does not require that the strength be restated.

B. At no time has DEA considered the use of stock or code numbers of the manufacturer or supplier alone to be sufficient identification for a controlled substance. However, when a supplier receives an order form which contains the stock or code numbers and the National Drug Code (NDC) number, it is permissible for a supplier to fill the order provided that the identity of the product and strength are unquestionable.

5151.3 Central Recordkeeping Permit

A. Registrants desiring to keep certain required records at a central location other than at the registered location are required to submit written notification to the SAC of the DEA division where the registrant is located as required in 21 C.F.R. § 1304.04. Written notification must be sent via registered or certified mail, return receipt requested (or equivalent commercial carrier).

1. All notifications must include:

    a. The nature of the records
    b. The exact location where the records will be kept.
    c. The registrant's name, address, registration number and type of registration
    d. Whether the records will be maintained in a manual or computer readable form.

2. Unless the registrant is informed by the SAC that permission is denied, the registrant may maintain records at the central location commencing 14 days after receipt of their notification by the SAC.

3. Registrants must provide access to any special equipment necessary to make the records easily readable.

4. Registrants maintaining an authorized central record location shall, upon receipt of a written DEA notification, deliver all or any part of such records to the registered location within two business days, or allow authorized DEA employees to inspect such records at the central location. No warrant is needed for such inspections.

5. If the registrant fails to comply with these conditions, the SAC may cancel the central recordkeeping authorization without a hearing and require all records at the central location be kept at the registered location n.

6. ARCOS participants must obtain a separate central reporting identifier to report from a site other than their registered location.

B. The Code of Federal Regulations specifies what records must be maintained at the registered location, including executed order forms, prescriptions, and inventories. Dispensing records and theft reports (DEA Form-106) are required to be kept at the registered location.

C. Records Permitted to be Stored at a Central Location.

1. Controlled substance financial and shipping records, such as invoices and packing slips.

2. A registered retail pharmacy that possesses additional registrations for automated dispensing systems at Long Term Care Facilities may keep records required for those additional registered sites at the retail pharmacy or other approved location.

3. Listed chemical records and reports. The regulations make no distinction between paper and electronic records and do not limit the type of records that can be stored at a central location.

D. Registrants need not notify DEA or obtain central recordkeeping approval to maintain records on an in-house computer system. DEA considers a central processing unit used for storage of computer records from multiple pharmacies to be an in-house computer system rather than a central recordkeeping system. DEA requires that records from such a system be available to DEA immediately upon request.

5151.4 Requirement for DEA Number on Distribution Invoices DEA registration numbers are required on distribution invoices according to 21 C.F.R. § 1304.22. However, DEA allows the supplier issuing the record to maintain DEA customer registration numbers in a central file in lieu of providing the number on each record, provided that the supplier keeps this central file up-to-date. This can be accomplished by conducting verifications with customers, by requiring photocopies of renewal registrations, statements setting forth the up-dated information, or through the verification tool on the website, www.DEAdiversion.usdoj.gov. The information on the website can be printed and filed and is the most current and accurate (See Section 5114, Registration Number Verification).

5151.5 Maintenance of Records on Microfilm/Microfiche, Photocopies and Scanned Images Microfilm/microfiche photocopies, and scanned images of receipt and distribution records are not acceptable to DEA as primary documents. The opportunity to alter the information on the original record as it is being copied or scanned makes these information storage methods vulnerable to manipulation in furtherance of diversion.

5151.6

5151.6 Institutional Practitioner Recordkeeping Requirements

A. Title 21 C.F.R. §§ 1304.04 and 1304.24 outline record keeping requirements particularly applicable to institutional practitioners. Institutional practitioners, including hospitals, are required to maintain records of all controlled substances received, dispensed, and otherwise disposed of. While the regulations set forth general requirements for how these records are to be maintained, they do not specify the precise manner. This flexibility allows for further statutes by state agencies and permits each hospital to set up a system which best suits its needs.

B. Generally, dispensing records for schedule II substances must be separate from all other records, and those for schedule III, IV, and V substances must be maintained in a readily retrievable manner, see 21 C.F.R. § 1304.04. Since certain hospital records may not meet these requirements, "Guidelines for Institutional Use of Controlled Substances" offers acceptable solutions to several issues routinely mentioned. (See the DEA Reference Book 5124A).

5151.7 Brokers and Drop Shipments

A. A broker is a third party that brings a supplier and customer together to transact business. DEA does not require that brokers of controlled substances register since they do not take physical possession of the controlled substances. Required records of receipt and distribution between the purchaser and the seller must contain all information found in 21 C.F.R. § 1304.22(b), including the name, address, and DEA registration of both parties.

B. The drop shipment of a controlled substance involves the delivery of a controlled substance from one DEA registrant to another DEA registrant. However, the required records of receipt and distribution, while meeting the requirements of 21 C.F.R. § 1304.22(b), may also contain information directing the supplier to send the bill to the domestic broker, or third party.

5151.8 Practitioners Who Dispense, Prescribe, or Administer Controlled Substances Title 21 C.F.R. § 1304.03 generally defines when an individual practitioner must keep records documenting his/her handling of controlled substances. Title 21 C.F.R. § 1304.03(b) and 21 C.F.R. § 1304.22(c) provide guidance to the practitioner on what records he/she is required to generate and maintain when controlled substances are dispensed, including samples. Title 21 C.F.R. § 1304.03(c) releases the practitioner from generating and maintaining records regarding his/her prescribing of controlled substances in schedules II-V, unless the practitioner is

prescribing these controlled substances in the course of opioid maintenance or detoxification treatment of an individual. Title 21 C.F.R. § 1304.03(d) outlines the conditions under which a practitioner must generate and maintain records documenting his/her administering of controlled substances in schedules II-V.

5152 ORDER FORMS

An Official Order Form (DEA-222), or its electronic equivalent, is required for each transfer of a controlled substance listed in schedules I or II. The transfer of a schedule I or II controlled

substance between two registrants will be affected either on the three-part Official Order Form or via a CSOS (Controlled Substance Ordering System) digital certificate, as outlined in 21 C.F.R. § 1311. Registrants may request the three-part Official Order Forms by contacting either the DEA Registration Technician in the DEA field office that covers their area or the Registration and Program Support Section, Office of Diversion Control or by ordering on the website www.DEAdiversion.usdoj.gov.

5152.1 Shipment of Schedule II Without Order Form

If Official Order Forms are not available and there is an emergency situation, field personnel should advise suppliers that authorization for shipments of Schedule II controlled substances without DEA Form 222 will be on a case-by-case basis. In the absence of an official order form, the purchaser must provide the supplier with a written request for the controlled substances on the purchaser's official letterhead, or on a copy of a DEA Form 222. The request must contain all the information that is required on Official Order Forms, including the signature of the person authorized to sign the Official Order Forms. The purchaser can fax this request to the supplier. If approved by DEA, the supplier can then transfer the shipment to the customer based on the purchaser's written request. Once available, the purchaser is required to provide the supplier with an Official Order Form for each shipment that occurred under this procedure. The supplier must attach this after-the-fact order form to the previously received written request. Suppliers remain responsible for the verifying the registration status of their customers regardless of the way in which they receive a request.

If Official Order Forms are not available in a non-emergency situation, DEA will advise the supplier to follow the procedure listed above, with the exception that the supplier may not ship the controlled substances to the purchaser until the supplier has the written request in its possession. The supplier cannot rely on a faxed copy for this purpose.

5152.2 Unacceptable or Defective Order Form

5152.21 Unacceptable Order Form

A. Title 21 C.F.R. § 1305.15 outlines the conditions under which an order form should be rejected and returned to the customer. A DEA Form 222 must not be filled if either of the following apply:

1. The order is not complete, legible, or properly prepared, executed, or endorsed
2. The order shows any alterations, erasures, or changes

B. If a supplier cannot fill the DEA Form 222 for any reason listed above, the supplier must return copies one and two to the purchaser with a statement as to the reason.

C. A DEA-registered supplier is not required to accept every Official Order Form that it receives. To maintain effective controls against diversion, a DEA-registered supplier should exercise due care in confirming the legitimacy of all orders prior to filling. A supplier may refuse to accept any Official Order Form and a justification of refusal is not required. A statement that the order has been refused is sufficient.

5152.22 Defective Order Form A defective order form may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

5152.3 Order Form Execution By Detailmen

Pharmaceutical sales representatives (i.e., detailmen) are considered agents of the registrant as long as they are also employees of the registrant. Receipt by a detailman of a complete and accurate Official Order Form from a purchaser is sufficient to allow the supplier to initiate a shipment of controlled substances. A supplier who places a detailman in this role is responsible for the detailman's actions. Consequently, DEA may pursue administrative, civil, or criminal action against a detailman's employer if a detailman's actions violate the CSA or its implementing regulations.

Although the distribution of controlled substance samples is a procedure authorized by DEA, the DEA discourages the distribution of controlled substance samples wherever possible due to decreased control, potential inventory problems, and a history of diversion by detailmen.

5152.4 Detailmen Concurrent Issuance of Order Form and Delivery of Controlled Substance DEA approves, on a non-routine basis, the procedure whereby a customer places a telephone order and a detailman makes delivery and picks up the customer's executed order form simultaneously. The supplier in this instance is responsible for the correctness of the Official Order Form as well as for the detailman's actions.

5152.5 Secondary Defense Analysis When directed by a court, schedule I or II controlled substances may be transferred to a designated analytical laboratory for a secondary analysis. The laboratory to perform the analysis is required to be registered with DEA as an analytical laboratory. The transfer can only be made pursuant to an Official Order Form from the laboratory to the police or crime laboratory. The Order Form cannot be directed to an unregistered party such as the police department or the court.

5152.6 Issuance of Order Forms

A. The standard number of order forms issued per request is as follows:
(DEA defines a book as seven DEA Form 222s)

1. Practitioner, researcher, analytical lab, teaching institution, exporter - 1 book
2. Retail pharmacy, hospital/clinic, narcotic treatment program - 6 books
3. Manufacturer, distributor - 9 books

B. Registrants may request DEA Form 222 in excess of the above quantities by contacting the Office of Diversion Control's Registration Section. DEA has authorized the representatives of this section to input appropriate requests into the Registrant Information Consolidated System/CSA 2. Registrants may also request additional Order Forms from personnel at the DEA field division in their area. However, prior to sending additional forms, the Registration Program Specialist or Diversion Investigator must conduct a NADDIS check to determine if criminal, civil, or administrative issues exist. Any identified issues will be addressed prior to granting a request for additional order forms.

5152.7 Narcotic Treatment Program (NTP) Dispensing Site A DEA registered Narcotic Treatment Program Compounder/Maintenance, Compounder/Detoxification, or Compounder/Maintenance and Detoxification may only distribute schedule II narcotic controlled substances in response to a valid DEA Form 222 or its electronic equivalent from another DEA registered Narcotic Treatment Program (21 C.F.R. § 1305.06(e)).

5152.8 "Open Ended" Order Forms DEA does not endorse the practice of "open-ended" order forms. 21 C.F.R. § 1305.12 lists the requirements for properly executing a DEA Form 222 including the obligation to note the number of line items completed. 21 C.F.R. § 1305.13(b) provides that if an order cannot be filled in its entirety, a supplier may supply the balance by additional shipments. While the Code of Federal Regulations does not directly address "open-ended" order forms, DEA does not endorse this practice because of the increased potential for diversion. By filling out every line on the 222 with the same product and same quantity, the purchasing registrant has no expectation that it will receive all the listed items within the 60-day period. If an employee at the supplier chose to divert one or more of the unused line items on the order form it is unlikely that the DEA, the supplier, or the customer would easily detect the diversion. In a regular order form transaction there is certainly the potential for diversion, but the potential is decreased by the "checks and balances" of the customer's expectations. Thus an open-ended order form does not meet the spirit and intent of 21 C.F.R. §§ 1305.12 or 1305.13(b).

Subchapter 516 Prescriptions

5161 PRESCRIPTIONS

A practitioner must issue an original controlled substance prescription for a legitimate medical purpose when acting in the usual course of professional practice.
All prescriptions—written, faxed, oral, or electronic—must contain certain information:

1. Date the prescription was issued
2. Full name and address of the patient
3. Drug name, strength, dosage form, directions for use, and quantity prescribed
4. Name, address, and DEA registration of the practitioner

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5. Written signature of the practitioner (not on oral prescriptions, 21 C.F.R. § 1306.05(a))

A photocopy of a prescription cannot be utilized as an original prescription and is not considered valid.

5161.1 Preparation of Written Prescriptions

A. Written prescriptions must be prepared as follows:

1. Have the practitioner's signature
2. Be written with ink or indelible pencil
3. If typewritten, must be manually signed

B. A written prescription may be prepared by the secretary or practitioner's agent for the practitioner's signature. However, the practitioner is responsible for ensuring that the prescription conforms to all aspects of the law and regulations (21 C.F.R. § 1306.05(a)).

5161.12 Special Written Prescriptions

A. If practitioners are prescribing a schedule III, IV, or V narcotic drug approved by FDA for "detoxification treatment" or "maintenance treatment," they must include the unique identification number issued by DEA upon their approval as a "qualifying practitioner" or a written notice stating that the practitioner is acting under the good faith exception of 21 C.F.R. § 1301.28(e) (21 C.F.R. § 1306.05(a)). The practitioner must then maintain a copy of this prescription information (21 C.F.R. § 1304.03(c)).

B. If a practitioner prescribes gamma-hydroxybutyric acid (GHB), the practitioner must note on the prescription the need of the patient for the prescription (21 C.F.R. § 1306.05(a)).

5161.13 Mailed Prescriptions A practitioner has the discretionary authority to initiate a written refill prescription without a patient visit. The Ryan Haight Act has clarified the definition of a "valid prescription" requirement as defined in 21 U.S.C. § 829 (e)(2)(A) to mean a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner or a covering practitioner who must conduct at least one in–person medical evaluation of the patient. The practitioner can mail the prescription to either the patient or the pharmacy. The practitioner is always responsible for exercising professional judgment when submitting a prescription orally or signing and mailing a written prescription. A copy of the U.S. postal regulations concerning mailing controlled substances is in Appendix 5161A.

5161.14 **Faxed Prescriptions**

A. **Schedule II Controlled Substances** Pursuant to Title 21 C.F.R. § 1306.11(e),(f), and (g), a pharmacist may dispense a controlled substance listed in schedule II pursuant to a facsimile of a

written, signed prescription transmitted by the practitioner or the practitioner's agent for the following reasons:

1. To be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion (e).
2. For a resident of a Long Term Care Facility (f).
3. Patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state (g).

Pursuant to Federal Register published May 19, 1994 titled "Prescriptions – Transmission by Facsimile" the facsimile copy of the prescription shall be retained as the original document by the dispensing pharmacy and it must contain all information required by 21 C.F.R. § 1306.05(a) including the date issued, full name and address of the patient (the address shall indicate that the location is a LTCF), name, address, DEA registration number and signature of the practitioner.

Title 21 C.F.R. § 1306.11(a) allows a prescription for a schedule II controlled substance to be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance.

B. **Schedule III, IV, and V Controlled Substances** Prescriptions manually signed by the practitioner for controlled substances in schedules III, IV, and V *may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile to dispense (21 C.F.R. § 1306.21(a)). The facsimile copy of the prescription shall be retained as the original document by the dispensing pharmacy and it must contain all information required by 21 C.F.R. 1306.05(a), including the date issued, full name and address of the patient, name, address, DEA registration number and signature of the practitioner.*

5161.15 Oral Prescriptions

A. **Schedule II Controlled Substances** A pharmacist may dispense a controlled substance listed in schedule II by oral authorization of a prescribing individual practitioner only in an emergency situation provided that:

1. The quantity prescribed is limited to the amount adequate to treat the patient during the emergency period.
2. The prescription is immediately reduced to writing;
3. The pharmacist makes reasonable efforts to determine the prescription comes from an authorized practitioner;
4. The prescribing individual practitioner writes a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist within seven days in person, or if by mail, postmarked within the seven-day period.

*Revisions
**Addition

5161.15

Central fill pharmacies may not dispense schedule II controlled substances upon receiving an oral authorization from a retail pharmacist or an individual practitioner (21 C.F.R. § 1306.11(d)(5)).

B. **Schedule III, IV, and V Controlled Substances** Oral prescriptions for controlled substances in schedules, III, IV, and V are permitted. The pharmacist must promptly convert these to writing (21 C.F.R. § 1306.21(a)).

5161.2 Corresponding Liability of Physician And Pharmacist Title 21 C.F.R. § 1306.03 thru 1306.06 place the responsibility for the proper prescribing and dispensing of controlled substance with the practitioner. However, it also outlines the corresponding responsibility that rests upon the pharmacist who fills the prescription.

5161.3 Authorized Changes to Prescriptions by Pharmacists Title 21 C.F.R. § 1306.11 establishes the requirement of a prescription for a schedule II controlled substance. Title 21 C.F.R. § 1306.21 establishes the requirement of a prescription for schedule III-V controlled substances.

A. In regard to schedule III-V prescriptions, the pharmacist may change the following information after contacting the prescribing practitioner: the patient address, drug strength, drug quantity, and directions for use.

B. The patient's address may be changed on the prescription at the request of the patient. The address may be verified by an additional source of information which may consist of but is not limited to, an identification card, telephone book, utility record, etc.

C. The following information cannot be added or changed by the pharmacist: patient's name, controlled substance prescribed (with exception of generic substitution as permitted by state law), or practitioner's signature.

5161.4 Pharmacy Technician Title 21 C.F.R. § 1306.06 establishes the parameters for the dispensing of a controlled substance in response to a prescription. A prescription for a controlled substance may only be filled by a pharmacist acting in the usual course of professional practice.

Pharmacy technicians are not authorized to fill prescriptions for controlled substances, although they may ensure the prescription has all the required information, put the controlled substance in a container, and attach the label. The actual filling of a prescription takes place when a controlled substance is dispensed to the ultimate user. The Diversion Investigator must be aware that each state has its own regulations on what activities a pharmacy technician is allowed to perform in regard to filling controlled substance prescriptions.

5161.5 Time Limit for Filling a Prescription

A. **Schedule II Prescriptions** There is no federal time limitation on filling prescriptions for scheduled controlled substances. However, some state laws set a time limitation on a schedule II prescription before the prescription becomes invalid. Prescriptions, especially narcotics for severe pain, presented several days after the issue date should be considered questionable and verified with the practitioner before being filled.

B. **Schedules III through IV Prescriptions** The requirements of 21 C.F.R. § 1306.22 make these prescriptions invalid six months after the date they are issued.

5161.51 Partial Filling Of Prescriptions

A. Schedule II Controlled Substances Federal regulations allow the partial filling of a prescription for schedule II controlled substances if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription. The pharmacist must make a notation of the quantity supplied on the face of the written prescription or the written record of the oral prescription. The remaining portion of the prescription must be filled within 72 hours of the initial partial filling. If the remaining portion is not or cannot be filled within this 72-hour period, the pharmacist shall notify the prescribing practitioner. The pharmacist shall not dispense any further controlled substances in response to this prescription beyond this 72-hour period. Any further dispensing must be in response to a valid new prescription (21 C.F.R. § 1306.13(a)).

B. Exceptions for Schedule II Controlled Substances A prescription for a schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or a patient with a medical diagnosis of "terminal illness" may be filled in partial quantities to include individual dosage units. The pharmacist must write "LTCF patient" or "terminally ill" on the prescription. The pharmacist must kept track of the partial fillings. The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for a LTCF patient or a patient with a diagnosis of "terminal illness" will be valid for a period not to exceed 60 days from the issue date (21 C.F.R. § 1306.13(b)).

C. Schedule III, IV, or V Controlled Substances Partial filling of a prescription for a controlled substance in schedules III, IV, or V is permissible provided:

1. Each partial filling is recorded in the same manner as a refilling
2. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
3. No dispensing occurs after 6 months following the issue date of the prescription (21 C.F.R. § 1306.23).

5161.52

5161.52 Refilling Prescriptions and Multiple Schedule II Prescriptions

A. **Schedule II Controlled Substances** The refilling of a prescription for a controlled substance in schedule II is prohibited (21 C.F.R. § 1306.12(a)).

B. **Schedule II** – Multiple Prescriptions An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of the same schedule II controlled substance provided the following conditions are met:

1. Each separate prescription is issued for a legitimate medical purpose in the usual course of professional practice.
2. Each prescription is issued on a separate prescription blank.
3. The practitioner provides written instruction on each prescription as to the earliest day on which a pharmacy may fill each prescription.
4. The practitioner concludes that providing the patient with multiple prescriptions do not create undue risk of diversion or abuse.
5. The issuance of multiple prescriptions is permissible under state law.
6. The practitioner complies fully with all other applicable requirements of the CSA, the C.F.R., and all applicable state laws (21 C.F. R. § 1306.12(b)).

C. Schedules III and IV Controlled Substances Prescriptions for controlled substances in schedules III and IV are to be refilled for no more than six months after the date on which they were issued, and no such prescriptions shall be refilled more than five times (21 C.F.R. § 1306.22(a)).

If allowed under state law, the transfer of original prescription information for a schedule III, IV, or V controlled substance for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization if certain requirements are met (21 C.F.R. § 1306.25(a)).

5161.53 Computerization of Prescription Information

5161.54 Prescription Refills

A. Title 21 C.F.R. § 1306.22(b) permits the use of an automated data processing system for the storage and retrieval of refill information, including the partial filling of schedule II controlled substance prescriptions, subject to certain conditions. Any computerized system must be capable of providing all refill data that the user pharmacy is responsible for maintaining under the Act and its implementing regulations.

B. DEA does not mandate the format in which the data is to be arranged in each system, but a computer system must have the capability of producing a specific printout for each controlled substance, as set forth in 21 C.F.R. § 1306.22(b)(4).

5161.55 Exceptions

A. In lieu of the pharmacy having the address of the prescribing practitioner listed on a computer record, the pharmacy may instead maintain a file, either hard copy or electronic, containing the name, address, and registration number of the practitioner. However, all such information, as required by 21 C.F.R. § 1306.05 must be on the original prescription.

B. In lieu of a pharmacy maintaining the name or initials of the dispensing pharmacist on a computer record for each refill, the pharmacy may instead maintain a file, either hard copy or electronic, containing this information as set forth in 21 C.F.R. § 1306.04.

5161.56 Central Storage Multiple pharmacies maintaining records at a central location may submit one notification for that location to cover all pharmacies participating in the system. Procedures for notification are set forth in 21 C.F.R. § 1304.04.

5162 UNIQUE PRESCRIPTION SITUATIONS

5162.1 Transfer of Original Prescription

A. The transfer of original prescription information for controlled substances listed in schedules III, IV, or V for refill dispensing is permissible between pharmacies on a one-time basis if allowed by state law. This transfer allows the receiving pharmacy the authority to then dispense up to the maximum number of refills still allowed by the prescription and the time left.

B. An exception to this rule would be pharmacies that electronically share a real-time, on-line database; they may fill prescriptions at any location up to the maximum refills permitted by law. The official record of total dispensation is centrally located.

C. The investigator can find further information outlining the specific requirements governing prescription transfers in 21 C.F.R. § 1306.25.

5162.2 Prescription Filled Across State Lines Neither Federal regulation nor DEA policy prohibits an individual from taking a prescription written in one state to another state to be filled. However, state laws may prohibit this practice. Inquiries regarding this matter should be directed to the appropriate state authorities.

5162.3 Simultaneous Multiple Refills A pharmacist is permitted to fill or refill a prescription only as expressly authorized. Refilling a prescription at a rate faster than a physician directs may indicate that the patient is abusing the drug. However, refilling a prescription at a faster rate than initially authorized may be reasonable in certain circumstances such as when the patient resides in a rural area, making the commute to the pharmacy difficult, or when the patient is going on vacation and will not be in the immediate area. Under both of the conditions cited, DEA advises that the pharmacist contact the prescribing practitioner for approval. At no time may a

pharmacist refill a prescription more than the total number of refills indicated on the prescription, or supply an amount exceeding the total quantity authorized by the physician.

5162.4 DATA Waived Physician Prescriptions

A. DATA refers to the Drug Addiction Treatment Act of 2000, which is Title XXXV, Section 3502, of the Children's Health Act of 2000 (PL 106-310).

B. This legislation waives the requirement for a qualified practitioner to obtain a separate DEA registration as a Narcotic Treatment Program (NTP) to administer or dispense (including prescribe) in his/her office any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration (FDA) for use in the maintenance or detoxification treatment of a narcotic dependent person (21 U.S.C. § 823 (g) and 21 C.F.R. § 1306.07(d)). Currently, the only two drugs approved by FDA for such treatment are Subutex® and Suboxone® (buprenorphine).

C. The requirements can be found on DEA's internal Website, DEA Requirements for DATAWaived Physicians (DWPs): Practitioners Who Treat Narcotic Addiction Using Buprenorphine. These requirements can also be found at the Substance Abuse and Mental Health Service Administration's (SAMHSA) website at www.samhasa.gov or by calling the Center for Substance Abuse Treatment (CSAT) Buprenorphine Information Center at 866-287-2728.

D. If an individual practitioner becomes certified by CSAT and is appropriately registered under 21 C.F.R. § 1301.13, DEA will issue the practitioner a new certificate with the unique identifier. The individual practitioner is required to include the DEA-issued unique identifier on all records and prescriptions when the practitioner prescribes schedule III, IV, or V narcotic controlled substances used in maintenance or detoxification treatment, in addition to the regular DEA registration number.

E. DATA Waived physicians may treat thirty (30) or up to one hundred (100) patients at any one time, depending on individual authorization from the Center for Substance Abuse Treatment (CSAT). Physicians who submitted a notification for initial authorization at least one year prior may submit a second notification of the need and intent to increase the patient limit from 30 patients up to 100 patients. Upon authorization by CSAT, DEA will issue a new DEA certificate of registration with a business activity code to identify whether the physician is authorized to treat 30 (Business Activity C1) or up to 100 patients (Business Activity C4).

F. The new certificate will have a second DEA number printed under the original number which will begin with the letter "X", which replaces the first letter of the original number. The purpose of the "X" is for legal differences in the CSA and DATA Waive law.

G. Under the authority of the Controlled Substances Act (CSA), 21 U.S.C. § 822(f), DEA is authorized to conduct periodic inspections of registrants to ensure compliance with the CSA and

its implementing regulations. Notwithstanding their DATA-waived status, these practitioners are still subject to periodic inspection by DEA. Memos dated March 26, 2009, Conducting DATA Waived Physician Complaint/Criminal Investigations, and May 15, 2009, Conducting Scheduled Investigations of DATA-Waived Physicians explain the details of the DATA-waived periodic inspection program.

5162.5 Electronic Prescription (Electronic Prescription Signatures)

Reserved

5162.6 Compounding Prescriptions Using More Than One Controlled Substance A pharmacy may receive a prescription that calls for the compounding of two or more controlled substances. If the pharmacy chooses to fill this prescription, it must file the original prescription in accordance with the regulations pertaining to the controlled substance with the greatest abuse potential, as shown by its schedule. The pharmacy should also make note of this prescription in the appropriate prescription files for the other controlled substances used to compound this product.

5162.7 Transferring Prescriptions to Central Fill Pharmacies

A. Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. Prescriptions for schedules II, III, IV, and V controlled substances may be transmitted electronically, including by facsimile, from a retail pharmacy to a central fill pharmacy. Requirements for doing this are set forth in 21 C.F.R. § 1306.15 for schedule II controlled substances and in § 1306.27 for schedules III, IV, and V controlled substances.

B. DEA regulations allow the central fill pharmacy to receive prescription information in a variety of ways. Whatever the method of receipt, these are now original documents that the central fill pharmacy must maintain in the same format as received. Thus, if the central fill pharmacy receives the information via facsimile it may not then scan the facsimile, destroy the original, and claim that the scanned copy is the pharmacy's required record.

C. Prescriptions for drug products that contain List I chemicals are specifically not "regulated transactions" and, thus, are not regulated by DEA statutory and regulatory authority. Therefore, it is permissible for a retail pharmacist to use central fill pharmacy services in the filling of prescriptions for drug products containing List I chemicals.

*Revision

D. Central fill pharmacies must not prepare a prescription for a schedule II controlled substance upon receiving an oral authorization from a retail pharmacist or an individual practitioner (21 C.F.R. § 1306.11(d)(5)).

5162.8 Hospital Medication Orders

A hospital medication order is an instruction for administration of a drug used by a DEA registered facility for a specific resident in that facility. An order for medication is not a prescription as defined by 21 C.F.R. § 1300.01(b)(35) and need not contain the required information of a prescription. Medication orders may not be treated by a pharmacy as a valid prescription for dispensing to residents who are not at a DEA registered facility.

The investigator should be aware that many hospitals own, operate, or otherwise control off-site Long Term Care Facilities, hospice care programs, ambulatory surgery centers, and clinics. Such facilities may incorrectly operate as if they were an extension of a DEA registered hospital or clinic with staff using medication orders in lieu of prescriptions to obtain supplies of controlled substances for patients from contracting pharmacies.

**5162.9 Internet Prescriptions

A. Controlled substances may not be delivered, distributed, or dispensed to an ultimate user by means of the Internet without a valid prescription as outlined in 21 U.S.C. § 829(e)(1). The following definitions are found in 21 U.S.C. § 829(e).

1. A valid prescription means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient, or by a covering practitioner.

2. An in-person medical evaluation means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

3. A covering practitioner means, with respect to the patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who has conducted at least one in-person medical evaluation or an evaluation through the practice of telemedicine within the previous 24 months and is temporarily unavailable to conduct the evaluation of the patient.

B. Telemedicine: The practice of telemedicine is defined in 21 U.S.C. § 802(54) and 21 C.F.R. § 1300.04(i).

C. The Ryan Haight Online Pharmacy Consumer Protection Act (The Ryan Haight Act) that was enacted by Congress on October 15, 2008 has defined two types of prescriptions in reference to the internet:

**Addition

5162.9

1. As it relates to controlled substances dispensed by means of the Internet, the term "filling new prescriptions for controlled substances in Schedule III, IV, or V," according to 21 C.F.R. § 1300.04(d), means the filling of a prescription for an individual for a controlled substance in Schedule III, IV, or V, if the pharmacy dispensing that prescription has previously dispensed to the patient the same controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of 21 U.S.C. § 829 and 21 C.F.R. §§ 1306.21 and 1306.22. This type of prescription will be referred to as the "original prescription." The pharmacy must also contact the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the new prescription for that individual for the same controlled substance the pharmacy has previously dispensed to the patient. The original prescription must be from a prescribing practitioner that while acting in the usual course of professional practice determines there is a legitimate medical purpose for the issuance of the new prescription.

2. As it relates to controlled substances dispensed by means of the Internet, the term "refilling prescriptions for controlled substances in Schedule III, IV, or V" according to 21 C.F.R. § 1300.04(k), means the dispensing of a controlled substance in Schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of 21 U.S.C. § 829 and 21 C.F.R. §§ 1306.21 and 1306.22 and does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

D. The Interim Rule implementing the Ryan Haight Act, entitled "Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008," was published in the Federal Register on April 6, 2009. Both the Act and the Interim Rule became effective on April 13, 2009. The Interim Rule needs to be taken into consideration in determining the validity of a prescription:

1. Legitimate medical purpose in the usual course of professional practice
2. At least one in-person medical evaluation by prescribing practitioner

However, the in-person medical evaluation does not in itself demonstrate that the prescription was issued for a legitimate medical purpose within the usual course of professional practice.

The Guidance Document, Dispensing and Purchasing Controlled Substances over the Internet" published in the Federal Register April 27, 2001, references the four elements that the Federation of State Medical Boards have identified as serving to indicate that a legitimate practitioner/patient relationship has been established producing a valid prescription:

1. A patient has a medical complaint
2. A medical history has been taken
3. A physical examination has been performed

**Addition

4. A logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed

E. Foreign Internet Sites Selling Controlled Substances: Foreign Internet sites cannot legally ship controlled substances to individuals in the United States. Only a DEA registered importer, or those specifically exempt from registration, may import controlled substances into the Customs Territory of the United States.

F. Pharmacists' Responsibilities in Filling Prescriptions: While not all controlled substance prescriptions authorized by a physician in a state other than that in which the pharmacy is located are illegal, the pharmacist that is presented such a prescription should make every effort to verify the authenticity of the controlled substance prescription, especially those written by practitioners unfamiliar to the pharmacist or for a "patient" unfamiliar to the pharmacist. Pharmacists have a corresponding responsibility to ensure they are filling a valid prescription; the pharmacist must now ensure that controlled substances are dispensed in conformity with the Ryan Haight Act. The same legal standard that has always applied in determining whether a pharmacist met this responsibility will also apply in determining whether the pharmacist acted properly in filling a prescription subject to the requirements of the Ryan Haight Act. If a prescription is suspicious, the pharmacist should not fill it until the legitimacy of the prescription is determined. Pharmacists who suspect that they have received an illegal Internet prescription should contact the DEA office in their local area. Refer to the Ryan Haight Act and the Guidance Document "Dispensing and Purchasing Controlled Substances over the Internet" for additional information.**

Subchapter 517 *Disposal and* Destruction of Controlled Substances

Reserved

Subchapter 518 ARCOS

5181 GENERAL

The Automation of Reports and Consolidated Orders System (ARCOS) is maintained by the DEA Office of Diversion Control, ARCOS Unit (ODRA). ARCOS is a comprehensive reporting system which monitors the flow of certain schedules of controlled substances from the point of manufacture through wholesale distribution to point of sale at the dispensing/retail level, as referenced in 21 C.F.R. § 1304.33.

Included in the list of controlled substance transactions tracked by ARCOS are the following: All schedule I and II materials (manufacturers and distributors); schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected schedule III and IV psychotropic drugs (manufacturers only).

*Revision

**Addition

5181

Instructions and procedures regarding ARCOS are available in the ARCOS Registrant Handbook online at the Office of Diversion Control website. Data collected from ARCOS is available to all Diversion Investigators through the DEA Information Systems inside Web Applications on the DEA Intranet. In addition, the Targeting and Analysis Unit (ODPT) located at Headquarters, provides information based on the ARCOS data for investigations. Diversion Investigators can inquire about reporting status of registrants by contacting the ODRA at Headquarters.

5181.1 Who and What Must Be Reported to ARCOS Manufacturers and distributors are required to report controlled substance inventories and transactions as follows:

A. Manufacturers of bulk and/or dosage form controlled substances

1. Inventories

   a. All controlled substances in schedules I and II
   b. All narcotic controlled substances in schedule III
   c. Selected psychotropic controlled substances in schedules III and IV

2. Acquisitions

   a. All controlled substances in schedules I and II
   b. All narcotic controlled substances in schedule III

3. Dispositions

   a. All controlled substances in schedules I and II
   b. All narcotic controlled substances in schedule III

4. Manufacturing Activities

   a. All controlled substances in schedules I and II
   b. All narcotic controlled substances in schedules III
   c. Selected psychotropic controlled substances in schedules III and IV.

B. Manufacturers that only label, re-label, package, or re-package controlled substances

1. All controlled substances in schedules I and II
2. All narcotic controlled substances in schedule III

C. Distributors of bulk and/or dosage form controlled substances

1. All controlled substances in schedules I and II
2. All narcotic controlled substances in schedule III

5181.2 Submitting Reports to ARCOS

A. ARCOS must receive reports by the 15th day of the month following the close of the reporting period. The reporting period may be either monthly or quarterly. Registrants must send written notification to the Office of Diversion Control, ARCOS Unit, to change the frequency in which they report. The annual inventory must be taken on December 31st of each year and received by DEA by January 15th of the following year.

B. Registrants may report in one of two ways:

1. Electronic Data Interface (EDI) on Diversion Website – EDI is a secure internet portal system that allows 24 hour reporting 7 days a week. When DEA receives the EDI request form from ARCOS participants, the ARCOS Unit will contact the responsible individual to set up user accounts and provide all the needed information for participation in the program, to include a user's guide.

2. DEA Form 333 ARCOS Transaction Reports

5181.3 ARCOS Reporters

A. Single Reporters – A registrant reporting only its own controlled substance transactions and inventories to DEA.

B. Registered Central Reporter – A registered central reporter has a DEA registration as a manufacturer or distributor and reports controlled substance transactions and inventories for itself and other ARCOS registrants within its corporate structure.

C. Non-registered Central Reporter – A non-registered central reporter neither manufactures nor distributes controlled substances. A non-registered central reporter does not have a DEA registration, does not perform controlled substance transactions or inventories, but reports the controlled substance transactions and inventories for the ARCOS registrants within its corporate structure.

5182 REPORTING TO ARCOS FROM A CENTRAL LOCATION

A. Registrants reporting to ARCOS from a central location are required to have an ARCOS Central Reporting Identifier. The procedure for applying for a Central Reporting Identifier can be found in Section 2.7 of the ARCOS Registrant Handbook.

B. ARCOS participants with Central Reporting Authorization are responsible for ensuring that the central reporting location has furnished the registered location a hard copy of the ARCOS report after the report is filed. All ARCOS reports as well as correspondences from ARCOS (error reports, etc) are required to be maintained at the registered location for a period of two

years, unless the registrant has central recordkeeping permission. If the registrant has central recordkeeping permission the records only need to be provided upon request.

Subchapter 519 Drug Scheduling

5191 GENERAL The Controlled Substances Act (CSA) establishes the authority and criteria to add or transfer substances between schedules or to delete substances. This authority is delegated to DEA (28 C.F.R. 0.100).

Title 21 U.S.C. § 812(c) schedule I through schedule V, describes the status of the substances in 1970 when the CSA became law. The most current list of controlled substances is found in 21 C.F.R. §§ 1308.11 through 1308.15. Control actions are reported in the Federal Register as they occur and are compiled in the C.F.R. annually.

5191.1 Types of Scheduling

**There are five types of scheduling:

A. Administrative (Formal Rulemaking):

1. Initiation by DEA, by request from the Department of Health and Human Services (HHS), or by petition from any interested person.
2. DEA collects data and conducts a scheduling review
3. DEA forwards data to HHS and requests an independent scientific and medical evaluation and a scheduling recommendation.
4. HHS sends DEA its review and scheduling recommendation.
5. If HHS recommends scheduling, DEA may propose control.
6. Comments and/or hearing request must be considered.
7. Final Notice is published in the Federal Register.
8. Appellate Court Review, if requested.

B. Congressional (legislative): The control and placement of a substance may be determined by congressional action.

C. Compliance with International Treaties, conventions, and protocols: The treaty organization notifies the Secretary of State that a scheduling action has been made and DEA controls the substance to meet treaty regulations. (See Section 5192 Specialized Scheduling).

D. Emergency – temporary scheduling: When the DEA Deputy Administrator finds that control of a substance is necessary "to avoid an imminent hazard to the public safety," the Deputy Administrator may act on an emergency basis to temporarily place the substance into schedule I for a year with a possible 6 month extension and bypass the required HHS medical/scientific

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reviews and scheduling recommendation. (See Section 5192 Specialized Scheduling).

E. Immediate Precursors of Controlled Substances: The DEA Deputy Administrator may place an immediate precursor of a controlled substance in the same schedule as that controlled substance or in any other schedule with a higher numerical designation without regard to the required HHS medical/scientific review or scheduling recommendation, potential for abuse or currently accepted medical use in the United States, See 21 C.F.R. §1308.47. The DEA Administrator may publish an order to the Federal Register controlling an immediate precursor of a controlled substance.**

5191.2 Scheduling Procedures

*A. Evidence of abuse potential is the threshold for determining if a substance should be controlled under the CSA.

B. HHS recommendation is binding on DEA with respect to scientific and medical evaluation. A conclusion by HHS that a substance should not be controlled is binding. (Any other recommendation will be evaluated by the DEA Deputy Administrator.)

C. The DEA Deputy Administrator is the ultimate authority for deciding placement in a schedule.*

5191.3 Factors to Consider

5191.31 Potential for Abuse

*A. A substance may be controlled administratively only if the DEA Deputy Administrator finds that it has a potential for abuse. To evaluate the potential for abuse, DEA gathers data to determine whether the drug or substance meets any of the four criteria listed in the CSA legislative history:

1. There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or
2. There is significant diversion of the drug or other substance from legitimate drug channels; or
3. Individuals are taking the drug or substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or
4. The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant

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diversion from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.* (DEA defines a book as seven DEA Form 222s)

5191.32 Data Sources for Determining Abuse Potential **DEA data collection is an active process. Data sought by DEA depends on the specific drug under review and populations at risk for abuse. Information is collected under the above mentioned four criteria.**

5191.4 Factors for Determining Schedule Placement **The CSA requires that the following eight factors with respect to each drug or substance proposed to be controlled or removed from the schedules are considered. Specific findings are not required for each factor. These factors are listed in the CSA under 21 U.S.C. § 811(c) as follows:

1. Its actual or relative potential for abuse.
2. Scientific evidence of its pharmacological effect, if known.
3. The state of current scientific knowledge regarding the drug or the substance.
4. Its history and current pattern of abuse.
5. The scope, duration, and significance of abuse.
6. What, if any, risk there is to the public health.
7. Its psychic or physiological dependence liability.
8. Whether the substance is an immediate precursor of a substance is already controlled under this subchapter. **

5191.5 Abuse Potential of Nonprescription Drugs DEA serves in an advisory capacity to the FDA concerning nonprescription drugs with abuse potential (21 U.S.C. § 829(d)). Whenever it appears to DEA that a drug not considered a prescription drug under the Federal Food, Drug, and Cosmetic Act should be so considered because of its abuse potential, DEA will advise HHS and furnish all available relevant data.

5192 SPECIALIZED SCHEDULING PROCEDURES

The CSA allows DEA to place substances into a schedule without following the specific procedures outlined in Section 5191 of this subchapter, to include scheduling list I chemicals, controlling substances because of international treaty obligations, or emergency scheduling of substances to avoid an imminent hazard to the public safety.

5192.1 International Obligations *The United States is a party to two international treaties that may require a drug or substance be controlled under the CSA, or rescheduled if existing controls are less stringent than those required by a treaty.

1. The Single Convention on Narcotic Drugs of 1961 (CND) is designed to establish effective control over international and domestic traffic in narcotics, cocoa leaf, cocaine, and cannabis.

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2. The Convention on Psychotropic Substances of 1971 is designed to establish comparable international control over stimulants, depressants, and hallucinogens.

Example: Scheduling of Oripavine as a basic class of controlled substance in schedule II. DEA was notified in July 2007 that the CND had added the narcotic oripavine to schedule I of the 1961 convention. As a CND signatory, the United States was obligated to control oripavine under the CSA as a schedule II substance, which satisfies the requirements of schedule I control under the CND. DEA designated oripavine as a basic class of controlled substance in schedule II in September 2007. Although oripavine was not previously listed in schedule II, it was in fact controlled under schedule II as a derivative of thebaine, a natural constituent of opium.*

5192.2 Emergency Scheduling *Under 21 U.S.C. § 811(h), the DEA Administrator may place a substance, on a temporary basis, into schedule I when necessary to avoid an imminent hazard to the public safety. This emergency authority permits the scheduling of a substance which is not currently controlled while the formal rule making procedures described in the CSA are being conducted. The temporary scheduling authority does not require DEA to seek a scientific and medical evaluation from the Secretary of the Department of Health and Human Services. The provision applies only to substances which are not approved by the Food and Drug Administration or subject to an investigational new drug exemption. A temporary scheduling order expires at the end of one year, but may be extended for an additional 6 months if formal scheduling procedures have been initiated. *

5192.3 Controlled Substance Analogues

**A. The Anti-Drug Abuse Act of 1986 provided for control of a new class of substances that were structurally and pharmacologically similar to schedule I or II controlled substance and had no legitimate medical use. A substance which meets the definition of a controlled substance analogue and is intended for human consumption is treated as a schedule I controlled substance under the CSA. (21 U.S.C. §§ 802 (32)(A) and 813)

B. To determine whether a substance is a "controlled substance analogue," a judge or jury must consider if the facts of the case meet the first criterion, then either criterion two or three as follows:

1. That a substance has a chemical structure substantially similar to a schedule I or II controlled substance. Then either:
2. The substance has a pharmacological effect substantially similar to or greater than a schedule I or II controlled substance, or;
3. The substance was represented by the seller to have a pharmacological effect substantially similar to or greater than a schedule I or II controlled substance.

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4. Finally, investigators must obtain evidence that an analogue drug was intended for human consumption in order for the drug to be treated as a schedule I controlled substance under federal law.

In order to convince the court of substantial structural and pharmacological similarities, the government provides expert witnesses to present testimony on such matters. The Drug and Chemical Evaluation Section (ODE) should be contacted for matters relating to the treatment of substances as "controlled substance analogues." A scientific analysis as to the chemical structure and pharmacological effect will be prepared, and the substance in schedule I or schedule II identified that best fulfills the criteria.

For additional information about controlled substance analogue scheduling, see the Drug and Chemical Evaluation (ODE) website.**

5193 EXCLUDED AND EXEMPTED PRODUCTS

The Controlled Substances Act (CSA) provides a process to exclude nonnarcotic drugs containing a controlled substance that are sold over the counter. *It also allows DEA to exempt specific nonnarcotic prescription drugs and chemical preparations from CSA requirements.*

5193.1 Excluded Substances

5193.11 Excluded Nonnarcotic Over-The-Counter (OTC) Substances

*A. Information regarding the exclusion of nonnarcotic drug products is contained in 21 U.S.C. § 811(g). In order to be excluded, the drug must be lawfully sold over-the-counter as authorized under the Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.). This exclusion applies only to drug products since FDA does not grant over the counter status to bulk chemicals. Specifically excluded nonnarcotic products are listed in 21 C.F.R. § 1308.22.

B. The manufacturer of excluded nonnarcotic products must register with DEA to obtain the controlled substance used to make the product and is required to maintain records of receipt and manufacture. The procedures to apply for exclusion of a nonnarcotic substance are contained in 21 C.F.R. § 1308.21.*

5193.12 Excluded Substance – Dextromethorphan

Dextromethorphan is a cough suppressant used in many OTC cough preparations. Dextromethorphan is *expressly exempt from certain aspects of the CSA including scheduling as a result of* 21 U.S.C. § 811(g)(2). The substance has no known addictive properties. Because it is an isomer of levomethorphan, a potent synthetic schedule II narcotic, Dextromethorphan would be a schedule II narcotic if it were not for the exclusion.

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5193.2 Exempted Prescription Drugs and Chemical Preparations

5193.21 Exempted Prescription Drugs

*A. Exemption requirements: 21 U.S.C. § 811(g) (3) (A), (B), and (C) provides specific exemption requirements for nonnarcotic prescription drugs; other compounds, mixtures, and preparations not intended for administration to a human or animal; and compounds, mixtures, or preparations that contain an anabolic steroid intended for administration to a human or animal but which does not present a significant potential for abuse due to formulation or delivery method. A manufacturer of such products must register with DEA to obtain the controlled substances used to make the exempted drug. A qualifying product is exempted from certain registration, record keeping, security, import, export, and labeling requirements which are described in 21 C.F.R. § 1308.32.

B. Applying for Exemption: The process to apply for exemption of a nonnarcotic prescription product is described in 21 C.F.R. § 1308.31. Individuals interested in obtaining a list of Exempted Prescription Products must submit a written request to the Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152. Only those products granted exempt prescription status by DEA are exempt, even though other products with the same formulations may be available.

5193.22 Exempted Chemical Preparations

A. Exemption Requirements: Authority by regulation and specific criteria to exempt chemical preparations is contained in 21 C.F.R. § 1308.23. Exemption may be granted for chemical preparations or mixtures intended for laboratory, industrial, educational, or special research and not intended for administration to a human or animal. Requirements affecting exempted chemical preparations are contained in 21 C.F.R. § 1308.24.

B. Applying for Exemption: The process to apply for exemption of a chemical preparation is also contained in 21 C.F.R. § 1308.23. To obtain a list of Exempted Chemical Preparations, individuals must submit a written request to the Chief, Drug and Chemical Evaluation Section,

Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152.*

C. Criminal liabilities still apply for illegal manufacture, distribution or possession of controlled substances contained in the exempt chemical preparations. Distribution, possession and use of an exempted chemical preparation are lawful for registrants and non-registrants only as long as

such distribution, possession, or use is intended for laboratory, industrial, or educational purposes and not for immediate or subsequent human or animal use pursuant to 21 C.F.R. § 1308.24(f).
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Subchapter 520 Import/Export

5201 INTRODUCTION

This section contains the general provisions governing the importation and exportation of controlled substances.

5201.1 General Practices

5201.11 Treaty Obligations

All United States imports and exports are subject to the provisions of the Single Convention on Narcotic Drugs, the Psychotropic Convention of 1971, and other international treaties to which the United States is a party.

5201.12 Broker/Forwarder A controlled substance import/export broker who handles paperwork and makes shipping arrangements, but does not take possession, is not required to register with the DEA. However, a DEA registered importer/exporter must be involved in the transaction and submit the required import/export documents, except as set forth in 5201.13 of this section.

5201.13 Permits and Declarations A. The import and export declarations (DEA Form 236) must be filed not less than 15 days prior to the proposed date of importation or exportation. Applications for permits should be filed two to three weeks before the permits are needed.

B. Diversion Investigators can find applications for permits, as well as applications for declarations of import and export, through WebSter on the Office of Diversion Control internal website. Likewise, the public may obtain applications for permits, as well as applications for declarations of import and export, from DEA's website at www.DEA.gov, or from the Office of Diversion Control website, www.DEAdiversion.usdoj.gov. These forms are processed by the Office of Diversion Control, Regulatory Section, Import/Export Unit (ODGI).

C. Provisions regarding import and export declarations or permits as set forth in 21 C.F.R. § 1312 also apply to registrants authorized to conduct activities coincident to their category of registration. **Researchers may import controlled substances as a coincident activity, and analytical labs may both import and export controlled substances, but only related to their business activities.**

5201.14 Re-Export of Controlled Substances **Re-export is the export of controlled substances from the United States to another country for subsequent export from that country to a second country if certain conditions and safeguards are satisfied. The re-export of schedule II

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controlled substances and narcotic controlled substances in schedules III and IV is reported on DEA Form 161R. The re-export of non-narcotic controlled substances in schedules III, IV, and V is reported on a declaration (DEA Form 236). Further information on this topic can be found in the Final Rule that DEA published in the Federal Register on December 26, 2007 and titled "Re-exportation of Controlled Substances.**

5201.15 Import/Export Returns

*A. Return of Non-Narcotic Schedule III, IV, and Controlled Substances in Schedule V: Shipments of non-narcotic controlled substances in schedules III, IV, and controlled substances in Schedule V exported from the United States that are refused by the consignee in the country of destination or are otherwise unacceptable or undeliverable may be returned to the regular exporter upon authorization by the DEA (21 C.F.R. § 1312.27(b)(5)(iv)). Authorization by either the Chief of Operations or Deputy Chief of Operations, Office of Diversion Control, would be considered, provided that the company is registered as an importer; however, this is not the sole requirement.

B. Return of Schedule I or II or Narcotic Schedule III or IV Controlled Substances: Controlled substances in Schedule I or II or narcotic Controlled Substances listed in Schedules III or IV may not be returned to the United States.*

5201.2 Specialized Practices

5201.21 Schedules I *and II* Importation for Non-Medical Purpose

*A. The importation of marijuana or other controlled substances for such purposes as making jewelry, decorative pieces, et cetera, is prohibited.

B. Any portion of the cannabis plant, or any product made from, or any product that is marketed as a "hemp" product, that is both excluded from the definition of marijuana and contains no THC (or any other controlled substance) is not a controlled substance, and, therefore, not subject to regulation.*

**C. Opium poppy seeds are excluded from the definition of "opium poppy" and are, therefore, not a controlled substance. However, it is still illegal to cultivate opium poppy in the United States without a DEA registration. Thus, opium poppy seeds may not be imported for the purpose of cultivation, and doing so may subject the importer to potential criminal liability under the Controlled Substances Act and the Controlled Substances Import and Export Act. **

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5201.22 Transshipments

A. The law and Federal regulations (21 U.S.C. § 954 and 21 C.F.R. § 1312) allow for the shipment of controlled substances into the United States for immediate exportation or transfer to the country of destination.

B. Schedule I substances may be transshipped only after issuance of a transshipment permit by DEA. The application procedures for transshipments are outlined in 21 C.F.R. § 1312.31.

C. Transshipment of schedule II, III, and IV controlled substances for immediate exportation (21 C.F.R. § 1312.32) is permitted provided that written notice of the transshipment or transfer is submitted to the Import/Export Unit (ODGI) 15 days prior to the expected transfer or transshipment. The parameters of transshipments or transfers are outlined in 21 C.F.R. § 1312.31(b) and (c). The request may be submitted by facsimile to the Import/Export Unit (ODGI) at 202-307-7503.

D. The transshipment of schedule V controlled substances is not reportable to DEA.

5201.23 Importation for Extraordinary Medical Needs

**A. Under very limited circumstances, DEA Headquarters may authorize a foreign practitioner to enter or transit the United States with controlled substances without benefit of an importer registration, import permit, or import declaration. This applies only when the foreign practitioner is acting in an official capacity as a team physician for a professional, collegiate, or Olympic team and is required to carry controlled substances to a competitive sporting event (e.g. a rodeo) inside the United States or in another country.

B. An international medical evacuation by a United States air medical service that maintains controlled substances on board for administration to patients would be authorized to enter the United States without benefit of an importer registration, import permit, or import declaration. The air medical service must be registered by DEA with a Mid-Level Practitioner, Practitioner, or Hospital/Clinic registration. For further information regarding registration see 5113.21.**

5201.24 Exportation for Extraordinary Medical Needs

*Under very limited circumstances, DEA Headquarters may authorize a DEA registered practitioner to exit the United States with controlled substances without benefit of an exporter

registration, export permit, or export declaration. The amount of controlled substances transported by the registrant must be the minimum amount needed for the stated purpose of travel. The Import/Export Unit (ODGI) will coordinate all requests for extraordinary medical needs with the appropriate DEA office (foreign and/or domestic).

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Examples of when this would apply are as follows:

A. The physician is part of an emergency medical team called upon to provide assistance following a natural disaster. Physicians who must leave on short notice to provide emergency medical care following a natural disaster may contact the Import/Export Unit (ODGI) and the appropriate field division by telephone and provide any documentation requested by facsimile. DEA must have sufficient notice so that the appropriate national authorities in the foreign country and the United States Customs and Border Protection at the port of departure may be contacted.

B. The physician, as the emergency medical technician, is participating in an expedition sanctioned by the host country's government.

C. The physician is required to perform or assist in the surgery of patients as part of a sanctioned medical teaching team providing humanitarian aid in another country (e.g., medical mission trip).

In order for the export to be approved, the following must be provided to the Import/Export Unit (ODGI) at least a month prior to departure:

1. A thorough itinerary of the individual registrant, including date and time of departure, place of departure, carrier name, flight number(s), arrival date and time in the foreign country, sponsoring agency in the foreign country, and the date and time of arrival back in the United States.
2. A complete description of all controlled substances to be carried, including dosage form, strength, and amount.
3. The name, address, and registration number of the physician responsible and in possession of the controlled substances.
4. A complete description of the purpose of the trip and why local controlled substances are not available.
5. When applicable, copies of any correspondence from foreign authorities indicating their knowledge of the importation into the foreign country.

Upon receipt and verification of the paperwork, a waiver exception letter is granted by DEA and sent to the physician for the specific mission. The exception letter is mission specific; the physician must resubmit paperwork for every trip.*

5201.25 Exportation and Importation for Personal Medical Use

*A. Federal regulations (21 C.F.R. § 1301.26) authorize an individual to enter or depart the United States with a schedule II, III, IV, or V controlled substance prescribed for personal medical use or for administration to an accompanying animal, provided that it is in the original

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container in which it was dispensed and that an appropriate declaration is made to the U.S. Customs and Border Protection. In addition to the foregoing requirements, a United States resident (principal dwelling in United States) may import into the United States no more than 50 dosage units combined of all such controlled substances in the individual's possession that were obtained abroad for personal medical use. The 50 dosage unit limitation does not apply to controlled substances lawfully obtained in the United States pursuant to a prescription.

B. Pursuant to a Final Rule published in the *Federal Register* (69 FR 55343) on September 14, 2004, entitled "Exemption from Import/Export Requirements for Personal Medical Use," United States residents are not permitted to travel to a foreign country for the sole purpose of obtaining controlled substances to bring back to the United States. The exception is intended for travelers entering and departing the United States who have a legitimate medical need for controlled substances during their journey. The allowance of importation and exportation of controlled substances for personal medical use is intended to accommodate those individuals who have an unavoidable legitimate medical need to import (or export) controlled substances as a result of their travel. The allowance is not meant to encourage United States residents to travel abroad to obtain their controlled substances for use in this country.

C. Controlled substances intended for use by an ultimate user may not be sent into or out of the country either by the person's physician, pharmacist, or a family member.*

5202 GENERAL INFORMATION

5202.1 Stringent Law Precedence

When federal law or regulations differ from state law or regulations, the registrant is required to abide by the more stringent aspects of both the federal and state laws and regulations.

5202.2 Research Confidentiality and Exemption From Prosecution Title 21 C.F.R. § 1316.23 sets forth detailed instructions on how a researcher may request confidentiality for research subjects. Title 21 C.F.R. § 1316.24 contains detailed instructions on how a researcher may request an exemption from prosecution, when possessing, distributing, or dispensing

controlled substances within the scope of his or her registration. Research subjects, however, may not be exempted from prosecution. A researcher desiring confidentiality for a research

subject, and also immunity from prosecution, may apply for both exemptions. Granting of one exemption in no way implies that the other has also been approved.

5202.3 Offering Incentives for Controlled Substance Purchases Although DEA does not favor the offering of incentives to persons purchasing controlled substances, restricting this

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practice is a violation of existing antitrust laws. ** The Diversion Investigator should, however, be aware that such incentives might temporarily increase the amount of controlled substances in a registrant's possession.**

5202.4 Advertising Controlled Substance Prescription Prices There are no federal regulations prohibiting the public distribution of retail price information.

5202.5 Use of Schedule I Controlled Substances for Research

*A. DEA Fully Supports Bona Fide Research Utilizing Schedule I Controlled Substances For legitimate purposes. DEA works closely with the FDA and the National Institute of Health to ensure that researcher applications are approved expeditiously.

B. Joint Federal researcher clearance procedures between FDA and DEA make possible research projects utilizing schedule I controlled substances without the necessity of state legislation.

C. Use of schedule I controlled substances on humans will continue to be categorized as research, with or without state legislation, until FDA officially determines that a schedule I controlled substance is safe and effective when used for a legitimate medical purpose, and the substance is subsequently rescheduled.

D. Every effort should be made to expedite any applications for schedule I research from legitimate individuals. The issuance of a DEA registration for non-clinical research is not dependent on the prior approval of a Notice of Claimed Investigational Exemption for a New Drug (Investigational New Drug (IND)) by FDA.

E. The usual preregistration investigation should be conducted, making sure that the DEA Form 225, Application for Registration (Type B), is properly completed and a curriculum vitae and protocol are attached.

For clinical investigations: As stated in 21 C.F.R. § 1301.18(b), in lieu of submitting a research protocol to DEA, the applicant shall submit three copies of an IND, with the statement of security to FDA pursuant to 21 C.F.R. § 1301.18(b). Neither DEA nor FDA approves protocols for clinical investigations until the Schedule I research applicant has obtained an IND approval.*

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CHAPTER 52 DIVERSION INVESTIGATIONS

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CHAPTER 52 DIVERSION INVESTIGATIONS

SUBCHAPTER 521 1801 INVESTIGATOR SCOPE OF AUTHORITY

5211 INTRODUCTION

Diversion Investigations are designed to meet DEA's responsibilities under the Controlled Substances Act of 1970 and to prevent diversion of controlled substances from legitimate distribution channels. Appropriate action is required when diversion is detected either through administrative, civil, or criminal sanctions. However, it does not include total abdication of activity by DEA Special Agents in investigations involving registrants. Where activities normally considered 1811 functions (i.e., undercover operations, surveillance, evidence purchase, etc.,) are necessary, field offices will ensure that diversion investigations receive Special Agent assistance. Investigators are therefore not to participate directly in the following activities.

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5211.1 UNDERCOVER PURCHASE OF EVIDENCE

Investigators will control cases they have developed involving illegal sale by a registrant, but are required to call upon an appropriate criminal investigator (i.e., Special Agent, U.S. Marshal, state agent, etc.) when assistance is needed for the actual undercover purchase. The Special Agent, of course, will control the actual circumstances of the buy situation and the advisability of such an approach.

5211.2 INFORMANTS

Investigators (1801's) may interview sources of information and assist in debriefing of established informants relating to diversion or availability of legitimate drugs. However, the controlling and paying of confidential informants will be conducted by Special Agents (1811's).

5211.3 SURVEILLANCE (MOVING OR STATIONARY)

These activities will be conducted by appropriately authorized Special Agents. On occasions involving registrants, Investigators may be present after the area is secured for technical assistance involving their discipline, i.e., identify drugs present, records or documents pertinent to the investigation.

5211.4 ARRESTS AND SEARCH WARRANTS

These activities are to be conducted by Special Agents (1811's). On occasions involving registrants, Investigators (1801's) may be present after the area is secured for technical assistance in their area of expertise of the case; i.e., identify the drugs present, identify records or documents important to the case, etc.

It is recognized that certain criminal investigative functions may complement diversion investigations where possible criminal violations have been indicated. In those investigations, field office management will ensure that Special Agent support is provided. Conversely, Investigators should be contacted for coordination in investigations involving Controlled Substances Act registrants, when an investigation is initiated by a Special Agent.

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SUBCHAPTER 522 PRE-REGISTRATION INVESTIGATIONS

5221 INTRODUCTION

The Controlled Substances Act (CSA) requires that each person or firm that proposes to handle controlled substances *or list I* chemicals must obtain a DEA registration unless exempted from registration under 21 United States Code (U.S.C.) § 822(c) or 21 Code of Federal Regulations (C.F.R.) §§ 1301.23 through 1301.27,*1309.25 and 1309.26. The purpose of the pre-registration investigation is to determine the fitness and suitability of the applicant to engage in the activities for which registration is requested. The pre-registration investigation is to ensure that the applicant is familiar with the responsibilities to prevent the diversion of controlled substances or list I chemicals. This will be accomplished through an on-site visit to the applicant.*

5221.1 State and Federal Licensing/Registration

All persons or firms submitting an application to handle controlled substances *or list I chemicals*must have all applicable state and federal licenses and permits prior to being approved by the DEA, unless exempt from such requirements. All state and federal licenses, permits, and registrations must be commensurate with the proposed activities, must be current, and at the proposed registered location. Not all state licensing agencies require practitioners to be registered at their business location. Diversion Investigators (DI), Special Agents (SA) assigned to Diversion Groups or Tactical Diversion Squads, (hereafter referred to as Investigators), and Registration Program Specialists (RPS), should be familiar with all applicable state laws and regulations.

5221.2 Verification of Application

Except as described below, persons or firms who register as a practitioner, mid-level practitioner, hospital/clinic, or pharmacy in schedules II-V controlled substances do not require a pre-registration investigation, only verification of their application and state/federal licenses. This does not preclude the Diversion Program Manager (DPM) or Assistant Special Agent in Charge (ASAC) from requiring pre-registration investigations if he or she feels it to be necessary. Refer to Subsection 5222.1 for further requirements.

5221.3 Pre-Registration Investigations

A. An on-site investigation is required for each applicant who proposes to manufacture, distribute, import, or export controlled substances in any schedule, *or manufacture, distribute, import or export list I chemicals*, or to treat for opiate addiction (Narcotic Treatment Program (NTP)).

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B. An application for registration as a researcher, analytical laboratory in schedules I through V, or as a teaching institution in schedules II through V, will be investigated on-site or by limited pre-registration interview at the discretion of each DEA Division. *There is no registration requirement for researchers using list I chemicals, provided that the researcher does not further distribute the listed chemicals.*

A change in a researcher address requires a new preregistration investigation to be conducted.

1. All pre-registration investigative reports will include information concerning the specific controlled substances to be handled, the quantities involved, identification of the business proposed, the person(s) responsible for controlled substances and their background and credentials. The investigative report should include a description of the security maintained by the applicant, a description of the recordkeeping and any other special requirements planned by the applicant, and a summary of an interview conducted with the researcher's supervisor, verifying the researcher's approval to conduct research.

2. Researchers making application to handle schedule I controlled substances must submit a research protocol containing information in accordance with 21 C.F.R. § 1301.32. This protocol must accompany the application for registration (DEA Form 225).

Dog handlers/K-9 Units who are applying as researchers in order to handle controlled substances need only submit one application for all schedules desired. Unlike other researchers applying for schedule I controlled substance privileges, the research protocol submitted by a dog handler will be evaluated by DEA alone, without any input from the Food and Drug Administration (FDA). (See Subsection 5113.47 for further information.)

3. Researchers are required to list the drug codes of schedule II controlled substances on their application if they import or manufacture these controlled substances as a coincidental activity of their registration. A statement listing the drug code number and amount of each schedule II controlled substance to be manufactured or imported must accompany each application. In addition, when conducting pre-registration interviews/investigations on schedule II researchers, obtain the necessary supporting statement, if required, before approving the registration and issuing the DEA number. Copies of all supporting statements will be filed with the Report of Investigation (ROI). It is also essential to document within the ROI and input into CSA2, the specific controlled substances, including drug codes and quantity to be handled in accordance with Subsection 5222.2.

C. An ROI will be prepared for all pre-registration investigations reflecting the points

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outlined in accordance with Subsection 5222.2 and Section 5252. * A completed pre-registration package, including copies of all attachments, for list I chemical applicants must be forwarded to the DEA's Synthetic Drugs and Chemicals Section (ODS) for final approval.*

5222 REQUIREMENT FOR REGISTRATION

Upon receipt of an Application for Registration, field office personnel are required to verify that the applicant is properly registered, licensed, or permitted to conduct business by the state in which he/she will operate. In states requiring multiple registrations (i.e., professional boards, departments of health, and separate controlled substance registration), verification of all applicable licenses/permits is required.

5222.1 Processing DEA Form 224 (Except Teaching Institutions)

State licenses will be verified and, at a minimum, a NADDIS records check will be conducted. Once state authorization has been verified and if NADDIS records are clear, the application will be approved in accordance with the procedures established in Subsection 5111.6. Many states require pharmacies that fill and mail prescriptions for out of state patients to be registered in the state where the patient resides. Therefore, special attention to mail order pharmacies must be made; such pharmacies must produce all applicable state licenses.

A. Practitioner Exempt from State Licensing - A practitioner or mid-level practitioner exempt from state licensing or registration in the state where he/she practices (military or FEDDOC practitioner who must have a valid state license in at least one state) must obtain a separate DEA registration to conduct private practice. The applicant may obtain a DEA registration under the following conditions:

1. The applicant is properly licensed or registered by the state in which the applicant proposes to practice. The field Registration Program Specialist (RPS) will verify the practitioner's state license.

2. If a state exempts the practitioner or mid-level practitioner from licensing or registration, the field RPS will obtain a letter from the state or a copy of the interstate agreement before approving the DEA registration.

B. Lack of State Registration.

1. Registration Function - When a field RPS determines an applicant does not have the necessary state licenses/permits and does not qualify for exemption from state licensure, it is the field's responsibility to notify the applicant and allow the applicant to

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either withdraw the application or acquire the necessary state licenses or permits within a reasonable length of time (not to exceed 30 calendar days). It is recommended that the RPS send official correspondence seeking information on the state license; the correspondence should also indicate that failure to respond will result in withdrawal of the application per 21 C.F.R. 1301.16(b).
This withdrawal of the application should conform to the procedures contained in Subsection 5111.6. Should the applicant fail to acquire state registration, the field RPS should forward the information to the Diversion Group to initiate action as authorized in 21 C.F.R. § 1301.15.

2. Diversion Function - If, after notification by the field RPS, the applicant contests the disapproval based upon lack of state license/permit, the application will be referred to the Diversion Group Supervisor for assignment. A signed statement must be obtained from the appropriate state licensing agency and forwarded with the application and an ROI written under a (b)(7)(E) for an Order to Show Cause, cross-referenced to
(b)(7)(E) GFXX-FY- Denial of Application/Revocation of Registration, stating the circumstances upon which denial was recommended. The issuance of an Order to Show Cause for denial will be coordinated by the Diversion Group Supervisor with the Office of Chief Counsel (CCD).

C. Assignment of DEA Form 224 for Investigation - In the following instances, a DEA Form 224 will be referred to the Diversion Group Supervisor for assignment:

1. Disapproval based upon lack of state license/permits and applicant contests the disapproval. (See Subsection 5222.1B.)

2. Suspicion of fraudulent application or intent to divert.

3. Prior drug-related felony conviction, denial, revocation, or surrender of previous registration.

D. Denial of DEA Form 224 Application - The denial of any Application for Registration **must** be pursuant to an Order to Show Cause proceeding. The Report of Investigation (ROI) recommending an Order to Show Cause to deny registration will set forth applicable circumstances and include evidence of these circumstances. The report will be sent to the Pharmaceutical Investigations Section (ODP) and to CCD for the issuance of an Order to Show Cause.

1. No State License - Procedures for processing applicants not licensed by the state appear in Subsection 5222.1B.

2. Falsification of Application - An investigation is required on applications suspected of being fraudulent. The purpose of an investigation is to determine the extent of falsification and to secure documentation to support an Order to Show Cause to deny

the registration. Falsification may consist of the applicant's failure to indicate a prior conviction of the owner-operator/officer or major stockholder of drug-related felony or revocation of a registration. Certified copies of conviction records and a copy of a Final Order will serve as documentation and are to accompany the request (ROI) for administrative action to CCD. Falsification of information on the application is also a violation of 21 U.S.C. § 843.

3. Revocation, Denial, or Surrender of Registration - Where there is suspected reason to cause a registration to be revoked or surrendered or to cause denial of registration, an investigation is required to document the circumstances. All ROIs, including those involving a practitioner whose state license has been reinstated after a prescribed period of revocation or suspension, are required to be forwarded to CCD for appropriate action.

4. Mandatory Exclusion from Participating in Medicare-Part B - If the applicant is presently excluded or denied from participating in Medicare-Part B, every effort should be made to obtain any official document as to the reason(s) for exclusion or denial, and should be attached to the Order to Show Cause.

5. Failure to maintain adequate controls against theft and diversion.

6. Registration would not be in the public interest.

E. Approval of DEA Form 224 Application - If all criteria for registration have been met by the applicant, the Investigator will prepare an ROI under GFXX-FY-[ ]for (b)(7)(E) applicants applying on DEA Form 224 and DEA Form 224a (Type A). The Report Re section should be titled "Approval of Application" and annotate the name of the registrant and the Document Control number. The reports should be distributed in accordance with Agents Manual 6242.3 and the Distribution of Reports which is found in Webster.

5222.2 Processing DEA Form 225 and DEA Form 224 for Teaching Institutions

A. Pre-registration investigations of analytical labs, researchers, and teaching institutions will be conducted in accordance with Subsection 5221.3B and will require the same information as required in Subsection 5222.2B. An ROI will be prepared for all pre-registration investigations reflecting the points outlined in accordance with Subsection5222.2 and Sections 5226 and 5252.

B. Pre-registration Investigations Requiring On-Site Investigations - An interview will be conducted with the individual who will have overall responsibility for the proposed operation and, if possible, those persons who will be directly maintaining records and handling controlled substances. The following areas must be covered:

1. State Licensure Approval - Prior to initiating the on-site investigation, all pertinent registration certificates will be examined (i.e., state controlled substances agency, department of health, DEA, etc.,) to determine if the applicant is properly licensed to conduct the proposed activities in the proposed drug schedules.

2. Accuracy and Completeness of Application - A review of the application with the firm's management should be made to determine that all information regarding the activity, schedules, and drug codes (when applicable) have been accurately presented. It must be impressed upon the firm's management only those activities and drug codes stated on the application may be handled at the registered address unless the firm later modifies its registration or submits an application for additional activities. The firm's address will be verified to ensure that all licenses/registrations cover the same premises. It should be noted in the ROI when no licensing or registration is required by the state. Any changes or modifications to the original application will be done in accordance with Section 5224.

3. Identification of Responsible Individuals - Those individuals that have the ultimate responsibility for the operations of the firm, as well as those who will have direct control over the recordkeeping, ARCOS, security, and handling of controlled substances will be fully identified. Management will provide sufficient information (address, date of birth, driver's license, etc.) for those responsible for or having access to controlled substances. Verification of this information should be made with these individuals or with the firm's Human Resources Department. Identify the total number of employees the firm proposes to employee, and of those, how many will have responsibility for or access to controlled substances.

4. Identification of Applicant and History of the firm.

a. For privately owned and operated enterprises or publicly traded companies, Investigators will obtain documentation of the firm's structure (limited liability partnership (LLP), incorporation, etc.), the principal officers and history dealing with controlled substances (if any). If new to controlled substances, the firm's business plan to handle those substances will be obtained.

b. For institutions such as universities, Investigators will obtain information of the department head, identify in full the affiliation with the university, and identify those individuals who will oversee the research project.

5. Determination of Compliance with DEA Regulations - The primary purpose of conducting a pre-registrant investigation is to determine the applicant's ability to operate consistent with the public health and safety. Thus the applicant is to be made aware of, and must comply with, all provisions of the CSA and C.F.R.

a. Obtain a complete and detailed description of the building, its age, construction, reinforcement, fencing, roofing, entry/delivery points, windows, square footage, and office configurations. Also determine how long the applicant has been at the present location. It is encouraged to obtain either photographs or an accurate diagram of the facility.

b. An in-depth inspection of both physical security and handling procedures is required to determine if there is adequate protection. An inspection and testing of schedule II vaults and safes and schedule III through V storage areas is necessary to determine whether the applicant meets existing regulations.

c. Alarm systems and alarm lines must be thoroughly tested. The effectiveness of the system as well as the security of the line(s) should be discussed in detail with representatives of the firm and the alarm company. Where the alarm company's representative cannot be present during the investigation, the representative should be contacted before granting approval.

d. Day-to-day drug handling procedures will be reviewed to ensure that employee theft and in-transit losses are minimized. The applicant will be instructed that all controlled substances must be returned to their respective, limited access, storage areas at the end of each work day. No controlled substances are to be stored for any period of time on a delivery truck. Drug destruction procedures will need to be discussed with the applicant during a pre-registration investigation.

e. Employee screening procedures, employee responsibility to report drug diversion, illicit activities by employees, and sources of information for employee checks will be reviewed with responsible individuals.

f. Contact the nearest police and fire departments and obtain their respective response times. Contact the local police department to determine the crime assessment for firm's location and area, to further ascertain if existing or proposed security measures are adequate.

g. Contact the city or county agency responsible for zoning requirements to ascertain if the type of business operation and building construction is commensurate with applicable zoning regulations.

6. Inventories and Records - An applicant will be informed that a complete inventory of controlled substances is required on the date of registration (even if zero) and at least once every two years thereafter (21 C.F.R. § 1304.11(b) & (c)). Procedures for the biennial inventories will be explained. Requirements for all other types of records, including reports of theft or loss, ARCOS (where applicable), etc., should be discussed.

ARCOS instructions will automatically be forwarded to new registrants handling schedule I, II, IIN, and III substances by Headquarters. The basic reporting requirements should be explained during the pre-registration investigation.

C. Miscellaneous Requirements.

1. All applicants for schedule I or schedule II controlled substances will be given a detailed explanation of the requirements for completing DEA Form222, Official Order Forms, including the signing, endorsing procedures, and the requirement that DEA receive Copy-2 (21 C.F.R. § §1305.03 – 1305.19).

2. If the applicant proposes to utilize the Controlled Substance Ordering System(CSOS), a detailed explanation of the requirements, record keeping, and reporting requirements will be provided (21 C.F.R. § §1305.21 – 1305.29).

3. The regulations regarding quotas, labeling, samples, and the handling of excepted, exempted, and excluded substances should be outlined where applicable (21 C.F.R. § §1303.11 – 1303.27).

4. Investigators will inform the applicant that once approval of the application has been made and a DEA registration number issued, the registrant will be required to maintain all records and requirements reviewed, discussed, and tested. The applicant must be instructed that any changes to procedures that impact controlled substances or security provisions covered by this pre-registration investigation planned by the firm cannot be implemented without prior review and approval by the DEA. The applicant, if a manufacturer or analytical lab, must be instructed to notify the DEA in writing if the firm desires to add or delete any controlled substances to the firm's planned inventory. The Investigator will inform the applicant that failure to inform the DEA of any such modifications could result in administrative action or delay/denial of the application or any renewal application.

D. Denial of DEA Form 225 Application - The denial of any Application for Registration **must** be pursuant to an Order to Show Cause proceeding.. The ROI recommending an Order to Show Cause to deny registration will set forth applicable circumstances and include evidence of these circumstances. The report will be sent to the ODP and to CCD for the issuance of an Order to Show Cause.

1. No State License - Procedures for processing applicants not licensed by the state appear in Subsection 5222.1B.

2. Falsification of Application - An investigation is required on applications suspected of being fraudulent. The purpose of an investigation is to determine the extent of falsification and to secure documentation to support an Order to Show Cause to deny the registration. Falsification may consist of the applicant's failure to indicate a prior

conviction of the owner-operator/officer or major stockholder of drug-related felony or revocation of a registration. Certified copies of conviction records and a copy of a Final Order will serve as documentation and are to accompany the ROI for administrative action to CCD. Falsification of information on the application is also a violation of 21 U.S.C. § 843.

3. Revocation, Denial, or Surrender of Registration - Where there is suspected reason to cause a registration to be revoked or surrendered or to cause denial of re-registration, an investigation is required to document the circumstances.

4. Failure to maintain adequate controls against theft and diversion.

5. Registration would not be in the public interest.

E. Approval of DEA Form 225 Application - If all criteria for registration have been met by the applicant, the Investigator will prepare an ROI under GFXX-FY[ ]for those applicants applying on DEA Form 225 and DEA Form 225a (Type B).The Report Re section should be titled "Approval of Application" and annotate the name of the registrant and the Document Control number. The reports should be distributed in accordance with Agents Manual 6242.3 and the Distribution of Reports which is found in Webster. (b)(7)(E)

5222.3 Processing DEA Form 363

Applications for NTPs will be processed following the applicable criteria set forth in Subsections5222.2B, and 5223.1.

5223 SPECIAL PRE-REGISTRANT INVESTIGATIONS

5223.1 Narcotic Treatment Programs (NTPs)

A pre-registration investigation of an NTP will include all pertinent information outlined in Section 5222, and the following:

A. Center for Substance Abuse Treatment (CSAT) Approval. In addition to state approval, an NTP must be authorized by CSAT to use methadone for maintenance or detoxification. Field offices should not delay a recommendation for approval in CSA2 solely on the basis of a lack of CSAT approval, when proper security and recordkeeping requirements have been met by the firm. ODRR will not approve any application until it has verified that the applicant has obtained CSAT approval.

B. DEA Categories of NTPs - Investigators must ensure that the applicant has properly identified the proposed business activity. The Investigator should note that an NTP

registration can be issued only to a location which dispenses. A "compounder" is one who compounds methadone for both on-site and off-site dispensing. An applicant who proposes to compound only is required to apply via a DEA Form 225 as a schedule II manufacturer and report to ARCOS.

C. Additional Security for NTPs - Additional security requirements for NTPs are outlined in 21 C.F.R. § 1301.74(h)-1307.74(k) (delivery procedures, authorization to administer, etc.). Depending upon the size of the program, DEA policy allows for variances in security for NTPs located within hospitals. Procedures for the dispensing of methadone must be reviewed to ensure that the possibility for loss or diversion is minimal.

D. Approval of DEA Form 363 Application - If all criteria for registration have been met by the applicant, the Investigator will prepare an ROI under GFXX-FY(b)(7)(E) The Report Re section should be titled "Approval of Application" and annotate the name of the registrant and the Document Control number. The reports should be distributed in accordance with Agents Manual 6242.3 and the Distribution of Reports which is found in Webster.

E. Denial of DEA Form 363 Application - The denial of any Application for Registration **must** be pursuant to an Order to Show Cause proceeding as set forth in Section 5282. The ROI recommending an Order to Show Cause to deny registration will set forth applicable circumstances and include evidence of these circumstances. The report will be sent to ODP and to CCD for the issuance of an Order to Show Cause.

1. No State License - Procedures for processing applicants not licensed by the state appear in Subsection 5222.1B.

2. Falsification of Application - An investigation is required on applications suspected of being fraudulent. The purpose of an investigation is to determine the extent of falsification and to secure documentation to support an Order to Show Cause to deny the registration. Falsification may consist of the applicant's failure to indicate a prior conviction of the owner-operator/officer or major stockholder of drug-related felony or revocation of a registration. Certified copies of conviction records and a copy of a Final Order will serve as documentation and are to accompany the ROI for administrative action to CCD. Falsification of information is a violation of 21 U.S.C. § 843.

3. Revocation, Denial, or Surrender of Registration - Where there is suspected reason to cause a registration to be revoked or surrendered or to cause denial of re-registration, an investigation is required to document the circumstances.

4. Failure to maintain adequate controls against theft and diversion.

5. Registration would not be in the public interest.

F. Additional Records for NTPs - Recordkeeping requirements outlined in 21 C.F.R. §§ 1304.28 and 1304.29 must be discussed with the applicant, as well as all other general recordkeeping requirements.

G. Miscellaneous. The applicant should be made aware that registration as a NTP only authorizes the use of methadone, Suboxone, and Subutex (or their generic equivalents) for maintenance/detoxification. The Investigator must advise the applicant that the dispensing, administering, or storage of any other controlled substance by the applicant may result in action taken against the registrant. The Investigator must advise the applicant that no controlled substances may be prescribed under the DEA registration of an NTP, and that the administering and dispensing of any other controlled substances may be made only pursuant to the DEA registration of an affiliated practitioner.

****5223.2 Processing DEA Form 510 Chemical Handlers**

5223.21On-Site Investigation

Prior to conducting the on-site pre-registration investigation of a list I chemical handler applicant, the Investigator will check NADDIS, CSA, CHEMS, and other systems concerning the applicant. To initiate the on-site pre-registration investigation, the Investigator(s) will present credentials and interview the individual who has overall responsibility for the proposed operation and, if possible, those persons who will be directly maintaining records and handling list I chemicals.

The Investigator will obtain information from the applicant/registrant required in accordance with the pre-registration checklist. The pre-registration checklist is a comprehensive guide to conducting investigations of both a new applicant and a current registrant who has requested a modification to the registrations.

5223.22 Background of Applicant

The Investigator must determine whether the business of the applicant is a corporation, partnership, sole proprietorship, etc. Subsidiary or related businesses should also be determined. The Investigator should determine how long the applicant has handled list I chemicals and in what capacity, i.e., manufacturing, distributing, importing or exporting. The Investigator should also obtain complete descriptions of the list I chemical product lines handled, brand names, and package sizes. It should also be determined what percentage list I chemicals will be of the applicant's total business.

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5223.23 Accuracy and Completeness of Application

A. A review of the application with the firm's management will be made to determine:

1. That all information regarding the activity, list I chemicals, and chemical code numbers has been accurately presented on the application.

2. That only those activities and/or list I chemicals stated on the application may be handled at the registered address unless the firm later modifies its registration or submits an application for additional activities.

B. The firm's address should be verified to ensure that all licenses/registrations cover the same premises. Applicants applying for registration at a bonded warehouse should put their name on the top line of the DEA-510, the name of the warehouse on the next line and the address of the warehouse on the remaining lines.

5223.24 Identification of Responsible Individuals

The Investigator will determine who has the ultimate responsibility for the operation of the firm, as well as those who will have direct control over the record keeping, security and handling of list I chemicals. Sufficient information on those who have direct control over the list I chemical handling (i.e., driver's license or state issued identification card, home address, home and business telephone numbers, date of birth, etc.,) must be obtained so that a review of NADDIS and CHEMS may be conducted. There is no requirement to obtain identifying information on all employees having access to list I chemicals.

During the on-site visit, the applicant's responsibilities will be discussed:

1. The applicant's procedures for security, record keeping and reporting will be reviewed.

2. The applicant will be provided available materials via DEA Form 12, such as the Chemical Handlers Manual and DEA warning notices outlining the illegal uses of hemicals in the illicit manufacture of controlled substances and general guidelines regarding the applicant's corresponding responsibility.**5223.25 Security**

An in-depth review of both physical security and handling procedures is required to determine if there is adequate protection of list I chemicals. A review of list I chemical storage areas is necessary to determine that the applicant is in compliance with the list I chemical security regulations. Although an alarm is not required for list I chemical handlers, the Investigator will document all alarm systems. Day-to-day list I chemical

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handling procedures will be reviewed to ensure that employee theft and in-transit loss is minimized. The applicant should be reminded that all list I chemicals must be returned to their storage areas at the end of each day, that no list I chemicals are to be left on delivery trucks, and that there must be limited access to storage areas. List I chemical destruction procedures will also be discussed with the applicant during the pre-registration investigation although DEA should not be involved in the destruction of list I chemicals.

5223.251 Security Requirements

A. Pursuant to 21 C.F.R. § 1309.71 list I chemicals shall be stored in containers sealed in such a manner as to indicate any attempts at tampering with the container. Where list I chemicals cannot be stored in sealed containers, access to the chemicals should be controlled through physical means or through human or electronic monitoring.

B. In evaluating the effectiveness of security controls and procedures, the Investigator shall consider the following factors:

1. The type, form and quantity of list I chemicals handled;
2. The location of the premises and the relationship such location bears on the security needs;
3. The type of building construction comprising the facility and the general characteristics of the building or buildings;
4. The availability of electronic detection and alarm systems;
5. The extent of unsupervised public access to the facility;
6. The adequacy of supervision over employees having access to list I chemicals;
7. The procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel in areas where list I chemicals are processed or stored;
8. The adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of list I chemicals in its operations.

C. Any registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate may submit material specifications and plans regarding the proposed security controls and procedures to the Special Agent in Charge of the Division.

5223.26 Reports and Records

A. The Investigator must discuss with the applicant the records and reports the applicant is required to make regarding listed chemicals. If the applicant has imported, exported or distributed listed chemicals prior to applying for registration, the Investigator must determine if the applicant has been complying with the record keeping, reporting and

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proof of identity requirements that have been in effect since the inception of the Chemical Diversion and Trafficking Act (CDTA) in 1989, Domestic Chemical Diversion Control Act of 1993 (DCDCA), Comprehensive Methamphetamine Control Act (CMCA) in 1996, and the Combat Methamphetamine Epidemic Act (CMEA) in 2005, and the Combat Methamphetamine Enhancement Act (MEA) in 2010.

B. The Investigator must advise the applicant of the applicant's obligation to report suspicious list I chemical regulated transactions to DEA at the earliest practicable opportunity and as much in advance of the conclusion of the transaction as possible, according to 21 C.F.R. § 1310.05(a).

The Investigator must advise the applicant that a written report of a suspicious listed chemical regulated transaction must be provided to the local DEA office within 15 days following the transaction, as required in 21 C.F.R. § 1310.05(b).

C. The Investigator must advise the applicant of the required content of listed chemical records and reports as required by 21 C.F.R. § 1310.06. This would include information regarding listed chemical suppliers and customers, including names, addresses, telephone numbers and other identifying information on the suppliers and customers. The Investigator will obtain supplier and customer lists unless such lists would be of no value in terms of CHEMS input or identifying relationships between chemical companies. These are necessary to establish a base line in order to support the legitimacy of the prospective registrant and identify possible connections to the many ongoing criminal cases. The Investigator will review all distributions in order to identify patterns of suspicious activity and report any findings in the ROI. The Investigator will determine if the applicant has been reporting "mail order" sales of pseudoephedrine, phenylpropanolamine, and ephedrine products to DEA.

The Investigator must discuss Proof of Identity requirements with the applicant. 21 C.F.R. § 1310.07

5223.27 Approval of Application

If all criteria for registration, as listed in 21 U.S.C. § 823(h), have been met by the applicant, and there are no grounds for denial, the ROI will be submitted to the Synthetic Drugs and Chemicals Section (ODS) at DEA headquarters for further evaluation and possible application approval. The following are some of the grounds for denial of an application:

A. Controlled substance or listed chemical conviction on the part of the applicant; or, if the applicant is a corporation, on the part of an officer, partner or stockholder.

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B. Falsified application.

C. Failure to comply with applicable Federal, state, and local law, including but not limited to record keeping, reporting, registration, proof of identity, or other requirements as contained in the CDTA, DCDCA, CMCA, CMEA, and/or MEA as incorporated into the CSA.

D. Involvement in diverting listed chemicals to the illicit market.

E. Lack of experience in handling listed chemicals.

F. Any other activity in which registration would be inconsistent with the public interest 21 U.S.C. § 823.

5223.28 Reporting the Chemical Pre-Registration Investigation

The following information will be contained in the body of the ROI reporting the pre-registration investigation (The report order should follow the pre-registration checklist). The information will be reported as numbered paragraphs under **"DETAILS."**

Any report exceeding two typed pages will be preceded by a synopsis that will contain a brief summary of the investigation.

A. The first paragraph of the pre-registration report will reference the Application for Registration and will include the name of the applicant, the address and appropriate telephone numbers of the proposed registered location, activity for which applying, list I chemicals to be handled, signer of the application, date of application and control number.

B. Subsequent paragraphs will include the following details:

1. Appropriate state and federal license numbers, when applicable. If a state license or registration is not required, a statement to that effect will be included. If a state license is required, all pertinent information pertaining to that license (i.e. expiration date, number, specific chemicals, and date of issue) should be included in the report. If the firm is incorporated, list the state of incorporation and the date. If the firm is a publicly-traded corporation, determine which stock exchange (e.g. NYSE) the firm's shares are traded. If the firm is privately held, state that in the report.

2. Basic identification data of the principals of the company having direct control over the list I chemical activities, to include business address and telephone number, and the results of NADDIS, CHEMS, and state and local regulatory agency checks.

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Investigators will use discretion in deciding how many principals need to be identified.

3. The names, titles and responsibilities of the persons contacted and the dates when these persons were contacted. If the firm takes an inordinate amount of time supplying the requested information that should be documented in the report.

4. A description of the type of list I chemical activity conducted by the applicant and any pertinent background information on the firm or individual. This will include the percentage of the applicant's total business involve list I chemicals.

5. Obtain a roster of all list I chemical customers. If there are more than 50 customers on the roster, an electronic copy must be obtained and sent to ODS. Describe the procedures the company uses to identify and verify customers. This will include a description of the types of documents obtained before establishing a customer and the sources and agencies contacted during the process of identifying and verifying the customer. The Investigator will conduct verification on customers who purchase the largest quantities of list I chemicals.

6. A description of the security measures to be employed, including a statement regarding the types and amounts of list I chemicals that will be handled, details of physical security provisions and handling procedures. The Investigator will also obtain the names, addresses, and dates of birth of the persons who will have primary responsibility for access to list I chemicals, as well as results of NADDIS, state and local regulatory agency record checks on these individuals. If the principals of the firm are U.S. citizens, that should be stated in the report. If they are not U.S. citizens, their country of citizenship should be obtained. It is not required that this information be obtained on all employees having access to list I chemicals, only supervisory personnel.

7. Detailed description of the proposed record keeping and reporting system, and also a statement that the applicant was advised of all pertinent requirements and given a Chemical Handler's Manual and/or other written information such as the DEA warning notices concerning the applicant's responsibilities under the CDTA, DCDCA, CMEA, CMCA, and MEA.

8. All other proposals or agreements discussed during the investigation including procedures for disposing of outdated or otherwise unwanted list I chemicals.

9. Any changes made to the initial application.

10. Results of the on-site interviews with company principals and document their statements reflecting attitude toward compliance with the regulations.

**Addition

11. The report must state that the Diversion Program Manager or ASAC has reviewed and concurs with the submission of the application to ODS for review and possible approval.

12. The final section of the ROI will be the Indexing Section. The name of the applicant and any other persons or names meeting the criteria in Subsection 6233.3 of the Agents Manual for indexing will be listed in the "Indexing Section," along with appropriate identifying information, including dates of birth, addresses, telephone numbers, driver's license numbers, height, weight, hair color and eye color. Social security numbers should not be requested during pre registration investigations.

All telephone numbers identified during the investigation should be included in the indexing section and a multi-source query should be done on each telephone number.**

5223.3 DATA Waived Physicians (DWPs)

The Drug Addiction Treatment Act of 2000 (DATA) was passed by Congress on October 17, 2000, and amended 21 U.S.C. § 823(g). The law waives DEA's separate registration requirement for NTPs for "qualified" physicians who want to treat opioid dependent patients. Under DATA, qualified physicians may administer, dispense and prescribe schedules III-V narcotic controlled substances approved by FDA specifically for use in maintenance and detoxification treatment. On October 8, 2002, the FDA approved two high-dose schedule III formulations of sublingual buprenorphine drug products (Suboxone and Subutex) for use in opioid addiction treatment. DWPs may be initially authorized to treat up to 30 and later authorized to treat up to 100 patients upon authorization by the Center for Substance Abuse Treatment (CSAT) and DEA, information is found at DEA Requirements for DATA Waived Physicians (DWPs).

A. A physician must first apply via notification to CSAT, [(866)-287-2728] prior to the initial dispensing or prescribing of approved opioid addiction treatment drugs under the DATA. Physicians who submitted the notification for initial authorization at least one year prior may submit a second notification of the need to increase the patient limit from 30 patients up to 100 patients. CSAT reviews the notification to determine whether all requirements, including verification of state licensure, required training, physician capability for patient counseling referrals, knowledge of the 30 to 100 patient limits, and any other requirements for the waiver are met.

B. CSAT forwards its findings to ODRR for review. Upon receipt by ODRR, the physician's DEA registration is verified for the correct drug schedules, address, and expiration date, as well as a query of NADDIS. If derogatory information is discovered, ODRR will contact the respective field office to request a recommendation for approval or denial which is then relayed to CSAT before final approval.

**Addition

C. Once CSAT makes a determination as to whether a physician is qualified for a waiver; it notifies each physician in writing and sends a copy to the DEA. In the letters to qualified physicians, CSAT notifies him or her that he or she is authorized to administer, dispense, and prescribe schedule III-V narcotic controlled substances that are approved by the FDA for use in maintenance and detoxification treatment. Qualifying physicians are issued a Unique Identification Number (UIN) by DEA that is identical to the physician's DEA registration number except that the first character is replaced by an "X" (i.e., registration number RC1234567 becomes XC1234567). A "C1" or "C4" business activity code is assigned in the CSA database for identification and tracking purposes.

(b)(7)(E)

(b)(7)(E) A new DEA registration certificate is then issued which contains the physician's registration number and his or her UIN.

5223.4 Etorphine HCl, Diprenorphine, and Carfentanil

A pre-registration investigation of applicants for etorphine HCl, diprenorphine, and carfentanil shall include the general information outlined in Subsection 5222.2, taking into consideration the additional recordkeeping and security requirements in accordance with 21 C.F.R. §§ 1301.74(g), 1301.75(d) and 1305.16. Document entitled "Procedures for Requesting Carfentanil, Etorphine, and Diprenorphine Authorization" is found in Webster. Reference is made to Subsection 5113.46 for additional information concerning etorphine HCl, diprenorphine, and carfentanil handlers.

5223.5 Anonymous Analytical Lab Program

Reserved

5223.6 Importer/Exporter

The pre-registration investigation of importers and exporters shall include all general information outlined in Subsection 5222.2 and also include a detailed explanation of the procedures to obtain required permits and for submissions of declarations.

5223.7 Peyote Distribution

An investigation is required on a person(s) applying for registration to distribute peyote to bona fide members of the Native American Church to determine the legitimacy as well as compliance with recordkeeping and security regulations. Such a distributor is exempt from ARCOS reporting as long as the peyote is for religious use only. Close coordination with headquarters and the state is required in conducting these pre-registration investigations.

Presently, all peyote distributors are located in the Rio Grande Valley in southwest Texas. The individuals harvesting and distributing have done so along the lines of cultural and ethnic tradition and, as a result, the same level of recordkeeping and security requirements as a distributor have not been imposed. The state of Texas presently issues permits to tribal representatives to purchase peyote. The requirement agreed upon by the Native American Church for membership is that the person be at least 25 percent Native American. This determination is made by the individual tribes.

5223.8 Importation and Distribution of Hoasca or Ayahuasca Tea

As of September 2010, two religious organizations in the United States are registered with DEA to import and distribute a substance referred to as hoasca or ayahuasca tea. (This substance can also be referred to as daime tea.) This sacramental tea, which is imported from Brazil, is made from two plants unique to the Amazon region and contains dimethyltryptamine (DMT), a schedule I hallucinogen. DEA's registration of these two organizations, the O Centro Espirita Beneficente Uniao do Vegetal (UDV) and the Church of the Holy Light of the Queen (CHLQ), is the result of lawsuits filed by each organization pursuant to the Religious Freedom Restoration Act (RFRA).

In 2006, in a lawsuit filed by the UDV, the Supreme Court held that action taken by DEA pursuant to the Controlled Substances Act (CSA) is subject to the requirements of RFRA. *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal,* 546 U.S. 418 (2006). Under RFRA, the federal government may not substantially burden a person's exercise of religion, even if the burden results from a generally applicable rule. 42 U.S.C. § 2000bb-1(a). The only limited exception is a circumstance where the government can demonstrate that the burden is the result of a compelling governmental interest and is the least restrictive means of achieving that interest. In settlement of the UDV litigation, DEA registered the UDV to import and distribute hoasca tea. In a similar lawsuit brought by the CHLQ, DEA is required by court order to register that organization. Because of the Supreme Court's decision in the *O Centro Espirita* case, it is possible that additional organizations may also obtain permission to import and distribute hoasca/ayahuasca tea in the future.

Although the UDV's and CHLQ's importation and distribution of hoasca/ayahuasca are regulated by DEA, they are not subject to all CSA regulatory provisions. **Before any office has contact with either of these churches with respect to the importation or domestic distribution of this substance, it is mandatory that you first consult with ODGR. Taking action without consulting DEA Headquarters may place DEA in violation of its settlement agreement or a federal court order.** This includes any inspection of registered locations for these organizations (churches may be registered in multiple locations), as well as any inquiries by the churches or any other action which might involve the seizure or detention of the tea or individuals who may be in possession of the tea.

5223.9 Religious Claims for Controlled Substances

The Supreme Court has held that action taken by the DEA pursuant to the Controlled Substances Act (CSA) is subject to the requirements of the Religious Freedom Restoration Act (RFRA). *Gonzales v. O Centro EspiritaBeneficenteUniao do Vegetal*, 546 U.S. 418 (2006). Under RFRA, the federal government may not substantially burden a person's exercise of religion, even if the burden results from a generally applicable rule. 42 U.S.C. § 2000bb-1(a). The only limited exception is a circumstance where the government can demonstrate that the burden is the result of a compelling governmental interest and is the least restrictive means of achieving that interest.

Application of the RFRA criteria is a sensitive inquiry that requires careful attention and specialized training. DEA has established a petition process to address requests for religious use of controlled substances. Any office that receives an inquiry about religious use of controlled substances should refer the requestor to DEA's published guidance on this topic and also notify **ODGR**. DEA's Guidance Regarding Petitions for Religious Exemption from the Controlled Substances Act Pursuant to the Religious Freedom Restoration Act is available on the OD website. It is important that ODGR be informed of any requests or inquiries concerning religious use of controlled substances.

5224 MODIFICATION OF APPLICATION

During the course of a pre-registration investigation, circumstances may often require that a change be made to the information which was originally provided by the applicant on the Application for Registration.

A. Where addition or deletion of a schedule or drug codes or minor changes to an address, (e.g., addition of a suite number), is required, input of the modification shall be accomplished in accordance with the procedures contained in Subsection 5113.3.

B. In the following situations, a new application is required. When a new application is submitted, the incorrect one must be withdrawn. New payment to cover the full amount of the registration fee must be obtained at the time of new application.

1. When the correct activity would require a different application form (e.g., if a medical doctor were to use a DEA Form225, and apply as a distributor, and should have applied on a DEA Form 224 as a practitioner).

2. When there is any difference in the registration fee, whether the difference is over or under (e.g., when a firm applies on a DEA Form 225 as a manufacturer, when the correct activity should be that of a distributor).

C. When the applicant cannot be reached either by phone or in person, a registered letter shall be sent to the address listed on the application. The letter shall state that the

application will be withdrawn after a set period of time (generally 30 days) if no response is received, as set forth in 21 C.F.R. § 1301.16(b).

SUBCHAPTER 523 INVESTIGATIVE TECHNIQUES

5231 INTRODUCTION

Diversion Investigators must ensure that all current and prospective registrants comply with the requirements of the Controlled Substances Act and its implementing regulations.

5231.1 Non-Practitioner Investigations

5231.11 Work Plan

The CSA requires that all non-practitioners registered with DEA be periodically inspected. DEA work plans are designed to provide a schedule for conducting on-site investigations of non-practitioners. Work plans, prepared by each field office, will list the controlled substance and list I chemical manufacturers, distributors, importers, exporters, NTPs, and DWPs to be investigated.

All field offices will provide ODG with a copy of the work plan for scheduled investigations not later than October 1st of each fiscal year (see Appendix 5231A).

5231.12 Registrants Requiring Periodic Investigations

DEA is required to conduct periodic on-site investigations of all controlled substances manufacturers, distributors, reverse distributors, importers, exporters, NTPs, and DWPs and *listed chemical manufacturers, distributors, importer, and exporters* to ensure they are in compliance with the CSA and are entitled to continued registration with DEA.

These registrants will be scheduled for investigation at least once every three years with the exception of DWPs, which will be conducted once every five years. Each office will prepare a work plan scheduling investigations each fiscal year.

Section 303 investigations of bulk form manufacturers and importers of schedule I and II controlled substances must be conducted annually (see Section 5246).

5231.13 Other Registrants

Investigations of researchers, analytical laboratories, and teaching institutions will be initiated and developed upon the following criteria:

*Revision

A. Two schedule I researchers handling special Headquarters approved controlled substances, which includes: drug code 2010(GHB), drug code 2012 (GHB preparations), drug code 7360 (marijuana), drug code 7370 (THC), drug code 7369 (Dronabinol), drug code 7405 (MDMA), drug code 9650 (opium poppy), and drug code 9670 (poppy straw concentrate), will be selected each fiscal year until all have been inspected, at which time the first two will be scheduled again.

B. Two schedule II –V researchers will be selected each fiscal year until all have been inspected, at which time the cycle shall begin again.

C. Analytical Laboratories affiliated with manufacturers are subject to scheduled investigation every three years in tandem with the affiliated manufacturer's scheduled investigation.

D. Excluded from the work plan are researchers/dog handlers, teaching institutions, and analytical laboratories (unless affiliated with a manufacturer's investigation).

(b)(7)(E)

*Revision

(b)(7)(E)

5231.3 Accompaniment Requirement

All investigative activities require the presence of at least two individuals (any combination of Diversion Investigators, Special Agents, Intelligence Research Specialist, and/or local law enforcement officers) at all times during the on-site portion of the investigation. In joint investigations with other agencies, the second investigator may be a representative from the other agency. When an investigation is conducted pursuant to an administrative inspection warrant, only those individuals authorized to execute an administrative inspection warrant pursuant to 21 U.S.C. § 880 can be on the premises during the investigation, unless they have independent authority under state law or pursuant to a separate warrant or are duly deputized members of a DEA Task Force.

5231.4 Investigator Conduct

(See memorandum, dated June 17, 2003, signed by William B. Simpkins, subject: U.S. Department of Justice Guidance Regarding the Use of Race by Federal Law Enforcement Agencies)

Investigators are professionals and accordingly are expected to conduct themselves in a businesslike manner. It is their responsibility to promote public confidence in the dependability and integrity of the DEA. The guidelines for conduct by DEA employees can be found in Subsection 2735.1 of the Personnel Manual. The Investigator is

*Revision

responsible for promptly notifying his or her supervisor of any situation or circumstance which could indicate a breach of integrity, misconduct, or impropriety on the part of any DEA employee. Further definitions of a breach of integrity can be found in the Agents Manual, Sections 6111, 6112, 6113, and the Planning and Inspection Manual, Section 8308. The following information will serve as a guide to some commonly encountered situations:

A. Gratuities - Departmental regulations (28 C.F.R. § 45.735-14(a)(2) and (4)) forbid the acceptance of gratuities while in the performance of official duties.

B. Consumption of Alcohol - Under no circumstances will an Investigator consume alcoholic beverages during an investigation.

C. Appearance and Attitude - The Investigator will be well-groomed and dressed appropriately for a business atmosphere. Should a firm require special clothing to comply with FDA's Good Manufacturing Practices (e.g., sterile clothing or hard hats to be worn in a particular area), Investigators are to comply with the required dress code. The Investigator should maintain a calm, businesslike attitude at all times. Politeness is appropriate but ***overfriendliness*** should be avoided. The mission is to investigate and establish a professional rapport with the firm's officials.

D. Privileged Information - Investigators will not reveal information about other firms or their practices. Be alert to avoid divulging any information which might compromise an Investigator's integrity or that of the DEA.

E. Credential Duplication - Under no circumstances will an Investigator allow his/her ***credentials to be photocopied.***

F. Personal Business Cards. The use of personal business cards is optional, within the following policy guidelines.

1. Authorization - Personal business cards are authorized only in the course of professional business, law enforcement, and regulatory contacts, but are not to be furnished to informants, defendants, or suspects.

2. Design - Business cards shall be printed in black or dark blue ink on white card stock and shall contain the following data: the name of the individual, position title, "United States Department Of Justice," "Drug Enforcement Administration," the office address, and the office telephone number. The DEA seal may be used.

3. Cost - Expenses incurred in printing business cards are reimbursable, according to OMB and DEA policy.

5231.5 Informed Consent - Notice of Inspection (NOI)

The burden of proof of consent to search is upon the Government. The Government must prove consent was given fully and intelligently, and no implied duress or coercion was used. As a result, the NOI contains a statement of rights and an acknowledgment of consent section.

Upon entering a registered location, Investigators will present their credentials, state the purpose of their visit, and present a NOI to the individual responsible for the operation of the firm, i.e., president, manager, owner, operator, agent in charge, or the person who signed the DEA initial or last renewal application.

Investigators will ensure that this person understands his/her rights and the scope of the Investigators' authority. When the NOI is signed by the individual, it should be witnessed by the two individuals authorized to conduct investigations. In some cases, a firm will elect not to sign the NOI, but will give verbal consent. In such cases of verbal consent, the Investigators will witness the NOI indicating in writing on the document that verbal consent was given. A copy of the document will be given to the responsible individual at the firm.

5231.6 Administrative Inspection Warrant (AIW)

In all cases where informed consent is not obtained from the owner/operator or agent in charge of the registered location, or in cases where consent is withdrawn, an AIW must be obtained.

Where the Investigator believes that civil prosecution or serious administrative action could result, an AIW should be sought regardless of whether informed consent was given previously. In these situations, one Investigator should remain on the premises during normal business hours, while another obtains the AIW.

A. Obtaining an AIW in doubtful situations will prevent the possibility of losing the case in court over a question of whether informed consent was freely and knowingly given or was withdrawn by the agent in charge of the controlled premises.

B. Title 21 U.S.C. § 880 describes the conditions under which an AIW can be used and also the procedures that are permitted. This section sets forth who may issue an AIW, i.e., any judge of the United States or a State Court of Record or any U.S. Magistrate within proper territorial jurisdiction. Rule 41, Federal Rules of Criminal Procedure, defines a State Court of Record as a court in which the proceedings will be recorded or made part of a public record. See Appendices 5231B, 5231C, 5231D, and 5231E for examples of AIWs and Affidavits concerning both registrants and regulated persons. These examples are the most common AIW formats; however, the extent of probable cause and the identification of a controlled premise can vary in each judicial district.

5231.61 Probable Cause

An AIW must meet the criteria of "Administrative Probable Cause" which, for an AIW, consists of a valid public interest in the enforcement of Title 21 to conduct investigations of premises where controlled substances or listed chemicals are being manufactured or distributed. Administrative Probable Cause for an AIW can be demonstrated by alleging that (1) a location that is required to be registered and/or keep records under the CSA has never been inspected before; or (2) that DEA has evidence of suspicious purchases/sales of controlled substances or listed chemicals since the last inspection. Only when the judge or magistrate is satisfied that "Administrative Probable Cause," as defined in section 510(d)(1) of the Act (21 U.S.C. 880(d)(1)) exists will he or she issue an AIW. When criminal probable cause is developed during an investigation, the local U.S. Attorney's Office shall be consulted to determine whether the investigation may continue or if a search warrant should be obtained.

5231.62 Obtaining an Administrative Inspection Warrant (AIW)

In order to obtain an AIW, application must be made via an affidavit and sworn before a magistrate or judge. The magistrate or judge will issue the warrant if satisfied that the following criteria are met:

A. Administrative Probable Cause exists.
B. Purpose of the investigation.
C. Proper identification of the area, premises, building, or conveyance to be investigated.
D. Type of property to be investigated.
E. Items to be seized, if applicable.
F. Execution of the warrant during normal business hours.

5231.63 Return of Administrative Inspection Warrant (AIW)

In all cases, the warrant must be returned to a judge or magistrate within 10 calendar days. If it is expected that an investigation at the controlled premises may require more than 10 days, a longer length of return should be requested from the judge or magistrate when obtaining the warrant. An extension of the 10 day return may be requested from the judge or magistrate if it becomes evident during an investigation that additional time is required to complete the on-site phase of the investigation.

5231.64 Removal of Records for Copying

If any records are removed for copying during execution of an AIW, a receipt must be given to the owner (via DEA Form 12) and an inventory list of the records removed must accompany the return of the warrant to the judge or magistrate. Once copying of the records has been completed the originals must be returned to the registrant.

5231.7 Refusal to Permit Inspection

If a registrant or his/her agent refuses to permit an inspection upon being served with an AIW, the Investigator should advise that such refusal constitutes a violation of 21 U.S.C. § 842(a)(6) and is punishable by imprisonment for not more than one year and/or a fine of not more than $25,000. If the registrant or his or her agent continues to refuse to permit the execution of an AIW or continues to impede the inspector in the execution of that AIW then the registrant or his/her agent shall be arrested and the inspection shall commence or continue. Special Agents may affect an arrest for committing a misdemeanor in his/her presence.

5231.8 Search Warrant

Search warrants will be issued in accordance with Subsection 5211.4of this manual and Subsection 6651.2 of the Agents Manual. A search warrant must be executed by Special Agents; however, Diversion Investigators may be present after the area is secured for purposes of technical assistance in identifying controlled substances, identifying records and documents important to the investigation, and collecting evidence.

In some investigations, it may become necessary for Diversion Investigators to swear to affidavits in obtaining a criminal search warrant. The Investigator will consult with the appropriate U.S. Attorney's Office with regard to obtaining the warrant. A search warrant may be obtained from a U.S. District Court Judge or a U.S. Magistrate. The written affidavit must include the information described in Section 6651 of the Agents Manual. (See "Involvement in Search Warrant by DEA Employees who are not Special Agents")

5231.9 Miranda Warning

Miranda warnings (DEA Form 13a) shall be given when a subject is in custody. Miranda warnings need not be given in situations governed by either regulatory action or civil prosecution; however, when in doubt the warnings should be given.

SUBCHAPTER 524 *SCHEDULED* INVESTIGATIONS

5241 DISTRIBUTOR

CONTENTS

5241.1 INTRODUCTION

A *scheduled* investigation is divided into three phases: preparation, on-site, and follow-up. The action taken by an Investigator during each phase is essential to the successful completion of the investigation.

5241.2 PREPARATION

During this phase, the Investigator will accomplish the following prior to the on-site portion of the investigation:

A. ***File Checks.*** Review *DEA files (to include (b)(7)(E) files)*, drug destructions, thefts, and NADDIS, for mention of the firm to determine history and whether any complaints have been submitted concerning the firm or its products.

B. ***ARCOS.*** If the firm is subject to ARCOS reporting requirements, the Investigator must be familiar with ARCOS information prior to entering the firm. An inquiry to the ARCOS unit should be made to determine if the registrant is submitting required reports and if significant problems are being encountered.

C. ***Registration.*** Determine registration category, status, and schedules of all registrations held at the location in order to be alert for unregistered activities. **Check with other licensing authorities for licensure status and intelligence information.**

D. ***Controlled Substances to be Audited.*** *Scheduled investigations will include an accountability audit with a minimum of eight controlled substances with no less than four (4) ARCOS reportable items, one (1) of which must be in Schedule II, if the firm is so registered. The type of controlled substances should be represented by those found in the illicit market. The audit period will be for a minimum of one year.*

E. ***Notice of Inspection (NOI) or Administrative Inspection Warrant (AIW).*** For a discussion of NOI and AIWs, see 5231.5 - 5231.9.

F. ***Support of *Nonscheduled*/Complaint Investigations.*** Determine if verifications or supplemental information

should be sought in support of ongoing *nonscheduled* complaint investigations.

5241.3 ON-SITE INVESTIGATION

Once the on-site investigation has been initiated the Investigators will work consistently toward completion of this phase of the investigation.

A. ***Initial *Procedures***

1. The Investigators will present their credentials and NOI and AIW to the person who has managerial responsibility for the operation of the firm relating to controlled substances. The investigators will state the purpose and indicate the scope of the investigation. A walk-through inspection of the firm's facility, including controlled substances storage areas, returned goods storage areas, and shipping and receiving areas should be conducted at this time to determine the firm's general procedures for handling controlled substances and whether any controlled substances are being stored in unsecured areas.

Also during the walk-through inspection, Investigators are to take note of the location of security measures employed/installed by the registrant.

2. Investigators will query the registrant regarding any known or suspected diversion of its products.*

B. ***Background Information***

1. Names, addresses, dates of birth, and social security numbers of corporate officers and/or owners of the firm should be obtained as well as identification of responsible individuals for record keeping and security. Identification should include whether a firm is a partnership, corporation, etc., where or when incorporated, as well as information regarding any subsidiary or related firms.

2. Information concerning the location of the firm should include how long the firm has been in business and length of time at the current location.

3. The percentage of the firm's business in controlled substances should be ascertained from a discussion with the firm's management or from business statistics.

4. Proper registration of the firm with the appropriate state, local or other Federal agencies should be determined.

5. The Investigators should determine the number of personnel employed by the firm, and the type of work they perform. The employees with access to controlled substances will be further identified by their social security number and date of birth.

6. The Investigators will ascertain whether the firm has had any losses or thefts of controlled substances since the last investigation or since they began business, if a new firm. Reporting procedures regarding thefts or losses should be explained. Where losses or thefts have occurred, DEA files will be reviewed to determine if they have been properly reported.

7. The Investigators should ascertain the firm's procedures for pre-employment checks, verification of DEA numbers, and the firm's system for identifying suspicious/excessive orders.

8. The Investigators should determine if the firm handles listed chemicals. If so, the Investigators should provide the firm with necessary "notices" and regulations pertaining to the handling of listed chemicals.**

C. ***Closing Inventory.*** The Investigators will conduct a closing inventory of controlled substances being audited as well as *additional controlled substances currently encountered in the illicit market*. The inventory figures for the additional controlled substances can be used in the event that a follow-up investigation is necessary or in situations where there is

some doubt as to the accuracy of the firm's inventories.

The closing inventory usually should be taken *at the beginning of, or at the close of* business hours so that no adjustments for transactions outside the accountability period are necessary. It is important to stress to management that an accurate inventory is necessary and advantageous. All shipping, receiving, and return areas as well as any other areas where controlled substances might be stored should be checked by the Investigator. When taking a closing inventory, a responsible employee of the firm should verify the Investigator's count at the same time. A statement should be elicited from that individual to the effect that all controlled substances selected for the accountability have been counted completely and accurately. This procedure serves to avoid any future questions concerning the accuracy of the inventory.

D. ***Initial Inventories.*** For the beginning or initial inventory, the Investigator must select an actual physical inventory (ARCOS annual inventory, general fiscal inventory, perpetual inventory, monthly count of all controlled substances, DEA biennial inventory, etc.,) that was taken by the firm or by DEA Diversion Investigators at least one year prior to the initiation of the on-site investigation in the case of a violative registrant or at least six months in the case of a nonviolative registrant. A responsible employee of the firm must attest that it represents an actual physical count and that the inventory is complete and accurate. This inventory should indicate the date on which it was actually taken as well as whether it was taken at the beginning or close of business. Regardless of what inventory is used as the initial inventory, the Investigators will ask to see the required biennial inventory. If a computer printout is utilized, a responsible employee of the firm must attest that it represents an actual physical count and that the inventory is complete and accurate.

E. ***Receiving Records: Schedule I and II Substances***

1. Official order forms will serve as the primary record documenting the receipt of Schedule I and II controlled substances.

2. The order form review will determine if the forms are properly and accurately completed, and executed within the allotted 60-day period.

3. ARCOS reports and purchase invoices may be reviewed on a selective basis to verify the accuracy of the Schedule I and II order form transactions.

4. The individual authorized to execute order forms should be identified and a review of the power of attorney should be made if one is in effect.

F. ***Receiving Records: Schedule III-V Substances***

1. Receiving records for Schedules III-V substances usually consist of vendor's invoices.

2. Primary receiving documents *(e.g., invoices) should be scrutinized to determine quantities received. Secondary records (e.g., computerized generated reports, perpetual inventories, etc.) may be used if they are attested to be accurate and complete by the firm. When secondary records are utilized a random cross-verification with the primary records should be conducted.*

G. ***Sales Records: Schedule I and II Substances***

1. Official order forms are the primary records for the sale of Schedule I and II controlled substances. The Investigators may use the official order forms or may use secondary records (e.g., computer generated reports, etc.) if they are attested to be accurate and complete by the firm. When secondary records are utilized a random cross-verification with the primary records should be conducted.

2. A representative sample of order forms should be reviewed to determine if they are appropriately completed in accordance with 21 CFR 1305.13, 1305.11, and DEA policy guidelines.

3. A sampling of Automation of Reports and Consolidated Orders System (ARCOS) records should be compared to primary records for Schedule I and II substances to verify the accuracy of the records.*

H. ***Sales Records: Schedule III-V Substances*

1. The quantity of Schedule III-V controlled substances distributed may be determined from a number of different types of records. The primary sales record is the distributor's sales invoice. However, if the registrant has another/secondary record keeping system, such as computerized records which contain all required information (i.e., customer's name, address, DEA numbers, substance, strength, quantity, date shipped, and invoice number) and attests to its accuracy, these records may be used in conducting the accountability.

2. If secondary records are used in the accountability, a random cross-verification with primary records should be conducted. In addition, a sampling of Schedule II narcotics sales should also be cross-checked with ARCOS reports. Sales encompass all dispositions from inventory including such withdrawals as documented and properly reported thefts or losses, or properly inventoried destructions. Sales also include complimentary samples or no charge shipments. If the firm being investigated has returned the controlled substance to its supplier, this should be considered a sale. Thus, a credit memorandum with the source document or an order form, if required, would document the transaction.**

I. ***Credits and Returns***

1. A review of credit memoranda must be made to ascertain that there was either physical movement of controlled substances or only monetary credit. Returned merchandise should be inspected to ensure that there is documentation showing disposition by destruction or return to inventory for resale.

2. Records for the disposal of controlled substances should be in accordance with DEA policy.

J. ***General Recordkeeping***

1. Investigators should ensure that responsible individuals have been contacted and they have verified to the Investigator that all of the firm's records pertaining to controlled substances have been seen.

2. A review of the firm's monitoring system for detecting unusual sales should be performed in order to determine whether it complies with regulations.

3. The Investigators should review the firm's procedures for making a "good faith inquiry" to determine if its customers are properly registered.

K. ***Accountability***

1. Investigator work papers, which substantiate the accountability as summarized on the computation chart, must adequately identify transactions. The work papers should include dates received/shipped, order forms or invoice numbers, supplier/customer names, drug names and strengths, package size, and quantity for each transaction.

2. The initial inventory, usually taken by the firm, is considered to be the starting point *of the accountability audit. This is combined with all receipts of controlled substances, including vendor receipts and customer returns, and represents the total that the firm is accountable for*.

The total accounted for is comprised of the closing inventory plus the sales or other dispositions, such as properly documented losses, destructions, vendor returns, etc. The equation can best be indicated by the following illustration:

Initial Inventory PLUS Purchases PLUS Customer Returns

EQUALS *Total Accountable For*

Compared With

Closing Inventory PLUS Sales PLUS Vendor Returns

PLUS Destructions PLUS Thefts of Losses

PLUS Other Miscellaneous Dispositions

EQUALS Total Accounted For

A comparison between ****Total Accountable For*** and ***Total Accounted For*** will result in either an overage or a shortage. Percentage of difference can be obtained by dividing the difference by the Total Accountable For*. In instances where extremely large inventory to activity ratios are noted, the Investigators should compare the amount of deviation with the amount of activity.

Significant discrepancies may be represented by either a percentile, or a numerical deviation. Further investigation will be conducted in an attempt to determine the source/reason for the discrepancies (e.g., inadequate record keeping, or diversion).

L. ***Security***

1. The security investigation is best conducted *at the first opportune time after commencing the on-site inspection. If deficiencies are noted, the firm should take immediate action to correct the deficiencies. The Investigators will ensure that the noted deficiencies are either corrected, or that remedial measures are in place to meet DEA security guidelines.*

2. Security evaluation should include the following:

a. General security of the firm should be reviewed to include the location of the firm (i.e., rural, residential, industrial, etc.,) crime classification of the area (as indicated by the local police), building construction, access restrictions (guards, fences, lighting, contact switches, lockable areas).

b. A description of all controlled substances storage areas should be outlined to include the size of the area, span of protection, type of construction, type of locks, alarm systems, personnel access, and a corresponding necessity for accessibility.

The Investigator *should also* document storage area specifications and consider attaching to the Report of Investigation floor drawings and photographs which should be obtained only with the registrant's permission.

c. An evaluation should be made of the alarm lines (direct or loop), or *any backup systems*, the central station, police response time, and other integrity devices. Contact should be made with the firm's alarm company in order to determine the aforementioned information.

d. The alarm system must be carefully tested to assure all controlled areas, vaults, cages, etc. are covered by functioning intrusion, protection devices. The Investigators should document the type of testing conducted on the system, such as walk test, pounding, etc. If the firm temporarily fails to have a functioning alarm system, it must provide a 24 hour guard service or a suitable alternative for the duration of the malfunction.

e. Security precautions employed in shipping and receiving areas, picking areas, and packaging areas must be analyzed to ensure proper security is provided.

f. The Investigators must be concerned with the packaging and sealing of controlled substances for shipping to ensure compliance with appropriate regulations.

g. The Investigators *should ascertain the procedures regarding* key control and combination confidentiality for controlled substance storage areas; procedures for after-hours entry; procedures for changing the locks; badge or identification system; and supervised access. Information should be obtained concerning the frequency of internal alarm checks, how documented, etc.

M. ***Discussion with Management***

1. At the discretion of the Group Supervisor, the Investigators should discuss their findings with him/her prior to discussing the alleged violations with the firm's management. Significant record keeping discrepancies should be supported with documentation. A copy of the computation chart will not be provided to the firm.

2. The firm should be informed of what courses of action against it are possible but not the specific action the Investigators intend to recommend. It is important for the Investigators to discuss all of the violations noted (including copies of violative documents) and to denote the appropriate section of the CFRs and/or the CSA which was violated. The Investigators should record the firm's explanations for the violations and any immediate corrective action the firm intends to take.

3. The Investigators should suggest changes that could be made in the firm's operation for the purpose of achieving compliance.

4. The Investigators are not to recommend individual or specific security companies or *[name] brands* of equipment which might solve the problems of the registrant. (Such a recommendation might be construed as an endorsement by DEA and should therefore be avoided.)

5. The Investigators will discuss the accountability of controlled substances audited. *Although a copy of the computation chart will not be provided to the registrant, at the Investigators' discretion, the disclosure of figures on the computation sheets may be discussed.* However, under no circumstances will the Investigators tell the firm the figures fall within an allowable percent or quantity deviation.

6. The discussion with management should either reinforce the Investigators' findings by the firm's acceptance of the cited violations and willingness to correct them or challenge the Investigators' findings by nonacceptance of the violations pointed out. If the latter is the case, the Investigators should attempt to understand the firm's opinions and reasons for them. If the firm's position is reasonable, the Investigators should verify the information and take appropriate action. The Investigators must control the direction and tone of this discussion. At no time should it be allowed to degenerate into an uncontrollable argument.

5241.4 FOLLOW-UP TO INVESTIGATION

A. ***Supplier/Customer Verifications.*** * After the on-site of the investigation is completed, verifications of purchases and sales should be performed. The extent of the verifications should be conducted within the field office where possible if the Investigators develop minor or no record keeping discrepancies. In an investigation where discrepancies are indicated, verifications will be made as appropriate to the circumstances of the investigation (e.g., the firm's history, investigative findings during the current investigation, and intelligence information concerning suspected illicit activities).

*When verifications are conducted in person informed consent, as explained in 5231.5 of this manual, is required. The investigator should present a Notice of Inspection (NOI) of Controlled Premises (DEA Form 82) to the individual responsible for the operation of the firm. The investigators are to ensure that the person understands his/her rights and

the scope of the investigator's authority. The NOI of Controlled Premises contains a statement of rights and an acknowledgment section. When the NOI is signed by the individual, it will be witnessed by two investigators. In some cases, a firm will elect not to sign the NOI, but will give verbal consent. In cases of verbal consent, the investigators will witness the NOI indicating on the document that verbal consent was given. A copy of the document will be given to the responsible individual at the firm.*

B. ***Referrals***. All documentation of problems which may pertain to other registrants in other areas should be gathered and referred to the appropriate DEA offices.

C. ***NADDIS Checks***. Under the heading of Indexing Section in the DEA-6, *the subject firm, and all persons who have access to/responsibility for controlled substances should be listed by at least name and NADDIS number. If any individual/firm does not appear in a NADDIS file, it should be so indicated by using the terminology "NADDIS negative". Criminal record checks of all indexed individuals/firms will also performed with a documented explanation of any positive hits.*

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5242 MANUFACTURER

CONTENTS

5242.1 TYPE OF MANUFACTURER

Manufacturers of controlled substances can be grouped into three specific categories: bulk manufacturer, dosage unit manufacturer, the repackager and relabeler.

A. ***Bulk Manufacturer.*** This manufacturer produces the bulk controlled substance used for the preparation of saleable dosage units. The bulk manufacturers can be classified into two types as determined by their operation.

1. Synthesizer. This manufacturer produces controlled substance raw materials from basic chemicals. They *usually start* with a noncontrolled substance and at some identifiable stage during the synthesis a controlled substance is manufactured.
2. Extractor. This manufacturer derives a drug from an organic source (usually a vegetable matter). All narcotics, excluding synthetic narcotics, are manufactured through extraction. The companies import the raw material (for example, raw opium and coca leaves) and extract the active ingredients which are the starting point for the further production of a variety of drugs.

B. ***Dosage Unit Manufacturer.*** The dosage unit manufacturer obtains the controlled substance raw material from a bulk manufacturer, mixes this active ingredient with inert materials, and formulates a saleable dosage form.

C. ***Repackager and Relabeler.*** *Repackagers and relabelers receive quantities of finished dosage forms and repackages

and/or relabels them.* Dosage unit manufacturers may do their own packaging and labeling and are to be distinguished from the repackagers and relabelers, who do not perform any formulation or bulk manufacturing.

5242.2 MANUFACTURING OVERVIEW

The ordinary manufacturing operation can be *categorized as follows:

A. ***Research and Development Department.*** Develops new drugs and improves the already existing drugs marketed by the company. Also included in this department may be development of new packaging and marketing techniques. (DEA policy does not permit the importation or manufacture of controlled substances under the guise of research for subsequent marketing to the general public.)

B. ***Purchasing Department.*** Orders all articles necessary for operation. Included are bulk raw material, maintenance material, chemical ingredients, etc.

C. ***Receiving Department.*** Receives merchandise which will be used in the day-to-day operations of the firm. This department logs in all receipts of materials entering the plant, including returns.

D. ***Manufacturing or Production Department.*** Manufactures the materials to be marked. The Manufacturing Department is responsible for recording the production and usage of raw materials. Batch records of manufactured goods and records of quality control are maintained in this department.

E. ***Packaging Department.*** Packages the material to be marketed. Maintains records on the packaging function of the firm.

F. ***Quality Assurance Department.*** Tests material used and also material manufactured to abide by FDA standards and to ensure the safety and efficacy of the product being produced.

G. ***Sales Department.*** Markets and sells the finished merchandise, and ensures that the supplies on hand will meet the demand.

H. ***Maintenance Department.*** Maintains the building, provides technical assistance for specialized projects, and repairs machinery which might break down.*

5242.3 PREPARATION FOR THE INVESTIGATION

Preparation prior to the on-site investigation will be in accordance with 5241.2.

In addition, Investigators should contact the Drug and Chemical Evaluation Section (ODE) to verify quota information.

5242.4 ON-SITE INVESTIGATION

Once the on-site investigation has been initiated, the Investigators will work consistently toward completion of this phase of the investigation.

Note: ** Initial procedures and background information should be conducted in accordance with 5241.3(A)(B). In addition, the Investigators should include any manufacturing and quality control areas in their initial walk-through.**

A. ***Closing Inventory.*** The Investigators will conduct a closing inventory of the controlled substances being audited as well as any other controlled substances *encountered in the illicit market.* The following points should be covered during the closing inventory:

1. Determine how frequently the firm's scales are calibrated and by whom.
2. Determine the firm's method for recording weights on containers (i.e., tare, gross, and net weights).

3. Determine the conversion factors used by the firm (e.g., base to salts).
4. Verify net weight volume for all open containers and spot check net weight/volume on sealed, unopened containers.
5. Ensure that all identifying information is included on the inventory (e.g., lot numbers, drum numbers, batch numbers, bottle numbers, etc.).
6. Identify the type and stage of production which the controlled substances are in (e.g., raw material, in-process, encapsulation waste, labeling waste, floor sweepings, samples, finished goods).
7. Ensure that all storage and in-process areas, including the manufacturing area, quarantine area, quality control laboratory, and sample retention area, have been inventoried.
8. When warranted, collect samples.

At the completion of the inventory, the Investigators must verify with a responsible employee of the firm that *all forms* of the relevant controlled substances have been identified and included in the inventory.

B. ***Initial Inventories.*** For the beginning or initial inventory, the Investigators must select an actual physical inventory (ARCOS annual inventory, general fiscal inventory, monthly count of all controlled substances, DEA biennial inventory, etc.,) that was taken by the firm or by DEA Diversion Investigators at least one year prior to the initiation of the on-site investigation. The investigators must verify with a responsible employee of the firm that *all forms* of the relevant controlled substances have been identified and included in the inventory. This inventory should indicate the date on which it was actually taken as well as whether it was taken at the beginning or close of business. If a computer printout is utilized, a responsible employee of the firm must attest that it represents an actual physical count and that the inventory is complete and accurate.

C. ***Accountability Procedures***

1. ***General.*** The accountability portion of the *scheduled* manufacturing investigation follows the flow of controlled substances activities *during the selected audit period*. The Investigators must determine the adequacy of the record keeping system, compute any losses or overages which occur *throughout the process*, be alert for indications of diversion, and detect violations relative to record keeping, quotas, labeling requirements, unauthorized activities, etc.

2. ***Manufacturing Records.*** Manufacturing record requirements are contained in *21 CFR 1304.22(a)*. A thorough knowledge of the manufacturing process is essential in determining if a firm's manufacturing records meet these requirements. The format used in preparing these records varies between registrants. Investigators should have the firm's representatives give a detailed explanation of production processes and the records used by the firm. These records must account for the use of controlled substances, batch-by-batch.

3. ***Accountability Work Papers.*** Information to be considered for inclusion in the work papers should include:

a. Firm name.

b. Product name, dosage form, and strength.

c. Batch or lot number.

d. Raw material *control number and* assay.

e. Name and quantity of controlled ingredients weighed into batch.

f. Quantity of finished dosage units produced.

g. Recoverable waste by type and/or where generated.

h. Samples removed.

i. Assay of finished dosage units.

j. Gross weight of one dosage unit.

k. Theoretical yield.

1. Actual yield.

m. *Numerical difference in accountability (theoretical versus actual yield).*

n. Percentile difference in accountability *(actual divided by theoretical)*.

4. ***Computation Chart Accountability Sheet.*** There are several basic features which all accountability sheets should follow; however, due to variances in a firm's type of activity, DEA does not use a standardized format for all computation charts. Accountability sheets are always separated into two major subsections: (a) quantity on hand at the beginning of the accountability period plus acquisitions *(total accountable for); and (b) quantity on hand at the closing inventory plus dispositions (total accounted for).*

A comparison between Total Accountable For and Total Accounted For will result in either an overage or a shortage. Percentage of difference can be obtained by dividing the difference by the Total Accountable For. In instances where extremely large inventory to activity ratios are noted, the Investigators should compare the amount of deviation with the amount of activity.

5. ***Computation Chart Compilations.*** In compiling the actual working papers, the Investigators must be able to break the overall controlled substance activity flow into manageable segments. A typical breakdown would be as follows:

a. ***Raw Material Accountability.*** The raw material accountability covers the flow of controlled substances from the point where the raw material is acquired until it becomes a disposition (e.g., weighed into production or sample removal). In order to utilize this accountability as a tool for detecting possible diversion, each lot of raw material should be accounted for individually. After all raw material lots for a product are listed on the working papers, an overall total is computed on the computation chart.

b. ***Batch Accountability.*** The batch accountability covers individual batches from the point where the controlled ingredients are weighed into a production batch until a finished product is produced, such as bulk tablets and capsules. All batches of a product which are manufactured during the accountability period are listed on the working papers. After all individual batches for a product have been listed on the working papers, an overall total is computed on the computation chart. Substantial variations between batches of the same product should be noted and discussed with management.

c. ***Packaging Accountability.*** The packaging accountability covers individual batches from the point where the finished product is weighed or counted into bulk containers until the product is packaged into commercial containers. All batches of a product manufactured during the accountability period are listed on the working papers and an overall total is computed on the computation chart.

d. ***Finished Product Accountability.*** The finished product accountability covers products from the point where they are packaged into commercial containers until the product is distributed.

6. ***In-Process Batches On Hand During *Initial* or Closing Inventory.*** Any in-process batches on hand during the closing inventory for which no assay is available must be "backed up" to a preceding stage of production for which accurate records are available. The Investigators must be cautious when considering any in-process batches on hand during the initial inventory for which no assay was available. The firm must explain what records at what particular state of production were used to document the quantity of controlled

substances reported on hand when the initial inventory was taken.

7. ***Miscellaneous Charts and Summary Sheets.*** Investigators need not be limited to accountability sheets and work papers during the accountability portion of the investigation. Specialized charts or summary sheets should be prepared as needed. Examples are as follows.

a. ***Flow Charts.*** If the manufacturing process is complex, it is helpful to prepare a flow chart which breaks down the process into its various stages. These flow charts should be enclosed in the Report of Investigation to aid Investigators in future investigations.

b. ***Accountability Summary Sheets for Samples.*** If a random verification of samples reveals discrepancies, then all samples should be verified. A typical summary sheet for sample verifications would have the following headings:

Batch Number	Samples or Quantity	Recorded on Batch Record	On Hand Accounted For
1234	500 to QC	Yes	No
1234	500 to Ret.	No	Yes

c. ***Waste Accountability Summary Sheet.*** If there are numerous discrepancies in the firm's accounting for waste, a summary sheet should be prepared. Headings on a typical summary sheet are as follows:

Batch Number	Samples or Quantity	Recorded on Batch Record	On Hand On DEA-41
1234	500 grams	Yes	No
1234	3,000 grams Floor Waste	No	Yes

8. ***Miscellaneous Procedures.***

a. ***Determining Composition of Waste.*** If waste material has not been assayed, then the assay of the finished product will normally be used. An optional method would be to compute a theoretical assay. To accomplish this, total the weight of all solids weighed into a production stage and divide the weight of the controlled ingredient by the total quantity weighed in (most firms have records documenting the solid content of liquids such as dyes and sugars). It is important to examine visually each waste quantity to determine if empty capsules, dirt or other noncontrolled matters were included as part of the weight. In these instances, the Investigators and the firm representative should estimate the percentage of foreign matter and deduct it from the total.

b. ***Reworked Batches.*** When a batch of material is reworked, it is normally considered two distinct batches and two corresponding batch records are generated by the firm. The original batch is similar to a normal production batch except it is terminated prior to *completion of the manufacturing process. Accountability* for the first batch is computed at the termination point. material assay. Include any additional controlled raw materials going into the batch. The reworked material weighed into the second batch is treated the same as raw material. To compute the quantity of the controlled ingredient going into the second batch, multiply the total weight of rework material by the rework.

c. ***Running Weights/Volumetric Fill Checks.*** When finished dosage units are withdrawn to establish running weight or volumetric fill checks, the batch record must indicate their disposition. These dosage units may have been returned to the process, used as samples or accumulated as waste. It is important to review running weights and volumetric fill checks to determine how uniform the finished dosage units are.

d. ***Verifying Theoretical Yields.*** Title 21 CFR 1304.22(a) *(v)(H)* requires the firm's manufacturing records to indicate theoretical yields. To verify the firm's calculations, divide the quantity of the controlled ingredient weighed into a batch by that ingredient's finished dosage label claim (e.g., 10 kg. weighed to make 10 mg. tablets should have a theoretical yield of 1 million tablets). If the calculation indicates a higher actual versus theoretical yield, it is possible the firm included a "spike". A spike is an additional quantity of the controlled ingredient which has been added because of high historical losses during the manufacturing process or to compensate for a low raw material assay. All such spikes should be discussed with the firm.

e. ***Controlled Substances Produced from Noncontrolled Ingredients.*** Production of controlled substances synthesized from noncontrolled ingredients need not be represented on a computation sheet. However, the Investigators must still review the firm's production records to verify the quantity of controlled raw material substance produced. In order to determine if diversion may have occurred during the manufacturing process, it is necessary to make a batch-by-batch comparison. If the product is manufactured infrequently, it may be necessary to compare batches produced prior to the beginning inventory date with those produced during the accountability period.

f. ***Allowable Percentage Losses in the Manufacturing Process.*** DEA accepts no "allowable percentage loss". Firms may historically document the loss of controlled substances within a certain percentage range (due to equipment, reaction, etc.), but Investigators should not accept this on its face. If a firm's historical losses appear high or if wide variations between batches of the same product are noted, the Investigators should discuss these findings with his/her supervisor prior to the discussion with management.

g. ***Production of Excluded, Excepted or Exempted Products.*** Subchapter 518 of this manual explains the scheduling of excluded, excepted, or exempted products. All products manufactured by a firm under one of these categories should be verified with the Drug and Chemical Evaluation Section, Office of Diversion Control.

An accountability should be conducted on these products until the ingredients become either excluded, excepted or exempted.

D. ***Verifying Production Quotas.*** Subchapter 514 explains the types of quotas and how they are established. During the preparation phase of the on-site portion of the case, the Investigator should have contacted the Drug and Chemical Evaluation Section to obtain copies of the firm's quota applications. These applications are reviewed and verified during the on-site investigation. After being verified, the quotas are compared to actual acquisitions to determine if any quotas were exceeded. Quotas extended from January 1 to December 31 and any material received after 31 must apply to the following year's quota. Quotas are never carried from one year to the next.

E. ***Receiving Records***

1. Incoming Raw Material. Raw materials in Schedules I and II must be purchased pursuant to official order forms. All such purchases must be accompanied by a quota certification as outlined in 21 CFR 1303.12(f). Receipts for raw materials in Schedules III through V will be maintained in accordance with 21 CFR 1304.22(a)(1)(iii).
2. Bulk synthesizers who produce Schedule I through V raw materials may transfer controlled substances from one department to another at the same registered location on internal production documents. These production documents are often part of the batch record and the quantity produced will normally be expressed as a "yield".

F. ***Distribution Records***

1. ***Distribution of Schedules I and II.*** All Schedule I and II controlled substances must be shipped pursuant to official order forms **(see Section 5241.3G as related to sales records for Schedules I and II substances in this manual).**

2. ***Distribution of Schedules III Through V.*** **See** Section 5241.3H **as related to sales records for Schedule III-V substances in this manual.** For distribution of these substances, the shipping record might be part of the batch record.
3. ***Coincident Activities.*** A manufacturer may distribute only those products manufactured (e.g., produced, repacked or relabeled). If a firm desires to distribute other controlled substances, it must register as a distributor. If a firm registers as both a manufacturer and distributor, this is considered two separate activities (registrations) and all records and stocks of controlled substances must be maintained separately for each activity *(see 21 CFR 1308.13 regarding other allowable coincident activities).
4. ***Drug Destructions.*** Records for the disposal of controlled substances will be in accordance with DEA policy.*

G. ***Credits and Returns.*** Credit and return procedures are included in 5241.3 paragraph I of this manual.

H. ***ARCOS.*** ARCOS records should be verified, by comparing them with production and distribution records, to ensure the firm is reporting to ARCOS properly. The Investigators and/or the supervisor have the prerogative to verify all production batches and/or random batches throughout the accountability of consecutive batches, for a portion of the accountability period.

I. ***Security.*** Evaluation of the firm's security will include the following areas in addition to those specified in 5241.3 paragraph L.

1. ***In-Process Areas.*** Security provisions governing in-process material are contained in 21 CFR 1301.73(a). These procedures should be discussed with the firm's representatives and all manufacturing and in-process storage areas shall be described in the security portion of the Investigator's report.
2. ***Limited Access in Manufacturing Areas.*** Procedures regarding limited access in manufacturing areas are contained in 21 CFR 1301.73(b) and (c). As outlined in these regulations, the firm must conduct controlled substance manufacturing activities in clearly defined areas with limited access. A responsible individual will be designated in writing for each area. The listing of responsible individuals should be reviewed to ensure that it is current.

J. ***Discussion with Management.*** Procedures for conducting a discussion with management are included in 5241.3 paragraph M.

5242.5 REPACKAGER/RELABELER

Many manufacturers specialize in repackaging or relabeling finished dosage units produced by another manufacturer. For registration purposes, there is no distinction between dosage form manufacturers and repackagers/relabelers. The guidelines set forth in 5242 of this manual apply to repackagers and relabelers. The only difference is that the repackagers and relabelers have chosen not to conduct some of the authorized activities of manufacturers. A typical accountability of a repackager/relabeler would include preparing computation charts and corresponding work papers as follows.

5242.51 Repackaging/Relabeling Computation Chart

This computation chart covers the controlled substance activities from the point where bulk-finished dosage units are received until they are repackaged into the registrant's commercial containers. Each lot of bulk dosage units purchased should be accounted for separately with an overall total for each product shown on the computation chart.

5242.52 Finished Package Size Distribution

The computation sheet covers the controlled substance activities from the point where the commercial containers are produced until they are distributed. Each package size by product will be accounted for.

5242.6 MANUFACTURING AND PROCUREMENT QUOTAS

5242.61 Background Information

Annual quotas are calculated based, in part, upon data supplied to DEA by the drug industry. During the last quarter of the calendar year, quota applications are mailed to the appropriate manufacturer registrants. Quota work sheets *must* be returned to DEA; applications for procurement quotas (DEA-250), must be returned to DEA by April 1; applications for manufacturing quotas (DEA-189), must be returned to DEA by May 1. (See DEA Reference Book 5242A-F). After reviewing this and other information, the revised aggregate quota is established for the current calendar year and the initial aggregate and procurement quotas are set for the following calendar year. Manufacturing and procurement quotas (revised) are sent out to the registrants *after* the end of the second quarter of the calendar year. Individual manufacturing and procurement quotas are revised on a continuing basis throughout the calendar year. Copies of the revision letters are forwarded to the appropriate DEA field offices.

The data that is submitted on the work sheets and quota applications is used to calculate the quotas without the benefit of any on-site verification. DEA will continue to establish quotas based upon such information, but "after the fact" verifications of the information contained on the work sheets and the quota applications are necessary if DEA is to maintain the integrity of the quota system. It is also necessary to determine if the registrant manufactured or procured a controlled substance in excess of an assigned quota.

5242.62 On-Site Investigation

Quotas will be thoroughly investigated during all scheduled regulatory investigations of Schedule I and II controlled substance manufacturers and reported in the body of the DEA-6. Any independent quota investigations will be problem oriented and directed by OD. The on site investigation will include a verification of the most recent data that was furnished to DEA on the quota work sheet and application. The registrant will be asked to provide the investigators with all of the primary records that are necessary to verify the data. The on-site portion of the quota review investigation may be conducted in conjunction with a *scheduled* investigation of the registrant or it may be conducted independently.

*Revision

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5243 NARCOTIC TREATMENT PROGRAM

CONTENTS

5243.1 PREPARATION

Prior to the investigation of a Narcotic Treatment Program (NTP), the Investigators will review the regulations pertaining to the activity and will examine all pertinent information which is contained in DEA files (CSA, NADDIS, etc.). The FDA or an equivalent *agency and appropriate state authorities will be contacted to determine the results of any pervious inspections to alert the Investigators to any problems which may exist.*

5243.2 ON-SITE INVESTIGATION

5243.21 Initial Interview

Upon arrival at the program site, the Investigators will identify themselves to the Program Director or other responsible individual, display their credentials, and issue a Notice of Inspection (NOI) (or an Administrative Inspection Warrant (AIW) if required). A preliminary interview will be conducted to explain the purpose of the investigation and to gain general information regarding the operation of the program, the identity of responsible individuals, the types of records maintained, etc. **Investigators will solicit intelligence information regarding current trends of abuse, addiction, and general client populations referenced in 5243.24. (No forms or checklist will be required to be completed by the program personnel or patients.)**

5243.22 Inventories

A. ***Initial Inventory.*** NTPs will be subject to an audit period of at least three months. For the beginning or initial inventory, therefore, the Investigators will select an actual physical inventory that was taken by the program at least three months prior to the initiation of the investigation. This inventory should be dated and it should indicate whether it was taken at the beginning or close of business. Regardless of what inventory is used as an initial inventory, the Investigators will ask to see the required biennial inventory.

B. ***Closing Inventory.*** The Investigators will make a physical count of all *forms* of methadone on hand. This will be verified by an official of the program and should be done prior to or after the day's dispensing hours or distribution period. The Investigator will note whether the inventory was taken at the opening or close of business.

5243.23 Accountability Procedure

A. Accountability procedures for NTPs are similar to those of other registrants in that all incoming material is balanced against dispositions.

Records of receipts will consist of order forms in all cases. In some instances in which the SAC has granted an exemption, the order forms will show a weekly or *monthly* amount in grams being transferred between a compounder and a dispensing site. When this exemption is granted, other records required to be maintained would show the actual number and strength of each dosage unit sent to a particular clinic.

B. The accountability may also be done by "dosage unit" in cases where a program receives its methadone in unit doses. This accountability must include all strengths and forms of methadone handled.

C. Dispensing records shall be used as records of distribution and their compliance with 21 CFR *1304.24* is to be verified. In reviewing dispensing records, all guidelines regarding patient confidentiality must be followed.

**D. If a program is authorized to compound for off-site as well as on-site dispensing, records of distribution shall be reviewed and treated as "sales" as required by 21 CFR 1304.25.

E. Records of returns (such as unclaimed dosages) as well as any thefts and losses should be included in the accountability as appropriate. Procedures for the disposal of returns or other unwanted methadone should be in accordance with DEA policy.

F. Computerized Dispensing and Recordkeeping Systems shall be used as records of distribution and their compliance with 21 CFR 1304.24 is to verified. In reviewing dispensing records, all guidelines regarding patient confidentiality must be followed.**

5243.24 Confidentiality of Patient Records

42 CFR 2.55 sets forth the regulations for the confidentiality of patient records maintained by narcotic maintenance and detoxification programs as they apply to inspections by DEA (Volume 40, No. 1 of the Federal Register on July l, 1975).

A. These regulations require that registrants maintain records in accordance with the CSA to account for narcotic drugs separately, and in addition to clinical records required by FDA regulations. Patients' clinical records ***will not be*** available to DEA Investigators except as authorized under a court order. They also require that records maintained by NTP's in accordance with the CSA need not identify patients by name, address, social security number, or otherwise except by an identifying number assigned by the registrant. Where such a system is used, the registrant shall maintain on a current basis a cross-index referencing each identifying number to the name and address of the person to whom it refers. Upon request at any time and without advance notice, DEA Investigators must be granted immediate access to any such index. This information may be used by DEA Investigators solely for auditing or verifying program records. Patient identities may at no time be disclosed to third parties, nor may any identifying information be compiled or used in any registry or personal data bank.

B. Portions of the rules and regulations on Confidentiality of Alcohol and Drug Abuse Patient Records which

particularly affect DEA are included as Appendix 5243A. If more information is required, consult Title 42, Chapter 1, Subchapter A, Part 2, Sections: *2:17, 2.61, 2.65, 2.66 and 2.67*. **Also, see 5243.24 and Appendix 5243B for more detail on Confidentiality of Patient Records.**

5243.25 ARCOS

NTPs authorized to compound methadone for both on-site and off-site dispensing are not required to report to ARCOS. Manufacturers (persons who compound methadone for off-site use only) will submit ARCOS reports.

5243.26 Security

Security for the storage of methadone will be reviewed for its compliance with 21 CFR 1301.72, 1301.73, or 1301.74 (1). The Investigators will be responsible for testing all alarm systems (including holdup buttons) and determining the adequacy of the protection, including the protection of the telephone line which connects the registrant to the central station or police agency. Contact with a representative of the alarm company is recommended for verification. **Security for automated dispensing and record keeping systems should be reviewed. Access to these systems should be limited. Password protection or encryption of the system should be employed to limit access to the system and data. Automated dispensing systems need to be calibrated on a regular schedule. The Investigators should review the calibration records for these systems.**

The Investigators should also review the program's procedures for the delivery, receipt, *and dispensing of methadone for compliance with 21 CRF 1301.74(h)(i)(j)(k)*. A list of persons authorized to receive deliveries should be reviewed for completeness.

5243.27 Discussion with Management

At the completion of the on-site investigation, the Investigators will advise the Program Director or a designee of the results of the investigation and the violations disclosed, if any. Deficiencies noted during the investigation will be discussed and comments concerning these violations shall be solicited. The Program Director's response should be noted together with any planned corrective action. *The Investigators will not discuss any proposed actions of DEA with the registrant.*

5243.28 Verification

A. Upon conclusion of the on-site portion of the investigation, verification of all purchases of methadone will be made with the appropriate suppliers. Verifications of distribution by compounders to other sites are also to be conducted.

B. ***NADDIS Checks*. Under the heading of Indexing Section in the DEA-6, the subject firm, and all persons who have access to responsibility for controlled substances should be listed by at least name and NADDIS number. If any individual/firm does not appear in a NADDIS file, it will be so indicated by using the terminology "NADDIS negative". Criminal record checks of all indexed individuals/firms will also performed with a documented explanation of any positive hits.**

*Revision

**Addition

5244 IMPORTER/EXPORTER

CONTENTS

5244.1 PREPARATION

Preparation for an investigation of an importer or exporter will be in accordance with 5241.2 of this manual. In addition, the Investigators will request from ODO information concerning the permits issued and declarations filed by the registrant.

5244.2 ON-SITE INVESTIGATION

A. The on-site portion of the import/export investigation will cover all applicable areas as described previously for distributors of controlled substances.

B. Records of receipts for importers will consist of import permits and/or declarations. Records of sales for exporters will consist of export permits and/or declarations. These records must be reviewed for completeness and accuracy. Export records should include authorization by the country of destination for the controlled substances being exported.

C. Unsolicited returns *to exporters will be handled on a case-by-case basis and coordinated with the International Drug Unit* (ODOI).

D. A review of security and discussion with management will be conducted as in other types of *scheduled* investigations.

5244.3 VERIFICATION

A. Verifications of domestic transactions (e.g., purchases by exporters, sales by importers) are to be conducted.

B. ***NADDIS Checks*. Under the heading of Indexing Section in the DEA-6, the subject firm, and all persons who have access to/responsibility for controlled substances should be listed by at least name and NADDIS number. If any individual/firm does not appear in a NADDIS file, it will be so indicated by using the terminology "NADDIS negative". Criminal record checks of all indexed individuals/firms will also be performed with a documented explanation of any positive hits.**

*Revision

**Addition

5245 COMPLAINT INVESTIGATIONS

CONTENTS

5245.1 INTRODUCTION

A complaint investigation is any in-depth investigation of a registrant or nonregistrant other than a scheduled cyclic investigation pursuant to 5231.11. All (b)(7)(E) investigations other than cyclic investigations, therefore, are to referred to as "complaint investigations". This category will include all investigations of practitioners, investigations of nonpractitioners which were not scheduled on the office's work plan, investigations leading to Public Interest Revocations (PIRs), etc.

Complaint investigations will be initiated against major diverters of controlled substances at all levels from the manufacturer to the retailer.

5245.11 Background

The Complaint Investigation Program replaces the former Targeted Registrant Investigation Program (TRIP). TRIP was established in 1980 to focus limited state and Federal resources on the most significant registrant violators. There is a

continuing need to concentrate DEA's resources on registrants suspected of high-level diversion. However, there is no longer a need for Headquarters, Office of Diversion Control (OD) to be as closely involved in the targeting of suspected registrant diverters as was the case when the program was initiated. Headquarters approval of investigations of practitioners is no longer required. The selection of targets is the responsibility of the SAC or designated ASAC or RAC. They should ensure that the registrants that are investigated pose the most serious diversion threat within their jurisdiction. TRIP, therefore, is cancelled in lieu of guidelines which recognize the responsibility of divisional management.

5245.12 Objectives

The DEA diversion program has two major objectives with respect to practitioner-level diversion. One objective is to identify, investigate and prosecute violators who are operating at levels which deserve Federal attention. The other objective is to assist the states with their responsibilities, both through active investigation and through information sharing. The complaint investigation program is designed to meet both of these objectives.

5245.13 Selecting Targets for Investigations

(See memorandum, dated June 17, 2003, signed by William B. Simpkins, subject: U.S. Department of Justice Guidance Regarding the Use of Race by Federal Law Enforcement Agencies (FFS: 060-01.3))

The criteria for initiating complaint investigations are broader than the criteria under TRIP. Targets having the potential of meeting Class I, II, or III criteria under G-DEP are to be investigated by DEA. Although targets meeting Class IV criteria should normally be referred to the appropriate state agency for investigation, these targets may be investigated by DEA if divisional management determines that they would significantly impact on a particular diversion problem in a geographic area.

An exception to the above targeting guidelines for initiating a complaint investigation is a case referred to DEA by state/local agencies which is essentially completed and which is appropriate for administrative action under DEA's traditional Show Cause authority or under the newer PIR authority.

The primary goal upon initiating a complaint investigation will be to determine if criminal violations have taken place and to prosecute the registrant accordingly.

5245.2 TECHNICAL ASPECTS

5245.21 Automation of Reports and Consolidated Orders System (ARCOS) Profiles

In many instances, state regulatory or enforcement agencies request ARCOS information with respect to practitioner registrants. Requests of this sort should not be handled independent of the complaint investigation program. If the suspect is a violator of sufficient magnitude to be a complaint investigation target, the requested information should be transmitted to the Drug Operations Section, Office of Diversion Control (ODO). Requests of this nature will be handled on a nonpriority basis. If the suspected violator is not operating at a sufficient level to warrant inclusion as a complaint target, state officials should be advised tactfully that DEA resources are not currently available for ARCOS profiles on violators who are not operating at high levels.

5245.22 Reporting Requirements

A. A report of a complaint investigation will be prepared using a (b)(7)(E) file number.

Unless there is substantial evidence, e.g., witness or informant, of criminal violations at the outset of a complaint investigation, all complaint investigations are to be carried on the DEA-351 using class code (b)(7)(E)
(b)(7)(E)

1. The Diversion Group Supervisor will be responsible for assuring that the investigations are conducted pursuant to

the Domestic Operations Guidelines, DEA Agents Manual, Appendix 66B.
2. Arrests, indictments, convictions, seizures, and licensing actions will be reported on the DEA-6.
3. Copy 6 of these reports will be forwarded to the appropriate staff coordinator at ODO.

B. A DEA-202 will be prepared upon classification of the complaint investigation as a criminal case in compliance with 6243 of the Agents Manual.

1. The DEA-202 will be submitted as outlined in the Agents Manual with an additional copy sent to the appropriate Staff Coordinator at Headquarters, ODO.
2. Copies of the DEA-202 will be distributed as set forth in Agents Manual 6223G, 6234.22E, 6612.27B, 6641.36 and 6642.3C. Instructions for preparing and distributing the DEA-210 are on the reverse side of the form as indicated in 6244 of the Agents Manual. A copy of the DEA-202 and DEA-210 will be provided to ODO.

C. A complaint investigation will be reported on the DEA-351 with the appropriate class code, i.e., noncriminal or criminal.

5245.23 Joint Investigation

An Investigator is responsible for preparing reports concerning actions of an investigation in which he/she participates regardless of whether the state, local agency or Diversion Investigation Unit (DIU) prepares a report.

5245.24 Administrative Inspection Warrant (AIW)

Subsection 5231.6 discusses the preparation of the AIW and under what circumstances it is to be served. In most instances of practitioner-type targeted investigations, entry should be made upon the use of an AIW. State and local officers are permitted to enter if specifically mentioned in the warrant. NOTE: If prior to entering the registrant's premise, probable cause to seek a search warrant exists, then a search warrant should be sought in preference to an Administrative Warrant.

5245.25 Automation of Reports and Consolidated Orders System (ARCOS)/Diversion Analysis and Detection System (DADS) Report

A targeted investigation may require the Investigator to secure information about the practitioner's ordering patterns, etc. The ARCOS personnel in DEA Headquarters can assist in this regard by supplying a report known as DADS.

As a subsystem of ARCOS, the DADS' reliability is totally dependent upon the ARCOS data base. All DADS reports are geared to reflect sales made to practitioner-type registrants, mainly pharmacies, hospital/clinics, and practitioners. Most of the existing DADS reports are listed by business activity in a designated geographical area for a specified time frame (i.e., retail pharmacy in a three digit zip code area of a state for a specified calendar year). The procedure involved in requesting this type of data is discussed in 5260.11 of this manual.

5245.26 Order Form History Report

During a target investigation it may become necessary, due to incomplete records, to obtain a history of order forms issued to a practitioner. A request by memorandum indicating the registrant's name, address, and DEA number should be made through appropriate channels and directed to the Registration Unit, Office of Diversion Control (ODOC).

Most offices retain DEA copies of official order forms for excessive purchases. These copies can be useful in the development of a case, especially in identifying vendor and practitioner ordering patterns.

5245.27 Additional Investigative Techniques

The type of investigation and the desired action may dictate the type of technique to be used, which may range from interviewing patients of the practitioner, interviewing employees, photo taking, and ultimately to Special Agent assistance for the purchase of evidence. The Grand Jury Subpoena or an Administrative Subpoena may also be used as

an investigatory tool. Each case represents a unique situation, and even though there may be similar circumstances, it has to be developed independently.

If, during the development of an investigation or after presentation to the Assistant U.S. Attorney for criminal prosecution, prosecution is declined and investigative efforts have been exhausted, additional consideration should be given to the possibility of pursuing the case for civil or administrative action. The Investigator should pursue all possible actions including prosecution in local or state courts.

5246 303 INVESTIGATIONS

5246.1 ON-SITE INVESTIGATION

A. Section 303 investigations are conducted *annually* as required by the Controlled Substances Act (CSA), Part C - Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, Section 303, Registration Requirements.

B. As renewal applications are received from importers of Schedules I and II basic classes and manufacturers of bulk substances in Schedules I and II, the 303 field investigation will be updated.

C. To complete the update, the Investigator who has been assigned the investigation is required to do the following:

1. Review the most recent 303 field investigation.
2. Compare the drug codes on the renewal application with those contained in the CSA data base.
3. Perform verifications with appropriate state authorities.
4. Review any reports of investigation in which the firm or its responsible employees were involved. This review period will extend from the previous 303 analysis or update to present.
5. Have the firm review any previous submissions and submit any changes in the firm's policies, procedures, or processes that affect the manner in which the firm meets essential registration elements.
6. Prepare a short DEA-6 and submit it along with the return application. This report will either document the updates or indicate there have been no significant changes since the previous 303 investigation. Any differences between the drug codes listed on the renewal application and those listed in the CSA data base should be fully explained. A brief description also of what the firm utilizes the bulk manufactured controlled substance for (i.e., bulk sale, ingredient for another bulk controlled substance, ingredient for a non-controlled product, etc.) should be included. The investigative report is not to include a recommendation for approval or denial.

D. Occasionally, there will be the need for a completely new 303 investigation due to major changes in management, product, or operation. *The investigation will include an on-site visit.*

*Revision

**Addition

5247 PRACTITIONER PUBLIC INTEREST REVOCATION (PIR) PROGRAM

The PIR authority of 21 U.S.C. 823 and 824 (enacted October 12, 1984) substantially supplements other DEA authorities directed against diversion. A major portion of DEA's Diversion Investigator resources is justified specifically for investigations under this authority.

CONTENTS

5247.1 AUTHORITY AND BACKGROUND

Section 511 of the Diversion Control Amendments (enacted October 1984), which amends 21 U.S.C. 823 and 824, provides additional grounds for the revocation, suspension or denial of a practitioner registration in the public interest. This authority does not replace the existing provisions of 21 U.S.C. 824 (conviction of a controlled substance related felony, lack of state authorization, and material falsification of an application). Cases involving these three criteria will continue to be submitted as Requests for Orders to Show Cause through established procedures.

It is the position of DEA that the states will continue to have primary responsibility for practitioner actions: Criminal, civil and administrative. DEA will continue efforts which encourage state licensing boards and state law enforcement agencies to fulfill their responsibilities in these areas. However, in passing the Diversion Control Amendments of 1984, Congress recognized that state investigations and licensing actions against practitioners have not been sufficient to deal with the problem. In appropriate circumstances, DEA is expected, as a major program component, to identify and collect information sufficient to act against a practitioner's registration.

Under the public interest criteria of 21 U.S.C. 823 and 824, revocation, suspension or denial of a DEA registration is not

a substitute for other actions as provided by policy and procedures established prior to October 1984. The new grounds provide one additional method to add to those which have existed. Criminal and civil prosecution should continue to be pursued when appropriate.

As a rule, field offices should target registrants who are suspected of diversion in accordance with the criteria for "complaint investigations" in 5245. Investigations which uncover criminal violations should be presented to the U.S. Attorney's Office for prosecution. Once an investigation has been accepted by the U.S. Attorney's Office for prosecution, the concurrence of the U.S. Attorney must be sought before the investigation can be referred to the Drug Operations Section, Office of Diversion Control (ODO) for an Order to Show Cause action.

Cases which are neither appropriate nor accepted for prosecution, but for which there is sufficient evidence to support administrative revocation, will be referred to ODO for review for possible Order to Show Cause action.

5247.2 SCOPE OF INVESTIGATION

The ability to revoke, suspend, or deny a registration because it would be inconsistent with the public interest permits investigative results to be presented in an administrative forum. Thus the burden to be met by the government is "substantial evidence" rather than "beyond a reasonable doubt." Evidentiary requirements are reduced in comparison to judicial procedures. Because of the previously mentioned factors, the amount of investigative time necessary to achieve the desired results will be substantially reduced.

5247.3 INVESTIGATIONS UNDER THE PIR PROGRAM

There are three categories of investigation in which revocation or denial based on the public health and safety ground should be pursued: (1) certain cases, which by their very nature, lend themselves to this procedure; (2) new investigations (a) which do not justify pursuit of a criminal prosecution, (b) where the amount of controlled substances diverted is small by comparison to other area violators, or (c) where prosecutive guidelines do not warrant pursuit of criminal prosecution; (3) those cases in which the Federal government must proceed due to lack of effective action by state licensing authorities.

5247.31 Cases Which Lend Themselves to the Public Interest Criteria

A. Cases in which the state cannot act:

1. Lack of state statutory authority (e.g., state does not require licensing of specific activities such as researchers).
2. Lack of state jurisdiction (e.g., violative acts which occurred in State A cannot be considered for licensing action by State B).
3. Judicial or administrative interpretation of the statute or regulations (e.g., state cannot revoke or suspend a license until all judicial appeals are exhausted, or state cannot act unless practitioner physically appears before the licensing board).
4. Case dismissed for procedural error or dismissal for technicality. (Note: In most instances, if the charges are dismissed as unfounded, or the practitioner found not guilty, or evidence illegally obtained, an Order to Show Cause will not be requested.)

B. Cases in which other prosecutorial or administrative avenues have been unsuccessful:

1. Criminal prosecution declined by state or Federal prosecutor.
2. Felony charges plea bargained to misdemeanor.
3. State licensing action deferred due to exigent circumstances (e.g., practitioner has considerable political influence in the state).

C. History of Violations:

1. State investigative authority without formal action (e.g., oral admonishments, or practitioner vacates jurisdiction before formal board action is implemented).

2. Cumulative or repetitive violations which individually did not warrant action.
3. Practitioner had previously surrendered a DEA or state registration or professional license in any jurisdiction in lieu of more stringent action.

5247.32 New Investigations

New investigations which do not warrant further pursuit of criminal prosecution include but are not limited to any of the following criteria:

A. The circumstances of the violations do not justify pursuit of criminal prosecution.

B. The quantity of controlled substances diverted is small in comparison to other violators in the same geographic area.

C. Other prosecutorial guidelines have not been met.

5247.33 Ineffective Action By a State

This category makes a distinction between the situation outlined in 5247.31A in which the state cannot act, and a situation in which the state will not take appropriate action. DEA policy requires that either of the following criteria be thoroughly documented before proceeding with an Order to Show Cause under this category:

A. DEA efforts seeking state action must have been formalized on a DEA-6.

B. State action was insufficient for DEA to take registration action under the criteria of 824 (A) (e.g., a state verbally restricts a physician's controlled substances privileges for only one drug or schedule, but the written decision allows the physician continued controlled substances privileges).

5247.4 PROCEDURES FOR PIR

In the above three categories, revocation or denial based upon inconsistency with the public interest should be pursued. However, if one of the above elements exist, the Group Supervisor should review the evidence to determine:

A. Does the case warrant further development for more stringent action?

B. Are there other factors which have not been presented that are relevant to the public interest?

C. Is there sufficient information present to pursue a revocation or denial on public interest grounds?

Note: Public interest grounds should not be used if any of the other three independent grounds for revocation/denial set forth in 21 U.S.C. 823 exist and are adequate for action; e.g., (a) lack of state license, (b) drug related felony conviction, or (c) falsification of registration application.

5247.5 DEA-6 REPORTING REQUIREMENTS FOR PIR

(See also 525 and 5262.)

A. DEA-6 will contain a (b)(7)(E) case number, re: Request for Order to Show Cause PIR. The first sentence of the report must specify that the registration is inconsistent with the public interest.

B. In addition to the reporting requirements of 525, PIR reports must contain a discussion of the following:

1. Summary of the evidence and investigational findings which support the ground for the Order to Show Cause action, as opposed to a mere listing of attachments or exhibits.
2. Specific recitation of the history of state administrative actions, or lack thereof.

C. PIR cases pursued by DEA will require personal knowledge by DEA Investigators of the information contained in the request for the Order to Show Cause. Therefore, DEA must provide independent investigative activity to support the Order to Show Cause. A state investigative report alone will not suffice. This requirement is also necessary to minimize the potential number of witnesses for the Show Cause Hearing. For example, if the major justification for PIR action is the result of a state investigation, the DEA Investigator, in addition to obtaining a copy of the state report, generally will have to interview the state agent regarding the state investigation, and conduct any necessary follow-up or confirmation.

5247.6 OTHER ISSUES

A. Use of non-controlled drug violations. It is DEA's intention that PIR Order to Show Cause's, as a matter of policy, must contain violations that relate to the handling of controlled substances. Other factors or violations that reflect upon the practitioner's competency or professional conduct will be developed and included in the Order to Show Cause request. Violations relating to areas such as Medicaid-Medicare fraud, handling prescription drugs, or other highly regulated activities are of particular interest and should be included.

B. Medical practice cases, with no other grounds, will not independently warrant PIR Order to Show Cause's; i.e., malpractice or "bad medicine" cases will be left to the state licensing authority in most instances.

C. Field offices must know the proper chain of authority with the state and not request a PIR Order to Show Cause based upon referral of information from an inappropriate level of state authority.

5247.7 OTHER REPORTING REQUIREMENTS FOR PIR

A. ***DEA-351, Bi-Weekly Activity Report*** (see also 5257.1). Investigative time resulting in administrative action under the public interest criteria of the Controlled Substances Act (21 U.S.C. 824(a)(4)) is to be reported according to the type of investigation being conducted, i.e., Complaint Investigation (Criminal or Noncriminal) or Pre-Registrant Investigation.

B. ***Code 1 Voluntary Surrender.*** If, as a result of investigation, the practitioner voluntarily surrenders controlled substances registration prior to formal action (i.e., state revocation hearing, DEA Order to Show Cause, or prosecution), prepare a DEA-6 (b)(7)(E) case number, Re: "PIR - Voluntary Surrender Code 1". The DEA-6 will fully document the investigation, public interest criteria, and circumstances of the acceptance of the Voluntary Surrender in sufficient detail to support denial in the public interest of any future registration application. Include a signed/witnessed DEA-104. After obtaining a signed/witnessed DEA-104 from the former registrant, the field office will confirm the voluntary surrender of registration in lieu of PIR by sending a letter corroborating this action. The letter will be signed by the SAC, ASAC, or RAC depending upon division policy. A copy will be sent to ODO and ODOC. An example of this form letter is included in the DEA Reference Book as 5247A. Also refer to 5262.7.

C. ***Voluntary Surrenders.*** Continue to submit Code 1 resulting from formal state action or prosecution as detailed in 5262.7, and not as "PIR - Voluntary Surrender". If a former registrant's certificate of registration expires before an Order to Show Cause is issued on Public Interest grounds, and a renewal application has not been timely filed, a Letter of Termination will be sent to the former registrant by the field office having jurisdiction. The letter will contain the signature of the appropriate individual (e.g., SAC, ASAC or RAC) as delegated by office policy. A copy of this letter will be sent to ODO and ODOC for their information. An example of this form letter is included in the DEA Reference Book as 5262F.

SUBCHAPTER 525 REPORTING REQUIREMENTS

5251 INTRODUCTION

The general reporting requirements for a scheduled investigation will conform to a standardized format outlined in this subchapter. All reports exceeding two typed pages will contain a synopsis.

CONTENTS

5251.1 TIMELINESS OF SUBMISSION

A scheduled regulatory investigation is not an "investigation" as defined in paragraph IA3 of the Domestic Operations Guidelines. Thus, the requirement that an investigative report be prepared and distributed within five working days after completion of the investigation does not apply to initiation of a routine diversion investigation (see Agents Manual 6211.1).

A report is generated by the operational DEA field personnel. The ultimate responsibility for timely submission rests with the SAC and a supervisory team. The SAC will institute an investigative reporting suspense system that will provide the necessary controls to ensure that all DEA reporting is completed in a timely and professional manner (see Agents Manual 6211 and 6212).

5251.2 GENERAL GUIDELINES FOR CONTENT

An investigative report shall be written in the third person and shall be a concise statement of all pertinent facts, including the source of information. The report will contain no opinions or actions taken. All reports of non-cyclic (b)(7)(E) investigations will be prepared in accordance with Section 0754 Organization of Investigative Files, Administrative Manual, Volume II.

5251.3 PRESERVATION OF WORKING PAPERS

All notes taken during an investigation are producible material under the Jencks Act (18 U.S.C. 3500) and must be produced at the time of a trial upon request. All notes must be clearly identified as to their content, including the period of the investigation, date of any specific interview, initials of Investigators, and name of person interviewed. The notes will be preserved in an envelope attached to the appropriate case file. The notes will be destroyed only when the case is closed. A notation to the effect that such notes have been destroyed will be included in the case closing DEA-6.

5252 REPORTING THE PREREGISTRATION INVESTIGATION

CONTENTS

5252.1 REPORTING REQUIREMENTS

A. The following information will be contained in the body of the DEA-6 reporting the preregistration investigation. The information will be reported as numbered paragraphs under Details. Requirements for the heading on DEA-6's are discussed in 5255.

NOTE: Any report exceeding two typed pages will be preceded by a synopsis which will contain a brief summary of the investigation.

1. The first paragraph of the preregistration report will reference the Application for Registration and will include the name of the applicant, activity, and schedules of controlled substances for which applying, dates of application, and control number.

2. Subsequent paragraphs will follow in logical order and will include the following details:

a. Appropriate state and Federal license numbers, when applicable. If a state licensure or registration is not required, a statement to that effect will be included.

b. The name of the person contacted, the date of contact, and the manner in which contact was made (i.e., by telephone, on-site).

c. A description of the type of activity conducted by the applicant and any pertinent background information on the firm, research project or individual.

d. A description of the security measures to be employed, including a statement regarding the type and amount of controlled substances which will be handled, explicit details of physical security provisions, handling procedures, etc. Names, addresses, dates of birth, and social security numbers of those persons who will have access to controlled substances will be listed as well as the results of files checks and NADDIS review.

e. Information regarding the proposed recordkeeping system, as well as a statement that the applicant was advised of all pertinent requirements. The status of the applicant regarding ARCOS reporting must also be stated.

f. All other proposals or agreements discussed during the investigation.

g. Any changes made to the initial application.

h. Recommended action (approval, denial, withdrawal).

5252.2 WITHDRAWAL OF APPLICATION

A. A report reflecting the withdrawal of an application need only set forth the information described in paragraphs 1 and 2b and the reasons for withdrawal. Reports requesting withdrawal should be accompanied by a letter from the applicant requesting same.

B. DEA may initiate a withdrawal of an application due to the applicant's failure to furnish required information, security, or failure to respond to DEA's efforts to conduct a preregistration investigation. This may be done by sending the applicant a registered letter advising that the application will be withdrawn in 30 days if a satisfactory response is not received (see 21 CFR 1301.37(b)).

C. The final section of the report shall be the "Indexial" section. The name of the applicant and key personnel interviewed should be listed in order indicating their name, address, other identifying information, and NADDIS number (if any). Reports recommending denial must be accompanied by all documentation necessary for the issuance of an Order to Show Cause (see 5262.65).

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5253 REPORTING THE IN-DEPTH INVESTIGATION

CONTENTS

5253.1 GENERAL

A DEA-6 must be an objective, third person account of all pertinent facts. No opinion or recommended administrative or judicial action shall be stated. Information regarding names, dates, descriptions of records, and security must be specific, and any differences between what has been told to the Investigator and what was actually found must be clearly documented by specific examples.

5253.2 FORMAT FOR REPORT BODY

A report of an in-depth diversion investigation will generally conform to the following format:

A. ***Synopsis.*** The synopsis will always be the first page of the report. It will contain a brief summary of the basis for the investigation, the type of operation conducted by the firm (including the type of controlled substance business and the schedules), accountability discrepancies, violations uncovered, and any corrective actions proposed by the firm. Paragraphs contained in the Synopsis will not be numbered.

B. ***Enclosure Page.*** The second page of the report will be the enclosure page which will enumerate the following enclosures:

1. Closing Inventory.
2. Notice of Inspection and Addendum (if used) or Administrative Warrant, Affidavit, and Return.
3. Computation Chart(s).
4. Other documents referred to in the report.

C. ***Basis for Investigation.*** State the basis for initiating the investigation (work plan, targeted investigation, etc.,) and explain the reasons for the category of the investigation.

D. ***Subject Firm's Background.*** A summary of the firm's background, including the type of business conducted; type of firm (corporation, partnership); name of owner(s), corporate officers, etc.; applicable Federal/state license (including DEA registration); names of any subsidiary or related firms; results of prior DEA investigations; and history with FDA/state agencies when applicable.

E. ***Persons Interviewed and Individual Responsibility.*** State the names of the Investigators, the name and title of the person to whom credentials were displayed, and the name and title of the person to whom the Notice of Inspection or Administrative Warrant was issued. The person who signed the Notice of Inspection will be mentioned, as well as a statement that the person was advised of his/her rights under 21 CFR 1316.08 not to have an inspection made without a

warrant.

The names and titles of all persons interviewed will be stated, as well as the names of those persons responsible for the various operations of the firm (e.g., production manager, controller, warehouse manager).

F. ***Scope of Investigation.*** This section will state the beginning and ending dates of the on-site portion of the investigation, the dates of the audit period, and the reasons for selecting it (i.e., category of investigation, availability of initial inventory).

A list of the controlled substances selected for audit will be included, as well as the reasons for which those items were chosen.

G. ***Recordkeeping.*** All categories of records listed below will be described in detail. All records used to compute the audit figures will be identified as such, along with the names of the Investigators who reviewed them and computed the totals. Other records maintained and required by the CSA must also be described, and all cross-checking of primary and secondary records must be explained. Specify that all records were provided and include the name of the individual attesting to this fact.

Specific problems noted with the records must be discussed and copies of records which indicated significant violations should be obtained and enclosed with the report.

1. ***Initial Inventory.*** Indicate the date of the initial inventory and the manner in which it conforms to or differs from the requirements of 21 CFR 1304.11 through 1304.19. If the required biennial inventory is not used, it must be reviewed and a statement as to its adequacy will be made. Required inventories such as the annual ARCOS inventory and inventories taken upon control or rescheduling of a product will also be reviewed for accuracy and completeness.
2. ***Closing Inventory.*** The time (beginning or close of business), date, and name of the Investigators who physically counted the controlled substances shall be stated. The name of the firm's representative who verified or assisted in the count will also be identified.
3. ***Receipts.*** A complete description of the firm's receiving records will be stated to include all primary and backup documents (i.e., order forms, invoices, receiving tickets, packing slips) used to verify the totals. The manner in which these records conform to 21 CFR 1304 must be explained.
4. ***Production Records.*** A complete account of all records reflecting the use of an accountability for controlled substances in the manufacturing process will be provided. An explanation of the manner in which accountability figures were computed is essential.
5. ***Distribution Records.*** All records reflecting the distribution of controlled substances (order forms, invoices, etc.) will be explained, as will the manner in which they comply or fail to comply with the regulations. If secondary records (computer printouts, microfilm) were used, a statement of their verification with primary records will be made. Distribution records may also include reports of theft or loss, records of distribution of physicians samples, either through detailment or by direct shipment, and DEA-41's reflecting destructions or surrenders.
6. ***Records of Returned or Damaged Goods.*** Returns by customers are receipts to inventory. The firm's manner of maintaining records of these receipts (credit memos) will be indicated. Returns by the firms to its suppliers are dispositions and the records reflecting these transactions (vendor credits) will be described.
7. ***ARCOS.*** A statement of the firm's ARCOS reporting status will be made. If the firm is an ARCOS participant, the Investigator will describe the verification of specified ARCOS reports with primary records and the results of this verification.
8. ***Quotas.*** Verification of quota information will be contained in this section and will include:

   a. The amount of Schedule I or II substances produced/or procured as compared with the firm's quota.

   b. The manner in which the information provided by the firm on its most recent quota application was verified.

H. ***Drug and Equipment Security.*** A detailed description of both the physical and operational security measures employed by the firm will be made. The specifications of controlled substance storage areas (vaults, safes, cages) will be stated, as will the type of alarm protection. Other information that will be provided is: the results of the alarm test,

the name of the alarm company, and the representative who acknowledged receipt of the signal. Copies of appropriate floor plans and alarm placement should be enclosed when available.

The names, addresses, dates of birth, and social security numbers of those persons having access (i.e., combinations and keys to storage areas) to controlled substances and the results of NADDIS and police checks of these individuals will be included in the body of the report.

I. ***Intelligence Information.*** Any information regarding counterfeit drugs or other areas of diversion which has been solicited from employees of the firm and local or state intelligence agencies shall be included.

Any other information regarding trends or buying patterns noticed during the investigation will be stated. A statement concerning whether excessive customer shipments were noted should be included. These purchases, however, should be documented on a separate DEA-6 and referred to the appropriate field offices or state enforcement agencies.

J. ***Foreign Suppliers and Customers.*** The names and addresses of all foreign suppliers and/or customers of controlled substances shall be listed.

K. ***Discrepancies and Discussion with Management.*** All violations discussed throughout the report will be listed with the appropriate CFR/GSA citation.

The manner in which these violations were discussed with the firm's management, as well as the persons with whom they were discussed, will be stated along with the firm's response. Any suggestions for corrective action made by the Investigator or the firm's management will be mentioned.

L. ***Verifications.*** The results of all verifications shall be reported if they are available at the time of the initial report. This section may require a subsequent report due to the time limitations.

Any discrepancies between records reviewed during the on-site investigations and those of customers/suppliers will be clearly documented.

M. ***Special Assignments.*** This section will briefly describe any special assignments which were conducted (collection of authentic samples, questions regarding the sale of precursor chemicals, glassware, laboratory equipment, etc.).

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5254 FILING REPORTS

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5254.1 SELECTION OF FILE TITLE AND NUMBER

The file title of the DEA-6 will generally be the name of the individual or establishment to which the report applies. Exceptions to this would be when "program" general files apply.

A. (b)(7)(E) These are standardized topical files to be used in reporting information on specific topics. See Appendix H and Section 6231.4 of the Agents Manual.

(See DEA Agents Manual 6144.23 for complete listing.)

B. (b)(7)(E) Name General Files for Registrants. In instances where a full case file would not be warranted, the field office general file may be used. These file numbers are assigned on an as-needed basis and are structured as follows:

File Title: YYZ Manufacturers, Inc.

No "status" is indicted for any general file. (b)(7)(E)

A DEA-6 is required when opening a (b)(7)(E) general file. The copy of the DEA-6 submitted to SARI will serve to notify the File Room that a new (b)(7)(E) file has been opened in a field office. Forms previously used which advised that a (b)(7)(E) had been opened to retain correspondence, newspaper clippings, etc., are no longer to be used.

C (b)(7)(E) Diversion Investigation Case Files. The file for all reports of in-depth diversion investigations will be the name and address of the registrant or its agent subject to investigation.

The file number consists of a two character identifier for the reporting office, the fiscal year in which the file was opened, and a four character sequential number beginning with (b)(7)(E) File numbers from (b)(7)(E) are reserved for enforcement files.

The following investigative activity will require the opening of a (b)(7)(E) file:

(a) Scheduled regulatory investigations of nonpractitioner registrants.

(b)(7)(E) (b) The initiation of a complaint investigation on persons/firms suspected of diverting controlled substances. Note: In order to open a [redacted] file in a joint investigation, DEA Diversion Investigators must be an integral part of the total investigative effort which may involve state, local, or other federal enforcement/regulatory agencies. DEA activity must significantly contribute to the investigation and must include such activity as conducting interviews, an accountability investigation, or prescription surveys. The mere providing of basic intelligence information (i.e., excessive purchases) to another agency is insufficient justification to open a joint investigative file.

(c) Processing a voluntary surrender (Code 1) or restriction (Code R) of a registration of a violative registrant in lieu of possible Show Cause action.

(d) Requesting an Order to Show Cause to deny, revoke or suspend a registration whether or not the primary investigation leading to the request was by DEA or another agency.

A separate [redacted] (b)(7)(E) number is to be assigned to each registered activity investigated.

When filing a report, consult Reports Processing (DEA Reference Book 5222A) for additional information regarding routing. This appendix covers numbered files, as well as other required reports that are not contained in the numbered filing system.

5254.2 PREPARATION

The following explains all information contained on the face sheet of the DEA-6.

A. Item 1 - Program Code. This block will only be used for special Headquarters approval activities (e.g., DOJ).

B. Item 2 - 6. Self-Explanatory.

C. Item 7 - Status

1. Closed. Files on which no action will be taken or on which all action has been finalized.
2. Requested Action Completed. When the DEA-6 is written in response to action requested by another office.
3. Action Requested By. When the report requests action by another office, enter the specific office from which action is requested and indicate the specific action requested in the report narrative.
4. All other cases are considered open.

D. Item 8 - Date Prepared. Actual date on which the report was completed in rough draft will be entered.

E. Item 9 - Other Officers. The names and titles (and agencies if non-DEA employees) of all other Investigators who participated in the investigation or the activity being reported.

F. Item 10 - Report Re. Enter a brief subject or title for the contents of the report (e.g., In-Depth, complaint or PIR). All [redacted] (b)(7)(E) case files will also include the four digit Diversion Class Code. (See DEA Reference Book 5254C).

G. Item 11 - Distribution. Other than routine distribution, list all offices (or other agencies) to which a copy of the report is being forwarded. The following are considered routine distributions:

1. Original - Retained in originating office's files.
2. Copy 1 - Headquarters File Room (SARI) for indexing and filing.
3. Copy 2 - Field Division copy. (No longer required.)
4. Copy 3 - Field office copy as required.
5. Copy 4 - Field Intelligence Unit.
6. Copy 5 - Forward or retain this copy in accordance with instructions contained in the DEA Reference Book (5222A).

H. Item 12 - Signature. The preparing Investigator will sign the report and enter the date signed in the space to the right of the signature.

Additional information regarding the establishment of case files may be found in 6232 of the Agents Manual.

5254.3 GEO-DRUG ENFORCEMENT PROGRAM (G-DEP)

G-DEP is a classification system for drug violators. (b)(7)(E) (b)(7)(E) The criteria for determining the structure of the G-DEP identifier may be found in 6221 of the Agents Manual.

5254.4 INDEXING

In addition to criteria found in 6234.21 of the Agents Manual, an individual or business will be indexed on a DEA-6 for input into NADDIS under the following situations.

A. An individual or business that is the subject of a DEA investigation whether this investigation is reported under (b)(7)(E) (b)(7)(E) file number. Corporate officers and employees encountered in a regulatory investigation should not be indexed in NADDIS unless they meet the criteria set forth below.

B. An individual or business that is the basis of the following reports will be indexed when there is reason to believe that this subject is involved in a controlled substance violation.

(b)(7)(E)

Drug Thefts

Excessive Purchases

Precursor Control Program

Narcotic Treatment Programs

Physician Intelligence

Pharmacy Intelligence

Drug Wholesaler/Distributor Diversion (Registrant)

Forged Prescriptions

Denial of Application of Registrant

C. An individual of business that is the subject of the following files:

(b)(7)(E)

Approval of Application, Class B

Approval of Application, Class A

Approval of Application, Narcotic Treatment Program (NTP)

D. An individual or business that is the basis of the following report, with headquarters designator, will be indexed when there is reason to believe that the subject is involved in a listed chemical violation.

AX-89 (b)(7)(E) Chemical Diversion

E. An individual that has direct access to controlled substances (whether the subject is a pharmacist, physician, nurse, methadone program director, etc.). "Direct access" is defined as someone who has the combination or keys to a storage area in which controlled substances are maintained.

F. An individual that has primary responsibility for the overall daily operations of the firm when this firm is subject to a criminal, civil or administrative action.

Additional indexing requirements may be found in 6233 of the Agents Manual. Specific information concerning criteria to be used when inputting information into NADDIS is contained in 6233.33.

5255 ADDITIONAL REQUIRED REPORTS

This chapter has dealt primarily with the routine reports submitted by Diversion Investigators. The Agents Manual explains the use of and instructions for preparing other investigative reports. Specific forms or reports which may relate to diversion cases are the: DEA-202, Personal History Report; DEA-210, Defendant Disposition Report; DEA-7, Report of Drug Property Collected, Purchased or Seized; DEA-440, Asset Removal Report; and DEA-6.

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5256 GENERAL REPORTS OF INVESTIGATORS

5256.1 BI-WEEKLY ACTIVITY REPORT (DEA-351)

The bi-weekly report, handwritten in ink, is required of Investigators. It is management's tool to track daily work hours.

Office Designator - Enter the designator of the office to which the Investigator is permanently assigned. (See the DEA Reference Book (5254A)).

A. Subsection A - Investigations. Case Number/G-DEP Identifier/Class Code. Report any investigative effort, including travel, report writing, file review, time spent in court, etc., directly related to an investigation identified by a DEA case file number. (b)(7)(E) (b)(7)(E) (See 5254.3.) The (b)(7)(E) class code will be used for cases referred to DEA by other agencies for administrative action even though there is evidence of criminal violations by the registrant.

B. If the G-DEP Identifier of an investigation has been changed during a reporting period and such changes have been documented in accordance with 6221F of the Agents Manual, those changes will be reflected on the DEA-351 by:

1. Crossing through the portion of the identifier which has been changed, and
2. Entering the new data directly above in the same column.

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5257 PERIODIC REPORTS

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5257.1 QUARTERLY REPORTS

A report to summarize the activity of each group will be submitted for each *fiscal* quarter no later than *15* working days following the end of the quarter. The report will satisfy the requirements of 6143 of the Agents Manual as well as 5272.51 of the Diversion Investigators Manual when submitted in the format as shown in Appendix 5257A. Each Group Supervisor, or Senior Diversion Investigator in offices not supervised by an 1801 Group Supervisor, will submit a report **through the Diversion Program Manager** for his/her group for inclusion in the Divisional composite report. A copy of this submission should be sent to *the following sections within the Office of Diversion Control: Drug Operations (ODO), Liaison and Policy (ODL), and Chemical Operations(ODC).*

Only the report for the second *fiscal* quarter will include Section *IV* giving assessment of the states' capabilities under the diversion unit's jurisdiction. The information provided will also follow the format of Appendix 5257A and Attachments 1 and 2/5257A.

Statistics on arrests, indictments, convictions, asset seizures, and fines may be credited to an office if DEA takes the action. Actions taken by a local or state agency in a joint investigative effort may be credited provided the criteria under 5254.1C concerning the opening of a (b)(7)(E) file are met and appropriate documentation is approved, i.e., DEA-202, DEA-210, or DEA-453.

5257.2 WORK PLAN

Work plans are to be prepared on a fiscal year basis and are to be submitted to Headquarters, ODO, by October 15. A format for submitting work plans is provided in Appendix 5257B.

In addition to listing firms *for scheduled investigations,*, work plans must also include the name, address and registration number of firms to be investigated for accuracy of quota submissions in accordance with 5242.6. Where these firms are being investigated solely as a quota review, this is to be indicated by the phrase "annual quota review" in parenthesis adjacent to listing the firm's business activity. In selecting *the number* of manufacturers, distributors, etc., for *scheduled* investigation on the work plan, firms scheduled for annual quota reviews are not to be counted toward the required number unless, in addition to the quota review, a full *scheduled* investigation is to be conducted.

*Revision

**Addition

SUBCHAPTER 526 ACTIONS AGAINST REGISTRANTS

5261 GENERAL PROCEDURES

Action is required by DEA in all instances where an investigation reveals violations of the Controlled Substances Act (CSA) and the implementing regulations.

A. The lead Investigator is responsible for discussing all violations with the Group Supervisor to determine the type of action which is appropriate. This discussion should refer to all violations noted during the investigation, as well as a description of all available evidence concerning these violations.

B. Upon determining a course of action, the lead Investigator is responsible for preparing the appropriate documents for review and/or signature by the Supervisor or SAC as appropriate.

The type of action against a registrant and the grounds for initiating the action is discussed in the following section.

5262 ADMINISTRATIVE ACTIONS

CONTENTS

5262.1 REVOCATION OF PRACTITIONER REGISTRATION OR DENIAL OF APPLICATION

Refer to 5111.2 for complete list of Administrative Codes.

A. A DEA practitioner registration may be revoked if at least one of the following has occurred:

1. The Application for Registration has been materially falsified.
2. The registrant (owner, officer, controlling stockholder) has been convicted of a controlled substance-related felony.
3. The registrant has had the state license or registration suspended, revoked, or denied and is no longer authorized by state law to handle controlled substances.
4. The registrant's registration is inconsistent with the public interest based upon the criteria set forth in 21 U.S.C. 823(f) (Section 511 of the Diversion Control Amendments enacted October 12, 1984). (See 5247 for further information.)

B. A practitioner registration or Application for Registration can be denied, revoked, or suspended by DEA only if one (or more) or these conditions has occurred. A practitioner's renewal application must be approved if none of these conditions is found.

C. Prescriptions and authorized refills of Schedule III-V controlled substances are no longer valid when the prescribing practitioner's DEA registration certificate has been surrendered, revoked or restricted in these schedules. DEA field offices are to expeditiously advise the appropriate state authorities of such action taken by DEA.

Any pharmacist who refills a Schedule III-V prescription, knowing that the prescribing practitioner's registration is no longer valid or has been restricted in the schedules the prescription was written, would be doing so in violation of 21 U.S.C. 841(a)(1).

5262.2 REVOCATION OF NONPRACTITIONER REGISTRATION OR DENIAL OF APPLICATION

A nonpractitioner DEA registration or Application for Registration may also be revoked, suspended, or denied if at least one of the conditions specified in 5262.1 is present. Factors to be considered in determining public interest include the following:

A. Maintenance of effective controls against diversion.

B. Firm's violative history.

C. Compliance with applicable state and local law.

D. Prior conviction record of applicant under Federal and state laws relating to the manufacture, distribution or dispensing of such substances.

E. Such other factors as may be relevant to and consistent with the public health and safety.

5262.21 Administrative Code 6

The Administrative Code 6, "no automatic renewal", is used to preclude the automatic renewal of applications submitted and is applied in conjunction with another action (i.e., administrative hearing, request for an Order to Show Cause). Although a firm's DEA registration number may expire and the renewal will not be processed, the firm is authorized to continue operating on a day-to-day basis until a final action (i.e., removal of code, voluntary surrender or denial of renewal application via show cause proceedings) is taken. In these cases, the application of a Code 6 serves the purpose of suspending approval of the renewal application, particularly when grounds for denial exist (e.g., when investigation shows that a firm has failed to maintain adequate controls against diversion).

5262.22 Assigning the Administrative Code 6

The Diversion Group Supervisor shall input the request for the Administrative Code 6 into the M-204 system in a timely manner and in accordance with the procedures contained in 5111.2 in order to preclude inadvertent approval of the renewal.

5262.23 Removal of the Administrative Code 6

Upon determination that removal of the Code 6 is warranted (e.g., the case is closed, violations corrected, etc.), the Diversion Group Supervisor will remove the Code 6 through direct input into the M-204 system. It is the responsibility of the Diversion Group Supervisor to monitor all outstanding Codes 6 and to remove them from the M-204 system as needed.

5262.3 INVESTIGATOR WARNING

A verbal warning by the Investigator will not be used. If only very minor violations are found and corrected on the spot, the Investigator will advise the firm's management of such violations at the time of the discussion with management. Any uncorrected violations will be documented by a letter to the registrant.

5262.4 LETTER OF ADMONITION

5262.41 Purpose

The purpose of a Letter of Admonition is to advise the registrant of any violations which are alleged to have occurred and to document these violations in written form. The letter allows for voluntary, corrective action by the registrant and also makes violations a matter of record should the same violations be encountered at a later date.

5262.42 Requirements for Letters of Admonition

A. A Letter of Admonition will be on official DEA stationary, signed by the SAC, and sent by registered mail, return receipt requested.

B. The Letter of Admonition will include a detailed explanation of all violations with specific citations from the CFR. A response by the registrant will be required within a specified time period (usually 30 days) as to corrective actions taken (see DEA Reference Book 5262A for sample Letter of Admonition).

5262.5 ADMINISTRATIVE HEARING

5262.51 General

An Administrative Hearing will be held when the severity of the violations and the firm's attitude toward them would render the Letter of Admonition ineffective. Consideration must be given to the severity of the violations or violative history of the firm in determining the need for an Administrative Hearing. The Administrative Hearing provides the opportunity for both DEA and the registrant to explain their respective views on the violations and to discuss the necessary remedial or corrective actions.

5262.52 Authority for Administrative Hearing

Authority to hold an Administrative Hearing is found in Section 513 of the CSA (21 U.S.C. 883). This section provides the Administrator with the authority to initiate informal proceedings to permit all persons against whom criminal proceedings are anticipated an opportunity to present their views and to comply with the law and the regulations. If, in the opinion of the Hearing Officer, subsequent to the hearing, the firm has not given a reasonable explanation for the violations or cannot give reasonable assurances that corrective action will be taken, the Hearing Officer may recommend immediate referral of the case to the U.S. Attorney's Office, submit the case for Order to Show Cause proceedings, or refer the matter to other appropriate agencies such as state professional boards. If adequate corrective

action is presented, it should be documented in a formal MOU.

5262.53 Procedures

A. Upon determination that a hearing is appropriate, the SAC will notify the Drug Operations Section, Office of Diversion Control (ODO), and request a Hearing Officer. Upon agreement as to dates the Hearing Officer will be available, the SAC will have a Notice of Hearing prepared. The registrant will be notified of the hearing by a Notice of Hearing (DEA-80), which will be sent via registered mail, return receipt requested (See DEA Reference Book 5262B). The notice will state the date, time, and place of hearing and will set forth a short summary of each violation in the "Charge" section. The Notice of Hearing will be distributed as follows:

1. Original to the firm.
2. One copy to the president of the firm.
3. One copy to AMRI.
4. One copy to ODO.
5. One copy for field office files.

B. The hearing should be held within 30 days of the issuance of the Notice of Hearing.

C. The hearing will be conducted by a representative from ODO. The Investigator who conducted the investigation of the firm will not act as the Hearing Officer, but should be present during the hearing.

D. The Hearing Officer will be completely familiar with the charges as stated in the Notice of Hearing, the case in general, and the firm's prior history. All documents necessary for the hearing shall be assembled and prepared for ready access.

E. At the outset of the hearing, all persons present on behalf of the respondent shall be identified and their responsibilities shall be defined. The Hearing Officer will state the purpose of the hearing and will inform the respondent of the applicable sections of the Act and the CFR. The respondent will then confirm that the violations did, in fact, occur or will offer evidence to the contrary. Proposals for corrective action will be discussed. Miranda warnings shall be given at the beginning of the hearing.

F. The Hearing Officer will conduct the hearing in a courteous, fair, but firm manner. An informal atmosphere should be maintained in order to promote free discussion of the facts.

G. If, in the opinion of the Hearing Officer, the respondent becomes unreasonable, and nothing could be gained by continuing the discussion, the hearing will be brought to a close.

H. After the respondent's case has been stated, extensive cross-examination or argumentative comments should be avoided. However, the respondent should be questioned about any weakness in position. Any questions about contradictory evidence and false or erroneous statements should be aired. In the final analysis, factual evidence will stand on its own merit.

I. At the conclusion of the hearing, a MOU (See DEA Reference Book 5262C) will generally be prepared by the case Investigator or Diversion Supervisor and reviewed by the Hearing Officer prior to the signature of the Deputy Director, Office of Diversion Control. If the registrant refuses to sign the MOU, a formal statement should be prepared citing the reasons for the registrant's refusal to sign.

5262.6 ORDER TO SHOW CAUSE

5262.61 Purpose of Issuance

An Order to Show Cause may be issued for denial, revocation, or suspension of a DEA registration.

5262.62 Authority

21 U.S.C. 823 and 824 set forth the grounds for denial, revocation, or suspension of a DEA registration.

5262.63 Practitioner Registration or Application

A practitioner's registration or Application for Registration may be denied, revoked or suspended under the circumstances described in 5262.1. (21 U.S.C. 823 and 824)

5262.64 Nonpractitioner Registration or Application

A nonpractitioner registration, Application for Registration, or reregistration may be revoked, denied, or suspended for one of these reasons (see 5262.2). Requests for Orders to Show Cause will be by memorandum from the SAC to the Chief, ODO, with the detailed DEA-6 attached. This memorandum will generally be prepared by the investigator who is handling the case and will detail the registrant's violative history and the basis for the Order to Show Cause request. A copy of the DEA-6 will also be sent to the Registration Unit, Office of Diversion Control (ODOC).

5262.65 Procedures

Order to Show Cause requests must be accompanied by evidence of the grounds for denial, revocation, or suspension. The following would be considered such evidence in the appropriate cases:

A. Material Falsification - 21 U.S.C. 824(a)(1)

1. A copy of the application in question (assuming that the original will be available at ODOC).
2. Copies of any and all DEA-6's which describe the nature and materiality of the false statements in question.

B. Felony conviction relating to a controlled substance - 21 U.S.C.824(a)(2)

1. A copy of the judgment and probation/commitment order (or, in some state cases, the "docket entry") evidencing the conviction (NOTE: The original should be maintained in the field office files until requested by Chief Counsel): (a) Order to Show Cause proceedings may be requested even though the registrant/defendant is appealing the conviction. (b) Previously, it was necessary to await the defendant's sentencing before requesting or serving an Order to Show Cause with immediate suspension. The "public interest" grounds have eliminated this necessity.
2. A copy of the indictment or information pursuant to which the potential respondent was tried and convicted.
3. Copies of any and all reports of investigation which describe the nature of the felony in question and the circumstances under which it was committed.
4. A memorandum or report indicating possible witnesses who could provide testimony at a hearing (witnesses include individuals who can testify as to the facts which demonstrate the aggravated nature of the potential respondent's criminal conduct, or who could provide facts which demonstrate the potential respondent's poor personal or professional reputation, lack of veracity, or credibility as a witness, etc.).
5. A memorandum or report indicating the last known business or personal address of the potential respondent, especially if the respondent is no longer at the address indicated on the certificate of registration or the registration application.

C. Lack of State Authorization - 21 U.S.C. 824(a)(3)

1. A copy of any final order rendered by the applicable state licensing authority either revoking or suspending the potential respondent's state registration or denying the respondent's last application for state registration.
2. A copy of any other official document, such as a "certificate of non-registration" form used in some states, which may be used as evidence of the individual's lack of state authorization.
3. A memorandum or report indicating the factual circumstances surrounding the potential respondent's loss of (or failure to acquire) state registration--this should include a reference to the specific drug law of the state in question. If it is a dual registration state, it shall be determined if the loss of an individual's license to practice a medical/professional art means a corresponding or automatic loss without further proceedings of that individual's privilege to handle controlled substances.

D. Registration Inconsistent with the Public Interest

1. Non-practitioners (21 U.S.C. 823). Copies of all DEA-6s, Letters of Admonition, MOUs, Civil Penalties showing violative history to support denial.
2. Practitioners (21 U.S.C. 823(f) and 824). (See 5247.)

   a. A DEA-6 setting forth the factual circumstances relating to the criteria of 21 U.S.C. 823(f) indicating registration is inconsistent with the public interest, including DEA follow-up to information documented by other agencies (i.e., interview of state investigator).

   b. Copy of any formal document or letter by any appropriate state authority documenting action or lack thereof against the practitioner.

   c. Certified copy of any court proceeding against the practitioner.

   d. A summary of all states in which the practitioner is currently registered or has been registered and documentation of contact with those states regarding any pending or previous action against the practitioner.

5262.66 General

A. Orders to Show Cause will not be requested when suspensions of a registrant's state authorization are for six months duration or less.

B. Orders to Show Cause may restrict denial, revocation, or suspension of registration to specific schedules of controlled substances.

C. A DEA-276 (Notification of Suspension or Revocation of License of a Practitioner) is used by some states to notify DEA of such action taken by the state.

D. If an immediate suspension of DEA registration is requested, the request must be closely coordinated by the originating office with OD and Chief Counsel. The request should state that the immediate suspension of registration is appropriate since the activity or violation conduct of the registrant is continuing, making the immediate suspension necessary to prevent imminent danger to the public health and safety (see 21 U.S.C. 824 (d)).

5262.7 VOLUNTARY SURRENDER

A registration to manufacture, distribute, import, export or dispense controlled substances may be voluntarily surrendered by the registrant at any time. In cases where state authorization has been temporarily suspended, a Voluntary Surrender can be used to place a violative registrant out of business.

A Voluntary Surrender will be accompanied by the registration certificate, unused order forms, controlled substances (a registrant may return or sell his or her controlled substances prior to the surrender), and a DEA-104 (DEA Reference Book 5262D) will be completed by the registrant and shall indicate whether the surrender is due to failure to comply with DEA regulations or due to a voluntary desire to discontinue business. The form will be signed by the registrant and witnessed by the Investigator. A DEA-41 (Registrants Inventory of Drugs Surrendered) also will be completed whenever there are drugs to be surrendered for destruction. In many cases, the Voluntary Surrender of controlled substances privileges may be solicited from the registrant using correspondence such as that contained in the DEA Reference Book 5262E.

The appropriate DEA field office will directly input the Administrative Code 1 or Code 7 and will assure that the supporting documentation is maintained in the case file. If a Code 1 is required, the field office will follow procedures set forth in 5111.2 of this manual.

5263 CIVIL OR CRIMINAL PROSECUTION

CONTENTS

5263.1 PUBLIC RELATIONS WITH ASSISTANT U.S. ATTORNEYS

The Investigator should maintain a good working relationship with Assistant U.S. Attorneys. The Investigator and particularly the supervisor should capitalize on every opportunity for any type of contact with Assistant U.S. Attorneys, primarily to make them familiar with the diversion function. The more familiar Assistant U.S. Attorneys become with the diversion function and the problems faced, the more likely they will consider a case for prosecution.

5263.2 INITIAL PRESENTATION OF A CASE FOR PROSECUTION

At that point in any investigation when a determination is made that significant violations, possibly warranting civil or criminal prosecution, have occurred, the U.S. Attorney's Office must be contacted and apprised of the findings. The U.S. Attorney may, with discretion, offer suggestions concerning how to proceed with the case. This contact with the U.S. Attorney's Office must be documented. The Investigator must have the facts in the case outlined in writing, including what specific CSA violations have occurred. An additional outline should incorporate what evidence the Investigator has to substantiate the violations (including copies, if appropriate). The most important aspect of the initial contact with the Assistant U.S. Attorney is that of organizing the facts and evidence by charts or graphs relative to the case.

Further documentation may involve history of past violations or seriousness of the present violations(s).

In situations where the U.S. Attorney indicates the case lacks sufficient evidence, the Investigator should elicit suggestions from the U.S. Attorney to develop the evidence. In cases where the U.S. Attorney indicates willingness to take the case, it is imperative for the Investigator to update all reports of the investigation for submission to the U.S. Attorney. In all situations where the U.S. Attorney declines prosecution of a case, an attempt should be made to obtain a written declination of prosecution.

If DEA field offices have specific cases for which the U.S. Attorney's Office has declined prosecution and the SAC feels the case has prosecutable merit, the Chief of the Drug Operations Section, Office of Diversion Control (ODO) should be notified. The report will be reviewed by ODO and the Chief Counsel. If both agree that the case is prosecutable, a copy of the report will be forwarded to the Chief of the Criminal Division, Narcotic and Dangerous Drug Section, Department of Justice (DOJ). Based on formal DOJ agreement, if the Criminal Division concurs, instructions may be given to the Assistant U.S. Attorney in the field to prosecute the case.

5263.3 CIVIL ACTIONS

Civil fines are an effective tool in dealing with registrants who have a history of failure to comply with DEA regulations or who, by virtue of their activities, should have familiarized themselves with DEA regulations, but failed to do so. However, they should not be treated as an objective of Field Management Plans or a stated goal of the Diversion Program; they are just one of a number administrative, civil and criminal sanctions that may be applied when the circumstances warrant. If applied inconsistently, civil actions can be damaging to the Diversion Program. Therefore, when contemplating a civil action against a registrant for violations of the CSA, the following factors shall be taken into consideration.

(b)(7)(E)

These guidelines represent a basic framework for assuring consistent application of civil penalties. Field management shall make the final determination whether civil prosecution is justified based on all relevant factors in the case.

SUBCHAPTER 527 SPECIAL PROGRAMS

5270 PURPOSE AND INTRODUCTION

This subchapter identifies and establishes policy concerning on-going DEA diversion activities in support of the program.

CONTENTS

5270.1 REQUEST FOR INFORMATION

A request for information regarding Automation of Reports and Consolidated Orders System (ARCOS)/Diversion Analysis and Detection System (DADS) will be forwarded to the Staff Coordinator, Drug Operations Section, Office of Diversion Control (ODO). Requests for information regarding Drug Abuse Warning Network (DAWN), Label, or Information Resources will be directed to the Chief, ODO. The following guidelines will be used in formulating the request:

A. Requests will be submitted in writing by any field office, or Diversion, Intelligence, or Enforcement Group Supervisor or above.

B. All completed requests will be disseminated to the requester or a designee.

C. The Headquarters Analyst assigned the specific request will communicate directly with the case coordinator or, if necessary, the individual actually requesting the data to assure clarity of instruction.

D. A follow-up telephone call will be made to the requester 30 days after furnishing the data so that Headquarters can determine the outcome of the analytical research efforts and can use each previous case as a reference for future cases. This follow-up call will request information on what aspects of the data provided were pertinent in working the case in the field and any criticism or suggestions for future cases.

E. Suggested standardized formats for ARCOS/DADS, DAWN, or Label requests are contained in the DEA Reference

Book (5270A and 5270B).

5270.2 ON-LINE DATA BASE QUERIES

The Investigator is given an access code which allows for query of a specific data base. If an Investigator is not familiar with query procedures for these programs, the word "HELP" can be transmitted. The response will be a listing of the various on-line programs and their acronym. To obtain information regarding a specific program, transmit the acronym (i.e., ARCOS, STRIDE, etc.).

5270.3 AUTOMATION OF REPORTS AND CONSOLIDATED ORDERS -SYSTEM/DIVERSION ANALYSIS AND DETECTION SYSTEM (ARCOS/DADS)

Each registrant required to report to ARCOS and all DEA field offices should have a copy of the ARCOS Manual. This manual defines the ARCOS program and gives registrants detailed reporting procedures. The object of the ARCOS program is to capture, store, analyze, and summarize data furnished by registrants.

DADS is a subsystem of the ARCOS system which provides intelligence related to actual and potential diversion of controlled substances from the licit distribution system. Reports generated from this system reflect sales made to the retail level (retail pharmacies, hospital clinics, physicians, and teaching institutions). Most of these reports are listed by business activity in a designated geographical area for a specific time frame. This system can be used as a tool in targeting potential diversion and plotting drug trends.

5270.4 DRUG ABUSE WARNING NETWORK (DAWN)

The purpose of DAWN is to identify drugs currently being abused and to determine existing patterns of abuse in a particular area. DAWN derives information from episode reports provided by selected hospitals, emergency rooms, and medical examiners. The information provided by DAWN is limited to drug abuse cases which are treated medically or psychologically in a participating hospital and drug abuse-related episodes reported to a medical examiner.

Project DAWN is currently being used for drug control and scheduling purposes, for following specific drug trends on a regional or local basis, for measuring the effectiveness of a drug control action, for allocating resources and staff relative to specific drug problems, and as a prototype for single state agencies and foreign governments in developing DAWN-type programs.

5270.5 SYSTEM TO RETRIEVE INFORMATION FROM DRUG EVIDENCE (STRIDE)

STRIDE is a system of computer programs. It consists of three subsystems: (1) manpower utilization, (2) laboratory analysis, and (3) the ballistics programs. The Manpower Utilization Program is used by the Office of Forensic Sciences as a management information system. The Laboratory Analysis Program is based upon the fact that when a DEA forensic chemist analyzes drug evidence, the chemist not only identifies the controlled substances present but also identifies certain physical characteristics. The Ballistics Program is based on the physical and chemical comparison of tablets and capsules. This data, with information supplied by the submitting officer, is fed into a computer. It can be retrieved for intelligence and other purposes.

5270.6 INFORMATION RESOURCES PROGRAM

Computerized information containing medical, toxicological and chemical extracts is available in the Drug and Chemical Evaluation Section, Office of Diversion Control (ODE). Also, the Liaison and Policy Section, Office of Diversion Control (ODL) produces the monthly DAWN Executive Summary, regional reports, and summary of regulatory activities.

Counsel.

5271 INTELLIGENCE COLLECTION AND REFERRAL

CONTENTS

5271.1 DEVELOPMENT AND REFERRAL OF LEADS

Since the primary responsibility for the control of legitimate drugs at the practitioner level has been relegated to the states with the exception of G-DEP I or II violators, DEA's policy is that all information regarding diversion at this level be forwarded to the proper state regulatory and/or enforcement agencies. The following practices will be followed:

A. The Diversion Group Supervisor will design a system to furnish information regarding possible illegal and/or unethical practices by practitioners to the state. Sources of information will be reports of excessive purchases, order forms, ARCOS/DADS reports, and complaint information received from reliable sources.

B. In some instances, DEA participation with the states in practitioner investigations may serve as a catalyst in ensuring that significant leads are cited. DEA's intention is that generally the states eventually assume complete responsibility for the policing at the practitioner level.

C. Continued failure by state agencies to follow up on the information provided will be clearly documented and explained in the field reports of the assessment of state capabilities.

5271.2 AUTHENTIC SAMPLE COLLECTION PROGRAM

DEA's Special Testing and Research Laboratory maintains samples of legitimately made controlled substances as standards for comparison with drugs which are purchased, seized, or otherwise encountered in the illicit market. This program is a valuable means of identifying the ultimate sources of diverted controlled substances. In order to maintain an up-to-date library, the Investigator will be responsible for submitting samples to the laboratory. Samples of "look-alike" drugs should also be collected, e.g., caffeine capsules which look like biphetamine capsules, etc.

5271.21 Authentic Sample Logbook

Each field office may maintain an authentic sample logbook which will serve as a history of all samples collected from dosage form manufacturers.

The logbook will list the name of the manufacturer; the names, dosage forms and strengths, and control number of all samples collected; the date on which the samples were collected; and the name of the collecting Investigator. A copy of the DEA-400, Receipt for Samples (see DEA Reference Book (5271B)), and a copy of the firm's catalog or price list shall also be included. Prior to the on-site investigation of a dosage unit manufacturer, this book will be consulted to determine the need to collect additional samples.

5271.22 Samples to Be Collected

A. Duplicate samples of products already in the Special Testing and Research files need not be collected unless:

1. Samples of compressed or coated tablets were collected more than three years prior.
2. Samples of capsules were collected more than six months prior.
3. Changes in product formulation or size of dosage unit have been made or new or rematched or repolished punches or dies have been used.

B. Samples of the following dosage forms will be collected:

1. Compressed tablets - a sample, consisting of at least 100 tablets, from each set of punches and dies used to manufacture the particular product.
2. Coated tablets - 100 tablets.
3. Hard gelatin capsules - at least 20 capsules from each lot produced since the last samples were taken, up to a total of four lots.

C. Samples of such products will be collected regardless of whether the product is sold under the firms's own label or is custom-made for another firm. Samples of soft gelatin capsules, liquids, and suppositories will not be collected.

5271.23 Handling of Authentic Samples

Upon collecting samples, the Investigator will issue a DEA-400, Receipt for Samples, to a representative of the firm. All samples will be adequately packed to avoid damage while in transit. The samples will be adequately safeguarded and will be sent by registered mail to:

```
Special Testing and Research Laboratory

(Chief Chemist)

Drug Enforcement Administration

Westgate Industrial Park

7705 Old Springhouse Road

McLean, Virginia 22101
```

5271.24 Information to Accompany Authentic Samples

The samples will be accompanied by a DEA-400 and a DEA-6 outlining the following information.

A. ***Dosage Forms.***

1. Determine exact qualitative and quantitative formula and date of manufacture. This can usually be facilitated by

securing a readable photocopy of the batch sheet. If the record lists in-house names such as "Base #506", secure the exact formula of these ingredients.
2. Determine and document where the product is manufactured.
3. If applicable, determine the type and source of the ink used on the dosage unit itself.
4. Determine whether the firm uses any tracers or markers in the product. If so, explain.
5. If applicable, determine formulation of coating material.
6. Obtain two copies of the firm's catalog or price lists. One copy is to be used by the field office for updating its authentic sample log book. The other should be forwarded to the Special Testing and Research Laboratory along with the Authentic Sample Collection Report.
7. Collect one label from each controlled substance sampled along with package inserts. Submit these with DEA-400. If the sample is contained in a commercial container bearing the firms's label, this will suffice for the label requirements.

B. ***Compressed Tablets.*** Also determine:

1. The number of punches per set.
2. The size of the punches.
3. If firm routinely polishes the punch faces and how often.
4. The make and model number of the press used.
5. If the firm has ever loaned the punches to anyone. If so, document with names, dates, etc.
6. The firm's security in its handling of punches. Advise the firm of the need to keep a log book on their punches. Such a record should contain the dates bought, refaced, loaned, sold, destroyed, etc.

C. ***Hard Gelatin Capsules.*** Also determine:

1. Type of filing machines.
2. Sources of empty capsules.
3. Formula of lubricant used to polish or clean the filled capsules.

Any documentation of the above information (batch records, etc.) will accompany the DEA-6.

5271.3 PROJECT LABEL

Pursuant to 21 CFR Section 1308.04, the Investigator shall ensure that the information is being properly submitted. Labels will be collected from all manufacturers and own label distributors. Copies of all labels, regardless of whether samples are involved, will be forwarded to ODO.

5271.4 DRUG SURVEY

In order to establish grounds for (a) scheduling, rescheduling, or Rescheduling of a substance, or (b) increasing or decreasing a quota for a Schedule I or II substance, DEA field offices periodically will be directed to conduct drug surveys. The purpose of the survey is to gather data to substantiate the abuse patterns of a particular substance or substances.

Substances included in the survey may be list I chemicals, noncontrolled drugs with a potential for abuse or substances already controlled under the Act.

A Headquarters directive will set forth the substances to be surveyed, the time period the survey will encompass, and any specific information which is to be gathered. Headquarters will also provide the general file title and number under which the information is to be reported by the field offices.

A. Sources of information for drug surveys are generally:

1. State and local police agencies/laboratories.
2. State and local licensing/regulatory authorities.

3. Poison control centers (if not reporting nationally to DAWN).
4. DEA theft reports.
5. Reports of Investigation (b)(7)(E)
6. Program files of DEA field Intelligence Units.
7. DEA Operations files.
8. Private industry.

B. Information from non-DEA sources will be identified by the name of the source (police crime lab, etc.) and a description of the information found (i.e., amount of drug encountered, type of mention such as suicide, injury, arrest, purchase, seizure, etc.). This data will be tabulated and reported by category for each contact made.

Detailed information such as file numbers, where and how obtained, data obtained, etc., must be included.

Information from private industry would include inventory, purchase, and sales patterns over the survey period.

Information regarding data contained in DEA files will be summarized as follows:

1. Theft Reports

a. Number of reports (DEA-106).

b. Number and type of registrants.

c. Number of dosage units per type of registrant.

d. Total.

2. Field Intelligence Program Files

a. Availability and price of substances.

b. Significant trends or patterns of abuse.

3. Enforcement Files

a. File title and number.

b. Brief description of case.

c. Number of dosage units involved.

d. Results (seizure, conviction, etc.).

Diversion investigations conducted simultaneously with a drug survey will include an accountability of the drug(s) in question if controlled. If a noncontrolled item is the subject of a survey, it will be audited if possible (i.e., appropriate records are available).

5272 DIVERSION PREVENTION PROGRAM

CONTENTS

5272.1 GENERAL

The underlying premise of the Diversion Prevention Program is that self-established constraints aid the effectiveness of legalistic restraints and complement effective compliance with the CSA.

The Diversion Prevention Program provides national associations, state professional associations, professional schools, and licensing boards with an important conduit to encourage registrants to identify potential diversion prevention programs, to communicate, and to cooperate. By relying on registrant's professional integrity, self-determination and trust, DEA is able to enlist the support of registrant groups in pinpointing areas of diversion.

5272.2 GOAL OF THE DIVERSION PREVENTION PROGRAM

The goal of the program is to prevent diversion of controlled substances by supporting and fostering self-enforcement among the drug industry and professions.

Inherent in this goal is the assumption that adversarial confrontations, misinformation, and poor communications are minimized and that the drug industry and professions will enhance their methods of self-policing. This concept implies the establishment of self-constraints by registrants, which is separate from, but complementary to, DEA's enforcement and compliance activities.

5272.3 MAJOR AREAS OF ACTIVITY OF THE DIVERSION PREVENTION PROGRAM

A. The program, which is aimed at increasing the efforts of the pharmaceutical industry and the professions to self-police and to prevent diversion, is implemented through four major areas of activity. These are: (1) communication and education; (2) self-regulation; (3) liaison; and (4) special programs and projects.

B. In an effort to obtain compliance from the health disciplines of dentistry, medicine, nursing, osteopathic medicine, pharmacology, podiatric medicine, veterinary medicine, manufacturers, and wholesalers, DEA has established working committees with manufacturers, distributors, pharmacists, and practitioners. Each committee consists of members from the particular professional or trade association as well as DEA officials. Each committee meets regularly to discuss problems of mutual concern.

C. Other Functions of the Diversion Prevention Program

1. Conduct conferences and training programs.
2. Participate in physician training courses.
3. Provide publications for professionals.
4. Publish DEA/Registrant Facts.
5. Publish articles in professional journals.
6. Participate in registrants' meetings and exhibits.
7. Formulate programs for use by the states to prevent diversion.

5272.4 FIELD DIVERSION PREVENTION

The large number of registrants and the great number of professional associations which represent them on the local, state, and national levels make it necessary for DEA to establish liaison at all levels. Consequently, it is important that the Diversion Prevention Program operate not only from Headquarters but also from the field offices.

To accomplish this, a major goal of diversion prevention is to increase the abilities of the field offices in their relation with the regulated industry and professions. The field offices are responsible for coordinating diversion prevention activities with state registrant groups through the diversion group supervisors.

5272.5 REPORTS

The Diversion Group Supervisors will prepare reports on their respective diversion prevention activities. The Office of Diversion Control (OD) staff will provide support in scheduling conferences, seminars, exhibits, and related activities. Followup and state coordination is the field's responsibility.

5272.51 Quarterly Summary

A summary of activities will be prepared and submitted as part of the Field Management Report (6143 of the Agents Manual).

5272.52 Assessment Report

An appraisal system is hereby implemented which will insure that the Diversion Prevention Program provides effective and responsive programs to the public, professional organizations, law enforcement agencies, pharmaceutical industry, and others. Such a system will provide Headquarters, OD with statistical and background data as well as with an assessment of the effectiveness and/or appropriateness of that program, for use in future presentations or in determining if future DEA participation is warranted.

Prepare a report within 20 days of the program's completion and submit it to OD. This report need not include all of the following elements, but should be specific enough to provide guidance for future programs. (File the report under FFS 601-04.)

A. Audience - Type (professional, students, law enforcement, etc.); Size; Location; Frequency of DEA participation (annually, as requested, etc.).

B. "Formal presentation given" If yes, give topic(s) covered.

C. Exhibits/equipment used.

D. Publications, handouts, etc., distributed.

E. Number and type of DEA personnel participating.

F. Narrative assessment - include a brief discussion of the perceived effectiveness of the program; how receptive or responsive the audience was; suggested improvements or changes for future programs; and other information which may be of value to the overall Diversion Prevention Program.

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**CHAPTER 53 CHEMICAL DIVERSION PROGRAM

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**CHAPTER 53 CHEMICAL DIVERSION PROGRAM

SUBCHAPTER 531 MISSION AND GOALS

5311 INTRODUCTION

The Diversion Chemical Program was initiated in two phases. The first phase was pursuant to the passage of the Chemical Diversion and Trafficking Act of 1988 (CDTA). The CDTA created a system of targeting companies which were suspected of selling chemicals to clandestine laboratory operators. The CDTA helped identify clandestine laboratory operators so that they could be neutralized through criminal or civil prosecution.

The second phase of the program was initiated pursuant to the passage of the Domestic Chemical Diversion Control Act of 1993 (DCDCA). The DCDCA established federal presence at chemical companies by giving DEA additional responsibility to implement a registration system for List I chemical handlers. The DCDCA also required certain records and reports to be maintained and imposed certain security requirements for List I chemicals.

The Comprehensive Methamphetamine Control Act of 1996 (CMCA) broadened controls initiated in the first two phases on listed chemicals used in the production of methamphetamine and other controlled substances. The CMCA also increased penalties for the trafficking and manufacture of methamphetamine and listed chemicals, and expanded regulatory controls to include the distribution of lawfully marketed combination ephedrine drug products and drug products which contain the list I chemicals pseudoephedrine and phenylpropanolamine. The CMCA also added iodine and hydrogen chloride gas (HCL) as List II chemicals. Exhibit 1 is a list of abbreviations and acronyms used in this Chapter.

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5311.1 THE PRIMARY FOCUS OF THE CHEMICAL PROGRAM

See 5012.2A.

5311.2 PERTINENT DATES REGARDING REGISTRATION AND OTHER CHEMICAL CONTROL INITIATIVES

See Appendix 5311/B.

Exhibit 1

ABBREVIATIONS/ACRONYMS USED IN CHAPTER 53

AIW	Administrative Inspection Warrant
CC	Office of Chief Counsel
CDTA	Chemical Diversion and Trafficking Act
CHEMS	Chemical Handlers Enforcement Management System
CMCA	Comprehensive Methamphetamine Control Act
CSA	Chemical Substance Act
DCDCA	Domestic Chemical Diversion Control Act
DOJ	Department of Justice
DOT	Department of Transportation
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HCL	Hydrogen Chloride
NADDIS	Narcotics Dangerous Drugs Information System
ODC	Chemical Registration
ODCD	Domestic Chemical Investigations Unit
PIRs	Public Interest Revocations
RISS	Regional Information Sharing System
SAC	Special Agent In Charge
SCBA	Self-Contained Breathing Apparatus

SUBCHAPTER 532 REGISTRATION

5322 REGISTRATION CATEGORIES

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5322.1 GENERAL

Title 21, CFR, Parts 1309, 1310 and 1313 contain the regulations for chemical handlers. In general, registration requirements are effective for the following categories of registrants:

A. **IMPORTER.** A chemical importer is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States. See 21 CFR 1300.02 (b) (8).

B. **EXPORTER**. A chemical exporter is a regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States. See 21 CFR 1300.02 (b) (6).

C. **DISTRIBUTOR**. A chemical distributor is a person who delivers a listed chemical. ("Deliver" includes the actual, attempted or constructive transfer of a listed chemical, whether or not there exists an agency.) See 21 USC 802 (8) and 802 (11).

D. **RETAIL DISTRIBUTOR.** A grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor of legal drug products containing listed chemicals are limited almost exclusively to sales for personal use, both in number and volume of sales, either directly to walk-in customers or in face to face transactions by direct sales, for combination ephedrine, pseudoephedrine and phenylpropanolamine products. (Personal use is defined as sub-threshold sales of less than 24 grams.) See 21 USC 802 (46)(A) and 802 (46)(B).

NOTE: Retail Distributors are exempt from registration if they limit their sales of combination ephedrine, pseudoephedrine and phenylpropanolamine products "almost exclusively, both in number of sales and volume of sales" to "walk-in customers for their personal use or in face-to-face transactions by direct sales." This exemption does not, however, apply to single entity ephedrine, which has a zero threshold for all transactions and requires that all distributors, including retail distributors, be registered. See 21 CFR 1309.29.

E. **MANUFACTURE (for Distribution)**. The term manufacturer means a person who produces, prepares, or compounds a List I chemical for delivery to another person.

5322.2 WAIVERS

The requirement of registration is waived for domestic distribution of a prescription drug product containing a List I

chemical, such as single-entity injectable ephedrine sulfate, per 21 CFR 1309.28. Registration is required, however, for importation or exportation of prescription drug products containing List I chemicals. Records required to be maintained pursuant to FDA regulations for prescription drug products shall be deemed adequate for satisfying DEA's record keeping requirements with respect to distribution of prescription drug products containing List I chemicals.

5323 APPLICATION FOR CHEMICAL REGISTRATION

CONTENTS

5323.1 SCOPE

The DEA chemical handler registration system provides for annual registration of manufacturers (that distribute), distributors, retail distributors, importers, and exporters of List I chemicals. All persons required to be registered shall apply on DEA Form 510, and shall specify by chemical code numbers the List I chemicals for which registration is requested. (FFS: 630-05)

5323.2 SUBMISSION OF APPLICATION

If a person, who is required to be registered, submitted a proper application for registration with DEA on or before the dates listed below, then the applicant can continue to handle the specified List I chemicals unless the Administrator has issued a final order denying the application or the applicant voluntarily withdraws the application:

A. 11/13/95 (For all List I chemicals and single-entity ephedrine products)

B. 07/12/97 (For ephedrine combination products)

C. 12/03/97 (For pseudoephedrine and phenylpropanolamine drug products)

5323.3 REGISTRATION EXPIRATION DATES

At the time a person is first registered, that person is assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. Expiration month is determined by the first letter of the last name of an individual or the first letter of the company name:

Letter/Month	***Letter/Month***	***Letter/Month***
A - 06	B - 07	C - 08
D - 06	E - 08	F - 09
G - 09	H - 10	I - 11

J - 12	K - 12	L - 03
M - 01	N - 10	O - 12
P - 03	Q - 04	R - 04
S - 02	T - 11	U - 05
V - 05	W - 05	X - 05
Y - 05	Z - 05	9 - 04

The expiration year is determined by the date that the registrant's application is approved. The above chart lists the letter of the registrant's last name and/or company along with the month of expiration. If eleven months remain between the approval date and expiration date, then the date is established. If eleven months are not remaining, one year is added to the expiration date, until the eleventh month interval is met. Therefore, the registration of a registrant whose last name begins with the letter "J" will expire in December. If approved in June, the expiration date will be established as December of the year following the year when the application was submitted.

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5324 FEES

5324.1 GENERAL

DEA is authorized under 21 U.S.C. 821 and 958 (f) to charge application fees for registration. Fee schedules are set forth in 21 CFR 1309.11.

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5325 CONSTRUCTION OF A DEA CHEMICAL REGISTRATION NUMBER

A DEA chemical registration number is easily distinguished from a controlled substance registration number. (b)(7)(E)

(b)(7)(E)

(b)(7)(E)

```
.....Manufacturer (for distribution)

.....Distributor

.....Retail Distributor

.....Importer

.....Exporter
```

5325.1 ADMINISTRATIVE CODES

See 5111.2.

5326 POWER OF ATTORNEY

See 5111.8.

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5327 EXEMPTION FROM CHEMICAL REGISTRATION

5327.1 EXEMPTIONS

The following persons are exempt from chemical registration:

A. ***Controlled Substance Registrants***. The requirement of registration is waived, pursuant to 21 CFR 1309.25, for any person who distributes a product containing a List I chemical, if that person is registered with DEA to manufacture, distribute or dispense a controlled substance.

The requirement of registration is waived, pursuant to 21 CFR 1309.25, for any person who imports or exports a product containing a List I chemical, if that person is registered with DEA to engage in the same activity with a controlled substance. Any person exempted from the chemical registration requirement, due to having a controlled substance registration, shall comply with the security, record keeping and reporting requirements for List I chemicals.

B. ***Law Enforcement Officials***. The requirement of registration is waived for law enforcement officials pursuant to 21 CFR 1309.26, in the following circumstances:

1. Any officer or employee of the Administration, any officer of the U.S. Customs Service, any officer or employee of the United States Food and Drug Administration, (FDA) and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to listed chemicals or controlled substances and is duly authorized to possess and distribute List I chemicals in the course of his official duties.

2. Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to listed chemicals or controlled substances and is duly authorized to possess and distribute List I chemicals within his or her official duties.

C. ***Certain Manufacturers of List I Chemicals***. The requirement of registration is waived for any manufacturer of a List I chemical, if that chemical is produced solely for "end use" by the manufacturer and there is no subsequent distribution or exportation of the List I chemical. See 21 CFR 1309.27.

D. ***Retail Distributors***. The requirement of registration is waived for any distributor of regulated drug products containing List I chemicals that meets the definition for a retail distributor as defined in 5322.1 D and 21 CFR 1309.29.

E. ***Exceptions to Regulations***. Any person may apply pursuant to 21 CFR 1307.03 for an exception to the application of any provision of parts 1301-1313, or 1316 of this chapter by filing a written request stating the reasons for such exception to the Drug Enforcement Administration, Department of Justice, Office of Diversion Control, Washington, DC 20537. The Administrator may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

F. ***Safe Harbor and Blister Pack Exemptions***. The term "ordinary" over-the-counter pseudoephedrine and phenylpropanolamine as defined by the CMCA and 21 USC 802 (45) is any product containing pseudoephedrine and phenylpropanolamine that is:

(Safe Harbor and Blister Packs exemptions only apply to Retail Distributors.)

1. Regulated pursuant to this title, and

2. Except for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base, and that is packaged in blister packs, each blister containing not more than two dosage units, or where the use of the blister packs is technically infeasible, that is packaged in unit dose packets or pouches.

3. For liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base.

NOTE: Future exemptions will be published in the Federal Register and the annual CFR.

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5328 SEPARATE REGISTRATION FOR INDEPENDENT ACTIVITIES

The following groups of activities are deemed to be independent of each other and require separate registration:

A. Retail distribution of List I chemicals.

B. Non-retail distribution of List I chemicals.

C. Importing List I chemicals.

D. Exporting List I chemicals.

Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, unless exempted by the Act. However, a person registered to import any List I chemical shall be authorized to distribute only those List I chemicals that were imported. Furthermore, a person who does several types of distribution of List I chemical drug products, for example, retail distribution, mail-order distribution, or wholesale distribution, requires only a "Distributor" registration. A person who both manufactures a List I chemical for "subsequent distribution" and "Distributes" List I chemicals will be registered under the "Manufacture for Distribution" category. This is because the registration is actually required for the distribution of the List I chemicals, but for administrative purposes, the "Manufacturer for Distribution" registration category will be used.

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5328.1 SEPARATE REGISTRATION FOR SEPARATE LOCATIONS

5328.2 GENERAL

A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported by a person, pursuant to 21 CFR 1309.23(a).

5328.3 PLACES NOT SUBJECT TO REGISTRATION

The following locations shall be deemed to be places not subject to the registration requirement, pursuant to 21 CFR 1309.23(b):

A. A warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly to customers from such warehouse locations other than the registered location from which the chemicals were originally delivered.

B. An office used by agents of a registrant where sales of List I chemicals are solicited, made or supervised, but neither contains such chemicals (other than chemicals for display purposes) nor serves as a distribution point for filling sales orders.

5329 MODIFICATION OF REGISTRATION

CONTENTS

5329.1 NAME AND/OR ADDRESS CHANGE

When a chemical registrant requests modification of its registration to effect a name or address change, or handling of additional List I chemicals, the registrant, pursuant to 21 CFR 1309.61, shall submit a letter requesting modification. The request for modification should be submitted to the Drug Enforcement Administration, Chemical Registration/ODC, PO Box 2427, Arlington, VA 22202-2427. The request shall contain the registrant's name, address, and registration number as printed on the certificate of registration and the new name or address and/or List I chemicals to be added to its registration. No fee is required for the modification. (FFS: 630-05)

5329.2 APPROVAL OF NAME AND/OR ADDRESS CHANGE

Absolutely no modifications will be made without a written request from the registrant. Upon receipt of such written notification by ODC from the registrant, ODC will contact the appropriate Diversion Program Manager or Group Supervisor for appropriate recommendation. If necessary, the request for modification shall be routed by ODC to the appropriate field office for investigation. Headquarters ODC will be responsible for inputting the modification of registration into the M-204 system which will be noted in the Remarks Section.

Some states may require a license or permit to handle List I chemicals. In these cases, the state authority may require a new license or permit when a DEA chemical registrant changes its name and/or address. If this is the case, DEA will also require the registrant to complete a new application for registration.

5329.3 TERMINATION OF REGISTRATION

Pursuant to 21 CFR 1309.62, a DEA chemical registration terminates if the registrant dies, ceases legal existence or discontinues business or professional practice. This section also provides procedures for disposing of List I chemicals on hand at that time.

SUBCHAPTER 533 RECORDS AND REPORTS

5331 REQUIRED RECORDS OF LISTED CHEMICALS AND CERTAIN MACHINES

Each regulated person who engages in a **regulated transaction** involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction, in accordance with 21 CFR 1310.06. Records of regulated transactions involving listed chemicals, or tableting or encapsulating machines, shall be maintained by the regulated person for two years after the date of the transaction. See 21 CFR 1310.04 (a) (b).

Required records shall be maintained at the regulated person's place of business where the transaction occurred, with the exception of those records that may be maintained at a single central location of the regulated person if the regulated person notifies DEA of their intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the SAC of the DEA Divisional Office for the area in which the records are required to be kept. See 21 CFR 1310.04 (c).

Required records will be kept, readily retrievable, and available for inspection and copying by authorized employees of DEA under provisions of 21 U.S.C. 880. Each record required shall include the following information:

A. Name, address, and, if required, DEA registration number of each party to the regulated transaction. In determining whether a customer needs a DEA registration number, the supplier's records should show what the customer does with the List I chemicals. See 21 CFR 1310.06 (a)(1).

B. Date of the regulated transaction. See 21 CFR 1310.06 (a) (b).

C. The name, quantity and form of packaging of the listed chemical or description of the tableting machine or encapsulating machine (including make, model and serial number). See 21 CFR 1310.06 (a) (3).

D. The method of transfer. See 21 CFR 1310.06 (a) (4).

E. The type of identification used by the purchaser and any unique number on that identification. See 21 CFR 1310.06 (a) (5).

5332 REPORTS REQUIRED TO BE MADE TO DEA PURSUANT TO 21 CFR SECTION 1310.05

Each regulated person shall report to the SAC of the DEA Divisional Office for the area in which the regulated person making the report is located. See 21 USC 830 (b) (1). (Written reports are required for A, C, and D only.):

A. Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate the chemical will be used in violation of the CSA. (See Appendix 5311/B.)

B. Any proposed regulated transaction with a person whose description or other identifying characteristic the Administration has previously furnished to the regulated person.

C. Any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

(NOTE: DEA-106 is not to be used. See 1310.06 for report format.)

D. Any domestic regulated transaction in a tableting or encapsulating machine.

Each report required above shall, whenever possible, be reported orally to the DEA Divisional Office for the area in which the regulated person making the report is located at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved and as much in advance of the conclusion of the transaction as possible. (FFS: 630-14)

Written reports of reportable transactions or losses are required to be filed within 15 days after the regulated person becomes aware of the circumstances.

5333 MAIL ORDER REPORTING

Each regulated person who engages in a transaction with a non-regulated person which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals) and uses or attempts to use the Postal Service or any private or commercial carrier, shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Drug Enforcement Administration, Office of Diversion Control, Domestic Chemical Investigations Unit (ODCD), Washington, DC 20537. These reports are to be submitted either via United States Mail or electronic filing (i.e., computer disk). The deadline for filing reports is the 15th day of the month following the month in which the reportable transaction(s) took place.

See 21 USC 830 (b) (3). The following information shall be contained on mail order reports that are submitted to DEA:

A. Supplier Name and Registration Number

B. Purchaser's Name and Address

C. Name/Address Shipped To (if different from purchaser's name/address)

D. Name of the Chemical Shipped

E. Product Name

F. Dosage Form (if any)

G. Dosage Strength (if any)

H. Number of Dosage Units (if applicable)

I. Package Type

J. Package Quantity

K. Lot Number (for drug products)

L. Date of Shipment

5334 PROOF OF IDENTITY REQUIREMENTS

CONTENTS

5334.1 GENERAL

Each **regulated person** who engages in a **regulated transaction** is required by 21 CFR 1310.07 to identify the other party to the transaction. A regulated transaction includes either a listed chemical or a tableting or encapsulating machine. The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, or tableting or encapsulating machine.

5334.2 DOMESTIC TRANSACTIONS

Domestic transactions may be accomplished by having the other party present documents to verify their identity or registration status at the time the order is placed. Verification of documents may be accomplished through the following sources:

A. Telephone directory

B. Credit bureaus

C. Local Chamber of Commerce

D. Local Better Business Bureau

NOTE: When transacting business with a new representative of a firm, the regulated person must verify the status of the representative.

5334.3 CASH SALES OR SALES TO INDIVIDUALS

For cash sales or sales to individuals, the proof of identity must consist of at least the signature of the purchaser, a driver's license and one other form of identification. If an individual presents an identification card issued by an appropriate state authority in lieu of a driver's license, such identification is acceptable as the primary identification provided that it contains the individual's name, address, a unique identification number, and the individual's photograph.

5334.4 NEW CUSTOMERS

For new customers who are not individuals or cash customers, the regulated person shall establish the identity of the authorized purchasing agent(s) and have on file that person's signature, electronic password or other identification. Once identity has been established the agent list may be updated annually.

5335 FELONY CONVICTION AND EMPLOYER RESPONSIBILITIES

The chemical registrant shall exercise caution in the consideration of employment of persons who will have access to listed chemicals. See 21 CFR 1309.72. Potential employees should be screened for:

A. Conviction of a felony offense relating to controlled substances or listed chemicals.

B. Having had an application for registration with DEA denied.

C. Having had a DEA registration revoked.

D. Having surrendered a DEA registration for cause.

It is the position of DEA that employees who possess, sell, use or divert listed chemicals or controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

5336 EMPLOYEE RESPONSIBILITY TO REPORT DIVERSION

Reporting of listed chemical diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information. A failure to report information of chemical diversion will be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. The employer shall inform all employees concerning this policy. See 21 CFR 1309.73.

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5337 SUSPICIOUS CUSTOMER IDENTITY FURNISHED BY DEA TO LISTED CHEMICAL HANDLERS

A regulated transaction may not be completed with a person whose description or other identifying characteristics has previously been furnished to the regulated person by DEA unless the transaction is approved by the Administrator. See 21 CFR 1310.05.

The Chief of Operations at DEA Headquarters is presently the only person authorized to issue letters to regulated persons giving descriptions of persons with whom regulated transactions may not be completed. Requests for these letters will be coordinated through ODC.

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SUBCHAPTER 534 RESERVED

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SUBCHAPTER 536 SAFETY GUIDELINES FOR HANDLING CHEMICALS

5361 CHEMICAL HANDLING PROCEDURES

Generally, Diversion Investigators assigned to domestic field offices will not be exposed to chemicals through their assigned duties. Any chemical samples which may be needed periodically will be taken by DEA chemists. Diversion Investigators assigned to DEA foreign country offices may find themselves in situations with foreign counterparts where chemical samples need to be taken. In those occasional situations it is important that the Investigator control his or her exposure to chemical hazards through proper chemical handling procedures. The following general safety guidelines will be followed if it is necessary for Investigators to handle chemicals:

A. Only handle the chemicals necessary for the operation.

B. Work in well ventilated areas.

C. Handle the minimum amount necessary for the job.

D. Notify company management and your G/S in the event of container damage or spill.

E. Keep the area clean and organized.

F. Follow label directions and/or instructions.

G. Identify all potentially incompatible chemicals in the area and eliminate potential contact.

H. Eliminate sources of ignition before examining flammable materials.

NOTE: Listed below are hazardous chemicals that should not be mixed together:

1. acids away from caustics

2. metals away from corrosives

3. oxidizers away from organic

4. corrosives away from water

5. oxidizers away from water

6. oxidizers away from acids

7. cyanide away from acids

8. cyanide and sulfides away from acids

CONTENTS

5361.1 GENERAL SAFETY GUIDELINES FOR CHEMICAL REGISTRANT INVESTIGATIONS

A. Investigators should be aware of any risks associated with particular chemical applicants/registrants and assume responsibility for prevention of their exposure to apparent chemical hazards. The Investigator must continually identify actual and potential hazards and evaluate their associated risks and determine the appropriate action to be taken. The following general guidelines should be followed for investigator safety in conducting chemical investigations:

1. Investigators should use a "common sense" approach to any potentially hazardous situation.

2. Investigators should recognize, assess and react to actual or potential hazards associated with the particular type of chemical handler.

3. Investigators should be aware of the environment, plan their activities and consider the consequences of their actions.

4. If possible, it is recommended Investigators work as a team conducting on-site chemical handler investigations.

B. Investigators should minimize their physical exposure to hazardous chemicals by avoiding unnecessary contact with open containers, packages, etc. and visible contamination.

C. During pre-registration investigations, Investigators will identify those areas of concern with the firm's management and conduct a visual verification. General walk-through of chemical plants, where chemical manufacturing may be in progress, is unnecessary.

5361.2 LISTED CHEMICALS FOR DESTRUCTION

Proper disposal of listed chemicals is the responsibility of the regulated chemical handler. At the time a chemical handler decides to dispose of a listed chemical, that chemical becomes a hazardous waste regulated by the Environmental Protection Agency (EPA). EPA strictly regulates the disposal of hazardous waste "from cradle to grave." All handlers and transporters of hazardous waste must be permitted to do so by the EPA and the shipments thereof require a Hazardous Waste Manifest. Therefore, acceptance of chemicals by DEA personnel for destruction without meeting these requirements would be a violation of EPA statutes.

NOTE: It is the policy of DEA that field offices will not accept surrendered listed chemicals for destruction.

Any chemical handlers contacting DEA field offices regarding the disposal of listed chemicals should be advised that DEA will not accept listed chemicals for destruction and that firms must dispose of the chemical pursuant to standard industry practices and in accordance with EPA and DOT regulations.

5362 CLANDESTINE LAB SETTING

**Clandestine Laboratory Certified Diversion Investigators may not enter a clandestine lab environment until it is deemed safe by the site Safety Officer.

Certification of an employee to enter a clandestine laboratory site requires initial and annual training to include an initial and subsequent annual medical examination. (See Agents Manual 6674.11 B.1.)

Although, there is no measurable level of chemicals in the air, there is still the potential for spills and fire. This program requires that only certified DEA employees enter a laboratory site unless approved by a Special Agent In Charge or appropriate entity for Diversion Investigators. (See Agents Manual 6674.4, paragraph D.)**

** Addition

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SUBCHAPTER 537 PROPOSED ACTIONS AGAINST CHEMICAL REGISTRANT APPLICANTS

5371 ADMINISTRATIVE ACTIONS

A DEA chemical registration for List I chemicals may be revoked or denied if at least one of the following has occurred:

A. The Application for Registration or renewal has been materially falsified.

B. The applicant/registrant (owner, officer, controlling stockholder) has been convicted of either a controlled substance or a listed chemical related felony.

C. The applicant/registrant has had their state license or registration suspended, revoked, or denied and is no longer authorized by state law to engage in the distribution of List I chemicals.

D. The applicant/registrant has committed such acts as would render their registration to distribute List I chemicals inconsistent with the public interest. A chemical registration or Application for Registration can be **denied, revoked,** or **suspended** by DEA **only** if one (or more) of the above conditions has occurred. Factors to be considered in determining public interest include the following:

1. Maintenance of effective controls against diversion.

2. Firm's violative history.

3. Compliance with applicable state and local law.

4. Prior conviction record of applicant under Federal or state laws relating to the manufacture, distribution or dispensing of controlled substances or listed chemicals.

5. Such other factors as may be relevant to and consistent with the public health and safety.

5372 ORDER TO SHOW CAUSE

An Order to Show Cause may be requested for denial, revocation, or suspension of a DEA chemical application and/or registration. 21 U.S.C. 823 and 824 set forth the grounds for denial, revocation, or suspension of a DEA registration. A chemical registration or application for registration may be revoked, denied, or suspended for one of the reasons set forth above.

NOTE: Requests for Orders to Show Cause will be by memorandum from the Diversion Program Manager (DPM) to the Office of Chief Counsel, (CC) with a DEA Report of Investigation attached and a copy sent to the Chemical Investigations Section. The memorandum will detail the applicant/registrant's violative history and the basis for the Show Cause request. (FFS: 330-07)

Investigators should follow the procedures as stated in 5262.65 as applicable to chemical applicants/registrants for Show Cause requests.

5373 VOLUNTARY SURRENDER OF REGISTRATION

A registration to manufacture (for distribution), distribute, import or export List I chemicals may be voluntarily surrendered by the registrant at any time. In cases where state authorization has been temporarily suspended, a Voluntary Surrender can be used to place a violative registrant out of business.

The DEA-104 should be amended as applicable to reflect the voluntary surrender of the DEA- 511, Domestic Chemical Diversion Control Registration Certificate. A Voluntary Surrender will be accompanied by the List I Chemical Registration Certificate. The DEA-104 shall indicate whether the surrender is due to failure to comply with DEA regulations or due to a voluntary desire to discontinue handling List I chemicals. The form will be signed by the registrant and the Investigator. The field office will directly input the Administrative Code 1 or Code 7, as appropriate, and will file supporting documentation in the case file.

SUBCHAPTER 538 COMPLAINT INVESTIGATION PROCEDURES

5381 COMPLAINT INVESTIGATIONS

CONTENTS

5381.1 INTRODUCTION

A complaint investigation is any in-depth investigation of a registrant or non-registrant other than a scheduled cyclic investigation pursuant to 5231.11. All (b)(7)(E) series investigations other than cyclic investigations, therefore, are to referred to as "complaint investigations." This category will include all investigations of List I and II chemical handlers, investigations of non-chemical registrants which were not scheduled on the office's work plan, and investigations leading to Public Interest Revocations (PIRs), etc.

Complaint investigations will be initiated against major diverters of List I and II chemicals at all levels from the manufacturer to the retail distributor. Care should be taken to convert a pre-registrant investigation to a complaint investigation when sufficient information is found to suggest a registration should not be issued.

5381.2 BACKGROUND

See 5245.11.

5381.3 OBJECTIVES

The DEA Diversion Program has two major objectives with respect to List I and II chemical diversion:

A. Identify, investigate and prosecute violators who are operating at levels which deserve Federal attention.

B. Assist the states with their responsibilities, both through active investigation and through information sharing. The complaint investigation program is designed to meet both of these objectives.

5381.4 SELECTING TARGETS FOR INVESTIGATION

The primary goal upon initiating a complaint investigation will be to determine if violations have taken place and to prosecute the registrant accordingly.

5381.5 TECHNICAL ASPECTS

5381.51 Chemical Handlers Enforcement Management System (CHEMS)

CHEMS is a database on the M204 system of over 11,000 firms handling List I and II regulated chemicals. The majority of the firms are located in the United States. CHEMS provides the location, the chemical activity, and a remarks section for each firm. CHEMS also identifies suppliers and customers of many firms.

CHEMS also provides formatted information on the location of the firm, a point of contact, a telephone number, the business activities, the regulated chemicals handled, and a free form remarks section which includes sources of information. These sources include customer lists, memoranda, letters from firms to DEA Diversion offices, DEA-486 records, teletypes and DEA-6's. Each source contains the DEA office or company author, a date, and related information on the firm. It also provides information on many firms regarding the supplier, customer and chemical relationship.

5381.6 REPORTING REQUIREMENTS

A. A report of a complaint investigation will be prepared using a (b)(7)(E) file number. Unless there is substantial evidence, e.g., witness or confidential source, of criminal violations at the outset of a complaint investigation, all complaint investigations are to be carried on the DEA-351 using Class Code [redacted] When evidence of criminal violations (b)(7)(E) is substantiated, a Case Initiation Report and a DEA-202 establishing a G-DEP identifier are to be prepared. Thereafter, investigative time is to be reported using a (b)(7)(E) Class Code followed by a G-DEP identifier. See 5245.22.

B. A report of a routine/general matter will be prepared using the following Headquarters Program File (b)(7)(E) file numbers:

(b)(7)(E)	
	Precursor Control Program
	Sale or Transfer/Encapsulating Machines
	Thefts of Listed Chemicals
	Chemical Company Diversion
	Suspicious Chemical Orders
	Surrender of Registration (Chemical)
	Approval of Application DEA-510 & 510a (Chemical)
	Withdrawal of Application DEA-510 & 510a (Chemical)
	Chemical Intelligence
	Pseudoephedrine
	Modification of Chemical Registration

5381.7 JOINT INVESTIGATION

See 5245.23.

5381.8 ADMINISTRATIVE INSPECTION WARRANT (AIW)

Subsection 5231.6 discusses the preparation of the AIW and under what circumstances it is to be served. When probable cause for a search warrant is lacking, an AIW should be used to obtain targeted chemical handler's records.

NOTE: If prior to entering the registrant's premise, probable cause to seek a search warrant exists, then a search warrant should be sought in preference to an Administrative Inspection Warrant.

5381.9 ADDITIONAL INVESTIGATIVE TECHNIQUES

The type of investigation and the desired action may dictate the type of techniques to be used, which may range from interviewing customers of the firm, interviewing employees, photo taking, and obtaining Special Agent assistance for the purchase of evidence. The Grand Jury Subpoena or an Administrative Subpoena may also be used as an investigatory tool. Each case represents a unique situation, and even though there may be similar circumstances, it has to be developed independently. See 5245.27.

5382 CIVIL OR CRIMINAL PROSECUTION

CONTENTS

5382.1 PUBLIC RELATIONS WITH ASSISTANT U.S. ATTORNEYS

See 5263.1.

5382.2 INITIAL PRESENTATION OF A CASE FOR PROSECUTION

See 5263.2.

If DEA field offices have specific cases for which the U.S. Attorney's Office has declined prosecution and the SAC feels the case has prosecutable merit, the Chief of the Chemical Investigations Section, Office of Diversion Control (ODC) should be notified. The report will be reviewed by ODC and Chief Counsel. If both agree that the case is prosecutable, a copy of the report will be forwarded to the Chief of the Criminal Division, Narcotic and Dangerous Drug Section, Department of Justice (DOJ). Based on formal DOJ agreement, if the Criminal Division concurs, instructions may be given to the Assistant U.S. Attorney in the field to prosecute the case.

5382.3 CIVIL ACTIONS

See 5263.3.

5383 FORFEITURE PURSUANT TO SUSPENSION OR REVOCATION OF REGISTRATION

5383.1 GENERAL

The CMCA allows for List I chemicals to be forfeited by DEA under certain conditions as follows:

A. The suspension or revocation of a registration pursuant to 21 USC 824(a).

B. The suspension of a registration pending final order pursuant to 21 USC 824(f).

C. The termination of a registration.**

** Addition

DIVERSION INVESTIGATOR APPENDICES

APPENDIX 5161A

POSTAL REGULATIONS CONCERNING THE CONTROLLED SUBSTANCES ACT

Title 18 United States Code (U.S.C.) § 1716(d): The transmission in the mail of poisonous drugs and medicines may be limited by the Postal Service to shipments of such articles from the manufacturer thereof, or dealer therein, to licensed physicians, surgeons, dentists, pharmacists, druggists, cosmetologists, barbers, and veterinarians under such rules and regulations as it shall prescribe.

Domestic Mail Manual – 601: Mailability

11.0: Other Restricted or Nonmailable Matter

11.11: Drugs

11.11.1: Over-the-Counter Drugs

11.11.2: Prescription Drugs

Prescription drugs are licensed medicines that require a written order by a medical doctor or pharmacist before they can be obtained. Prescription drugs, including those that contain controlled substances, may be mailed by drug manufacturers or their registered agents, pharmacies, or other authorized dispensers as permitted by 21 C.F.R. § 1307.12 or in compliance with any regulation of the Food and Drug Administration or other applicable law.

11.11.3: Controlled Substances

A controlled substance means any anabolic steroid, narcotic, hallucinogenic, stimulant, or depressant drug in schedules I through V of the Controlled Substances Act, 21 U.S.C. § 801, and 21 C.F.R. § 1300. Controlled substances may be mailed by drug manufacturers or their agents, pharmacies, or other authorized dispensers when distribution is lawful under 21 U.S.C. § 801 and 21 C.F.R. § 1300 and if the mailer or the addressee meets one of the following conditions:

a. The mailer or the addressee is registered with the Drug Enforcement Administration.

b. The mailer or the addressee is exempt from the Drug Enforcement Administration registration in performing official duties such as military, civil defense, and law enforcement personnel.

11.11.4: Packaging and Markings

Securely package all mailable drugs so that the contents cannot become damaged or dislodged during mailing. Follow the general packaging instructions in 601.1.0 through 601.8.0. Do not identify the nature of the contents on the outside of the mailpiece.

11.11.5: Return of Prescription Drugs

Mailers may use merchandise return service to return prescription drugs for purposes of drug recalls, voluntary manufacturer withdrawals, and dispensing errors such as incorrect drug, dosage, or strength, as permitted by 21 C.F.R. § 1307.12 or other applicable law. The mailpiece must be addressed to the manufacturer or its registered agent. Manufacturers or their registered agents must furnish mailing containers to their customers for the purpose of mailing

back identified drugs. Manufacturers or their registered agents must use merchandise return service (see 507.10.0) with First-Class Mail or Priority Mail for these mailpieces. Manufacturers or their agents continue to be responsible for maintaining records in compliance with any regulation of the Drug Enforcement Administration and/or the Food and Drug Administration.

11.11.6: Mailing Standards

If distribution of a controlled substance is lawful under 21 § U.S.C. 801, et seq., and any implementing regulation in 21 C.F.R. § 1300, et seq., the USPS considers such distribution by mail to constitute the mailing of matter not outwardly or of its own force dangerous or injurious to a person's life or health and accordingly mailable, subject to these standards:

a. The inner container of any package containing controlled substances is marked and sealed under the applicable provisions of the Controlled Substances Act (21 U.S.C. § 801, et seq., and any implementing regulation in 21 C.F.R. § 1300, et seq.) and placed in a plain outer mailing container or securely overwrapped in plain paper.

b. If the mailing includes prescription drugs containing controlled substances, the inner container is also labeled to show the prescription number and the name and address of the pharmacy, practitioner, or other person dispensing the prescription.

c. The outer mailing wrapper or container is free of markings that indicate the nature of the content.

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WORK PLAN FORMAT

FY _____ WORK PLAN FOR THE _____ OFFICE

I. Number and Type of Current Registrants Subject to Scheduled Investigations:

Manufacturers

Analytical Laboratories (affiliated with above manufacturers):

Distributors (including Reverse Distributors):

Importers:

Exporters:

Chemical Manufacturers, Distributors & Importers/Exporters:

Narcotic Treatment Programs (NTPs):

DATA-Waived Physicians (DWPs):

Researchers (schedule I Researchers handling Code H):

Researchers (schedules II-V):

Total

II. Number and Type of Activities Scheduled for Investigation on this Work Plan:

Manufacturers

Analytical Laboratories (affiliated with above manufacturers):

Distributors (including Reverse Distributors):

Importers:

Exporters:

Chemical Manufacturers, Distributors & Importers/Exporters:

Narcotic Treatment Programs (NTPs):

DATA-Waived Physicians (DWPs):

Researchers (Schedule I Researchers handling Code H):

Researchers (Schedules II-V):

Total

III. Name and Grade of 1801s Assigned to your Group:

IV. List the Firms Scheduled for Investigation by NAME, ADDRESS, DEA NUMBER, and ACTIVITY: [NOTE: If the investigation is strictly to be an annual 303 Investigation, indicate "303 Investigation" in parenthesis next to the activity.]

EXAMPLE OF AFFIDAVIT FOR ADMINISTRATIVE INSPECTION WARRANT - COMPLAINT AND CYCLIC INVESTIGATIONS (REGISTRANTS)

UNITED STATES DISTRICT COURT
FOR THE _____ OF
_____

IN THE MATTER OF THE ADMINISTRATIVE INSPECTION OF

Magistrate's Docket No.
Case No.

Before
United States Magistrate
United States District Court for

The undersigned, being duly sworn, deposes and says:

That the affiant, _____, is a duly appointed Diversion Investigator (Special Agent) of the Drug Enforcement Administration, United States Department of Justice, assigned to the _____ Division (Resident) Office.

That pursuant to Sections 878(2) and 880(b)(1), (2), and (3), Title 21, United States Code (U.S.C.), and Section 3, Appendix to Subpart R. Title 28, Code of Federal Regulations (C.F.R.), your affiant is authorized to execute administrative inspection warrants for the purpose of inspecting controlled premises of persons and firms registered under the Controlled Substances Act (CSA) (21 U.S.C. 800) et seq in order to inspect, copy and verify the correctness of all records, reports and other documents required to be kept or made under Section 827, Title 21, U.S.C. and Section 1304.01 et seq. Title 21, C.F.R.

That _____ (name of registrant) is registered under the provisions of the CSA, Title 21, U.S.C., Section 823 et seq., as a _____ and has been assigned DEA registration number _____ in Schedules _____, and is doing business at _____ (address of registrant). That said place of business is a controlled premises within the meaning of Section 880(a), Title 21, U.S.C. and Section 1316.02(c), Title 21, C.F.R.

That _____ (registrant) is required to keep complete and accurate records of all controlled substances received, sold, delivered or otherwise disposed of by him pursuant to 21 U.S.C. 827 and 21 C.F.R. § 1304.01 et seq. on the controlled premises.

That the affiant has examined the files and records of the Drug Enforcement Administration and has determined that _____ (registrant) was last inspected on _____ (date) and _____ (results of inspection) (or has never been inspected by DEA, etc)---ADD ANY OTHER FACTS WHICH YOU WISH TO INCLUDE AS ADMINISTRATIVE PROBABLE CAUSE SUCH AS SUSPICIOUS PURCHASES, INFORMATION FROM STATE AGENCIES, RESULTS OF STATE INSPECTIONS, ETC. The affiant further represents that the need for the inspection of _____ (registrant) and the need for verifying the correctness of inventories, records, reports, and other documents required to be kept under the CSA and the need for verifying the security provisions utilized by the registrant in storing and handling controlled substances result from a valid public interest in the effective enforcement of the CSA and implementing regulations.

The affiant further states that the inspection will be conducted within regular business hours, and that the Investigator's (Agent's) credentials will be presented to the registrant, and that the inspection will begin as soon as practicable after the issuance of the warrant and will be completed with reasonable promptness and that the warrant will be returned within _____ days.

The affiant further states that the inspection will extend to the inspection and copying of inventories, records, reports, (prescriptions), order forms, invoices, and other documents required to be kept and the inspection of all other things therein including records, files, and papers appropriate for the verification of the records, reports, and documents required to be kept under the CSA. The inspection will also extend to the inspection and inventory of stocks of controlled substances, finished or unfinished substances and pertinent equipment associated with the storage and handling of controlled substances, and if necessary any applicable records and/or samples of controlled substances will be seized.

The affiant will be accompanied by one or more Investigators who are employees of the Attorney General authorized to conduct administrative inspections.

A return will be made to this Magistrate (Court) upon the completion of the inspection. The affiant further states that he/she has verified and has knowledge of the facts alleged in this affidavit and that they are true to the best of his/her knowledge.

_____
Name of Affiant
Title of Affiant
Drug Enforcement Administration

Sworn to before me and subscribed in my presence on this _____ day of _____, 20___.

_____
United States Magistrate

EXAMPLE OF WARRANT FOR INSPECTION - COMPLAINT AND CYCLIC INVESTIGATIONS (REGISTRANTS)

UNITED STATES DISTRICT COURT
FOR THE _____ OF
_____

IN THE MATTER OF
ADMINISTRATIVE INSPECTION OF
INSPECTION
(Name and Address of
Registrant)
_____

WARRANT FOR

To _____ (Diversion Investigator or Special Agent) and any other duly authorized investigator or agent of the Drug Enforcement Administration of the United States Department of Justice.

Application having been made and probable cause as defined by Section 880(d)(1), Title 21, United States Code (U.S.C.) having been shown by the affidavit of Diversion Investigator (or Special Agent) _____ of the Drug Enforcement Administration for an inspection of the controlled premises of and described as _____ (name and address of registrant) and described as _____ (physical description of controlled premises) and it appearing that such inspection is appropriate pursuant to Section 880, Title 21 of the U.S.C.

Therefore, pursuant to Section 880, Title 21 of the U.S.C., you are hereby authorized to enter the above-described premises during ordinary business hours and inspect in a reasonable manner and to a reasonable extent, including the collection of samples if necessary, all finished or unfinished controlled substances on the premises, all pertinent equipment, records, files, reports, official order forms, (prescriptions), and documents required to be made, kept and maintained under the provisions of the Controlled Substances Act, 21 U.S.C. 800, et seq. and the Controlled Substances Import and Export Act, 21 U.S.C. 900, et. seq., for the purpose of verifying that said records, files, official order forms, reports, (prescriptions), documents and controlled substances are properly kept and maintained.

You are hereby further authorized to seize from the above-described controlled premises the following records, reports, documents, files and inventories as are appropriate to the effective accomplishment of the inspection and for the purpose of copying or

verifying their correctness or that are used or intended to be used in violation of the Controlled Substances Act:

(1)

(2)

A prompt return shall be made by the inspecting officers to the undersigned magistrate, showing that the inspection has been completed and accounting for all property seized pursuant to this warrant, not later than ____ days from the issuance of this warrant.

_____
Magistrate
United States District Court for the
_____ of _____
Dated:

RETURN

I received the attached administrative inspection warrant on _____.

On _____ at _____ a.m., I conducted administrative inspection of the premises described in the warrant and I left a copy of the warrant with _____.

(name of individual)

The following records and/or samples of controlled substances were seized pursuant to the warrant:

(either list or indicate that receipts are attached)

_____

Diversion Investigator
Drug Enforcement Administration

Subscribed and sworn to and returned before me this _____ day of _____, 20__.

_____
United States Magistrate

EXAMPLE OF AFFIDAVIT FOR ADMINISTRATIVE INSPECTION WARRANT –LIST I AND LIST II CHEMICAL AND TABLETING/ENCAPSULATING MACHINE HANDLERS (REGULATED PERSONS)

UNITED STATES DISTRICT COURT
FOR THE _____ OF

_____

IN THE MATTER OF THE ADMINISTRATIVE INSPECTION OF

Magistrate's Docket No.
Case No.

Before

United States Magistrate

United States District Court for

The undersigned, being duly sworn, deposes and says:

That the affiant, _____, is a duly appointed Diversion Investigator (Special Agent) of the Drug Enforcement Administration, United States Department of Justice, assigned to the Division (Resident) Office.

That pursuant to Sections 878(2) and 880(b)(1), (2), and (3), Title 21, United States Code (U.S.C.), and Section 3, Appendix to Subpart R. Title 28, Code of Federal Regulations (CFR), your affiant is authorized to execute administrative inspection warrants for the purpose of inspecting controlled premises of persons and firms regulated under the Controlled Substance Act (CSA) (21 U.S.C. 800 et. seq.) in order to inspect, copy and verify the correctness of all records, reports and other documents of listed chemicals, tableting machines and encapsulating machines required to be kept or made under Section 830, Title 21, U.S.C. and Parts 1310 and 1313, Title 21, C.F.R.

That _____ (name of regulated person) is a regulated person under the provisions of the CSA and the Controlled Substances Import and Export Act, Title 21, U.S.C., Section 800 et. seq. and Section 900, et. seq. doing business at _____ (address of regulated person). That said place of business is a controlled premises within the meaning of Section Title 21, U.S.C. and Section 1316.02(c), Title 21, C.F.R.

That _____ (name of regulated person) is required to keep records and reports of regulated transactions involving listed chemicals, tableting machines, or encapsulating machines pursuant to 21 U.S.C. 830 and 21 C.F.R., Parts 1310 and 1313 at the controlled premises.

That the affiant has examined the files and records of the Drug Enforcement Administration and has determined that _____ (name of regulated person) was last inspected on _____ (date) and _____ (results of inspection) (or has never been inspected by the **Drug Enforcement Administration, etc.)---ADD ANY OTHER FACTS WHICH YOU WISH TO INCLUDE AS ADMINISTRATIVE PROBABLE CAUSE SUCH AS EXCESSIVE PURCHASES OR SALES, RESULTS OF STATE INSPECTIONS, ETC.**

The affiant further represents that the need for the inspection of _____ (name of regulated person) and the need for verifying the correctness of records, reports and other documents of listed chemicals, tableting machines and encapsulating machines required to be kept under the CSA result from a valid public interest in the effective enforcement of the CSA and implementing regulations.

The affiant further states that the inspection will be conducted within regular business hours, and that the Investigator's (Agent's) credentials will be presented to the regulated person and that the inspection will begin as soon as practicable after the issuance of the warrant and will be completed with reasonable promptness and that the warrant will be returned within _____ days.

The affiant further states that the inspection will extend to the inspection and copying of records, reports, invoices, and other documents of listed chemicals, tableting machines and encapsulating machines required to be kept and the inspection of all other things therein including records, files, and papers appropriate for the verification of the records, reports, and documents required to be kept under the CSA. If necessary and applicable, records and reports of transactions involving listed chemicals, tableting or encapsulating machines will be seized.

The affiant will be accompanied by one or more Investigators who are employees of the Attorney General authorized to conduct administrative inspections. A return will be made to this Magistrate (Court) upon the completion of the inspection.

The affiant further states that he/she has verified and has knowledge of the facts alleged in this affidavit, and that they are true to the best of his/her knowledge.

_____
Name of Affiant
Title of Affiant
Dug Enforcement Administration

Sworn to before me and subscribed in my presence on this _____day of, 20__.

_____
United States Magistrate

EXAMPLE OF WARRANT FOR INSPECTION –LIST I AND LIST II CHEMICAL AND TABLETING/ENCAPSULATING MACHINE HANDLERS (REGULATED PERSONS)

UNITED STATES DISTRICT COURT
FOR THE _____ OF
_____

IN THE MATTER OF
ADMINISTRATIVE INSPECTION OF
(Name and Address of
Regulated Person)

WARRANT FOR INSPECTION

To _____ (Diversion Investigator or Special Agent) and any other duly authorized investigator or agent of the Drug Enforcement Administration of the United States Department of Justice.

Application having been made and probable cause as defined by Section 880(d)(1), Title 21, United States Code (U.S.C.) having been shown by the affidavit of Diversion Investigator (or Special Agent) _____ of the Drug Enforcement Administration for an inspection of the controlled premises of _____ (name & address of registrant) and described as _____ (physical description of controlled premises) that such inspection is appropriate pursuant to Section 880, Title 21 of the U.S.C.

Therefore, pursuant to Section 880, Title 21, U.S.C., you are hereby authorized to enter the above-described premises during ordinary business hours and inspect in a reasonable manner and to a reasonable extent, including the collection of samples if necessary, all finished or unfinished listed chemicals on the premises, all pertinent equipment, records, files, reports, and documents required to be made, kept, and maintained under the provisions of the Controlled Substances Act, Title 21, U.S.C. 800 et seq., and the Controlled Substances Import and Export Act, Title 21, U.S.C. 900, et seq. for the purpose of verifying that said records, files, reports, documents, are properly kept and maintained.

You are hereby further authorized to seize from the above-described controlled premises the following records, reports, documents and files as are appropriate to the effective accomplishment of the inspection and for the purpose of copying or verifying

their correctness or that are used or intended to be used in violation of the Controlled Substances Act:

(1) _____

(2) _____

(3) _____

A prompt return shall be made by the inspecting officers to the undersigned magistrate, showing that the inspection has been completed and accounting for all property seized pursuant to this warrant, not later than _____ days from the issuance of this warrant.

_____
Magistrate
United States District Court
for the _____ of _____.
Dated:

RETURN

I received the attached administrative inspection warrant on _____.

On _____ at _____ a.m. I conducted an administrative inspection of the premises described in the warrant and I left a copy of the warrant with _____: The following records and/or samples of listed chemicals were seized pursuant to the warrant:

(either list or indicate that receipts are attached)

_____
Diversion Investigator (Special Agent)
Drug Enforcement Administration

Subscribed and sworn to and returned before me this _____ day of _____, 20__.

_____
United States Magistrate

Appendix 5243A

CONFIDENTIALITY OF ALCOHOL AND

DRUG ABUSE PATIENT RECORDS

NOTE

Subpart D, Section 2.55(b) is of particular interest to all Investigators because it requires that if, during the on-site portion of an investigation of a Narcotic Treatment Program (NTP), we want to cross-check dispensing records with patient name and address in order to verify the dispensing records, we must follow the procedures outlined in Subpart D, Section 2.54.

It is the position of the DEA that under the authority of Section 307 of the Act, our Investigators are authorized to examine all records which pertain to the receipt and disposition of controlled substances. Therefore, we will not use any special form to obtain permission to review patient records for the purpose of verifying information included on dispensing records.

If a NTP refuses to show DEA Investigators patient records, each field office may prepare and use a brief statement to the effect that no record of patient identifying information will be made or retained by or on behalf of the Investigator in connection with the investigation.

Appendix 5243B

UNDERCOVER AGENTS AND INFORMANTS

NOTE

Title 42, Chapter 1, Subchapter A, Part 2 Section 2.17 requires the following restriction on placement and the use of information as follows:

a. ***Restrictions on placement***. Except as specifically authorized by a court order granted under 2.67 of these regulations no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

b. ***Restriction on use of information***. No information obtained by an undercover agent or informant, whether or not the undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

DEA SENSITIVE
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Appendix 5257A

*FORMAT FOR SUBMISSION OF QUARTERLY REPORT

DIVERSION QUARTERLY REPORT

I. TRENDS AND INTELLIGENCE

A. Most Commonly Abused Drugs and Chemicals

List those pharmaceutical drugs and listed chemicals most abused or diverted in your geographical jurisdiction. Also indicate any drug combinations that are being used illicitly. Only list brand name versions of a controlled substance if it is specifically being abused. For diverted listed chemicals, such as pseudoephedrine tablets, it is very important to list specific brand names, such as Mini-Tabs, Revive, etc. Include intelligence about non-regulated chemicals and other non-controlled substances if patterns of abuse or diversion are seen in your area.

B. New Substances of Abuse

List any pharmaceutical drugs or chemicals that appear to be gaining in prominence as drugs of abuse or diverted chemicals and provide whatever background and intelligence in that regard as may be available.

C. Street Prices

List the current street prices for the most abused and diverted drugs and chemicals reported in Subsection A above. If known, include the dosage strength of the substances for which prices are reported. Also include current street prices of other drugs and chemicals for which there is recent intelligence.

D. Methods of Diversion

Outline the ways in which controlled substances and listed chemicals are most commonly diverted in your area. Discuss any new trends or significant changes that have occurred during the past quarter.

II. STATE LEGISLATIVE/BOARD ACTIVITY, LIAISON, AND TRAINING GIVEN

Report any pertinent information regarding these activities.

III. OTHER ISSUES

Report information/concerns regarding issues such as staffing changes, equipment requirements, training needs, etc.

IV. STATE ASSESMENT – (Include in 2nd Quarter only)

A separate assessment will be completed for each state within your jurisdiction. This section will include:

A. A summary of Sections I and II for the past year.

B. Significant activities initiated or completed within the past year directed toward upgrading the capabilities of each state and their results.

C. Additional measures needed in order to upgrade state capabilities. Include training needs, enforcement operations and changes in law, regulations and/or administrative procedures.

D. Assess the cooperation among Federal, state and local authorities. Include steps taken to improve or maintain good working relationships among these entities. Identify any significant problems in improving cooperation.

E. Discuss any factors which have enhanced or inhibited the overall effectiveness of the state diversion control problem.

F. Identify a schedule of specific goals to be taken in the next year to remedy any deficiencies noted above.

DIVERSION QUARTERLY REPORT

STATISTICAL PART

See following attachment for format.*

Appendix 5257B

WORK PLAN FORMAT

FY _____ WORK PLAN FOR THE _____ OFFICE

I. Number and Type of Current Registrants Subject to *Scheduled Investigations:*

Manufacturers:

Distributors:

Importers:

Exporters:

NTPs:

Total _____

II. Number and Type of Activities *Scheduled for Investigation* on this Work Plan:

Manufacturers:

Distributors:

Importers:

Exporters:

NTPs:

Total _____

III. Name and Grade of 1810s Assigned to your Group:

IV. List the Firms *Scheduled for Investigation* by NAME, ADDRESS, DEA NUMBER, and ACTIVITY: [NOTE: If the investigation is strictly to be an annual quota review, indicate "Quota Review" in parenthesis next to the activity.]

Appendix 5311A

**REQUIREMENT TO REPORT SUSPICIOUS ORDERS

Registrants are required to inform the Drug Enforcement Administration (DEA) of suspicious listed chemical orders in accordance with 21 CFR 1310.05(a). **DEA Field Offices are not to approve or disapprove supplier shipments of listed chemicals. The responsibility for making the decision to ship rests with the supplier**. Investigators may advise, where appropriate, that they consider a proposed transaction suspicious. If the registrant chooses to make that transaction he assumes liability for any future appropriate prosecution and/or administrative actions should he fail to take adequate independent measures to resolve the issue. An exception to this occurs when a supplier complies with a DEA Field Office's request to initiate a controlled delivery of listed chemicals.

DEA Field Offices will provide the supplier with the related registration information (i.e., whether the customer is currently registered with DEA) needed to assist the supplier in making an independent decision on whether to ship listed chemicals.

Registrants who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical or commercial use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern without determination of adequate reason. The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of listed chemicals shipped to customers of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that listed chemicals are possibly being diverted. An investigation will be conducted for possible violation of the Controlled Substances Act and regulations upon determining that the reporting registrant, as a general practice, does not voluntarily halt shipments of listed chemicals to customers involved in suspected diversion or to customers against whom previous action has been taken. In these instances, the registrant is subject to the appropriate prosecution and/or administrative action.**

** Addition

DEA SENSITIVE
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Appendix 5311B

**PERTINENT DATES REGARDING REGISTRATION AND OTHER CHEMICAL CONTROL INITIATIVES:

1. **3/24/94:** Federal Register announcement giving "temporary exemption" from registration under DCDCA requirement.

2. **4/16/94:** DCDCA became effective. Single-entity ephedrine drug products subject to record keeping and reporting requirements. Threshold for ephedrine remains at 1 kg, which equates to 48,826 dosage units of 25 mg ephedrine tablets.

3. **11/10/94:** Effective date of regulation which set the threshold for single entity ephedrine to zero. Therefore any distribution of ephedrine powder or single-entity ephedrine drug products is considered a "regulated transaction" and is subject to the record keeping and reporting requirements.

4. **6/22/95:** Final Order published in the Federal Register establishes 8/21/95 effective date for the registration requirements under the DCDCA.

5. **Extension granted to 11/13/95** for regulated person operating under "temporary exemption" provision to apply for registration.

6. **10/3/96:** Comprehensive Methamphetamine Control Act of 1996 became effective and required monthly reporting for mail order transactions to non-regulated persons, added iodine as a List II chemical for domestic transactions, placed controls on domestic transactions for hydrogen chloride gas, and modified the exemption for legal drug products which contain either ephedrine, pseudoephedrine or phenylpropanolamine. The modification requires registration, record keeping and reporting.

7. **5/12/97:** Deadline for importers, exporters and/or non- retail distributors of combination ephedrine drug products to submit registration applications and be allowed to continue importing, exporting and non-retail distributing of combination ephedrine drug products pending final action by DEA on the application. This deadline was extended to 7-12-97.

8. **12/3/97:** Deadline for importers, exporters and or non- retail distributors of pseudoephedrine and phenylpropanolamine drug products to submit a registration application and be allowed to continue such importing, exporting and non-retail distributing pending final action by DEA on the application.**

** Addition

DIVERSION INVESTIGATOR REFERENCES (HANDBOOK)

5262D Voluntary Surrender of Controlled Substances Privileges

5262E Letter Requesting Voluntary Surrender

5262F Letter of Termination

5270A ARCOS (Diversion Support Data Request)

5270B Label (Suggested Standardized Format for Report)

5271B Receipt for Samples (DEA-400)

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REFERENCE 5111A

*POLICY ON DEA REGISTRATION ACTIONS - **Completion of each assigned workload will generate the registration certificate.**

DIVERSION INVESTIGATOR/DIVERSION GS WORKLOAD:

- **Yes to Liability, DI Review** – If a **liability question** is answered "**yes**" and is less than 5 years old, workload is generated for a DI to review and investigate to determine if further action is warranted. (b)(7)(E) (b)(7)(E)
- **Address Change** – Excluding business activities A, C, M (pharmacies, practitioners, and mid-level practitioners (MLPs)).

(b)(7)(E)

- **Schedule Change** – Occurs when an increase to approved schedules is requested by registrant. For example, a registrant is approved for schedules 3, 4, & 5 and requests 2 or 2N.

(b)(7)(E)

- **Drug Codes Added** – Occurs when a request is made by registrant to add additional drug codes.

(b)(7)(E)

- **Field Investigation** – Occurs when a record is a placed Under Review/ Investigation. (b)(7)(E) (b)(7)(E)
- **New App - DEA 6 Required** – A preregistration inspection for a new application may or may not require a physical inspection (distributors, manufacturers, importers, exporters, chemical applications, and NTPs require a physical inspection). (b)(7)(E) (b)(7)(E)
- **303 InvestigationRequired** – An inspection requirement of new or renewal bulk manufacturers and schedule I importers. (b)(7)(E) (b)(7)(E)
- **Order to Show Cause (OTSC)** – If an OTSC is issued by Chief Counsel, a DI must change the status of

registration from Under Review/Investigation to OTSC, and (b)(7)(E)
(b)(7)(E)

- **Suspend Registration** - If a suspension of registration is issued by Chief Counsel, a DI must change the status of the registration from Under Review/ Investigation to Suspend Registration, (b)(7)(E)
(b)(7)(E)

REGISTRATION PROGRAM SPECIALIST (RPS) WORKLOAD:

- **NADDIS Check Required** – Run NADDIS check.

(b)(7)(E)

(b)(7)(E)

- **State/CDS License Change**– Check state medical license and controlled substance license (if applicable) with state boards.

(b)(7)(E)

- **New Last/Business Name** – Verify name change with state license.

(b)(7)(E)

- **Address Change** - A, C, M business activities (pharmacies, practitioners, and mid-level practitioners (MLPs)).

(b)(7)(E)

HQ/REGISTRATION & PROGRAM SUPPORT SECTION (ODR) WORKLOAD:

- **Military Doctors/HQ ONLY** – The Customer Response Unit (ODRR) requests for new and renewal **military registrations** are processed by HQ in conjunction with the service branch credentialing office.

- **Exempt – Verify Federal/State Entity** – ODR R reviews, processes, and verifies new and renewal requests for **fee exempt status** in accordance with 21 C.F.R. § 1301.21.

- **CSAT Verification** – ODRR, in conjunction with the Department of Health and Human Services, Center for Substance Abuse Treatment, reviews for compliance all requests for DATA-waived status for use of buprenorphine products for addiction treatment. (DATA is an abbreviation for Drug Addiction Treatment Act of 2000.)

- **303 Memorandum, Forward to ODG/Notice of Application, 303 Pending/Notice of Registration, 303 Pending** – An ODG process by which applications for bulk manufacturing are approved and published in the Federal Register.

- **HQ – Drug Codes Added** – When a registrant requests the addition of certain schedule II drug codes, ODG approval is required. (b)(7)(E)

- **Approve Chemical Application** – ODS reviews for compliance all new and renewal chemical business activity applications. Pending notification from ODS, (b)(7)(E)

- **Schedule I Researcher, Review Protocol** – The Drug and Chemical Evaluation Section (ODE) reviews for validity and completeness all schedule I research protocols.

- **Chain Pharmacy** – ODRR processes all new and renewal applications for chain pharmacies and DEA laboratories.

*Revision

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*REFERENCE 5112.2

REGISTRATION APPLICATION FORMS

Form	Form Number
New Application for Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institute or Mid-Level Practitioner	224
Renewal Application for Retail Pharmacy, Hospital/ Clinic, Practitioner, Teaching Institute or Mid-Level Practitioner	224A
Retail Pharmacy Registration Affidavit for Chain Renewal	224B
New Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter	225
Renewal Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter	225A
New Application for Narcotic Treatment Program	363
Renewal Application for Narcotic Treatment Program	363A*
**New Application for Chemical Registration	510
Renewal Application for Chemical Registration	510A**

* Revision
**Addition

REFERENCE 5113A

RESEARCH PROTOCOL

1. Investigator

i. Name and Address -

Security Police Group (91)

Colonel Robert A. Smith

Minot AFB, ND 58701

ii. Institutional Affiliation - United States Air Force

iii. Qualifications - Performs duties as the Chief, Security Police. Advises and coordinates, with the installation commander, security police functions, policies, information, capabilities, and requirements. Advises and assists all local commanders in formulating and enforcing policies and procedures for eliminating conditions which adversely affect the discipline of the base, for preventing and reducing crimes and offenses, and for maintaining discipline. Participates in actions on and off base necessary to combat conditions that are harmful to the health, welfare, and moral well-being of base personnel. Takes actions necessary to declare certain establishments off limits and to prevent or eliminate illegal or improper handling of drugs. Maintains liaison with civil and military law enforcement and investigative agencies.

2. Research Project:

i. Title of Project - Military Working Dog Heroin Detection Training

ii. Statement of Purpose - The purpose of this program is to maintain military working dog proficiency in the detection of heroin.

iii. Controlled Substances and Amount Needed - Heroin (1 gram). It is anticipated this quantity can be utilized for six months. After six months, the odor allegedly decreases significantly. Thus, each base should order one gram of heroin every six months. We do not, however, anticipate having more than one gram per heroin detection dog on hand at any one base.

iv. Description of the Research to be Conducted - During July and August 1973, the Strategic Air Command had six military working dogs (one each from Barksdale, Castle, Ellsworth, Fairchild, Grissom, and Kincheloe) undergoing a nine-week pilot program. The program consisted of not only the normal marihuana detection training but heroin detection as well. Once training was completed and the military working dog teams returned to their base of assignment, field evaluation and follow-up training were required. This was necessary in order to validate training methodology and maintain dog handler proficiency. Narcotic training aids were thus required to provide realistic field training. The one gram of heroin was made into training aids (containers that prevent dogs from getting drugs in their mouths) which were hidden. The dogs then attempted to detect the training aids. Thus, proficiency was maintained when the dogs were not being used in actual searches. The Strategic Air Command's objective is to have the

heroin detection capability at each of its host bases. This objective would thus require each base to possess heroin training aids to maintain the proficiency of the military working dog team.

v. Location Where the Training Will be Conducted - The training will be conducted at Minot AFB; however, the military working dog team could be called on to give support to another military installation or even a federal or civil law enforcement agency.

vi. Statement of Security Provisions - The Chief, Security Police, will appoint a chief custodian and at least one alternate in writing. The kennel master should be the chief custodian and the trainer-supervisor the alternate. The commander will publish special orders authorizing heroin custodians and patrol/detectors performing official duties. A patrol/detector dog team going on temporary duty for drug detection searches needs to take heroin training aids. The special orders must include a statement that the handler is designated as custodial agent for control of a specified amount of heroin to be used during the temporary duty period. When not in use, all heroin and heroin training aids must be stored in a file cabinet with locking bars or a safe.

Only designated custodians are allowed access to the storage facility, and they may remove only the number of heroin training aids actually required for their daily training. An access list will be attached to the outside of the storage cabinet or facility and issue and turn-in records will be maintained inside the storage facility. The records will indicate receipt, issue, turn-in, and destruction of heroin. When heroin is issued, the date and time of issue, destination, amount, and the signatures of the individuals issuing and receiving the heroin will be indicated. When the heroin is returned, the date, time, amount, and the signatures of individuals returning and receiving the heroin will be indicated. All heroin training aids must be turned in and secured on the same date that withdrawal was made, except when they are to be overnight on temporary duty or used for special purposes. The entire supply of heroin must be weighed at least twice a month and verified by a disinterested person who certifies the exact weight (in grams) in the weight record. The chief custodian must also sign the inventory.

A minor weight loss can be expected from small particles adhering to containers or leakage from containers damaged by the dogs. The date on which the inventory was taken and whether it was taken at the beginning or the end of the workday must also be indicated. The inventory records must be maintained at the location appearing on the registration for at least two years. When a new supply of heroin is received, it should be weighed and its weight recorded. When heroin becomes unusable, weigh it before destroying and record the exact weight in grams on AF Form 145, Certificate of Destruction. The chief custodian destroys the heroin by burning it in an incinerator.

A disinterested person in the grade of E-7 or above witnesses the destruction and signs as witnessing official on AF Form 145. The chief custodian maintains the original certificate of destruction per AFM 12-50 and sends a copy of the form to the organization or agency from which the heroin was obtained. The original is destroyed per Rule 4, Table 168-7 of AFM 12-50.

REFERENCE 5113B

EMERGENCY KITS FOR LONG TERM CARE FACILITIES

STATEMENT OF POLICY:

The placement of emergency kits containing controlled substances in non-federal registered Long Term Care Facilities (LTCF) shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures which delineate:

A. The source from which a LTCF may obtain controlled substances for emergency kits. The source of supply must be a DEA registered hospital/clinic, pharmacy or practitioner.

B. Security safeguards for each emergency kit stored in the LTCF which may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

C. Responsibility for proper control and accountability of such emergency kits within the LTCF to include the requirement that the LTCF to include the requirement that the LTCF and the providing DEA-registered hospital clinic, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of these controlled substances, plus the requirement to take periodic physical inventories.

D. The emergency medical conditions under which the controlled substances may be administered to patients in the LTCF to include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions 21 CFR 1306.11 and 21 CFR 1306.21.

E. Prohibited activities which can result in the state revocation, denial, or suspension of the privilege of having or placing emergency kits, containing controlled substances, in a LTCF.

F. This material was published in the Federal Register, Volume 45, No. 70, dated Wednesday, April 9, 1980, under the heading Rules and Regulations.

SUMMARY:

The Drug Enforcement Administration has received numerous requests from State licensing and regulatory boards, pharmaceutical associations, and professional organizations concerning this agency's policy for the use and handling of controlled substances in emergency kits for patients in Long Term Care Facilities (LTCF). The Drug Enforcement Administration has determined that an amendment to current regulations is not necessary or desirable, in that LTCF's are not controlled premises under Federal law. However, issuance of a Statement of Policy will provide the individual State licensing and regulatory boards with general guidelines under which they may, in turn, promulgate specific rules for the use and handling of controlled substances in emergency kits in Long Term Care Facilities. Additionally, this course of action should improve health care services to such patients and decrease the quantities of controlled substances which might otherwise accumulate at Long Term Care Facilities which federally are non-registered locations.

REFERENCE 5123A

DEA POLICY ON THE "GRANDFATHER CLAUSE"

At the December 14, 1978, DEA/Distributors Working Committee meeting a question was raised concerning alterations to Schedule II vaults approved under 21 CFR 1301.72(a)(2), the Grandfather Clause. Specifically, the question concerned the upgrading of some aspect of the existing security, such as the vault door, and whether this would negate the approval of the entire vault as no longer being "grandfathered" because of the new construction. Having taken many factors into consideration and keeping in mind that the intent of the security regulations is to provide effective controls to guard against theft and diversion of controlled substances, DEA has formulated the following policy:

Any alteration to the security of a Schedule II vault, constructed prior to September 1, 1971, which has been previously approved by DEA, will not automatically negate the approval of the entire vault under 21 CFR 1301.72(a)(2). However, the alteration of any aspect of security of such a vault must be such as to bring that aspect of the security into compliance with 21 CFR 1301.72(a)(3). For example, if a door of a "grandfathered" vault is replaced, it may only be replaced with a door that meets the requirements of 21 CFR 1301.72(a)(3).

To avoid any unnecessary confusion, the Drug Enforcement Administration should be contacted in accordance with 21 CFR 1301.71(d) prior to any alteration of an approved security system, since the determination of compliance with existing regulations rests with the DEA.

Voluntary upgrading of some aspect of the security of a "grandfathered" vault in no way exempts the affected firm from the provisions of 1301.71(c), which may be applied to the entire vault if security controls are deemed inadequate due to the conditions outlined in that section. This should especially be kept in mind when, after being compromised by a burglary, the vault is being altered. This will result in an overall reevaluation of the existing security by DEA.

REFERENCE 5124A

ASHP GUIDELINES FOR INSTITUTIONAL USE OF CONTROLLED SUBSTANCES

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ASHP Reports Institutional use of controlled substances

ASHP technical assistance bulletin on institutional use of controlled substances

Am J Hosp Pharm. 1987; 44:580-9

Introduction

Federal regulation of controlled substances was consolidated by the enactment of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91-513). Enforcement of the Act is generally administered by the Drug Enforcement Administration (DEA), created in 1973 as an arm of the Department of Justice. While the Food and Drug Administration (FDA) retains the authority to regulate specified habit-forming drugs, such substances may be subject to regulation by both the FDA and the DEA. DEA regulations appear in Title 21, Code of Federal Regulations, Part 1300

to the end. FDA regulations can be found in Title 21, Part 291.

Despite the comprehensiveness of the act, its amendments, and its regulations, questions concerning their application to the practice of pharmacy in hospitals, nursing homes, health maintenance organizations (HMOs), licensed residential-care facilities, and other institutional settings remain. ASHP originally approved guidelines to the regulations in 1973 in order to provide assistance to hospital pharmacists in interpreting the regulations.

The purpose of this revised document is to provide an interpretation of present legal requirements that will assist in establishing acceptable professional practices under the Controlled Substances Act (CSA). The guidelines should be used in connection with the law and regulations. They are not intended as a substitute for knowledge of the law and regulations.

Just as with patient care, accountability is the responsibility of every discipline within an institution. However, we also recognize that the pharmacist has primary responsibility for the distribution of drugs throughout the institution, and improved control methods designed to ensure accountability of the controlled substances will decrease diversion. (Surveys estimate that a minimum of one-half million dosage units of controlled substances are diverted each year from hospitals.) The pharmacist must, therefore, assume the leading role in the control of drugs that are subject to diversion and misuse.

In adopting the following guidelines, the requirements of the CSA have been interpreted to ensure compliance with the law while still allowing the institution to promote high-quality patient care in accordance with acceptable legal and professional standards. ASHP believes that these guidelines provide effective controls against diversion or misuse while, at the same time, ensuring that a proper level of professional attention to the needs of patients is maintained.

Research, laboratory procedures, and instructional uses are dealt with separately under their own heading. Methadone is also discussed separately in its own section.

A final word of caution is in order. Some state laws are more stringent than federal laws. Where this is the case, the stricter law also must be followed.

Definitions

The following selected definitions are derived from the CSA or regulations of the DEA. The definitions are presented here because they are critical to understanding the law or because of their effect upon certain operative provisions of the law and its regulations. Most of the language contained in the definitions comes directly from the CSA or from DEA regulations. However, in certain instances, language has been added to assist in the understanding and application of the definitions.

1. ***Person***. The term "person" is defined in the DEA regulations [21 CFR 1301.02(j)] but not in the CSA. It includes an individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity. It would generally include a hospital but not the hospital pharmacy.

2. ***Agent***. The term "agent" is defined in the CSA [CSA Section 102(3): 21 USC Section 802(3)] but not in the DEA regulations. It means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier or warehouseman when acting in the usual and lawful course of the carrier's or warehouseman's business.

3. ***Pharmacist***. The term "pharmacist" is defined in the DEA regulations [21 CFR 1304.02(g)] but not in the CSA. It means any pharmacist licensed by a state to dispense controlled substances and also includes any other person (e.g., pharmacist intern) authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by that state.

4. ***Practitioner***. The term "practitioner" is defined in the CSA [CSA Section 102(20); 21 USC 802(20)] but not in the DEA regulations. It means a physician, dentist, veterinarian, scientific investigator, pharmacy,

hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the practitioner practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

5. ***Individual Practitioner***. The term "individual practitioner" is defined in the DEA regulations [21 CFR 1306.02(b)] but not in the CSA. It means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice. It does not include a pharmacist, a pharmacy, or an institutional practitioner.

6. ***Institutional Practitioner***. The term "institutional practitioner" is defined in the DEA regulations [21 CFR 1306.02(c)] but not in the CSA. It means a hospital, intermediate-care facility (ICF), skilled-nursing facility (SNF), federally qualified or state-licensed health maintenance organization, or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice. It does not include individual practitioners or a pharmacy.

7. ***Dispense***. The term "dispense" is defined in the CSA [CSA Section 102(10); 21 USC 802(10)] but not in the DEA regulations. It means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for delivery.

Additionally, the term "dispenser", as defined in the CSA [CSA Section 102(10); 21 USC 802(10)] and the DEA regulations [21 CFR 1304.02(c)], means an individual practitioner, institutional practitioner, pharmacy, or pharmacist who dispense a controlled substance.

8. ***Administer***. The term "administer" is defined in the CSA [CSA Section 102(2); 21 USC 802(2)] but not in the DEA regulations. It means the direct application of a controlled substance to the body of a patient or research subject by either a practitioner (or, in his presence by his authorized agent) or, the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other route.

9. ***Prescription***. The term "prescription" is defined in the DEA regulations [21 CFR 1306.02(f)] but not in the CSA. It means an order for medication that is dispensed to or for an ultimate user but does not include an order for medication that is dispensed for immediate administration to the ultimate user. A medication order is not considered to be a prescription when it is dispensed from a pharmacy registered in the name of, and located at, an institution for an ultimate user who is a patient in the institution.

10. ***Readily Retrievable***. The term "readily retrievable" is defined in the DEA regulations [21 CFR 1304.02 (h)] but not in the CSA. It means that entries for controlled substances not maintained in separate written records are visually identifiable from other items appearing in the records (e.g., the use of asterisked or red-lined notations or, in the case of prescriptions, the letter "C" in red ink); or, where records are kept by automated data processing systems or other electronic or mechanized record-keeping systems, the system possesses the capability to produce the controlled substance records in a reasonable time.

Registration

Persons Required To Register - Forms Fees. Every person who manufactures, distributes, dispenses, conducts research with controlled substances, conducts narcotic maintenance or detoxification programs, or proposes to engage in any of these activities must obtain registration(s) unless exempted by law or DEA regulations. However, dispensers may obtain registration for a period of up to three years, as determined by DEA. Manufacturers and distributors must obtain registration annually. Registration is accomplished by use of DEA forms 224, 224a, 225, 225a, 363, and 363a, as required. The appropriate registration fee must be paid when the form is submitted to DEA.

Types of Activities. *Dispensing.* Separate registration is required for dispensing. The hospital registration covers both

inpatient and outpatient dispensing unless outpatient dispensing is operated from a detached ambulatory-care pharmacy.

Distribution. Separate registration is required for distribution of controlled substances to persons other than employees or agents of the registrant who will make final transfer to the ultimate user. If a hospital regularly orders controlled substances for other institutions, it is in effect acting as a wholesaler and must register as a distributor.

An exception to the regulations allows for occasional distribution to other registrants without registration as a distributor provided that the annual total number of dosage units of all controlled substances so distributed does not exceed 5% of the total number of dosage units of all controlled substances dispensed.

Place of Business. Separate registration is required for each principal place of business or professional practice. A principal place of business is considered to be one general physical location, If a hospital has multiple pharmacies at different addresses at which controlled substances are maintained, each location is required to register and obtain a separate DEA number.

The hospital registration covers the entire institution. Separate registration is not required for satellite or decentralized pharmacy stations in the same hospital.

Contract Pharmacy. A leased or contract pharmacy located on the premises of an existing DEA-registered hospital may operate under the hospital registration ***provided that*** the hospital assumes full responsibility for the pharmacy operations and assures full compliance with all applicable federal regulations governing the use of controlled substances. This would only be permissible if the hospital's responsibility for the operation is clearly set forth in the contract between the hospital and the contract pharmacy. Under these conditions, the pharmacy may perform all the functions of a hospital pharmacy, including the dispensing of controlled substances pursuant to medication orders.

If the hospital does not wish to assume this responsibility, DEA registration as a retail pharmacy would be required, and a prescription would be required to dispense controlled substances to hospital patients.

A registered hospital is authorized to fill outpatient prescriptions without obtaining a retail pharmacy registration, provided that this practice is allowed by state law. The same records as required of a retail pharmacy must be maintained.

Pharmacy Not Onsite. Since registration is required for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed, a pharmacy not onsite at the institution must obtain a separate registration from that of the hospital and maintain all records required for retail pharmacy.

Practitioners within the Institution. Where the hospital is the registrant, its agents and employees are exempt from registration. The exemption permits hospital personnel to carry out functions of the hospital personnel to carry out functions of the hospital with respect to controlled substances without being personally registered, provided that they are acting in the usual course of their business or employment. Thus, pharmacists do not need separate registration. (For application of this principle to unregistered interns, residents or foreign-trained physicians, see the related subheading in the "Prescriptions" section of these guidelines.) State law determines for purposes of the CSA which agents or employees are authorized to have access to or responsibility for controlled substances. Hospitals should have written policies that interpret state law and assign staff responsibility accordingly.

Termination of Registration

1. The Administrator of DEA has authority under the Controlled Substances Act to suspend or revoke registration where the registrant

a. Has materially falsified any application filed pursuant to or required by Title II or III of the CSA,

b. Has been convicted of a felony under the CSA, or a felony under any other federal or state laws relating to controlled substances, or

c. Has had his state license or registration suspended, revoked, or denied and is no longer authorized by state law to manufacture, distribute, or dispense controlled substances, or has had the suspension, revocation, or denial of his registration recommended by competent state authority.

The registration of a practitioner may now be denied if it is determined that such registration would be "inconsistent with the public interest." In determining the public interest, DEA may consider (1) the recommendations of the appropriate state licensing board or professional disciplinary authority, (2) the experience of the applicant in dispensing or conducting research with respect to controlled substances, (3) the applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances, (4) compliance with applicable state, federal, or local laws pertaining to controlled substances, and (5) such other conduct that may threaten the public-health safety.

These considerations along with the three existing grounds noted above also allow for the input of competent state authority recommending the suspension, revocation, or denial of a registration.

These factors expand DEA's authority to deal with problems of diversion at the practitioner level. Registrants have recourse to established administrative procedures under Section 1031.45 of the DEA regulations to ensure due process of law prior to suspension or revocation of registration.

2. The registration of any person terminates if and when such person dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the certificate of registration. The DEA must be promptly notified of the reason for termination. Where there is a change of name or address, the registrant is required to report this change.

3. Registration may not be assigned nor transferred except in compliance with conditions designated in writing by DEA.

Records and Inventory

General. Every registrant under the act must maintain, on a current basis, complete and accurate records of the receipt and disposition of all controlled substances. The records must include the following information for each controlled substance:

1. The name of the substance.

2. A description of each product in finished form (e.g., 10-mg tablet or 10-mg per mL concentration) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-mL vial).

3. The number of commercial containers of each such finished form received from other persons, including the date of receipt and number of containers in each shipment and the name, address, and registration number of the person from whom the containers were received.

4. The number of units or volume of products in finished form dispensed, including the name of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.

5. The number of units or volume of products in finished form and/or commercial containers disposed of in any other manner by the registrant, including the date of disposal and the quantity of the substance in finished form disposed.

All records must be kept for a two-year period. Records of Schedule I or II substances must be maintained separately from all other records of the registrant, while those records of substances listed in Schedules III, IV, or V need not be kept separately, provided that the information is "readily retrievable."

Inventory. To establish a starting point, the law requires a physical inventory of all controlled substances on the effective date of the act or when the registrant first engages in business. A person registered to dispense controlled substances shall include in his inventory for each controlled substance in finished form, the name and finished form of the substances (e.g., Pentobarbital 100-mg tablets) and the number of containers and units/volume in each container; for substances that are damaged, outdated, awaiting disposal, being held for quality control, or maintained for extemporaneous compounding, the name, quantity, and reason for the continued maintenance of the substance are required. In determining units in an open commercial container, an exact count or measure of Schedules I and II shall be made; an estimated count of Schedules III, IV, and V shall be made unless the container holds more than 1000 tablets or capsules, in which case an exact count will be made. An inventory must be taken every two years thereafter. Subsequent inventories may be prepared on the registrant's regular general physical inventory date if it does not vary more than six months from the date that would otherwise apply. For this biennial inventory and any other DEA-required inventories, the institution must record on that inventory if it was taken at the beginning or closing of that day's business and should note the name, initials, or signature of the person or persons taking that inventory. If the registrant elects to take the biennial inventory on his regular general physical inventory date or another fixed date, DEA must be notified of the election and of the date on which the biennial inventory will be taken. The law specifically states that a perpetual inventory is not required. Nor does the law require periodic "audits." However, these procedures may be desirable in selected high-risk areas or where diversion is suspected.

Records of Receipts. ***Order Forms.*** In order to purchase substances in Schedules I or II, the law requires an official order form, DEA Form 222c. After a substance purchased through Form 222c has been received, Copy 3 of the order form serves the requirement of a "separate" record and must be filed separately. No further record is needed. Order forms may be obtained only by registered persons. If the hospital pharmacist prepared and signed the registration application, he may obtain order forms on his own signature. If the hospital administrator signed the application for registration, the administrator should execute a power of attorney (to be retained on file) for DEA order forms to permit the pharmacist to obtain and execute order forms on his behalf. In a large institution it may be desirable to designate more than one pharmacist on this power of attorney.

The order form is prepared in triplicate. The purchaser submits Copy 1 and Copy 2 of the form to the supplier and retains Copy 3 in his own files to be used to record the quantity and the date on which the controlled substances are received. As stated above, the order forms must be maintained separately from all other records of the registrant.

Purchase Orders, Invoices, and Other Forms. For substances in Schedules III, IV, or V, purchase orders, invoices, packing slips, and other business forms may serve as records of receipt if accurately reconciled against the drugs actually received. If non-controlled substances are listed on the same business form, controlled substances should be made readily identifiable by use of a red line, asterisk, or some other annotation that facilitates visual identification to assist in meeting the requirement that the records be readily retrievable. An alternative to using business forms as the record of receipt is the maintenance of a log book or inventory-card system. However, in order to meet the retrievability requirements of the regulations, a single system (not both) should be used.

Computer Records. If a computer or other automated data processing equipment is used, separate written records, as described above, are not required for controlled substances in any schedule, provided that DEA order forms are maintained in accordance with DEA regulations, specific information in the data bank can be retrieved within a reasonable period of time, and such information is retained for a period of two years and includes all of the information required by DEA as described earlier in this section under the "General" subheading.

Patient Records. ***Administration Records.*** The basic records of disposition within the hospital are patient medical records. Medical records contain physicians' original drug orders authorizing the dispensing and administration of medications. It is not necessary for the physician to sign and write his DEA registration number on each order for a controlled substance. However, his registration number should be kept on file in the pharmacy. If it is not on file in the pharmacy, the physician should enter his number in the medical record.

If the prescriber is an unregistered intern, resident, or foreign-trained physician in the employ of the institution, he may use the hospital registration number in lieu of individual registration. In order to write outpatient prescription orders for controlled substances, he must be assigned a suffix code in addition to the institution's number. (See the related subsection in the section on Prescriptions.)

The medical record also contains nurses' entries indicating that drugs were administered to patients. This information is contained either in the "nursing notes" section, in progress reports, or on a medication treatment form.

Working solely from the medical record can be burdensome, especially with respect to reconciliation of medications issued and those administered. In addition, records for Schedule II substances must be maintained separately and those for Schedules III, IV, or V substances must be readily retrievable. Hence, it is desirable to maintain a derivative record from the medical record for control purposes with minimum interference to patient care. Adequate accountability does not require the use of any specific system or form. One type of effective and convenient-to-maintain record is a medication administration record (MAR). Variations of this record that achieve the same purpose may also be used. This record constitutes a separate section in the patient's chart apart from the physicians' progress notes and nurses' notes.

For record-keeping purposes, the MAR has a number of advantages. Most hospitals already use, in one form or another, a medication administration record that contains necessary information for patient-care purposes. Use of this record for control purposes eliminates the need to rewrite the same information on another record form, resulting in a significant savings of nursing and pharmacy time. If diversion does occur, the chances of discovery are increased, since all clinical personnel are using the same records in caring for patients.

A second method of record keeping is a derivative record maintained by computer. Records of disposition used to provide information for computers or other automated data processing equipment need not conform to any particular format, provided that all required information (previously listed) is put into the system. The system must be designed so that records of Schedule II controlled substances can be retrievable separately from Schedule III, IV, and V records. As with other record-keeping systems, computer records of disposition may be reconciled by comparing the quantities of controlled substances used and remaining against the quantities received.

A third form of record that could be used is the "certificate of disposition" or "proof-of-use" sheet. The same basic information is necessary as with other methods. Each time a dost of a controlled substance is administered, hospital personnel are required to make an entry on the form. All controlled substances recorded as administered are reconciled against the physical inventory. One difficulty with this system is that these records do not contain the physicians' drug orders, complicating verification that drugs administered were in fact ordered. Patient charts are primary-care records and are in constant use by physicians, nurses, pharmacists, and other personnel. Proof-of-use sheets are not used as often and, in fact, for some seldom-used drugs, may not be used for many days. Thus, falsification of proof-of-use sheets may go undetected for longer periods of time than do primary patient records such as the MAR. DEA generally does not consider patient profiles to be acceptable documents for record keeping, since required information is often not included.

Outpatient Dispensing. Prescriptions for outpatients (see related section under "Prescriptions") must be filed separately if for substances in Schedules I or II. Prescriptions for Schedules III, IV, or V substances may be kept with other prescriptions if they are stamped in red ink, in the lower right-hand corner, with a letter "C" that is no smaller than one-inch high.

Transfers between Pharmacies. The transfer of original prescription information for Schedule III-V controlled substances for the purpose of refill dispensing is permissible between pharmacies on a one-time basis provided that

1. The transfer is communicated directly between two licensed pharmacists;

2. The transferring pharmacist records "void" on the invalidated prescription and records the name, address, and DEA number of the pharmacy to which it was transferred, the name of the pharmacist receiving the information, the date of the transfer, and the pharmacist transferring the information;

3. The receiving pharmacist reduces to writing the word "transfer" on the face of the prescription; the date of issuance of the original prescription; the original number of refills authorized; the date of original dispensing; the number of valid refills remaining; the date of the last refill; the name, address, DEA number, and original prescription number of the pharmacy from which it was transferred; and the name of the transferring pharmacist;

4. Both pharmacies maintain the required records for two years from the date of the last refill; and

5. Pharmacies electronically accessing the same prescription record satisfy all information requirements of a manual mode of prescription transferral.

This procedure is permissible only if allowable under existing state or other applicable law.

Waste and Disposal. Controlled substances may be disposed of other than by administration to a patient. An ampul might be dropped and broken, the patient may refuse a dose of medication, the medication may become contaminated or decomposed, or the prescriber may cancel an order. Whenever possible, all such medications should be returned to the pharmacy for final disposition.

The DEA regulations require that a registrant who desires or is required to dispose of controlled substances in his possession must request authority and disposal instructions from the Special Agent in Charge of the DEA Office in the area where the registrant is located. If an institution is registered only as a dispenser of controlled substances and is not required to make periodic reports to DEA, then the request for disposal is made on DEA Form 41. The registrant must list the controlled substances for disposal and submit the form in triplicate to the Special Agent in Charge. The Special Agent in Charge shall authorize disposal by

1. Transferral to a person registered under the act and authorized to possess the substance,

2. Delivery to an agent of the DEA or to the nearest office of DEA,

3. Destruction in the presence of an agent of DEA or other authorized person.

4. Other means determined by the Special Agent in Charge that ensure that the controlled substance does not become available to unauthorized persons, or

5. Under specified conditions, by an annual one-time disposal without a witness from DEA. Contact the local DEA office for details. In the event that the hospital is required to regularly dispose of controlled substances, upon written request from the registrant the Special Agent in Charge may authorize the hospital to dispose of those substances without prior authorization on the condition that records are maintained of such disposals and periodic reports are filed with DEA summarizing those disposals. Conditions may be placed on the disposal, such as the method of destruction and the frequency and details of the periodic reports. These requirements do not affect or alter any procedures established by the state in which the institution is registered. To ensure that the hospital is in compliance with state laws and regulations regarding disposal, the registrant should contact the appropriate state regulatory board before proceeding.

In lieu of disposal by DEA, authority has been granted for disposal of unwanted, outdated, controlled substances to agents of the individual states' narcotics control authorities and professional licensing board inspectors or investigators. Contact should be made with DEA or state boards to determine if the state in which the hospital is located performs these destructions.

Prescriptions

General. Substances in Schedules II, III, or IV (and, in some states, V) may be dispensed or administered only pursuant to a written or oral prescription from a prescribing individual practitioner or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user. All such orders, or direct copies thereof, should be received and interpreted by the pharmacist before administration. The practitioner's order is the keystone to any control system. Without it, the entire system is rendered useless since bogus administration records could be entered as the means for diverting controlled substances. Administration of emergency medications from floor stock or emergency supplies should be provided for in written policies and procedures. In a small hospital or nursing home without onsite pharmaceutical services, all controlled substances must be dispensed pursuant to prescriptions.

Outpatients. Controlled substances may not be dispensed to outpatients for home use unless all the prescription requirements of the law are met. Prescriptions for controlled substances in all schedules must include the name and strength of the drug to be dispensed, the name and address of the patient, and the name, address, and registration number of the prescriber. Further, they must be dated as of, and signed on, the day they are issued.

Persons Entitled To Dispense Prescriptions. A prescription for controlled substances may be dispensed only by a pharmacist acting in the usual course of his professional practice. The pharmacist must be either registered or employed in a registered pharmacy or registered institutional practitioner.

Schedules II, III, IV, and V. ***Requirement of Prescription.*** A pharmacist may dispense a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner except that, in the case of an emergency situation, a pharmacist may dispense a controlled substance listed in Schedule II upon oral authorization provided that

1. The quantity prescribed and dispensed is limited to the amount needed to treat the patient during the emergency period.

2. The prescription is immediately reduced to writing by the pharmacist,

3. The pharmacist makes a reasonable effort to determine that the oral authorization came from a registered individual practitioner, and

4. The prescribing individual practitioner delivers or mails a written prescription to the pharmacist within 72 hours. Upon receipt, the pharmacist should attach the written prescription to the oral emergency prescription. If a written prescription is not received, the pharmacist should notify the nearest office of the DEA or risk forfeiture of the authority to dispense without a written prescription conferred by the regulations.

Controlled substances listed in Schedules III-V, however, may be dispensed pursuant to either a written prescription or a telephonic order.

Refills. Refills of prescriptions for Schedule II controlled substances are prohibited, but partial refills are permitted if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and a notation is made of the quantity supplied on the face of the written prescription. However, the remaining portion may be filled only within the 72-hour period. If the remaining portion is not filled within the 72-hour period, the pharmacist must notify the prescribing individual practitioner. Prescriptions for Schedule II controlled substances written for patients in long-term-care facilities may be refilled in partial quantities, except that such prescriptions shall not exceed 60 days from the issue date.

Refills for Schedules III or IV controlled substances may not be made more than six months after the date of issue and may not be refilled more than five times.

Refills for Schedules III-V controlled substances may be made only if expressly authorized by the prescribing individual practitioner on the prescription.

Interns, Residents, or Foreign-Trained Physicians. Interns, residents, or foreign-trained physicians on a hospital staff who do not have their own registration numbers may use the number of the hospital plus a suffix code assigned to each by the hospital.

The use of the hospital registration in lieu of personal registration is contingent upon the practitioner's being authorized under the law of the jurisdiction to prescribe, dispense, and administer drugs. The hospital must also verify the practitioner's status under local law.

The practitioner must be authorized by the hospital to use its number to dispense or prescribe, and the practitioner's activities must be within the scope of employment and in the usual course of professional practice.

A current list of the internal suffix codes must be kept by the hospital and made available to other registrants and law enforcement agencies upon request for the purpose of verifying authority to prescribe. The list must identify each practitioner with the appropriate individual suffix code.

Labeling

Intrahospital Distribution. Controlled substances, as with all medications, must be properly labeled before distribution within the institution. In addition to the usual identifying information, the controlled status of such products may be indicated on the label by the use of a symbol or color code. In this matter, nursing personnel will know which items need identification in charting.

Outpatient Dispensing. The labeling for all schedules of controlled substances dispensed to outpatients must contain the date of filling, the institution's name and address, the serial number of the prescription, name of patient and prescriber, directions for use, and the statement "Caution: Federal Law prohibits transfer of this drug to any person other than the patient for whom it was prescribed."

Offsite Pharmacy Services. The DEA regulations provide an exception to the labeling requirements in cases where controlled substances are prescribed for administration to an institutionalized patient and dispensed from a separately registered pharmacy serving the institution. The controlled substance must not be in the possession of the patient, appropriate safeguards and records must be maintained, and the labeling system used must be adequate to identify the supplier, the product, and the patient and to set forth proper directions for use. No more than a seven-day supply of Schedule II controlled substances or, in the case of Schedules III and IV, no more than a 34-day supply or 100 dosage units, whichever is less, may be dispensed at one time under this labeling system.

Security

General. Only personnel authorized by written policies of the institution may have access to medication storage areas and supplies.

Central Storage Areas. Controlled substances in the pharmacy or other central storage areas should be stored in a securely locked, substantially constructed cabinet, vault, closet, or similar enclosure. As an alternative, controlled substances, except Schedule I drugs, may be dispensed throughout the stock of noncontrolled substances in such a manner as to obstruct theft or diversion. Controlled substances of any schedule that require refrigeration should be stored in a refrigerator within the locked storage room where other controlled substances are maintained, or within a lock box that has been secured to the inside of the refrigerator within the nursing station, or in a locked refrigerator in the pharmacy or nursing station.

Other Hospital Areas. ***Nursing Units.*** When controlled substances kept as floor stock are stored on nursing units for extended periods of time, they should be in a securely locked, substantially constructed cabinet.

Carts. Delivery carts containing controlled substances should be locked if they are used for storage or left unattended at nursing units. Unit dose carts do not have to be locked if they contain less than a 24-hour supply of medications and are attended by authorized hospital personnel.

If a cart containing controlled substances is delivered to the nursing unit and serves as a storage facility, it must have a secure lock.

Operating or Delivery Room. There are a number of solutions for the control and security of controlled substances routinely used in the operating room. Three possibilities follow.

1. Use the same physical security as at nurses' stations for floor stock and the same beginning- and end-of-shift inventories; use the same type of record of administration as used for floor stock. (Record identifies drug, physician or anesthetist, date, adequate patient identification, notation made in patient chart as to medications received, date, specific operating room.)

2. Maintain no stocks of controlled substances in the operating room, but have the anesthetist bring the assigned stocks for each operation, delivery, or other procedure. The anesthetist would maintain the stock and all appropriate records for controlled substances, and the stock would be replenished on an as needed basis.

3. Locate a "pharmacy annex" in the immediate area of the operating rooms. This annex could stock those supplies that would routinely be necessary to the anesthesiologist. Medication could be signed out to the individual anesthesiologist before each operation or for all procedures scheduled for a given date.

Emergency Vehicles and/or Mobile Dispensaries. Controlled substances needed for emergency vehicles may be supplied in small quantities as an extension of the hospital if the service is operated by the hospital; if it is a private ambulance service, small quantities may be supplied based upon a written agreement with one hospital to supply the medications for the emergency kit. In either of these two instances, the hospital is responsible for the controlled substances supplied.

As an alternative, the emergency vehicle may acquire controlled substances under the registration of a consulting practitioner who must be registered at the central office location of the owner or operator of the emergency service.

The hospital must develop record-keeping and security measures that will minimize diversion potential. When the hospital supplies controlled substances to a private service, no more than one kit per vehicle will be supplied; subsequent distributions will be on a replacement basis only.

The Special Agent in Charge may supply written approval of emergency vehicles. A written request outlining scope of operations, proposed security, and record keeping is required of the registrant by the Special Agent in Charge. If adequate, written approval will be granted.

Proper state authorization for either method is required; if the operation is disapproved by the state, DEA approval will not be given.

If diversion does occur, the Special Agent in Charge will determine if additional safeguards are needed or if DEA approval is to be withdrawn. In either case, the registrant will be notified in writing.

Placement of emergency kits containing controlled substances in (unregistered) long-term-care facilities. The placement of emergency kits containing controlled substances in non-federally registered long-term-care facilities is in compliance with CSA if the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures for their use, security, record keeping, and accountability.

The individual state authorities should be contacted to determine if such procedure is permissible in the state in which the institution is located.

Employee Screening (Nonpractitioners). Registrants should screen employees who have access to controlled substances for any prior convictions or for histories of drug abuse, and employees with knowledge of illicit drug diversion by fellow employees are responsible for reporting the illicit activity to the employer.

Research, Laboratory Procedures, and Instructional Uses

Registration. ***General.*** Persons engaged in research, laboratory procedures, or instructional uses with controlled substances are required to register under the Controlled Substances Act. A person already registered to dispense controlled substances in Schedules II-V is authorized by virtue of such registration to use controlled substances in research and related activities, including preclinical and clinical investigations of drugs, laboratory procedures, and instructional use without separate registration, provided that they are otherwise permitted to do so under applicable federal and state laws. Methadone research or dispensing is not authorized for persons registered to dispense controlled substances unless the general requirements discussed in the Methadone section of these guidelines are complied with. A hospital analytical laboratory conducting chemical analysis for the hospital is not required to have a separate registration; however, if that laboratory will conduct analysis for other institutions, a separate registration will be

required. Such analysis activities include urinalysis for narcotic treatment programs, chemical analysis for the coroner, or other work that is independent of the hospital.

Use of Schedule I Drugs. The conduct of research with controlled substances listed in Schedule I requires separate registration. Hospital registrations do not suffice. Registration for Schedule I research requires submission of a research protocol with the application describing each research project. Research will be authorized only with those substances listed in an approved research protocol.

Separate Locations. If research or related activities are conducted with controlled substances in more than one principal place of business or professional practice at one general physical location, a separate registration is required for each principal place of business or professional practice.

Records and Reports. ***General Requirement.*** Each person registered or authorized to conduct research or related activities with controlled substances is required to keep records. A registered person using a controlled substance, in preclinical research or in teaching at a registered establishment, does not have to maintain separate records if the establishment maintains records. The registered person must notify DEA of the name, address, and registration number of the establishment maintaining the records. Notice to DEA is given in the form of an attachment to the application for registration or re-registration.

Inventory. The inventory requirements of a person registered to dispense or authorized to conduct research or related activities with controlled substances shall include the same information required for the inventories of dispensers (see Records and Inventory section).

Receipt and Dispensing. Receipt and dispensing records must be kept by the registrant. If the registrant is a hospital, the required records should be kept by the pharmacist in the same manner as records for other controlled substances (Records and Inventory section). It should be noted that records for substances *used* in chemical analysis or other laboratory work are not required. However, records must be maintained of controlled substances transferred to the laboratory and those distributed or destroyed by the laboratory.

Research. When research is conducted on human subjects, informed consent forms signed by the patient are required and must be retained in the patient's records.

Security. In a registered institution, the pharmacist should be the custodian of all controlled substances. Controlled substances may be dispensed only to or for authorized investigators, laboratory personnel, or instructors. The pharmacist should be responsible for the security of controlled substances used in research and related activities.

Methadone

Registration and Approval. ***General.*** The use of methadone in an institution is controlled jointly under FDA and DEA regulations. The FDA methadone regulations [21 CFR 291.50 and 291.505] provide for approved uses of methadone in a hospital and in a methadone treatment program. A hospital may be approved to dispense methadone for detoxification and temporary maintenance of inpatients. If a hospital desires to establish a methadone treatment program for detoxification and maintenance of drug-dependent persons, separate approval is required. In either case, the hospital must be registered with DEA to dispense Schedule II controlled substances in addition to receiving approval under the FDA methadone regulations.

Hospital Use of Methadone. In order for a hospital pharmacy to lawfully receive or dispense methadone for its approved hospital use for detoxification, the hospital must submit Form FD2636, "Hospital Request for Methadone for Detoxification and Temporary Maintenance Treatment." The application must be approved by the responsible state authority and the FDA. The form requires detailed information about the hospital, including the name of the pharmacist responsible for receiving and securing supplies of methadone.

Methadone Treatment Programs. To obtain approval to establish a methadone treatment program, the sponsor must submit Form FD 2632, "Application for Approval of Use of Methadone in a Treatment Program." The application must receive the approval of the responsible state authority and the FDA with the concurrence of DEA. In order to ensure that each participating physician in a methadone treatment program is aware of his professional and administrative

responsibilities, the FDA requires that Form FD 2633, "Medical Responsibility Statement for Use of Methadone in a Treatment Program," be completed by each physician licensed to dispense or administer methadone in an approved program. These statements must accompany the program application. All patients in the program are required to give their consent for treatment by signing Form FD 2635, "Consent for Methadone Treatment."

Dispensing. Only a licensed practitioner or an agent of the practitioner may administer or dispense methadone. The agent must be a pharmacist, registered nurse, licensed practical nurse, or other health-care professional authorized by federal and state law to administer or dispense narcotic drugs. Methadone may be dispensed or administered only in oral form when used in a treatment program. Take-home medication must be labeled in accordance with the requirements covered under Labeling-Outpatient Dispensing and must also include the treatment center's address and telephone number. If in liquid form, methadone should be non-sweetened and contain a preservative to discourage refrigeration.

Records and Reports. ***Hospital Use of Methadone.*** All records must be kept in compliance with the DEA requirements for Schedules I and II controlled substances. Hospitals must also maintain accurate records traceable to specific patients and they must include dates, quantity, and batch or code marks of the drug dispensed. Methadone records must be retained for a three-year period instead of the two-year period required for other controlled substances. The hospital does not have to submit a detailed annual report.

Methadone Treatment Program. All records must be kept in compliance with the DEA requirement for Schedules I and II controlled substances. The FDA methadone regulations require also that there be accurate records traceable to specific patients, and they must include dates, quantify, and batch or code marks of the drug dispensed. The record retention period for methadone records is three years. The methadone treatment program is required to file an annual report with the responsible state authority and the FDA. The content of the annual report is detailed in Form FD 2634, "Annual Report for Treatment Program Using Methadone."

Security. The FDA regulations require that the security for methadone treatment programs must be in compliance with DEA guidelines prior to final FDA approval.

Approved by the ASHP Board of Directors, November 19, 1986. Developed by the ASHP Council on Legal and Public Affairs. Supersedes the previous version, which was approved on November 19, 1973.

A letter from DEA Administrator John C. Lawn relating to this subject appears in the appendix to this document.

Appendix--DEA Comment

Dear ASHP Member:

Our Nation's commitment to combating drug abuse has never been more important than it is now. A crucial element of this task is the effective control of scheduled drugs in the institutional setting. While the implementation of Federal regulations designed to accomplish this objective may often require extra effort on your part, they are nonetheless vital if we are to be successful.

The guidelines that appear here have been developed by the American Society of Hospital Pharmacists and the Drug Enforcement Administration. Every effort has been made to accurately reflect your responsibilities under the Controlled Substances Act and its implementing regulations. The final word, however, remains with the law and the regulations.

Your compliance with these guidelines will contribute greatly to our overall mission of eliminating drug abuse in this country.

Sincerely,

John C. Lawn

Administrator

REFERENCE 5161A

DRUG DESTRUCTION LETTER

Dear (Registrant):

We have reviewed the attached DEA Form 41 submitted by you concerning disposal of controlled substances.

After reviewing the type and quantity of controlled substances you wish to destroy, the following instructions are provided concerning the disposal of this material:

( ) *You are authorized to destroy all the drugs as listed on the DEA Form 41, provided that the disposal is conducted by at least two persons who are either licensed physician-, pharmacists or nurses, or state or local law enforcement officers, or any combination thereof. Every effort should be made to assure that one of the witnesses is a state or local law enforcement officer. The manner and date of disposal, along with the names and occupations of the persons doing the destruction, must be clearly stated on the DEA Form 41. A copy of the completed form must be sent to our office. Please retain a copy for your records.

( ) *You are authorized to destroy only the controlled substances checked (X) by our office in accordance with the above instructions. List the remaining items on a separate DEA Form 41, if not already on a separate DEA Form 41, and send them to our office for disposal. You must also send a copy of the completed DEA Form 41 indicating that the items authorized to be destroyed by you have, in fact, been destroyed.

( ) Send the controlled substances listed on the DEA Form 41 directly to our office for disposal. If the drugs are shipped by the U.S. Postal Service, you must use certified mail, return receipt requested. Please note the instructions for shipping on the DEA Form 41.

( ) Please hold the drugs until arrangements can be made for an Investigator from our office to witness the destruction at your site.

*Prior to implementing your method of destruction, we suggest you contact your local environmental authorities to ascertain that hazards are not associated with your method of destruction.

Sincerely,

/s/

Special Agent in Charge

REFERENCE 5222A

REPORTS PROCESSING

File Number	Routing and Transmittal Slip Office Symbols	Diversion and Complaint Investigations (Copy No. 6 of DEA Form 6)
XX-95-2XX	1) (b)(7)(E)	Nonactionable, or Letter of Admonition only, in-depth diversion investigations which include ARCOS reporting information
	1) (b)(7)(E)	Nonactionable, or Letter of Admonition only, in-depth diversion investigations which include non-ARCOS reporting information.
	1) (b)(7)(E)	Actionable (hearing or stronger action), in-depth diversion investigations.
	1) Appropriate OD	In-depth diversion

		Office Symbol investigation, in which additional action is requested from other OD sections (i.e., ARCOS package, registration change, ODOC, etc.), write the specific action requested in the report in the "re:" section and include the office symbol.
	1) (b)(7)(E)	Complaint investigation.

File Number	Routing and Transmittal Slip Office Symbols	Surrender of Registration
		Surrender of Registration
XX-95-(b)(7)(E) (practitioner)	1) (b)(7)(E)	Code 7-surrender of registration, practitioner or
XX-95-(b)(7)(E) (nonpractitioner)		nonpractitioner. Use only if the surrender is strictly voluntary without prejudice and registrant can re-register at own discretion. Input Code 7 in accordance with Section S262.7. Attachments (originals): DEA Form 104 (check box 2), Registration Certificate; Order Form Deletion Sheet; any other

		documents. This document must be maintained on file.
XX-95-(b)(7)	1) (b)(7)(E)	Code 1-surrender of registration, practitioner, or nonpractitioner
XX-95 (b)(7)(E) (practitioner)	1) (b)(7)(E)	If the surrender was prompted by Federal or state administrative or judicial action, or was in lieu of Federal or State administrative or judicial action. Attempts to re-register would trigger a DEA review. Attachments: DEA Form 104 (check box 1); voided DEA Form 223; sufficient legal documentation to support Code 1. DEA 6 must include a request for Code 1. The Code 1 can be input by the field office.
	1) (b)(7)(E)	Code R. practitioner or nonpractitioner. If a registrant is restricted to certain schedules, a DEA 6 will be prepared requesting a Code R. If the restriction was

the result of Federal or state administrative or judicial action, supporting documentation must accompany the Report of Investigation. The Code R can be input by the field office.

File Number	Routing and Transmittal Slip Office Symbols	Reporting of Drug Thefts
XX-95-(b)(7)(E) XX-95-(b)(7)(E)	1) (b)(7)(E)	Drug Thefts-Note: If the theft by its nature is significant or OD requires a Report of Investigation, a teletype will be directed immediately to (b)(7)(E) Attachments: DEA 106 (copy); any other documentation. Note: No changes on the routine distribution of DEA 106.

File Number	Routing and Transmittal Slip Office Symbols	Approval of Applications for Registration
XX 95 (b)(7)(E)	1) (b)(7)(E)	Pre-Registrant. This file number issued for interim

		reports pertaining to current pre-registration investigations. Note: this file will not be used for approval, withdrawal, denial, or modification of registrations.
XX-95-(b)(7)	1) (b)(7)(E)	Approval of Application, DEA 225 and 225a. Attachments: Application for Registration (original); any other documentation. Last paragraph must include clear-cut recommendation that the application be approved. Any modifications of the original application must be listed under remarks of the Routing and Transmittal Slip. Approval will be input by (b)(7)(E)

File Number	Routing and Transmittal Slip Office Symbols	Withdrawal of Applications
XX-95-(b)(7)(E)	1) (b)(7)(E)	Approval of Application, DEA 224 and 224a. Attachments (originals): Application for Registration; any other

		documentation. Approvals will be input by field offices. Original applications will be retained in the field office until all actions in that batch have been completed, the entire batch of original applications will be forwarded to ODOC for filing.
XX-95 (b)(7)(E) Crossfile:	1) (b)(7)(E)	All approvals for the use Etorphine/Diprenorphine. Also, enter Etorphine/Diprenorphine on the Routing and Transmittal Slip.
XX-95 (b)(7)(E)	1) (b)(7)(E)	Approval of Application, Narcotic Treatment Program (DEA 363 and 363a).
		Attachments: Original Application for Registration; any other documentation. Last paragraph must include a clear cut recommendation that the application be approved. Any modification of the original application must be listed under remarks on the Routing

File Number	Routing and Transmittal Slip Office Symbols	Withdrawal of Applications
		and Transmittal Slip. Approvals shall be entered by ODO.
XX-95(b)(7)(E)	1) (b)(7)(E)	Withdrawal of Application, DEA 224 and 224a. Attachments Application for Registration (original). Last sentence must state the applicant requests that application be withdrawn. This file is only used for voluntary withdrawals. Withdrawal of the application shall be input by the field office.
XX-95(b)(7)(E)	1) (b)(7)(E)	Withdrawal of Application, DEA 225, 225a, 363, and 363a. Attachments: Application for Registration (original); any other documentation. Last sentence must state the applicant requests that application be withdrawn. This file is only used for voluntary withdrawals.

Withdrawal of the application shall be input by the field office.

Routing and Transmittal Slip

File Number	Office Symbols	Referrals To/From
XX-95 (b)(7)(E)	1) (b)(7)(E)	Referrals to or from other agencies both Federal and local.
XX-95		
XX-95		
XX-95		
XX-95		
XX-95		Attachments
XX-95		Copy of any documentation received from or forwarded to other agency.
XX-95		
XX-95		DEA 6 must be indexed and specific as to identification of subject.
XX-95		
XX-95		
XX 95		
XX-95		
XX-95		
XX-95 (b)(7)(E)		
XX 95		
XX-95		
XX-95		
XX-95		
XX 95		
XX-95		

XX 95 (b)(7)(E)

XX-95

XX 95

XX-95

XX-95

XX-95

1) (b)(7)(E) Excessive purchases.

Attachments: Any documentation.

Routing and Transmittal Slip

File Number	Office Symbols	Modification of Registration
XX-95 (b)(7)(E)	1) (b)(7)(E)	Modification of registration. This file number is to be used for changing practitioner registrant's address, drug schedules add schedules, name changes (not ownership), or other changes where the registrant maintains the same DEA registration, and a pre-registration investigation or a separate application for registration is not required. Attachment: Request from registrant; any other documentation. Modifications shall be accomplished in accordance with Subsection

All other reports	1) (b)(7)(E)	All reports not specifically covered in this Reference Book will be forwarded to (b)(7)(E) unless other procedures are applicable (i.e., XX-95-(b)(7)(E) Authentic Ballistics Samples-Registrants, etc.) For Chemical Reports Processing, see the Chemical Guidelines.

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REFERENCE 5223A

MEMORANDUM OF UNDERSTANDING

Between the

DRUG ENFORCEMENT ADMINISTRATION

and the

FOOD AND DRUG ADMINISTRATION

I. ***Purpose.*** This Memorandum of Understanding outlines the working arrangement. between the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) regarding the approval or denial procedures for narcotic treatment programs (hereinafter referred to as treatment programs) and the cooperative efforts of both agencies in any denial or revocation of approval by FDA, or denial or revocation of registration by DEA initiated against these treatment programs. Treatment programs under the agreement include all programs that use any narcotic drug for the treatment of narcotic addiction.

II. ***Background.*** The methadone regulation in Sec. 310.505 (21 CFR 310.505) requires that prior approval by FDA be obtained before a treatment program may receive shipments of methadone. Before FDA may give such approval, it must consult with DEA to determine if the applicant He in compliance with the Controlled Substances Act of 1970 (CSA) and the Narcotic Addict Treatment Act (NATA) of 1974. Prior approval of the state authority is also required, except programs wholly operated by an agency of the U.S. Government.

The NATA of 1974 amended the CSA by requiring that all treatment programs appropriately register with DEA. DEA may not register an applicant without consulting FDA in order to determine if the program meets the medical standards established by the Secretary of Health, Education, and Welfare.

Both agencies have the authority to deny or revoke approval of a treatment program independently of each other, or at the recommendation of the other agency or a state authority, for violation of laws or regulations governing the operations of such programs.

DEA and FDA will continue to work in close cooperation to prevent treatment program. from beginning operations without the required approvals of both agencies, to coordinate any denial or revocation proceedings, and to provide for the disposition of the narcotics if a program's approval or registration is revoked.

III. ***Substance of Agreement***

A. Each agency shall obtain prior approval of the other before a new application for a treatment program is approved by FDA or registered by DEA. Before FDA may give approval, prior approval by the appropriate state authority is necessary, except in the case of a program wholly operated by the U.S. Government.

B. The agencies shall notify each other of Any denial or revocation of approval or registration of treatment programs when such action is initiated and shall keep each other informed of the outcome of such action.

C. Investigation. of treatment programs by either agency that reveal suspected violations of the regulations promulgated by the other agency shall be promptly reported to that agency.

D. When one agency recommends denial or revocation of approval or registration to the other, the recommending agency shall provide the other agency with all necessary reports, documents, and testimony for successful completion of the action.

E. Both agencies shall cooperate with each other in terminating illegally operating programs and in seizing or accepting surrender of the program's drug supply, as well as the supplies of other programs terminated for any reason.

F. FDA shall obtain DEA approval prior to approving treatment program requests for:

1. Alternate dispensing site;

2. Alternate method. of distribution;

3. Exceptions that involve storage of methadone at locations for that purpose by either FDA or DEA, e.g., Jail facilities or wholesalers who only store methadone for a program;

4. Establishment of medication units.

G. FDA shall consult with DEA before approving program-wide, a. opposed to individual patient, requests for additional take-home medication not provided for by the regulation.

H. The agencies shall hold periodic meeting. to discuss resolution of procedural problems related to mutual enforcement activities.

I. In the forum of the Federal Methadone Treatment Policy Review Board (composed of designated representatives from the Drug Enforcement Administration, Food and Drug Administration, National Institute on Drug Abuse, and the Veterans Administration), DEA and FDA will discuss with each other, and other members of the board, any proposed new regulations, regulation changes, or any significant interpretative modification with regard to treatment programs that will impact on the other agency.

IV. ***Liaison Officers***. For DEA: Mr. Ronald W. Buzzeo, Chief, Diversion Operations Section, Office of Diversion Control.

Address:

Drug Enforcement Administration

Diversion Operations Section

Room E-6293, Washington, D.C. 20537

Telephone No.: (202) 307-7163

For FDA: Ms. Lyvon Covington, Acting Director, Division of Methadone Monitoring (HFD-340), Bureau of Drugs.

Address:

5400 Fishers Lane

Rockville, Maryland 20852

Telephone No.: (301) 443-3414

V. ***Period of Agreement***. When accepted by both agencies, the agreement will have an effective period of performance from the date of signature with no expiration date. It may be modified by mutual consent of both parties or may be terminated by either party upon thirty (30) days advance written notice to the other.

At such time as the Secretary delegates authority and responsibility pursuant to the Narcotic Addict Treatment Act of 1974, this agreement shall be emended to reflect any change. which may be appropriate.

Approved and accepted for the Drug Enforcement Administration:

By: _____

Title: Administrator
Drug Enforcement Administration

Date: May 27 1976.

Approved and accepted for the Food and Drug Administration:

By: _____

Title: Commissioner of Food and Drugs

Date: MAY 2 8 1976.

REFERENCE 5242A

WORKSHEET FOR DOSAGE FORM MANUFACTURERS

WORKSHEET FOR DOSAGE FORM MANUFACTURERS

Controlled Substance Procured _____ Schedule _____
DEA Controlled Substances Number _____
Company Name: _____ Contact Person _____
Address: _____ Phone Number _____
Final 1995 Procurement Quota Granted _____
Quantity Acquired in 1995 to Replace Authorized Destructions _____ (List Below)

*EXPRESS ALL AMOUNTS AS KG. OF ANHYDROUS ACID, BASE, OR ALKALOID. NOT AS SALT**

Inventories	(Actual Statistics, not Estimates)	
December 31 (Year End) Inventory:	1994	1995
Bulk Controlled Substance (Procured/Acquired)		
In-Process Material in All Forms		
Finished Dosage Forms (in Bulk and/or Packaged)		
Other Materials (Specify)		
ACTUAL TOTAL ENDING INVENTORY		1995
Acquisitions During 1995		
Domestic Procurement (purchases or transfers)		
Importations		
Returns by customers for Credit, Salvage, Rework, Etc		
Other acquisitions to be Accounted for (Give Details)		
TOTAL ACQUIRED IN 1995		
TOTAL TO BE ACCOUNTED FOR DURING 1995 (Beginning Inventory Plus 1995 Acquisitions)		
Dispositions During 1995		1995
Domestic Sales to: Pharmacies, Doctors, Hospitals, Clinics		
Other Manufacturers		
Distributors		
Researchers		
Other Federal, State, or County Agencies		
Exports		
Returns from you to your suppliers (Give Details)		
Losses (Specify)		
Authorized Destructions		
Other Dispositions (Specify)		
TOTAL DISPOSED OF IN 1995		
TOTAL ACCOUNTED FOR DURING 1995 (Ending Inventory Plus 1995 Dispositions)		

DIFFERENCE BETWEEN ACCOUNTABLE AND ACCOUNTED FOR: _____; AS A % _____
Please provide an explanation for any differences.

List separately by drug and category the amounts of bulk controlled substances put into process to make Schedule III, IV, V, excluded, excepted or exempted preparations.

DO NOT INCLUDE ANY DATA FOR MATERIALS (EXCEPT RETURNS) ACQUIRED WITHOUT A QUOTA.
DO INCLUDE QUANTITIES ACQUIRED DURING 1995 TO REPLACE AUTHORIZED DESTRUCTIONS. DO PROVIDE IN COVER LETTER, SALES AND INVENTORIES OF "SCHEDULE II ONLY" PRODUCT.

SPECIFIC INSTRUCTIONS

FOR COMPLETING THE WORKSHEET

All dosage form manufacturers, repackages and manufacturers of exempt preparations are required to furnish the following data by January 31, 1996:

- 1995 starting inventory (opening of business January 1, 1995) and 1995 ending inventory (close of business December 31, 1995). **The 1994 ending inventory from last year's worksheet and the 1995 starting inventory for this year's worksheet should match!**
- For codeine, diphenoxylate, morphine, opium, dihydrocodeine and dextropropoxyphene, please indicate separately in your cover letter the total quantities of these drugs in the form of schedule II material dispersed as sales during 1995.
- Complete the "Manufacture of Controlled Substances into Schedules III, IV or V Preparations and Excluded, Excepted, Exempted or Non-controlled Preparations and Materials" to account for the quantities used in 1995 for the production of these products. Please list excluded, excepted or exempted use separately.
- List the 1995 acquisitions of raw materials (i.e. bulk chemicals) from manufacturers. Also, include goods returned to the applicant for credit, salvage, etc.
- List the 1995 dispositions including losses in production, authorized destruction, thefts, samples, etc. and sales. Sales should indicate separately the quantities sold to: hospitals, pharmacies, clinics, physicians, dentists, veterinarians, and researchers; other manufacturers; wholesalers, and distributors; exports; U.S. government agencies, state and local governments. If possible, separate Department of Defense sales from purchases by the VA and the Public Health Service.
- All numbers are expressed as anhydrous acid or base.
- Dosage form manufacturers of amphetamine, methamphetamine and tetrahydrocannabinol are to complete separate worksheets for each isomer.
- Do not include any data for material acquired, except returns, without a quota. For example codeine dosage forms or directly compressible tablet granulations.

It is also requested that each registrant furnish DEA with the name and telephone number of someone to whom questions concerning the data can be directed.

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REFERENCE 5242B

WORKSHEET FOR MANUFACTURERS OF BULK CHEMICAL DRUG SUBSTANCES

WORKSHEET FOR MANUFACTURERS OF BULK CHEMICAL DRUG SUBSTANCES
(To account for the controlled drug substance itself, not dosage form)

Controlled Substance _____ Schedule _____
DEA Controlled Substances Number _____
Company Name: _____ Contact Person _____
Address: _____ Phone Number _____
Final 1995 Quota Granted _____
Quantity Acquired in 1995 to Replace Authorized _____ Destructions _____ (List Below)

*EXPRESS ALL AMOUNTS AS KG. OF ANHYDROUS ACID, BASE, OR ALKALOID, NOT AS SALT**

Inventories (Actual Statistics, not Estimates)		
December 31 (Year End) Inventory:	1994	1995
In-process Chemical (As End Product, Not Precursor)*		
Bulk Chemical Ready for Transfer, Conversion, or Sale		
Bulk Chemical in Other Forms (Specify)		
ACTUAL TOTAL BULK CHEMICAL ENDING INVENTORY		1995
Acquisitions During 1995		
Manufactured/Produced/Synthesized/Extracted (Assay value)		
Importations		
Returns by customers for Credit, Salvage, Rework, Etc.		
Other acquisitions to be Accounted for (Give Details)		
TOTAL ACQUIRED IN 1995		
TOTAL TO BE ACCOUNTED FOR DURING 1995 (Beginning Inventory Plus 1995 Acquisitions)		
Dispositions During 1995		1995
Domestic Transfers or Sales to Dosage Form Manufacturers**		
Researchers		
Exports		
Used in Chemical Conversion to Other Drugs		
Losses (Specify)		
Authorized Destructions		
Other Dispositions (Specify)		
TOTAL DISPOSED OF IN 1995		
TOTAL ACCOUNTED FOR DURING 1995 (Ending Inventory Plus 1995 Dispositions)		

DIFFERENCE BETWEEN ACCOUNTABLE AND ACCOUNTED FOR: _____; AS A % _____
Please provide an explanation for any differences.

Note: Difference in assay value and yield value(Yield) will be considered normal process losses unless they differ significantly from historical yields. Please provide an explanation in those cases.

*In-process inventories should be expressed in terms of end-products and not precursors. Do not include in-process end-product inventories in precursor inventories and do not include any precursor inventories in end-product in-process inventories. Once precursor material has been changed or put into process for the manufacture of a specified end-product, it must no longer be counted as part of precursor stocks available for conversion or use but rather as part of end-product in-process inventories.

**Include transfers to other areas of your firm making dosage forms. The dosage form accountability should be done using a dosage form worksheet.

SPECIFIC INSTRUCTIONS

FOR COMPLETING THE WORKSHEET

All bulk manufacturers are requested to furnish the following information by January 31, 1996:

- List the 1995 starting inventory (opening of business January 1, 1995) and 1995 ending inventory (close of business December 31, 1995). **The 1994 ending inventory from last year's worksheet should match the 1995 beginning inventory on this year's worksheet!**
- List 1995 acquisitions including production, manufacture, domestic purchases, importations, and returns to the applicant for credit or salvage.
- List 1995 dispositions including sales, exports, utilization in the production of other drugs, losses in production, losses in conversion, theft, samples not returned to processing, authorized destruction, etc. Indicate separately the amounts sold to: hospitals, physicians, dentists, veterinarians, pharmacies, clinics and researchers; other manufacturers; wholesalers and distributors; exports; U.S. government, or state and local governments. If possible, separate Department of Defense sales from purchases by the VA or the Public Health Service.
- If the bulk manufacturer produces the bulk form of a controlled substances as well as the dosage form of this substance, then a bulk manufacture worksheet and dosage form worksheet must be completed.
- All numbers are to be expressed as anhydrous base or acid.
- Bulk manufacturers of amphetamine, methamphetamine and tetrahydrocannabinol are to complete separate worksheets for each isomer.

It is also requested that each registrant furnish DEA with the name and telephone number of someone to whom questions concerning the data can be directed.

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REFERENCE 5242C

WORKSHEET FOR BULK CHEMICAL MANUFACTURERS WHO PROCURE THEIR PRECURSOR MATERIALS

WORKSHEET FOR BULK CHEMICAL MANUFACTURERS WHO PROCURE THEIR PRECURSOR MATERIALS

Controlled Substance Procured _____ Schedule _____
DEA Controlled Substances Number _____
Company Name: _____ Contact Person _____
Address: _____ Phone Number _____
Final 1995 Procurement Quota Granted _____
Quantity Acquired in 1995 to Replace Authorized Destructions _____ (List Below)

*EXPRESS ALL AMOUNTS AS KG. OF ANHYDROUS ACID, BASE, OR ALKALOID. NOT AS SALT**

Inventories (Actual Statistics, not Estimates)		
December 31 (Year End) Inventory:	1994	1995
Controlled Precursor Material (as procured/acquired)		
Other Materials (Specify)		
ACTUAL TOTAL - CONTROLLED PRECURSOR INVENTORY		
Acquisitions During 1995		1995
Synthesized or Procured (Assay, not yield value)		
Importations		
Returns by customers for Credit, Salvage, Rework, Etc.		
Other acquisitions to be Accounted for (Give Details)		
TOTAL ACQUIRED IN 1995		
TOTAL TO BE ACCOUNTED FOR DURING 1995 (Beginning Inventory Plus 1995 Acquisitions)		
Dispositions During 1995		1995
Put into process for conversion to other substances		
Returns by you to your suppliers (Give Details)		
Losses (Specify)		
Authorized Destructions		
Other Dispositions (Specify)		
TOTAL DISPOSED OF IN 1995		
TOTAL ACCOUNTED FOR DURING 1995 (Ending Inventory Plus 1995 Dispositions)		

DIFFERENCE BETWEEN ACCOUNTABLE AND ACCOUNTED FOR:_____; AS A %_____

Please provide an explanation for any differences.

Note: Differences in assay value and yield value will be considered normal process losses unless they differ significantly from historical yields. Please provide an explanation in these cases.

*In-process inventories should be expressed in terms of end-products and not precursors. Do not include in-process end-product inventories in precursor inventories and do not include any precursor inventories in end-product in-process inventories. Once precursor material has been changed or put into process for the manufacture of a specified end-product, it must no longer be counted as part of precursor stocks available for conversion or use but rather as part of end-product in-process inventories.

SPECIFIC INSTRUCTIONS

FOR COMPLETING THE WORKSHEET

All bulk manufacturers are requested to furnish the following information by January 31, 1996:

- List the 1995 starting inventory (opening of business January 1, 1995) and 1995 ending inventory (close of business December 31, 1995). **The 1994 ending inventory from last year's worksheet should match the 1995 beginning inventory on this year's worksheet!**
- List 1995 acquisitions including production, manufacture, domestic purchases, importations, and returns to the applicant for credit or salvage.
- List 1995 dispositions including sales, exports, utilization in the production of other drugs, losses in production, losses in conversion, theft, samples not returned to processing, authorized destruction, etc. Indicate separately the amounts sold to: hospitals, physicians, dentists, veterinarians, pharmacies, clinics and researchers; other manufacturers; wholesalers and distributors; exports; U.S. government, or state and local governments. If possible, separate Department of Defense sales from purchases by the VA or the Public Health Service.
- If the bulk manufacturer produces the bulk form of a controlled substances as well as the dosage form of this substance, then a bulk manufacture worksheet and dosage form worksheet must be completed.
- All numbers are to be expressed as anhydrous base or acid.
- Also complete the "Report of the Utilization of Drugs for Chemical Conversion to Other Drugs."
- Bulk manufacturers of amphetamine, methamphetamine and tetrahydrocannabinol are to complete separate worksheets for each isomer.

It is also requested that each registrant furnish DEA with the name and telephone number of someone to whom questions concerning the data can be directed.

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REFERENCE 5242E

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA (DEA-189)

SEE INSTRUCTIONS ON REVERSE SIDE	APPLICATIONS FOR INDIVIDUAL MANUFACTURING QUOTA FOR A BASIC CLASS OF CONTROLLED SUBSTANCE	OMB APPROVAL NO. 043K 0547

No individual manufacturers quota may be issued unless a completed form has been received. 1303.33 CFR 21.

NAME AND ADDRESS OF APPLICANT (Include No., Street, City, State and ZIP Codes) Telephone	CALENDAR YEAR DEA REGISTRATION NUMBER
1. NAME OF BASIC CLASS DESIRED	2. SCHEDULE NUMBER 3. DEA CONTROLLED SUBSTANCE NO.

4. TOTAL AMOUNT OF BASIC CLASS DESIRED Grams	5. QUOTAS PREVIOUSLY ISSUED BY DEA Current Year 19 ___	Last Year 19 ___	6. NAME OF PERSON TO WHOM QUESTIONS CONCERNING THIS APPLICATION CAN BE DIRECTED

NOTE: All quantities are to be expressed in grams of anhydrous acid, base or alkaloid (NOT AS SALTS)

7. IF THE PURPOSE IS TO MANUFACTURE ANOTHER CONTROLLED SUBSTANCE BY CONVERSION OF THE QUOTA HEREIN APPLIED FOR, STATE THOSE SUBSTANCES WITH THE PERCENTAGE YIELD (Historical and theoretical) WHICH WILL BE DERIVED FROM CONVERSION.

NAME OF NEW SUBSTANCE	DEA CONTROLLED SUBSTANCE NUMBER	% YIELD (Theoretical)	% YIELD (Historical)	AMOUNT USED FOR THIS PURPOSE: CURRENT YEAR	1ST PRECEDING YEAR	2ND PRECEDING YEAR

8. PRODUCTION DATA	2nd PRECEDING YEAR 19	1st PRECEDING YEAR 19	ESTIMATE FOR CURRENT CALENDAR YEAR 19	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED 19
I. INVENTORY AS OF DEC. 31				
a. Bulk controlled substance				
b. In-process material (See item (c) on reverse side)				
c. Contained in Finished Dosage Format				
TOTAL (a + b)				
II. DISPOSITION / UTILIZATION				
a. Domestic				
b. Exports				
TOTAL (a + b)				
III. ACQUISITIONS / PRODUCTION				
a. Domestic Sources				
b. Importation				
TOTAL (a + b)				

9. REMARKS:

SIGNATURE OF APPLICANT	PRINT or TYPE NAME and TITLE of SIGNEE	DATE

DEA Form (Nov 1972) - 189

Previous edition is Obsolete

REFERENCE 5242F

APPLICATION FOR PROCUREMENT QUOTA FOR CONTROLLED SUBSTANCE (DEA-250)

SEE INSTRUCTIONS ON REVERSE SIDE	APPLICATION FOR PROCUREMENT QUOTA FOR CONTROLLED SUBSTANCE	OMB APPROVAL no. 1117-0008

No procurement quota may be issued unless a completed application form has been received. [305 12(b) CFR 2.]

NAME AND ADDRESS OF APPLICANT (Include No., Street, City, State and ZIP Code)	CALENDAR YEAR
	DEA REGISTRATION NUMBER
Telephone	EXPIRATION DATE

The applicant above named, being properly registered to manufacture controlled substances, hereby makes application to the Administrator, Drug Enforcement Administration, for a procurement quota for the basic class indicated for use in manufacturing or formulating, and in support thereof supplies the following information:

1. NAME OF THE BASIC CLASS DESIRED	2. SCHEDULE NUMBER	3. DEA CONTROLLED SUBSTANCE NUMBER

4. TOTAL AMOUNT OF THE BASIC CLASS DESIRED	5. QUOTAS PREVIOUSLY ISSUED BY DEA		6. NAME OF PERSON TO WHOM QUESTIONS CONCERNING THIS APPLICATION CAN BE DIRECTED
	Current Year	Last Year	
	19__	19__	
Grams			

NOTE: All quantities are to be expressed in grams of anhydrous acid, base or alkaloid (NOT SALTS)

7. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	DEA CONTROLLED SUBSTANCE NUMBER	% YIELD (Theoretical)	% YIELD (Historical)	AMOUNT USED FOR THIS PURPOSE		
				CURRENT YEAR	1st PRECEDING YEAR	2nd PRECEDING YEAR

8. PRODUCTION DATA	2nd PRECEDING YEAR 19	1st PRECEDING YEAR 19	ESTIMATE FOR CURRENT CALENDAR YEAR 19	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED 19
I. INVENTORY AS OF DEC. 31				
a. Bulk controlled substance				
b. In-process material				
c. Contained in FINISHED Dosage Forms				
TOTAL (a + b + c)				
II. DISPOSITION / UTILIZATION				
a. Domestic				
b. Exports				
TOTAL (a + b)				
III. ACQUISITION / PRODUCTION				
a. Domestic Sources				
b. Importation				
TOTAL (a + b)				

9. IF THE PURPOSE IS TO MANUFACTURE THE BASIC CLASS INTO DOSAGE FORMS, FURNISH THE FOLLOWING INFORMATION:

NAME OF DOSAGE FORM	SCHEDULE	AMOUNT USED FOR THIS PURPOSE			ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED 19
		CURRENT	1st PRECEDING YEAR	2nd PRECEDING YEAR	

SIGNATURE OF APPLICANT	PRINT or TYPE NAME and TITLE of SIGNEE	DATE

DEA Form 250 (Nov. 1978) Previous edition is Obsolete

REFERENCE 5243A

CONFIDENTIALITY OF

ALCOHOL AND DRUG

ABUSE PATIENT RECORDS

Federal Register, Vol. 40, No. 127

Tuesday, July 1, 1975

Title 42--Public Health

CHAPTER 1--PUBLIC HEALTH SERVICE,

DEPARTMENT OF HEALTH, EDUCATION,

AND WELFARE

Subchapter A--General Provisions

PART 2--CONFIDENTIALITY OF ALCOHOL

AND DRUG ABUSE PATIENT RECORDS

RULES AND REGULATIONS

Subpart A--Introductory Statement

2.1 Statutory authority--drug abuse.

(a) Statutory provisions effective May 14, 1974. Insofar as the provisions of this part pertain to any program activity relating to drug abuse education, training, treatment, rehabilitation, or research, such provisions are authorized under section 408 of Pub. L. 92-255, the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) as amended by section 303 of Pub. L. 93-282 (88 Stat. 137). That section reads as follows:

408. Confidentiality of patient records.

(a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (c), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b)(1) The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) may be used to initiate or substantiate any criminal charge against a patient or to conduct any investigation of a patient.

(d) The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be patient.

(e) The prohibitions of this section do not apply to any interchange of records--

(1) within the Armed Forces or within those components of the Veteran's Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) The director of the Special Action Office for Drug Abuse Prevention, after consultation with the Administrator of Veteran's Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(c), as in the judgment of the Director are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(b) Amendments effective June 30, 1975. Effective on the date specified in section 104 of the Drug Abuse Office and Treatment Act of 1972 (June 30, 1975), the first sentence of section 408(g) above, will be amended by striking "Director of the Special Action Office for Drug Abuse Prevention" and inserting in lieu thereof "Secretary of Health, Education, and Welfare", and the second sentence of such section will be amended by striking "Director" and inserting "Secretary" in lieu thereof. Also effective on that date, section 408, above, will be further amended by (1) striking out "The" and inserting in lieu thereof "Except as provided in subsection (h) of this section, "the" in the first sentence of subsection (g) of such section; and (2) adding at the end of such section the following new subsection:

(h) The Administrator of Veterans' Affairs through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations established by the Secretary under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from drug abuse. In prescribing and implementing regulations pursuant to this subsection, the Administrator shall from time to time, consult with the Secretary in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

2.13 General rules regarding confidentially.--Rules.

(a) In general. Records to which this part applies shall be confidential and may be disclosed only as authorized by this part, and may not otherwise be divulged in any civil, criminal, administrative, or legislative proceeding conducted by any Federal, State, or local authority, whether such proceeding is commenced before or after the effective date of this part.

(b) Unconditional compliance required. The prohibition upon unauthorized disclosure applies irrespective of whether the person seeking disclosure already has the information sought, has other means of obtaining it, enjoys official status, has obtained a subpoena, or asserts any other justification or basis for disclosure not expressly authorized under this part.

(c) Information covered by prohibition. The prohibition on unauthorized disclosure covers all information about patients, including their attendance or absence, physical whereabouts, or statue as patients, whether or not recorded, in the possession of program personnel, except as provided in paragraph (d) of this section.

(d) Crimes on program premises or against program personnel. Where a patient commits or threatens to commit a crime on the premises of the program or against personnel of the program, nothing in this part shall be construed as prohibiting personnel of the program from seeking the assistance of, or reporting such crime to a law enforcement agency, but such report shall not identify the suspect as a patient. In any such situation, immediate consideration should be given to seeking an order under Subpart E of this part to permit the disclosure of such limited information about the patient as may be necessary under the circumstances.

(e) Implicit and negative disclosures prohibited. The disclosure that a person (whether actual or fictitious) answering to a particular description, name, or other identification is not or has not been attending a program, whether over a period of time or on a particular occasion, is fully as much subject to the prohibitions and conditions of this part as a disclosure that such a person is or has been attending such a program. Any improper or unauthorized request for any disclosure of records or information subject to this part must be met by a noncommittal response.

(f) In-patients and residents. The presence of any in-patient in a medical facility or resident in a residential facility for the treatment of drug or alcohol abuse may be acknowledged to callers and visitors with his written consent. Without such consent, the presence of any in-patient or resident in a facility for the treatment of a variety of conditions may be acknowledged if done in such a way as not to indicate that the patient is being treated for drug or alcohol abuse.

2.14 Penalty for violations.--Rules.

(a) Penalty provided by law. Any person who violates any provision of the authorizing legislation or any provision of this part shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(b) Application to subsequent offenses. Where a defendant has committed one offense under either section authorizing this part or any provision of this part authorized by that section, any offense thereafter committed under the same section or any provision of this part authorized under that section shall be treated as a subsequent offense.

Subpart D--Disclosure Without Patient Consent

2.52 Research, audit, and evaluation.--Rules.

(a) Research, audit, and evaluation. Subject to any applicable specific provision set forth hereinafter in this subpart, the content of records pertaining to any patient which are maintained in connection with the performance of a function subject to this part may be disclosed, whether or not the patient gives consent, to qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit or evaluation, or otherwise disclose patient identities in any manner. For the purposes of this subpart and for the purposes of subsection (b) (2) (B) of the authorizing legislation, the term "qualified personnel" means persons whose training and experience are

appropriate to the nature and level of the work in which they are engaged and who, when working as part of an organization, are performing such work with adequate administrative safeguards against unauthorized disclosures.

(b) Use of disclosures of patient identifying information.

(1) Where a disclosure made to any person pursuant to paragraph (a) of this section includes patient identifying information with respect to any patient, such information may not be further disclosed, and may not be used in connection with any legal, administrative, supervisory, or other action whatsoever with respect to such patient, except as provided in paragraphs (b) (2) and (b) (3) of this section.

(2) The inclusion of patient identifying information in any written or oral communication between a person to whom a disclosure has been made pursuant to paragraph (a) and the program making such disclosure does not constitute the identification of a patient in a report or otherwise in violation of paragraph (a).

(3) Where a disclosure is made pursuant to paragraph (a) of this section to a person qualified to determine, on the basis of such disclosure, the presence of a substantial risk to the health and well being, whether physical or psychological, of any patient, and, in the judgment of such person, such a risk exists and the situation cannot be dealt with solely by means of communications as described in paragraph (b)(2) of this section without intensifying or prolonging the risk as compared with other means of dealing with it, then the initial disclosure under paragraph (a) and any subsequent disclosure or redisclosure of patient identifying information for the purpose of reducing the risk to the patient involved shall be subject to the provisions of 2.51.

2.54 Patient identifying information in connection with examinations--Rules.

(a) Definitions. For the purposes of this section--

(1) The term "examination" means any examination to which this section is made applicable by paragraph (b) of this section.

(2) The term "examiner" means any individual or any public or private organization, including any Federal, State, or local governmental agency, which conducts an examination to which this section applies.

(b) Applicability. This section applies to any examination of the records of a treatment program which is carried out for the purpose of or as aid to ascertaining the accuracy or adequacy of its financial or other records, or the efficiency or effectiveness of its financial, administrative, or medical management, or its adherence to financial, legal, medical, administrative, or other standards, regardless of whether such examination is called an audit, an evaluation, an inspection, or by any other name.

(c) Statement required for disclosure of patient identifying information in connection with examination. No program may make, and no examiner may require, any disclosure of patient identifying information in connection with an examination unless the examiner furnishes to the program a written statement:

(1) That no record of patient identifying information will be made or retained by or on behalf of the examiner in connection with the examination without notice to the program in accordance with paragraph (c)(2) of this section, or

(2) Setting forth the specific purpose for which a record of patient identifying information is being retained by or on behalf of the examiner, the location at which such information will be kept, and the name, official title, address, and telephone number of a responsible individual to whom any inquiries by the program about the disposition of such record should be directed.

(d) Disposition of record of patient identifying information in connection with examination. After any record of patient identifying information retained in connection with an examination has served its purpose, or within the time prescribed in paragraph (e) of this section, whichever is earlier, the examiner shall destroy or return to the program all records

(including any copies thereof) containing patient identifying information which have been in its possession in connection with such examination.

(e) Maximum time allowed for disposition. The action required by paragraph (d) shall be completed:

(1) Except as provided in paragraph (e)(2) of this section not more than two years after the record was acquired by or on behalf of the examiner, or

(2) Where the record is needed in connection with a formal legal proceeding against the program commenced or to be commenced not more than two years after the record was acquired, and written notice to this effect is furnished to the program within two years after the record was acquired, not later than the termination of such proceeding.

(f) Notice of final disposition. When an examiner disposes of records as required by paragraph (d) of this section, or not later than the time prescribed by paragraph (e) of this section, whichever is earlier, the examiner shall furnish to the program concerned a written statement:

(1) That there has been compliance with this section and with the provisions of this part prohibiting any disclosure of patient identifying information from records held by auditors or evaluators, or

(2) Specifying the particulars in which there has been a failure of compliance.

2.55 Supervision and regulation of narcotic maintenance and detoxification programs.--Rules.

(a) Definition of "registrant". For the purposes of this section, the term "registrant" means a person who (1) has pending an application for registration under section 303(g) of the Controlled Substances Act (21 USC 823(g)), or (2) has been registered under such section and whose registration has not expired or been surrendered or revoked.

(b) Drug Enforcement Administration. Duly authorized agents of the Drug Enforcement Administration shall have access to the t premises of registrants for the purpose of ascertaining compliance (or ability to comply) with standards established by the Attorney General under Section 303(g)(2) of the Controlled Substances Act (21 USC 823(g)(2)) respecting the security of stocks of narcotic drugs and the maintenance of records (in accordance with section 307 of the Controlled Substances Act, 21 USC 827) on such drugs. Registrants shall maintain such records separate from and in addition to patients' clinical records required to be maintained under 21 CFR 310.505(d)(7)(iii), which shall not be available to such agents except as authorized under a court order in accordance with Subpart E of this part. Records maintained by registrants for the purposes of section 307 of the Controlled Substances Act (21 USC 827) need not identify patients by name, address, Social Security number, or otherwise except by an identifying number assigned by the registrant, but where such a system is used, the registrant shall maintain on a current basis a cross-index referencing each identifying number to the name and address of patient to whom it refers. Upon request at any time and without advance notice, but subject to the provisions of 2.54, such agents shall be granted immediate access to any such index. Such agents may use names and addresses so obtained strictly for the purposes of auditing or verifying program records, and shall exercise all reasonable precautions to avoid inadvertent disclosure of patient identities to third parties. Names and other identifying information so obtained may not be compiled or used in any registry or personal data bank of any description.

REFERENCE 5247A

VOLUNTARY SURRENDER OF REGISTRATION

IN THE MATTER OF

John Doe, M.D.

18 Chapel Street

Redmond, Georgia 27705

VOLUNTARY SURRENDER OF REGISTRATION

This is to confirm the voluntary surrender of our registration privileges in Schedules II through V on March 10, 1996 under DEA Registration Number _____. By Surrendering your registration privileges in Schedules II through V, you have waived your right to an administrative hearing to determine if your registration would be consistent with the public interest under Title 21 U.S.C. 823(f).

Concurrent with the surrender of your registration, you are no longer authorized to order, distribute, possess, dispense, administer, prescribe or engage in any activities with controlled substances.

If you have any questions regarding this matter, you may correspond with (name), Drug Enforcement Administration, Diversion Group Supervisor, (address).

Sincerely,

Tom Jones

Special Agent in Charge

Atlanta Division

cc: ODO

Appendix G

DEA Office Code Designators

Revised 06/14/12

Codes utilized by DEA Offices in investigative reporting and OFFICE field in NADDIS.

CONTENTS

DOMESTIC OFFICES		
OFFICE	**OFFICE CODE**	**NCIC ORI**
Atlanta Field Division		
Field Division Office	G3	GADEA0600/GADEA0600
Augusta POD		GADEA0700
Charleston RO	G7	SCDEA0100
Beaufort POD		
Charlotte DO	KF	NCDEA0300
Asheville (NC) POD		
Chattanooga RO	KX	TNDEA0400
Columbia DO	G2	SCDEA0200
Columbus (GA) RO	GX	GADEA0400
Florence RO	K4	SCDEA0400
Greensboro RO	GE	NCDEA0100
Greenville RO	KW	SCDEA0300
Knoxville RO	KC	TNDEA0300
Johnson City POD		TNDEA0500
Macon RO	KQ	GADEA0500
Memphis RO	GN	TNDEA0100
Jackson (TN) POD		
Nashville DO	GK	TNDEA0200
Raleigh RO	KN	NCDEA0400
Savannah RO	G9	GADEA0200
Wilmington (NC) RO	GG	NCDEA0200
Boston Field Division		
Field Division Office	CC	MADEA0100/MADEA0800
Boston OCDETF Strike Force (Watertown)		MADEA1000
Bridgeport RO	CV	CTDEA0200
Burlington RO	CF	VTDEA0100
Manchester RO	CG	NHDEA0200
Portsmouth (NH) POD		

Hartford RO	CD	CTDEA0100
New Bedford RO	CZ	MADEA0400
New Haven DO	CQ	CTDEA0300
Portland (ME) RO	CE	MEDEA0300
Bangor POD		
Providence RO	CH	RIDEA0100
Springfield (MA) RO	CU	MADEA0200
Caribbean Field Division		
San Juan FD Office	G5	PRDEA0100/PRDEA0400
Bridgetown (BB) Country Office	KJ	BBDEA0100
Curacao (NX) Country Office	ZV	NXDEA0100
Kingston (JM) Country Office	GA	JMDEA0100
Paramaribo, Suriname Country Office	Z1	ZCDEA0000
Ponce RO	GO	PRDEA0300
Port-au-Prince (HT) Country Office	KG	HTDEA0100
Port of Spain (TR) Country Office	K9	TTDEA0000
St. Croix RO	K6	VIDEA0100
St. Thomas (VI) RO	KS	VIDEA0000
Santo Domingo (DR) Country Office	KA	DRDEA0100
Chicago Field Division		
Field Division Office	I1	ILDEA0100/ILDEA0600
Fargo RO	IM	NDDEA0200
Bismarck POD		NDDEA0300
Indianapolis DO	I2	INDEA0100
Evansville POD		INDEA0400
Madison RO	BF	WIDEA0400
Merrillville RO	I5	INDEA0200
Ft. Wayne POD		INDEA0300
Milwaukee DO	I3	WIDEA0100
Green Bay RO	IX	WIDEA0300
Minneapolis-St. Paul DO	IJ	MNDEA0100
Rockford RO	IY	ILDEA0500

Springfield (IL) RO	I4	ILDEA0200
Dallas Field Division		
Field Division Office	M1	TXDEA0500/TXDEA2500
Ft. Worth RO	MW	TXDEA1800
Lubbock RO	MB	TXDEA1200
Amarillo POD		TXDEA3300
McAlester RO	K8	OKDEA0300
Oklahoma City DO	M4	OKDEA0100
Tulsa RO	MG	OKDEA0200
Tyler RO	KK	TXDEA2100
Denver Field Division		
Field Division Office	MK	CODEA0100
Billings RO	RM	MTDEA0100
Missoula POD		MTDEA0200
Cheyenne RO	MV	WYDEA0100
Casper POD		WYDEA0200
Colorado Springs RO	KM	CODEA0200
Grand Junction RO	MZ	CODEA0400
Durango POD		
Glenwood Springs POD		CODEA0300
Salt Lake City DO	ML	UTDEA0100
St. George POD		UTDEA0200
Detroit Field Division		
Field Division Office	I7	MIDEA0100/MIDEA0700
Cincinnati RO	I9	OHDEA0100
Cleveland RO	I8	OHDEA0200
Columbus (OH) DO	IB	OHDEA0300
Dayton RO	K2	OHDEA0500
Grand Rapids RO	IC	MIDEA0200
Lansing POD		MIDEA0600

Kalamazoo POD		
Lexington RO	KT	KYDEA0200
London (KY) RO	BA	KYDEA0300
Louisville DO	IA	KYDEA0100
Madisonville POD		KYDEA0500
Saginaw RO	IP	MIDEA0300
Toledo RO	IW	OHDEA0400
Youngstown RO	IU	OHDEA0600
El Paso Field Division		
Field Division Office	M7	TXDEA1700/TXDEA3200
Albuquerque DO	MM	NMDEA0100
Alpine RO	MJ	TXDEA0100
Las Cruces RO	MS	NMDEA0200
Midland RO	MC	TXDEA2200
Houston Field Division		
Field Division Office	M3	TXDEA1000/TXDEA2900
Austin RO	M8	TXDEA0200
Beaumont RO	MH	TXDEA2000
Brownsville RO	M9	TXDEA0300
Corpus Christi RO	MA	TXDEA0400
Eagle Pass RO	MD	TXDEA0700
Del Rio POD	ME	TXDEA0600
Galveston RO	MX	TXDEA1900
Laredo DO	M6	TXDEA1100
McAllen DO	M5	TXDEA1300
San Antonio DO	M2	TXDEA1400
Waco RO	K5	TXDEA2400
Los Angeles Field Division		
Field Division Office	R1	CADEA0200/CADEA2400/CADEA2700 CADEA2000
Hagatna, Guam RO	RB	GMDEA0100
Honolulu DO	R4	HIDEA0100

Wailuku POD		HIDEA0200
Maui POD		HIDEA0200
Las Vegas DO	R5	NVDEA0100
Orange County RO	RQ	CADEA1200
Reno RO	RA	NVDEA0200
Riverside DO	RP	CADEA1400
Ventura County RO	RS	CADEA1600
Miami Field Division		
Field Division Office	G1	FLDEA0200/FLDEA1300/FLDEA1500
Ft. Lauderdale DO	GS	FLDEA0800
Ft. Myers RO	GU	FLDEA0700
Port St. Lucie RO	K7	FLDEA1400
Freeport (BD) RO	KP	BDDEA0200
Gainesville RO	KD	FLDEA1000
Jacksonville DO	G4	FLDEA0100
Homestead RO	GY	FLDEA0900
Key West POD		FLDEA2100
Nassau, Bahamas Country Office	GV	BDDEA0100
Orlando DO	GB	FLDEA0500
Titusville POD		
Panama City RO	GT	FLDEA0600/FLDEA1600
Pensacola RO	KV	FLDEA1200
Tallahassee RO	KH	FLDEA1100
Tampa DO	G6	FLDEA0400
West Palm Beach DO	G8	FLDEA0300
New Jersey Field Division		
Field Division Office	C3	NJDEA0100/NJDEA0500
Paterson POD		NJDEA0600
Atlantic City RO	CA	NJDEA0300
Camden RO	CX	NJDEA0400
New Orleans Field Division		
Field Division Office	GH	LADEA0200/LADEA0500

Baton Rouge RO	GP	LADEA0100/LADEA0400
Lafayette POD		LADEA0600
Birmingham DO	GL	ALDEA0100
Huntsville POD		
Fayetteville RO	KY	ARDEA0200
Ft. Smith POD		ARDEA0300
Gulfport RO	KU	MSDEA0200
Jackson (MS) DO	GM	MSDEA0100
Little Rock DO	GJ	ARDEA0100
Mobile RO	GQ	ALDEA0200
Montgomery DO	KI	ALDEA0300
Oxford RO	KZ	MSDEA0300
Shreveport RO	KB	LADEA0300
New York Field Division		
Field Division Office	C1	NYDEA0300/NYDEA0400/NYDEA1100 NYDEA1200/NYDEA1500
Albany DO	C7	NYDEA0100
Plattsburgh RO	BJ	NYDEA1600
Buffalo RO	C2	NYDEA0200
JFK Airport	CJ	NYDEA0600
Long Island DO	C5	NYDEA0500
New York Task Force (Associate SAC #3)	CT	NYDEA0800
New York OCDETF Strike Force (Associate SAC #4)	BZ	NYDEA1700/NYDEA1800
Rochester RO	C9	NYDEA0700
Syracuse RO	CO	NYDEA1000
Westchester RO	BD	NYDEA0900
Philadelphia Field Division		
Field Division Office	CK	PADEA0100/PADEA0900
Allentown RO	CY	PADEA0400
Harrisburg RO	CW	PADEA0300
Pittsburgh DO	CM	PADEA0200
Scranton RO	BG	PADEA0800

Wilmington (DE) RO	CP	DEDEA0100
Dover POD		DEDEA0200
Phoenix Field Division		
Field Division Office	MN	AZDEA0400/AZDEA0800
Nogales RO	MP	AZDEA0300
Sierra Vista RO	KL	AZDEA0700
Tucson DO	MQ	AZDEA0600
Yuma RO	MT	AZDEA0500
Lake Havasu City POD		
San Diego Field Division		
Field Division Office	R2	CADEA0400/CADEA2600/CADEA3100
Carlsbad RO	RV	CADEA1900
Imperial County DO	R6	CADEA0100
San Ysidro RO	RU	CADEA0800/CADEA1700
San Francisco Field Division		
Field Division Office	R3	CADEA0500
Bakersfield RO	RZ	CADEA2300
Fresno RO	R9	CADEA0700
Modesto POD		
Oakland RO	BB	CADEA2500
Sacramento DO	R7	CADEA0300
San Jose RO	RC	CADEA1100
Santa Rosa RO (Sonoma in Windsor, CA)	BK	CADEA3200
Seattle Field Division		
Field Division Office	RE	WADEA0200
Anchorage DO	RG	AKDEA0100
Fairbanks POD		
Bellingham RO	RL	WADEA0100
Boise RO	RK	IDDEA0100
Eugene RO	RN	ORDEA0200
Bend POD		

Medford RO	RX	ORDEA0300
Portland DO	RF	ORDEA0100
Salem RO	BC	ORDEA0400
Spokane RO	RH	WADEA0300
Tacoma RO	RY	WADEA0500
Yakima RO	RT	WADEA0400
Tri-Cities POD (Kennewick, WA)		
St. Louis Field Division		
Field Division Office	IF	MODEA0200
Cape Girardeau RO	IS	MODEA0300
Cedar Rapids RO	IQ	IADEA0200
Quad Cities POD		ILDEA1300
Des Moines RO	IH	IADEA0100
Fairview Heights RO	IZ	ILDEA0400
Carbondale POD		ILDEA1100
Garden City RO	BE	KSDEA0300
Kansas City DO	IE	KSDEA0200
Topeka POD		
Omaha DO	IG	NBDEA0100
N Platte POD		NBDEA0200
Sioux City RO	K3	IADEA0300
Sioux Falls RO	IN	SDDEA0100
Rapid City POD		SDDEA0200
Springfield (MO) RO	IT	MODEA0400
Wichita RO	IL	KSDEA0100
Washington Field Division		
Field Division Office	GD	DCDEA0100/DCDEA0700
Winchester (VA) POD		
Baltimore DO	GC	MDDEA0100
Salisbury POD		MDDEA0700
Charleston (WV) RO	ID	WVDEA0100

Clarksburg POD		WVDEA0200
Wheeling POD		WVDEA0300
Hagerstown RO	BH	MDDEA0500
Norfolk RO	GW	VADEA0100
Hampton POD		VADEA0600
Richmond DO	GZ	VADEA0200
Roanoke RO	KR	VADEA0400
Abingdon POD		VADEA3200

FOREIGN OFFICES		
OFFICE	**OFFICE CODE**	**NCIC ORI**
Accra, Ghana Country Office	UX	GGDEA0000
Almaty, Kazakhstan Country Office	UY	KTDEA0000
Ankara, Turkey Country Office	XU	TYDEA0100
Istanbul RO	XV	TYDEA0200
Asuncion, Paraguay Country Office	ZG	PVDEA0100
Athens, Greece Country Office	X6	GCDEA0100
Bangkok, Thailand County Office	WA	THDEA0100
Chiang Mai RO	WB	THDEA0200
Udorn RO	WR	THDEA0400
Beijing, China Country Office	WT	RCDEA0000
Belmopan, Belize Country Office	TJ	BHDEA0100
Frankfurt RO	XH	GEDEA0200
Bern, Switzerland Country Office	UN	SZDEA0100
Bishkek, Kyrgyzstan Country Office	UR	KZDEA0000
Bogota, Colombia Country Office	ZE	CBDEA0100
Cartegena RO	ZU	CBDEA0500
Brasilia, Brazil Country Office	ZJ	BZDEA0100
Sao Paulo RO	ZQ	BZDEA0200
Brussels, Belgium Country Office	XK	BGDEA0100
Buenos Aires, Argentina Country Office	ZA	ATDEA0100
Cairo, Egypt Country Office	X4	EYDEA0100

Canberra, Australia Country Office	WP	ASDEA0100
Caracas, Venezuela Country Office	ZB	VZDEA0100
Copenhagen, Denmark Country Office	XT	DKDEA0100
Dubai, United Arab Emirates (U.A.E.) Country Office	UU	TCDEA0000
Dushanbe, Tajikistan Country Office	UI	TJDEA0000
Guatemala City, Guatemala Country Office	TG	GTDEA0100
Hanoi, Vietnam Country Office	WG	VMDEA0100
Hong Kong Country Office	WH	HKDEA0100
Islamabad, Pakistan Country Office	XZ	PKDEA0100
Peshawar RO	UM	PKDEA0400
Jakarta, Indonesia Country Office	WM	IODEA0100
Kabul, Afghanistan Country Office	XY	AFDEA0100
Kuala Lumpur, Malaysia Country Office	WE	MZDEA0100
Lagos, Nigeria Country Office	UP	NGDEA0100
Lima, Peru Country Office	ZH	PUDEA0100
Lisbon, Portugal Country Office	UO	PTDEA0000
London, England Country Office	XC	ENDEA0100
Lyon, Paris (Interpol)		MMDEA0600
Madrid, Spain Country Office	XD	SPDEA0100
Manila, Philippines Country Office	WJ	PIDEA0100
Managua, Nicaragua Country Office	TL	NUDEA0000
Mexico City, Mexico Country Office	TA	MMDEA0100
Ciudad Juarez RO	TM	MMDEA0700
Guadalajara RO	TB	MMDEA0200
Hermosillo RO	TC	MMDEA0300
Matamoros RO	TQ	TADEA0000
Mazatlan RO	TE	MMDEA0400
Merida RO	TH	MMDEA0500
Monterrey RO	TD	MMDEA0600
Nogales RO	TU	SODEA0000
Nuevo Laredo RO	TP	TADEA0100
Tijuana RO	TN	MMDEA0800

Monterrey, Mexico Country Office		MMDEA0600
Montevideo, Uruguay Country Office	ZM	UYDEA0100
Moscow, Russia Country Office	XI	RADEA0100
New Delhi, India Country Office	X1	IIDEA0100
Nicosia, Cypress Country Office	X9	CSDEA0100
Nairobi, Kenya Country Office	UV	KEDEA0000
Ottawa, Canada Country Office	X7	ONDEA0100
Panama City, Panama Country Office	ZC	PMDEA0100
Paris, France Country Office	XA	FNDEA0100
Pretoria, South Africa Country Office	UT	SFDEA0000
Quito, Ecuador Country Office	ZD	EUDEA0100
Guayaquil RO	ZP	EUDEA0200
Rangoon, Burma Country Office	WQ	BRDEA0000
Rome, Italy Country Office	XL	ITDEA0200
San Jose, Costa Rica Country Office	TF	CRDEA0100
San Salvador, El Salvador Country Office	TK	ELDEA0000
Santiago, Chile Country Office	ZL	CQDEA0100
Seoul, Korea Country Office	WL	KODEA0100
Singapore Country Office	WF	SRDEA0100
Sofia, Bulgaria Country Office	UW	BUDEA0000
Tashkent, Uzbekistan	UZ	UZDEA0100
Tegucigalpa, Honduras Country Office	TI	HDDEA0100
The Hague, Netherlands Country Office	XQ	NEDEA0100
Tokyo, Japan Country Office	WK	JADEA0100
Vancouver, Canada RO	RJ	BCDEA0000
Vienna, Austria Country Office	XP	AUDEA0100
Warsaw, Poland Country Office	XO	PODEA0000

OM APPROVED GROUP TYPE LIST	
CODE	**DESCRIPTION**
AC	OFFICE OF THE ASAC
AG	ADMINISTRATIVE SUPPORT GROUP

AR	ASSET REMOVAL GROUP
AS	OFFICE OF THE ASSOCIATE SAC
CO	COUNTRY OFFICE
DG	DIVERSION GROUP
DI	DIVISION OFFICE (SAC)
DM	OFFICE OF THE DIVERSION PROGRAM MANAGER
DO	DISTRICT OFFICE
ED	EXECUTIVE PROTECTION DETAIL GROUP
EG	ENFORCEMENT GROUP
FA	ADMINISTRATIVE SUPPORT GROUP (FOREIGN)
FE	ENFORCEMENT GROUP (FOREIGN)
FG	FINANCIAL GROUP
FI	OFFICE OF THE FIELD INTELLIGENCE MANAGER
FO	INTELLIGENCE GROUP (FOREIGN)
FR	RESIDENT OFFICE (FOREIGN)
FS	FIELD SUPPORT
HD	HIDTA TASK FORCE GROUP
HI	HIDTA INTELLIGENCE GROUP
HQ	HEADQUARTERS GROUP
IG	INTELLIGENCE GROUP
MG	MET GROUP
OS	OCDETF STRIKE FORCE GROUP
PD	POST OF DUTY
PT	PROVISIONAL TASK FORCE GROUP
RO	RESIDENT OFFICE
SO	STAFF/OTHER
SP	SPECIAL PROJECTS GROUP
SS	SPECIAL SUPPORT GROUP
TD	TACTICAL DIVERSION GROUP
TF	TASK FORCE GROUP
TK	TECHNICAL OPERATIONS GROUP

		REGION CODE	REGION
TJ	BELMOPAN, BELIZE	1R	North & Central America Regional Area
TG	GUATEMALA CITY, GUATEMALA	1R	North & Central America Regional Area
TL	MANAGUA, NICARAGUA	1R	North & Central America Regional Area
TA	MEXICO CITY, MEXICO	1R	North & Central America Regional Area
TM	CIUDAD JUAREZ, MEXICO	1R	North & Central America Regional Area

TB	GUADALAJARA, MEXICO	1R	North & Central America Regional Area
TC	HERMOSILLO, MEXICO	1R	North & Central America Regional Area
TQ	MATAMOROS, MEXICO	1R	North & Central America Regional Area
TE	MAZATLAN, MEXICO	1R	North & Central America Regional Area
TH	MERIDA, MEXICO	1R	North & Central America Regional Area
TD	MONTERREY, MEXICO	1R	North & Central America Regional Area
TU	NOGALES, MEXICO	1R	North & Central America Regional Area
TP	NUEVO LAREDO, MEXICO	1R	North & Central America Regional Area
TN	TIJUANA, MEXICO	1R	North & Central America Regional Area
X7	OTTAWA, CANADA	1R	North & Central America Regional Area
RJ	VANCOUVER, BC	1R	North & Central America Regional Area
ZC	PANAMA CITY, PANAMA	1R	North & Central America Regional Area
TF	SAN JOSE, COSTA RICA	1R	North & Central America Regional Area
TK	SAN SALVADOR, EL SALVADOR	1R	North & Central America Regional Area
TI	TEGUCIGALPA, HONDURAS	1R	North & Central America Regional Area
ZE	BOGOTA, COLOMBIA	2R	Andean Regional Area
ZU	CARTEGENA, COLOMBIA	2R	Andean Regional Area
ZB	CARACAS, VENEZUELA	2R	Andean Regional Area
ZD	QUITO, ECUADOR	2R	Andean Regional Area
ZP	GUAYAQUIL, ECUADOR	2R	Andean Regional Area
UX	ACCRA, GHANA	3R	Europe & Africa Regional Area
UV	NAIROBI, KENYA	3R	Europe & Africa Regional Area
UN	BERN, SWITZERLAND	3R	Europe & Africa Regional Area
XK	BRUSSELS, BELGIUM	3R	Europe & Africa Regional Area
XT	COPENHAGAN, DENMARK	3R	Europe & Africa Regional Area
XH	FRANKFURT, GERMANY	3R	Europe & Africa Regional Area
UP	LAGOS, NIGERIA	3R	Europe & Africa Regional Area
XC	LONDON, ENGLAND	3R	Europe & Africa Regional Area
XD	MADRID, SPAIN	3R	Europe & Africa Regional Area
XA	PARIS, FRANCE	3R	Europe & Africa Regional Area
UT	PRETORIA, SOUTH AFRICA	3R	Europe & Africa Regional Area
XL	ROME, ITALY	3R	Europe & Africa Regional Area
XM	MILAN, ITALY	3R	Europe & Africa Regional Area
XQ	THE HAGUE, NETHERLANDS	3R	Europe & Africa Regional Area
XP	VIENNA, AUSTRIA	3R	Europe & Africa Regional Area
XO	WARSAW, POLAND	3R	Europe & Africa Regional Area
UO	LISBON, PORTUGAL	3R	Europe & Africa Regional Area
WA	BANGKOK, THAILAND	4R	Far East Regional Area
WB	CHIANG MAI, THAILAND	4R	Far East Regional Area
WR	UDORN, THAILAND	4R	Far East Regional Area

WT	BEIJING, CHINA	4R	Far East Regional Area
WP	CANBERRA, AUSTRALIA	4R	Far East Regional Area
WG	HANOI, VIETNAM	4R	Far East Regional Area
WH	HONG KONG	4R	Far East Regional Area
WE	KUALA LUMPUR, MALAYSIA	4R	Far East Regional Area
WJ	MANILA, PHILIPPINES	4R	Far East Regional Area
WQ	RANGOON, BURMA	4R	Far East Regional Area
WL	SEOUL, KOREA	4R	Far East Regional Area
WF	SINGAPORE	4R	Far East Regional Area
WK	TOKYO, JAPAN	4R	Far East Regional Area
WC	VIENTIANE, LAOS	4R	Far East Regional Area
WM	JAKARTA, INDONESIA	4R	Far East Regional Area
UR	BISHKEK, KYRGYZSTAN	5R	Middle East Regional Area
UW	SOFIA, BULGARIA	5R	Middle East Regional Area
XU	ANKARA, TURKEY	5R	Middle East Regional Area
XV	ISTANBUL, TURKEY	5R	Middle East Regional Area
X6	ATHENS, GREECE	5R	Middle East Regional Area
X4	CAIRO, EGYPT	5R	Middle East Regional Area
UU	DUBAI, UNITED ARAB EMIRATES	5R	Middle East Regional Area
UI	DUSHANBE, TAJIKISTAN	5R	Middle East Regional Area
XI	MOSCOW, RUSSIA	5R	Middle East Regional Area
X1	NEW DELHI, INDIA	5R	Middle East Regional Area
X9	NICOSIA, CYPRUS	5R	Middle East Regional Area
UZ	TASHKENT, UZBEKISTAN	5R	Middle East Regional Area
UY	ALMATY, KAZAKHSTAN	5R	Middle East Regional Area
ZG	ASUNCION, PARAGUAY	6R	Southern Cone Regional Area
ZJ	BRASILIA, BRAZIL	6R	Southern Cone Regional Area
ZQ	SAO PAULO, BRAZIL	6R	Southern Cone Regional Area
ZA	BUENOS AIRES, ARGENTINA	6R	Southern Cone Regional Area
ZK	LA PAZ, BOLIVIA	6R	Southern Cone Regional Area
ZX	COCHABAMBA, BOLIVIA	6R	Southern Cone Regional Area
ZW	SANTA CRUZ, BOLIVIA	6R	Southern Cone Regional Area
ZZ	TRINIDAD, BOLIVIA	6R	Southern Cone Regional Area
ZH	LIMA, PERU	6R	Southern Cone Regional Area
ZL	SANTIAGO, CHILE	6R	Southern Cone Regional Area
ZM	MONTEVIDEO, URUGUAY	6R	Southern Cone Regional Area
KJ	BRIDGETOWN, BARBADOS	7R	Caribbean Regional Area
ZV	CURACAO, NETHERLANDS ANTILLES	7R	Caribbean Regional Area
GA	KINGSTON, JAMAICA	7R	Caribbean Regional Area
Z1	PARAMARIBO, SURINAME	7R	Caribbean Regional Area

K9	PORT OF SPAIN, TRINIDAD, TOBAGO	7R	Caribbean Regional Area
KG	PORT-AU-PRINCE, HAITI	7R	Caribbean Regional Area
KA	SANTO DOMINGO, DOM REP	7R	Caribbean Regional Area
GV	NASSAU, BAHAMAS	8R	Miami Field Division (FOREIGN OFFICES ONLY)
KP	FREEPORT, BAHAMAS	8R	Miami Field Division (FOREIGN OFFICES ONLY)
XZ	ISLAMABAD, PAKISTAN	9R	Southwest Asia Regional Area
UM	PESHAWAR, PAKISTAN	9R	Southwest Asia Regional Area
XY	KABUL, AFGHANISTAN	9R	Southwest Asia Regional Area

	HEADQUARTERS OFFICES - Office Code Designators	**ACRONYM**
	(used in case files - 8000, 9000, CAST, WRS, DEA Forms 351, 352, and 421, etc.)	(HQs mail stop)
AA	Office of the Administrator	A
AB	Office of the Deputy Administrator	AD
AC	Operational Support Division	SC
AD	Special Operations Division (SOD)	OS
AE	Executive Equal Opportunity and Employee Assistance Program	ADE
AF	OCDETF Fusion Center	NF
AI	Inspection Division (Chief Inspector)	IG
AJ	Office of Administrative Law Judges	LJ
AL	Intelligence Division	NC
AM	Office of Forensic Sciences	SF
AN	Office of Global Enforcement	OE
AO	Office of Administration	SA
AP	El Paso Intelligence Center	NE
AR	Aviation Division	OA
AS	Office of Chief Counsel	CC
AV	Office of Congressional and Public Affairs	CP
AX	Office of Diversion Control	OD
AZ	Executive Policy and Strategic Planning	ADS
FA	Office of Acquisition & Relocation Management	FA
FC	Financial Management Division (Chief Financial Officer)	FC
FN	Office of Finance	FN
FO	Office of Financial Operations	FO

FR	Office of Resource Management	FR
HB	Board of Professional Conduct	HRB
HC	Career Board	HRC
HR	Human Resources Division	HR
NN	Office of National Security Intelligence	NN
NS	Office of Special Intelligence	NS
OC	Operations Division (Chief of Operations)	OC
OG	Global Enforcement Office of Administrative Support	OG
OM	Office of Operations Management	OM
OT	Global Enforcement Special Projects Branch	OT
PI	Office of Inspections	IN
PR	Office of Professional Responsibility	OPR
PS	Office of Security Programs	IS
SI	Office of Information Systems	SI
TR	Office of Training	TR
ST	Office of Investigative Technology	ST

"RELOCATED" OFFICES		
OFFICE	**OFFICE CODE**	**NCIC ORI**
Barranquilla (Now Cartagena)	ZU	CBDEA0500
Berlin (Now Frankfurt)	XG	GEDEA0200
Calexico (Now Imperial County)		CADEA0100
Concord (Now Manchester)	CG	NHDEA0200
Great Falls (Now Billings)		MTDEA0100
Hammond (Now Merrillville)		INDEA0200
Ft. Pierce (Now Port St. Lucie)	K7	FLDEA1400
Key Largo (Now Homestead)		FLDEA0900
Santa Barbara (Now Ventura County)		CADEA1600

OBSOLETE DESIGNATORS AND CLOSED OFFICES		
OFFICE	**OFFICE**	**NCIC ORI**

CODE		
AK	Ottawa (Now X7)	
B1	Boston (Now CC)	
B2	Hartford (Now CD)	
B3	Newport (Closed)	
B4	Portland (ME) (Now CE)	
B5	Houlton (Closed)	
B6	Bangor (Closed)	
B7	Burlington (Now CF)	
B8	Concord (Now CG)	
B9	Providence (Now CH)	
C4	Montreal (Closed)	
C6	Toronto (Closed)	
C8	Rouses Point (Closed)	
CB	NY DEA/FBI Investigation Team (Obsolete)	
CN	Newark Airport (Obsolete)	
CR	New York Regional Office (Obsolete)	
CS	New York Special Projects (Obsolete)	
D1	Philadelphia (Now CK)	
D2	Pittsburgh (Now CM)	
D3	Wilmington (DE) (Now CP)	
D4	Atlantic City (Now CA)	
D5	Baltimore (Now GC)	
D6	Washington (Now GD)	
D7	Greensboro (Now GE)	
D8	Charleston (WV) (Now ID)	
D9	Norfolk (Now GW)	
DA	Wilmington (NC) (Now GG)	
E1	Baltimore (Now GC)	
E2	Washington (Now GD)	
E3	Greensboro (Now GE)	
E4	Charleston (WV) (Now ID)	

E5	Norfolk (Now GW)	
E6	Wilmington (NC) (Now GG)	
GR	Miami Regional Office (Obsolete)	
H1	Detroit (Now I7)	
H2	Cleveland (Now I8)	
H3	Cincinnati (Now I9)	
H4	Louisville (Now IA)	
H5	Columbus (OH) (Now IB)	
H6	Grand Rapids (Now IC)	
HT	Detroit Task Force (Obsolete)	
I6	Chicago DEA/FBI Investigation Team (Obsolete)	
IK	Duluth (Closed)	
IX	Green Bay (POD Using I3)	
J1	New Orleans (Now GH)	
J2	Little Rock (Now GJ)	
J3	Nashville (Now GK)	
J4	Birmingham (Now GL)	
J5	Jackson RO (Now GM)	
J6	Memphis (Now GN)	
J7	Baton Rouge (Now GP)	
J8	Mobile (Now GQ)	
K1	Minneapolis (Now IJ)	
KE	Key West (Closed)	
L1	Kansas City (Now IE)	
L2	St. Louis (Now IF)	
L3	Omaha (Now IG)	
L4	Des Moines (Now IH)	
L5	Little Rock (Now GJ)	
L5	Minneapolis (Now IJ)	
L6	Duluth (Closed)	
L7	Wichita (Now IL)	
L8	Fargo (Now IM)	

Appendix H-2

Headquarters Program General Files (9000 Series) - By Number

Revised 04/11/12

Files also available sorted *By Title*

SEQUENCE #	FILE TITLE
(b)(7)(E)	Official Aircraft Utilization (Discontinued)
	Surrender of Registration - Class A Practitioner
	Surrender of Registration - Class B Non-Practitioner
	Drug Thefts
	In Transit Loss or Theft of Drugs (Discontinued)
	Pre-Registrant
	Approval of Application - Class B / DEA Forms 225 / 225a
	Domestic Marijuana Harvesting / Eradication
	Surrendered Illicit Drugs
	DEA/Customs Cooperation (Discontinued)
	Customs Designation (Discontinued)
	Referrals to Customs
	Referrals from Customs
	Referrals to / from Secret Service
	Interpol Inquiry / Reports
	INS/DEA Cooperation (Discontinued)
	Expended Official Funds (Discontinued)
	Use of Flash Rolls (Discontinued)
	Significant State & Local Seizures - DEA-185 (Discontinued)
	Assaults / Threats / Shootings
	Assaults on Informants (Discontinued)
(b)(7)(E)	Customs TECS Lookouts
	Customs TECS Lookouts - Results
	DHS Lookouts (formerly INS)
	DHS Lookouts - Results (formerly INS)

	(b)(7)(E)	DHS/TECS Combined Lookouts (formerly INS)
		US Coast Guard Lookouts
		US Coast Guard Lookouts - Results
		NLETS Lookouts
		NLETS Lookouts - Results
		Customs Aircraft Lookouts
		Customs Aircraft Lookouts - Results
		FAA Lookouts
		FAA Lookouts - Results
		FAA Transponder Lookout Notifications
		FAA Transponder Lookout Notifications - Results
		Referrals to FBI
		Referrals from FBI
		Referrals to IRS
		Referrals from IRS
		Referrals to ATF
		Referrals from ATF
	(b)(7)(E)	Referrals to US Coast Guard
		Referrals from US Coast Guard
		Referrals to DHS (formerly INS)
		Referrals from DHS (formerly INS)
		Referrals to Border Patrol
		Referrals from Border Patrol
		Referrals to Other Federal Law Enforcement Agencies
		Referrals from Other Federal Law Enforcement Agencies
		Referrals to State Law Enforcement Agencies
		Referrals from State Law Enforcement Agencies
		Referrals to Local Law Enforcement Agencies
		Referrals from Local Law Enforcement Agencies
		Referrals to Foreign Law Enforcement Agencies
		Referrals from Foreign Law Enforcement Agencies
		Referrals to State Regulatory Agencies

	(b)(7)(E)	Referrals from State Regulatory Agencies
		Referrals to FDA
		Referrals from FDA
		Referrals to Military Installations
		Referrals from Military Installations
		Approval of Application - Class A / DEA Forms 224 / 224a
		Withdrawal of Application - Class A
		Withdrawal of Application - Class B / DEA Forms 225, 225a, 363, 363a
		Customs Mail Importation Program/Seizures
		Excessive Purchases (Discontinued 10/25/2010, see 9464)
		Precursor Control Program
		Organized Crime
		Drug Evidence Importation - DEA Form 360
		Currency Transaction and Transportation Reports
		Americans Arrested Abroad
		Extremist / Terrorist Activities
		Couriers
	(b)(7)(E)	Smuggling - Aircraft
		Suspect Vessels
		Corrupt Officials
		Motorcycle Clubs
		Anonymous Letters
		Citizen Complaints and Public Inquiries
		Counterfeit Drugs
		New Drugs of Abuse
		Congressional Inquiries
		Diluents
		Methadone
		Stimulants
		Barbiturates
		Etorphine / Diprenorphine
		Talwin

	(b)(7)(E)	Dilaudid
		Drug Security (Discontinued)
		Anonymous Street Sample Labs
		Import / Export (Discontinued)
		Project DAWN (Discontinued)
		Narcotic Treatment Programs
		Approval of Application - Narcotics Treatment Program - DEA Forms 363, 363a
		Physician Intelligence
		Pharmacy Intelligence
		Drug Wholesaler - Distribution Diversion (Registrant)
		Permits for Central Bookkeeping (Discontinued)
		Authentic Ballistics Samples (Registrant)
		Drug Quotas (Discontinued)
		Computerized Prescription Service
		Nursing Homes (Long-Term Care Facilities)
		Medical Addicts / Chronic Illness
		Drug Destruction
	(b)(7)(E)	Medical Use of Schedule I Substances
		Forged Prescriptions
		Piperidine Report
		Financial Privacy Act Information
		Modification of Registration
		Denial of Application / Revocation of Registration
		Referrals to / from DIU
		Pharmaceutical Look-Alikes
		Abandoned Drugs
		Airline Employees
		Airport Programs / Intelligence
		Arms Smuggling
		Asian Heroin
		Clandestine Airfields
		Clandestine Labs and Refineries

	(b)(7)(E)	
		Cocaine
		Afghanistan
		Africa
		Algeria
		Argentina
		Austria
		Australia
		Barbados / Windward Islands
		Belgium
		Belize
		Bolivia
		Brazil
		Bulgaria
		Burma
		Canada
		Chile
		Colombia
	(b)(7)(E)	Costa Rica
		Cuba
		Czechoslovakia
		Cyprus
		Denmark
		Ecuador
		El Salvador
		United Kingdom
		Finland
		France
		Germany, West
		Greece
		Guam
		Guatemala
		Guyana

	(b)(7)(E)		
			Honduras
			Hong Kong
			Hungary
			Iceland
			India
			Indonesia
			Iraq
			Ireland
			Israel
			Italy
			Japan
			Korea (Discontinued) see 9406 and 9407
			Laos
			Lebanon
			Luxembourg
			Macao
			Malaysia
	(b)(7)(E)		Mexico
			Monaco
			Morocco
			Nepal
			Netherlands
			Curacao (formerly Netherlands Antilles)
			New Zealand
			Nicaragua
			Norway
			Pakistan
			Panama
			Paraguay
			Peoples Republic of China
			Peru
			Philippines

L9	Sioux Falls (Now IN)	
MF	Falcon Heights RO (Closed)	
MR	Dallas Regional Office (Obsolete)	
MU	Douglas (Closed)	
MY	Yuma (Using MT)	
N1	Denver (Now MK)	
N2	Salt Lake City (Now ML)	
N3	Albuquerque (Now MM)	
N4	Phoenix (Now MN)	
N5	Nogales (Now MP)	
N6	Tucson (Now MQ)	
N7	Las Cruces (Now MS)	
N8	San Luis (Closed)	
N9	Douglas (Closed)	
NA	Lukeville (Closed)	
NB	Cheyenne (Now MV)	
P1	Seattle (Now RE)	
P2	Portland (Now RF)	
P3	Anchorage (Now RG)	
P4	Spokane (Now RH)	
P5	Vancouver (Now RJ)	
P6	Boise (Now RK)	
P7	Blaine (Now RL)	
P8	Great Falls (Closed)	
P9	Fairbanks (Closed)	
PA	Eugene (Now RN)	
R8	Tecate (Closed)	CADEA0600
RD	Los Angeles DEA/FBI Investigation Team (Obsolete)	
RR	Los Angeles Regional Office (Obsolete)	
RW	Monterey RO (Closed)	
UA	Ankara (Now XU)	
UB	Istanbul (Now XV)	

	(b)(7)(E)	Poland
		Ponape
		Portugal
		Romania
		Commonwealth of the Northern Marianas (CNMI)
		Singapore
		Spain
		Sri Lanka
		Surinam
		Sweden
		Switzerland
		Syria
		Taiwan
		Thailand
		Turkey
		UAR (Egypt)
		Uruguay
	(b)(7)(E)	USSR
		Yugoslavia
		Financial Intelligence
		Hallucinogens
		Hashish
		Heroin
		Impersonation of Federal Agents
		Israel Mafia
		JANUS
		Japanese Organized Crime
		LSD
		Marijuana
		Major Traffickers
		Marine Intelligence
		Methaqualone

	(b)(7)(E)		Morphine Base
			Non-Prosecutable Cases
			Opium
			Potential Informants
			Prison Intelligence
			Referrals to / from RCMP
			Religious Cults
			Smuggling by Land
			Smuggling by Ship
			Suspected Drug Traffickers
			Termination and Transfer of Business (Registrant)
			Thai Trawler Program
			Walk-In
			Venezuela
			Referrals to / from State Department
			Referrals to / from CIA
			Vietnam
	(b)(7)(E)		Cambodia
			Federated States of Micronesia (FSM)
			Belau (Pelau)
			Marshall Islands Government
			German Democratic Republic
			Bermuda
			Malta
			Bahamas
			Cayman Islands
			Dominican Republic
			French West Indies
			Haiti
			Jamaica
			Polygraph Examinations
			Mail Seizures - Southeast Asian Refugees

	(b)(7)(E)		Trinidad and Tobago
			Referrals to NNBIS
			Referrals from NNBIS
			Turks and Caicos Islands
			Heroin Domestic Monitor Program
			Papua and New Guinea
			Solomon Islands
			Vanuatu
			New Caledonia
			Nigeria
			SATTRACK Lookouts
			SATTRACK Lookouts - Results
			United Arab Emirates
			Saudi Arabia
			Maldives
			Bangladesh
			Iran
			Asian Organized Crime (Domestic)
			Jordan
			Organization of East Caribbean Countries
			Sentry - Drug Sample Purchases
9271			Samoa
9272			British Virgin Islands
9273			Liechtenstein
9274			Andorra
9275			Referrals to / from Postal Service
9276			Money Laundering
9277			TIR Trucks
9278			Glutethimide
9279			Crack Cocaine
9280			Kuwait
9281			Qatar

	(b)(7)(E)	MDMA
		Carfentanil
		Customs Title 21 Investigations
		Referrals for Lead Development
		Referrals to FINCen
		Referrals from FINCen
		US Virgin Islands
		Harassment of DEA Employees
		Referrals to CABINET
		HIDTA
		Anabolic Steroids
		Referrals to / from Bureau of Land Management
		Referrals to / from Bureau of Indian Affairs
		Referrals to / from National Park Service
		Referrals to / from US Fish and Wildlife
		OCDETF Cases without DEA or FBI Participation
		International Drug Enforcement Conference (IDEC)
	(b)(7)(E)	Employment Waivers 21 C.F.R.-1301 (A)
		Jose Santacruz-Londono TKO
		Rodriguez-Orejuela Brothers TKO
		Helmer Herrera-Buitrago TKO
		Jairo Urdinola-Grijales TKO
		Jaime Garcia-Garcia TKO
		Duvan Orboleda TKO
		Roberto Juri-Feghali TKO
		Pablo Escobar-Gaviria TKO
		Ochoa Brothers TKO
		Fentanyl
		Monzer Al Kassar TKO
		Chang Chi-Fu TKO
		Haji Mirza Mohd Iqbal Baig TKO
		Estonia

	(b)(7)(E)		Latvia
			Lithuania
			Pharmaceutical Returns
			Armenia
			Georgia
			Azerbaijan
			Kazakhstan
			Kyrgyzstan
			Tajikistan
			Turkmenistan
			Uzbekistan
			Albania
			Belarus
			Moldova
			Slovenia
			Croatia
			Ukraine
	(b)(7)(E)		Russia
			Slovak Republic
			Czech Republic
			Kingpin Program
			Sale or Transfer of Tableting or Encapsulating Machines
			Thefts of Listed Chemicals
			Chemical Company Diversion
			Suspicious Chemical Orders
			Gibraltar
			Anguilla, British West Indies
			Antigua & Barbuda, West Indies
			Montserrat, BritishWest Indies
			St. Christopher & Nevis, West Indies
			Surrender of Registration (Chemicals)
			Approval of Application - DEA-510 & 510a (Chemical)

	(b)(7)(E)		Withdrawal of Application - DEA-510 & 510a (Chemical)
			Chemical Intelligence
			Former Yugoslavia Republic of Macedonia (FYROM)
			Violent Crime
			Khat (Catha Edulis)
			Investigative Leads
			Pseudoephedrine
			Mobile Enforcement Team (MET) Investigations
			Parcel Interdiction
			Hotel Interdiction
			Weed and Seed Program
			Methamphetamine
			Modification of Chemical Registration
			Chemical Preregistrants
			Ephedrine
			Rohypnol / Flunitrazepam
			Drug Suppression Program
	(b)(7)(E)		Serbia / Montenegro
			Bosnia / Herzegovina
			International Prisoner Transfer Program
			Denial of Application (Chemical)
			China - NOTE: FILE NUMBER CANCELLED. USE 9183 OR 9198.
			Telecommunications Exploitation Development
			Palestine
			Drug Trafficking Computer Alert
			Street Gang Activity
			Witness Security Program
			S Visa Program
			Prisoner Utilization Program
			Turkish Republic of Northern Cyprus (TRNC)
			Colombian Traffickers
			Mexican Traffickers

	(b)(7)(E)		Mid-level Practitioner Intelligence
			Nurse/Hospital Diversion
			In-transit Theft/Loss
			Hydrocodone
			Individuals Determined to be Unsuitable Confidential Sources
			South Africa
			Pharmaceutical Monitor Program
			Internet Pharmaceutical Sales
			Internet Chemical Sales
			Mongolia
			Threat Assessments - Mexico
			Ethnic Albanian Drug Trafficking Groups
			Joint Interagency Task Force East
			Joint Interagency Task Force West
			Medical Maintenance
			Operation CHEM DOUGH
			Operation CONTACT
	(b)(7)(E)		Freight Forwarding Facilities
			Oxycontin
			BC Bud
			Exemption from Chemical Registration
			Canadian Pseudoephedrine
			Referrals to / from Tribal Police
			HOASCA (Ayahuasca) - Tea made in South America that contains the Schedule I hallucinogen Dimethyltriptamine
			Buprenorphine
			Internet Intelligence
			Integrated Border Intelligence Team (IBIT)
			Crystal Ball
			Korea (North)
			Korea (South)
			Fugitives
			Fiji Islands

	(b)(7)(E)		Tonga Islands
			Report Officer Summaries
			Computer Forensics
			Referrals to / from NDPIX/NVPS
			Support of Priority Target Program/Investigations
			Support of OCDETF Program/Investigations
			Palladone
			Diversion Hot Line
			Caribbean Corridor
			High Intensity Financial Crime Area/HIFCA
			Gulf Hurricanes (Formerly Katrina) includes Rita, Reimbursable / Disaster Recovery-Assistance
			Gulf Hurricanes (Formerly Katrina) includes Rita, Non Reimbursable / Support DEA Continuity
			Cocaine Retail Monitor Program
			Methamphetamine Retail Monitor Program
			Concealment Trap Initiative - Financial Operations
			Bulk Currency Initiative - Financial Operations
	(b)(7)(E)		National Trucking Initiative - Financial Operations
			Serbia
			Montenegro
			San Marino
			Tri-Border Area Initiative
			Maritime Threats
			Terrorist Screening Center (TSC)
			Patriot Improvement and Reauthorization Act
			Reserved for OPR
			California Wildfires, Disaster Recovery-Assistance
			National Money Counter Initiative - Financial Operations
			License Plate Reader Initiative - Financial Operations
			Back Azimuth Initiative - Financial Operations
			East Timor

	(b)(7)(E)	Afghan Threat Finance Cell - Financial Operations
		OFAC Kingpin/Executive Order Designations - Financial Operations
		Operation SIN FRONTERAS
		Operation Safeguard
		Operation Control Alt Delete
		Operation Black Asphalt - Financial Operations
		Operation COMPLIANCE
		Oman
		Southwest Border Intelligence Collection Plan
		Operation Express Delivery
		Europol
		Operation Pangea II
		Africa Intelligence Collection Plan
		Domestic Intelligence Collection Plan
		Foreign Intelligence Collection Plan
		Operation Savant - Financial Operations
		Haiti Earthquake Relief Operations
	(b)(7)(E)	South America Intelligence Collection Plan
		Bolivia Outside/In
		Pharmaceutical Take Back Initiative
		Operation Opioid Overload
		Cabo Verde
		Operation Pangea III
		Prepaid Access Card Initiative - Financial Operations
		Suspicious Orders/Transactions
		Andean Region Intelligence Collection Plan
		Southern Cone Intelligence Collection Plan
		Researcher Intelligence
		Joint Interagency Task Force South (JIATF-S) Intelligence Collection Plan
		Ultra Light Air Incursion
		Far East Region Intelligence Collection Plan
		Zetas DTO

	(b)(7)(E)		Native American Indian Initiatives
			Central Asian Regional Information and Coordination Center (CARICC)
			Project FOSOD
			Guinea Bissau
			Senegal
			ESF 13 DEPLOYMENT MINOT ND
			Nuevo Leon RIOCC Strategic Intelligence
			Tamaulipas RIOCC Strategic Intelligence
			Coahuila RIOCC Strategic Intelligence
			Operation Axis
			Zacatecas RIOCC Strategic Intelligence
			Veracruz RIOCC Strategic Intelligence
			Southeast European Law Enforcement Training Center (SELEC)
			Gulf Cartel
			Operation Illumine
			Ghana
			Kenya
	(b)(7)(E)		Mozambique
			Tanzania
			Impact of Mexican Extraditions
			Methamphetamine Collection Requirements
			Air Intelligence

REFERENCE 5254C

DIVERSION CLASS CODES

A. First two Characters - TYPE OF REGISTRANT

(b)(7)(E)

- Bulk Manufacturer
- All Other Manufacturers
- Distributor IE-Importer/Exporter
- Narcotic Treatment Program
- Researcher/Analytical Laboratory/Teaching Institution
- Retail Pharmacy
- Hospital Pharmacy
- M.D.
- D.O.
- D.V.M.
- D.D.S.
- Non-Registrant (International)
- Other Registrant

B. Third and Fourth Characters - TYPE OF INVESTIGATION

(b)(7)(E)

- Cyclic
- Follow-up to Cyclic
- Security Investigation (general file)
- Drug Theft Investigation (general file)
- Precursor Control Program Investigation

(b)(7)(E)

- Complaint Investigation - Criminal (must have G-DEP)
- Complaint Investigation - Noncriminal
- (not in use)
- Pre-Registrant Investigation (general file)
- Other Registration Investigation (general file)**

REFERENCE 5262A

LETTER OF ADMONITION

8400 N.W. 53rd Street

Miami, Florida 33166

REGISTERED MAIL

Mr. Charles J. Jones

President, ABC Drugs

123 N.W. 14th Street

Miami, Florida 33100

File G1-82-0007

Dear Mr. Jones:

During the month of June 1982, Investigators of this office conducted an investigation of your firm which revealed record keeping inadequacies and security deficiencies. The discrepancies noted are as follows:

1. Supplier copies of the DEA order forms denoting Males of Schedule II controlled substances were not being recorded with the date of shipment or quantity shipped. Section 1305.09 of Title 21 of the Code of Federal Regulations requires the supplier to record the quantity shipped and the date of shipment on copies 1 and 2 of the Official Order Form.

2. Invoices documenting the sale. of-Schedule III, IV, and V controlled substances were not readily retrievable in that they were not maintained separately from all other record. or in such form that the information required is visually identifiable apart from other items appearing on the records an required by Section 1304.04(b)(2) of Title 21, Code of Federal Regulations.

3. The cage storage area for Schedule III, IV, and V controlled substances was not equipped with an alarm system to detect unauthorized entry. Section 1301.72(b)(4) of Title 21 of the Code of Federal Regulations requires this cage to be equipped with an alarm system which upon unauthorized entry will transmit a signal directly to a central station protection agency or a law enforcement agency, each having a legal duty to respond.

This letter is formal notification that your failure to maintain adequate record. and security for controlled substances constitutes violations of the Controlled Substances Act. At this time, you are being afforded the opportunity to comply with the requirements of the Controlled Substances Act which were outlined by the Investigator" with the management of your firm on June 19, 1982.

Please advise this office in writing within thirty (30) days the action taken or planned to correct these violations. If you have any questions concerning this matter, please contact Group Supervisor Kenneth Davis, telephone number (305) 824-8000.

REFERENCE 5262B

NOTICE OF HEARING (DEA-80)

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

8400 N.W. 53rd Street
Miami, Florida 33166

In reply, refer to:
G1-82-2020

Date of Notice:
May 1, 1982

NOTICE OF HEARING

REGISTERED MAIL

XYZ Drug Distributors, Inc.
and
Mr. William R. Jones, President
123 S.W. 20th Street
Miami, Florida 33121

AUTHORITY Section 513 of the Controlled Substances Act states: "Before any violation of this Act is reported by the Administrator of the Drug Enforcement Administration to any United States attorney for institution of a criminal proceeding, the Administrator may require that the person against whom such proceeding is contemplated be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding."

FINDING Investigation by this Administration indicates your responsibility for violation of the Controlled Substances Act, with respect to the following prohibited act(s):

21 USC 842(a)(5)

CHARGE

1. Failure to maintain a complete and accurate record of Schedule III, IV, and V controlled substances received and distributed in violation of 21 USC 827(a)(3) and 21 CFR 1304.21(a).
2. Failure to maintain a complete and accurate biennial inventory of all controlled substances in violation of 21 USC 827(a) and 21 CFR 1304.11(a).

(NOTE: Plain bond paper may be used as a continuation sheet.)

HEARING An informal hearing will be held at the above address on June 3, 1982 *(date)* at 10:00 *(time)*

to give you an opportunity to present your views in this matter. You may appear in person, with or without an attorney (or your attorney may appear for you); you or your attorney may answer in writing; you also have the option of not answering at all. If you desire representation by an attorney and the above hearing date does not allow sufficient time for you to acquire an attorney, so advise the undersigned on or before the hearing date set out above and a new hearing date will be established. If no response is received on or before the date set, our decision as to the disposition of this matter will be based on the evidence at hand.

By direction of the Attorney General

Signature

Special Agent-in-Charge
Title

DEA Form 80 (Jan. 1974)

Previous edition, 8/71, is obsolete.

DOJ-1974-11

CHARGE: 3. Failure to document the receipt of Schedule II controlled substances by recording the date and quantity received on the Official Order Forms as required by 21 CFR 1305.09(e).

REFERENCE 5262C

MEMORANDUM OF UNDERSTANDING (DEA REGISTRANT)

Mr. William R. Jones, President

XYZ Drug Distributors, Inc.

123 S.W. 20th Street

Miami, Florida 33121

Dear Mr. Jones:

Enclosed are an original and three (3) copies of the Memorandum of Understanding between XYZ Drug Distributors, Inc., and the Drug Enforcement Administration. Please have them signed, dated, and notarized. Return all copies to the Drug Enforcement Administration, Diversion Operations Section, Room E-6293, Washington, D.C. 20537.

Upon completion by this office, a copy will be returned to you for your records. If you have any further questions in this matter, please contact _____, Diversion Group Supervisor, (Division/Resident) Office at (telephone number).

Sincerely,

_____, Chief

Drug Operations Section

IN THE MATTER	Drug Enforcement Administration
	File Number G1-84-2020
XYZ DRUG DISTRIBUTORS, INC.	Hearing Pursuant to Section 513
123 S.W. 20th Street	of the Comprehensive Drug Abuse
Miami, Florida 33121	Prevention and Control Act of
	1970

MEMORANDUM OF UNDERSTANDING

On May 1, 1984, a Notice of Hearing as provided by Section 513 of the Controlled Substances Act (21 USC 883) was issued to the Respondent, XYZ Drug Distributors, Inc., on behalf of the Drug Enforcement Administration. The Notice of Hearing informed the Respondent that an informal hearing would be held at the Drug Enforcement Administration's Miami District Office, 8400 N.W. 53rd Street, Miami, Florida, on June 4, 1984, the provide the Respondent an opportunity to reply to all allegations contained in the Notice of Hearing.

The Notice of Hearing alleged that prohibited acts have occurred in violation of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and the regulations promulgated thereunder -- namely, that the Respondent, XYZ Drug Distributors, Inc., has:

(1) Failed to maintain a complete and accurate record of Schedule III, IV, and V controlled substances received and distributed as required by 21 USC 827(a)(3) and 21 CFR 1304.21(a).

(2) Failed to maintain a complete and accurate biennial inventory of all controlled substances as required by 21 USC 827(a) and 21 CFR 1304.11(a).

(3) Failed to document the receipt of Schedule II controlled substances by recording the dates and quantity received on the Official Order Forms as required by 21 CFR 1305.09(e).

Pursuant to the Notice of Hearing, a meeting was held on June 4, 1984, at the Miami District Office of the Drug Enforcement Administration, 8400 N.W. 53rd Street, Miami, Florida.

Appearing on behalf of the Respondent were:

William R. Jones, President John S. Smith, Attorney

Appearing on behalf of the Drug Enforcement Administration were:

William G. Wilson, Hearing Officer

Harry E. Redford, Group Supervisor

Jack L. Davis, Investigator

The Respondent, having been fully advised of the prohibited acts which have occurred, has agreed to comply with the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and the regulations issued thereunder as hereafter set forth:

(1) Respondent will maintain a complete and accurate record of all Schedule III, IV, and V controlled substances received and distributed as required by 21 USC 827(a)(3) and 21 CFR 1304.21(a).

(2) Respondent will prepare and maintain an accurate biennial inventory by including all controlled substances on hand at the time of inventory as required by 21 USC 827(a) and 21 CFR 1304.11(a).

(3) Respondent will document the receipt of Schedule II controlled substances by accurately recording the date and quantity received on Official Order Forms as required by 21 CFR 1305.09(e).

William R. Jones, President of XYZ Drug Distributors, Inc., acknowledges and states that he has read the foregoing and knows and agrees with the contents thereof; that he has the authority to act on behalf of the corporation named in this matter; and that he has signed this Memorandum of Understanding pursuant to said authority.

XYZ Drug Distributors, Inc.

By:

Sworn to before me

this _____ day of _____ 1984

Attest

(Name of Deputy Director), Office of Diversion Control Headquarters, Drug Enforcement Administration, acknowledges and states he/she has read the foregoing and knows and agrees with the contents thereof; that he/she has authority to act on behalf of said Administration in this matter; and that he/she has signed this Memorandum of Understanding pursuant to said authority.

_____(signature)

By: Deputy Director

Office of Diversion Control

Drug Enforcement Administration

REFERENCE 5262D

VOLUNTARY SURRENDER OF CONTROLLED SUBSTANCES PRIVILEGES

SEE REVERSE FOR PRIVACY ACT INFORMATION	VOLUNTARY SURRENDER OF CONTROLLED SUBSTANCES PRIVILEGES	DEA USE ONLY FILE NO.

After being full advised of my rights, and understanding that I am not required to surrender my controlled substances privileges, I freely execute this document and choose to take the actions described herein.

☐ In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part;

☐ In view of my desire to terminate handling of controlled substances listed in schedule(s) _____ ;

I hereby voluntarily surrender my Drug Enforcement Administration Certificate of Registration, unused order forms, and all my controlled substances listed in schedule(s) _____ as evidence of my agreement to relinquish my privilege to handle controlled substances listed in schedule(s) _____. Further, I agree and consent that this document shall be authority for the Administrator of the Drug Enforcement Administration to terminate and revoke my registration without an order to show cause, a hearing, or any other proceedings, (and if not all controlled substances privileges are surrendered, be issued a new registration certificate limited to schedule(s) _____).

I waive refund of any payments made by me in connection with my registration.

I understand that I will not be permitted to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other controlled substance activities whatever, until such time as I am again properly registered.

NAME OF REGISTRANT *(Print)*	ADDRESS OF REGISTRANT	
SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL	DATE	DEA REGISTRATION NO.

WITNESSES:

NAME AND DATE	TITLE
NAME AND DATE	TITLE

DEA Form -104 (Sept 1976) Previous edition dated 1-74 is OBSOLETE. DOJ

PRIVACY ACT INFORMATION **DEA-104**

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513)

PURPOSE: Permit voluntary surrender of controlled substances.

ROUTINE USES: The Controlled Substances Act Registration Records produces special reports as required for statistical analytical purposes. Disclosure of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (Public Law 91-513) for the purpose of verifying the registration of customers and practitioners.

EFFECT: Failure to provide the information will have no effect on the individual.

REFERENCE 5262E

LETTER REQUESTING VOLUNTARY SURRENDER

Dear (Registrant):

On (***date***), the Drug Enforcement Administration received information from the (***name of agency***) that your license to practice (medicine, etc.) including the prescribing, administering, and dispensing of controlled substances, has been (***revoked, etc.***) in the State of (***name of state***) effective (***date***).

Pursuant to the provisions of 21 USC 823(f), a practitioner's Federal authorization to prescribe, administer, dispense, or otherwise handle controlled substances depends upon authorization by the state or Jurisdiction in which he or she practices. The (***name of agency***) action in this matter has terminated that authority. Therefore, you are currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of (***name of state***).

Under the provisions of 21 USC 824 and Applicable Administrative Decisions, your current DEA Certificate of Registration is subject to revocation. We are now in the process of requesting such proceedings.

However, if you desire to waive your right to a hearing in this matter, you may voluntarily surrender your DEA registration. A DEA Form 104, Voluntary Surrender of Controlled Substances Privileges, has been enclosed for your convenience. If you choose to voluntarily surrender your controlled substances privileges, sign the enclosed form and send your DEA registration certificate, unused order forms, and any controlled substances in your possession to this office. If you have any questions in this matter, please contact Investigator (***name of investigator***) at (***telephone number***).

Sincerely,

/s/

Special Agent in Charge

REFERENCE 5262F

LETTER OF TERMINATION

John Doe, DMD

18 Chapel Street

Redmond, Georgia 27705

Dear Dr. Doe:

On June 30, 1995, the Drug Enforcement Administration Certification of Registration _____ issued to you expired. You are currently without authority to possess, procure, or distribute controlled substances.

Our records show that you have not applied for a renewal of your DEA registration. In the event you do apply for a registration, the Administrator of DEA has the option of issuing an Order to Show Cause to deny your application for registration. The Controlled Substances Act (Title 21 U.S.C. 824(a)(4) authorizes the Administrator to deny an application for registration if the applicant has committed such acts as would render the registration under Section 823 of this title inconsistent with the public interest.

Correspondence in this matter should be directed to the undersigned, (address).

Sincerely,

Tom Jones

Special Agent in Charge

Atlanta Division

cc: ODO

REFERENCE 5270A

ARCOS (DIVERSION SUPPORT DATA REQUEST)

(Suggested Standardized Format)

I. District:

II. Case Coordinator:

Telephone Number:

III. Date Report Required:

IV. Investigation Brief:

A. Complete name, address, activity, and DEA Registration Number of case subject(s).

B. Specific type of data required, i.e., sales, purchases, thefts, etc.

C. Specify category, particular drug code(s) or drug to be targeted, i.e., Amphetamines, Ritalin, Dilaudid, 1630, etc.

If a specific drug manufacturer's product is desired, provide this information.

D. Specify any source(s) of supply to be targeted from your Divisional area or any other Divisional area.

E. Indicate period of time to be covered in diversion research.

F. Indicate whether or not the case i. being conducted in conjunction with another DEA field office or another Federal or state agency.

V. Indicate any requests or suggestions for specific report format or new reports which may be of help in field investigations. (Please note: any new report requested may require additional time due to programming.)

REFERENCE 5270B

LABEL (SUGGESTED STANDARDIZED FORMAT FOR REPORT)

I. District/Resident:

II. Label Contact:

Telephone Number:

III. Date Report Required:

IV. Information Required:

A. Name and address of individual who is requesting Project Label date.

B. Specific type of Project Label data or report that is needed.

C. Purpose or reason why the Project Label information is needed.

V. Indicate any requests or suggestions for specific report format or new reports which may be of help in field investigations.

REFERENCE 5271B

RECEIPT FOR SAMPLES (DEA-400)

US DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

RECEIPT FOR SAMPLES

NAME AND TITLE OF RESPONSIBLE INDIVIDUAL	FILE NO
John Smith, Production Manager	GFCE-82-3004
FIRM NAME	**DEA REGISTRATION NO**
ABC Pharmacal, Inc.	AB1234563
REGISTERED ADDRESS *(No Street City State and ZIP CODE)*	**TELEPHONE NO** *(Include Area Code)* 212-678-5530
723 N. Main Street Johnstown, Maine 22713	**DATE** June 15, 1982

The following samples were collected and receipt is hereby acknowledged pursuant to Section 510(b)(3)(C) [21 U.S.C. 880(b)(3)(C)] of the Controlled Substances Act of 1970 and 21 C.F.R. 1301.26(c) and 1316.03(d)*:

PRODUCT	CONTROL NUMBER	DOSAGE *(Form & Strength)*	AMOUNT
Phenobarbital	B30643	Tablets 30mg	100
Secobarbital	D30691	Capsules 100mg	100
Dextroamphetamine sulfate	D30329	Tablets 5 mg	100

TOTAL COST $ _____ ☐ Paid in Cash ☐ Billed ☒ No Cost

*SEE REVERSE OF THIS PAGE

SIGNATURE *(DEA Special Agent or Compliance Investigator)*	DATE
/s/ A.J. Arnold	June 15, 1982
SIGNATURE	**DATE**
/s/ J. Smith	June 15, 1982

DEA Form 400
May 1977

Supersedes BND 83 and BND 84 which are OBSOLETE

21 CFR 1301.26(c):

Any official exempted by this section may procure any controlled substance in the course of an inspection, in accordance with paragraph 1316.03(d), or in the course of any criminal investigation involving the person from whom the substance was procured.

21 CFR 1316.03(d):

Collecting samples of controlled substances or precursors (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 400 to the owner, operator, or agent in charge of the premises).

Section 510(b)(3)(C) of the Controlled Substances Act is quoted below:

"(C) to inventory any stock of any controlled substance therein and obtain samples of any such substance."

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