

The Acting Administrator of the Environmental Protection Agency, Bob Perciasepe, signed the following proposed rule on April 5, 2013 and we are submitting it for publication in the Federal Register. While we have taken steps to ensure the accuracy of this Internet version of the proposal, it is not the official version of the rule. Please refer to the official version in a forthcoming Federal Register publication, which will appear on the Government Printing Office's FDSys website (<http://fdsys.gpo.gov/fdsys/search/home.action>) and on Regulations.gov (<http://www.regulations.gov>) in Docket No. EPA-HQ-OAR-2007-0268. Once the official version of this document is published in the Federal Register, this version will be removed from the Internet and replaced with a link to the official version.

**6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OAR-2007-0268; FRL-9707-2]**

**Updates to Protective Action Guides Manual: Protective Action Guides (PAGs) and Planning Guidance for Radiological Incidents**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of document availability for interim use and public comment.

**SUMMARY:** As part of its mission to protect human health and the environment, the Environmental Protection Agency (EPA) publishes protective action guides to help federal, state, local and tribal emergency response officials make radiation protection decisions during emergencies. EPA, in coordination with a multi-agency working group within the Federal Radiological Preparedness Coordinating Committee (FRPCC), is proposing updates to the 1992 Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, referred to as "The 1992 PAG Manual" (EPA 400-R-92-001, May 1992).

The updated guidance in this revised 2013 PAG Manual – Protective Action Guides and Planning Guidance for Radiological Incidents (“2013 PAG Manual” hereafter) applies the PAGs to incidents other than just nuclear power plant accidents, updates the radiation dosimetry and dose calculations based on current science and incorporates late phase guidance.

While there is no drinking water PAG provided in the proposal, the Agency continues to seek input on this. The newly proposed 2013 PAG Manual is available for interim use and review at [www.regulations.gov](http://www.regulations.gov).

**DATES:** Comments must be received on or before 90 days after date of publication in the Federal Register.

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**ADDRESSES:** Submit your comments, identified by Docket ID No. **EPA-HQ-OAR-2007-0268**, by one of the following methods—

- [www.regulations.gov](http://www.regulations.gov): Follow the on-line instructions for submitting comments.
- Email: to [a-and-r-docket@epa.gov](mailto:a-and-r-docket@epa.gov); Docket ID No. **EPA-HQ-OAR-2007-0268**.
- Fax: (202) 566-1741
- Mail: Air and Radiation Docket and Information Center, Environmental Protection

Agency, Mail Code: 6102T, 1200 Pennsylvania Ave., NW, Washington, DC 20460

*Instructions:* Direct your comments to Attn: Docket ID No. **EPA-HQ-OAR-2007-0268**.

The Agency's policy is that all comments received will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the

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use of special characters, any form of encryption and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

*Docket:* All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. EPA has established a docket for this action under Docket ID No. [EPA-HQ-OAR-2007-0268; FRL-9707-2]. Publicly available docket materials are available either electronically through [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Air and Radiation Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20004. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket is (202) 566-1742. In accordance with EPA's regulations at 40 CFR Part 2 and in accordance with normal EPA docket procedures, if copies of any docket materials are requested, a reasonable fee may be charged for photocopying.

**FOR FURTHER INFORMATION CONTACT:** Sara DeCair, Radiation Protection Division, Center for Radiological Emergency Management, Mail Code 6608J, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 343-9108 ; fax number: (202) 343-2304; E-mail: [decair.sara@epa.gov](mailto:decair.sara@epa.gov).

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## **SUPPLEMENTARY INFORMATION:**

### **A. What authority does EPA have to provide Protective Action Guidance?**

The historical and legal basis of EPA's role in the 2013 PAG Manual begins with Reorganization Plan No. 3 of 1970, in which the Administrator of EPA assumed all the functions of the Federal Radiation Council (FRC), including the charge to "...advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with states." (Reorg. Plan No. 3 of 1970, sec. 2(a) (7), 6(a) (2); § 274.h of the Atomic Energy Act of 1954, as amended (AEA), codified at 42 U.S.C. § 2021(h)). Recognizing this role, FEMA directed EPA in their Radiological Emergency Planning and Preparedness Regulations to "establish Protective Action Guides (PAGs) for all aspects of radiological emergency planning in coordination with appropriate federal agencies." (44 CFR 351.22(a)). FEMA also tasked EPA with preparing "guidance for state and local governments on implementing PAGs, including recommendations on protective actions which can be taken to mitigate the potential radiation dose to the population."(44 CFR 351.22(b)). All of this information was to "be presented in the Environmental Protection Agency (EPA) 'Manual of Protective Action Guides and Protective Actions for Nuclear Incidents.'"(44 CFR 351.22(b)).

Additionally, section 2021(h) charged the Administrator with performing "such other functions as the President may assign to him [or her] by Executive order." Executive Order 12656 states that the Administrator shall "[d]evelop, for national security emergencies, guidance on acceptable emergency levels of nuclear radiation...." (Executive Order No. 12656,

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sec.1601(2)). EPA's role in PAGs development was reaffirmed by the *National Response Framework, Nuclear/Radiological Incident Annex* of June 2008.

## **B. What is the PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents?**

The 2013 PAG Manual provides federal, state and local emergency management officials with guidance for responding to radiological emergencies. A protective action guide (PAG) is the projected dose to an individual from a release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended. Emergency management officials use PAGs for making decisions regarding actions to protect the public from exposure to radiation during an emergency. Such actions include, but are not limited to, evacuation, shelter-in-place, temporary relocation, and food restrictions.

Development of the PAGs was based on the following essential principles, which also apply to the selection of any protective action during an incident—

- Prevent acute effects.
- Balance protection with other important factors and ensure that actions result in more benefit than harm.
- Reduce risk of chronic effects.

The 2013 PAG Manual is not a legally binding regulation or standard and does not supersede any environmental laws; PAGs are not intended to define “safe” or “unsafe” levels of exposure or contamination. This guidance does not address or impact site cleanups occurring under other statutory authorities such as the United States Environmental Protection Agency's

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(EPA) Superfund program, the Nuclear Regulatory Commission's (NRC) decommissioning program, or other federal or state cleanup programs. As indicated by the use of non-mandatory language such as "may," "should" and "can," the 2013 Manual only provides recommendations and does not confer any legal rights or impose any legally binding requirements upon any member of the public, states, or any other federal agency. Rather, the 2013 PAG Manual recommends projected radiation doses at which specific actions may be warranted in order to reduce or avoid that dose. The 2013 PAG Manual is designed to provide flexibility to be more or less restrictive as deemed appropriate by decision makers based on the unique characteristics of the incident and the local situation.

### **C. What Updates are in the 2013 PAG Manual?**

The draft updates to the 1992 PAG Manual were developed by a multi-agency Subcommittee of the Federal Radiological Preparedness Coordinating Committee (FRPCC) and are published by EPA with concurrence from the Department of Energy (DOE); the Department of Defense (DoD); the Department of Homeland Security (DHS), including the Federal Emergency Management Agency (FEMA); the Nuclear Regulatory Commission; the Department of Health and Human Services (HHS), including both the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA); the U.S. Department of Agriculture (USDA); and the Department of Labor (DOL).

The 2013 PAG Manual focuses on the following key objectives—

- Clarify that the 1992 PAGs and protective actions are useful for all radiological and nuclear scenarios of concern, based both on the 1991 symposium, "Implementation of Protective

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Actions for Radiological Incidents at Other Than Nuclear Power Reactors” and the 2008 interagency “Planning Guidance for Protection and Recovery Following Radiological Dispersal Device (RDD) and Improvised Nuclear Device (IND) Incidents.”<sup>1</sup>

- Refer the reader to DOE’s Federal Radiological Monitoring and Assessment Center (FRMAC) Assessment Manuals<sup>2</sup> for calculation methods and measurable derived response levels (DRLs) and other appropriate dose assessment methods so that PAGs are implemented using the latest science.
- Refer users to the current Food PAGs published in FDA's “Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies,” as issued in 1998.<sup>3</sup>
- Recommend a simplified PAG approach for administering potassium iodide (KI) as a supplementary protective action based on FDA guidance issued in 2001.<sup>4</sup>
- Provide basic planning guidance on reentry, cleanup and waste disposal.
- Substantively incorporate the 2008 “*Planning Guidance for Protection and Recovery Following Radiological Dispersal Device (RDD) and Improvised Nuclear Device (IND) Incidents*” particularly for late phase cleanup after a nationally significant radiological incident, like a disaster at a NPP, an RDD or an IND. The 2008 RDD-IND Planning Guidance will remain in effect until the PAG Manual, with public comments incorporated, is finalized for use.

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<sup>1</sup> Planning Guidance for Protection and Recovery Following Radiological Dispersal Device (RDD) and Improvised Nuclear Device (IND) Incidents, DHS/FEMA (73 FR 45029, Aug 1, 2008).

<sup>2</sup> See: <http://www.nv.doe.gov/nationalsecurity/homelandsecurity/frmac/manuals.aspx>

<sup>3</sup> Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies, FDA (63 FR 43402, Aug 13, 1998).

<sup>4</sup> Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies, FDA (66 FR 64046, Dec. 11, 2001).

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- Streamline the Manual to enhance usability, while retaining the 1992 PAG Manual in its entirety as a historical online reference.

## **D. What Should I Consider as I Prepare My Comments for EPA?**

### *1. Submitting Confidential Business Information (CBI):*

Do not submit this information to EPA through [www.regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

### *2. Tips for Preparing Your Comments:*

When submitting comments, remember to—

- Identify the rulemaking by docket number, subject heading, *Federal Register* date and page number.
- Follow directions—EPA may ask you to respond to specific questions or organize comments by referencing the chapter number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.



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- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow it to be reproduced.
- Illustrate your concerns with specific examples and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

#### **E. What Specific Comments are Being Sought?**

While all comments regarding any aspect of the 2013 PAG Manual are welcome, comments on the following issues are specifically requested—

##### *Issues across the scope of the entire 2013 PAG Manual:*

- To implement the PAGs, the reader is referred to dose calculations in the Federal Radiological Monitoring and Assessment Center (FRMAC) Assessment Manuals. The Assessment Manuals are updated with current International Commission on Radiological Protection (ICRP) dosimetry models (i.e., ICRP 60 series) and dose coefficients. The FRPCC also encourages the use of computational tools such as DOE's Turbo FRMAC, RESRAD RDD and NRC's RASCAL or other appropriate tools and methods to implement the PAGs. We request comment on the usefulness of this approach and seek feedback on how to facilitate implementation of these methods in emergency management plans.
- The Agency recognizes a short-term emergency drinking water guide may be useful for public health protection in light of the Fukushima nuclear power plant accident, which impacted some Japanese drinking water supplies. Input on the appropriateness of, and possible values for, a drinking water PAG is being sought.

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- FDA's 1998 food guidance is incorporated by reference. Since it is already final and published, comments are not requested on the Food PAGs.

#### *Chapter 2-Early Phase:*

- The most substantive PAG change in the Early Phase is the 2001 guidance from the FDA that lowers the threshold for administration of potassium iodide (KI) to the public from 25 rem projected adult thyroid dose to 5 rem projected child thyroid dose. Chapter 2 includes a streamlined implementation scheme based on FDA's guidance. Please comment on the usefulness of this simplified guidance in the text of Chapter 2.
- The skin and thyroid evacuation thresholds were removed to avoid confusion with the KI threshold. The skin and thyroid doses were 5 and 50 times higher, respectively, than the 1 to 5 rem whole-body dose guideline. Please comment specifically on the appropriateness of not retaining the skin and thyroid evacuation thresholds.

#### *Chapter 3 - Intermediate Phase:*

- The most substantive PAG change in the Intermediate Phase is the removal of the 5 rem over 50 years relocation PAG which was potentially being confused with long term cleanup. Please comment on the appropriateness of this change.
- As an extension of the PAGs, new guidance on reentry to relocation areas is provided to inform plans and procedures to protect workers and members of the public as the Intermediate Phase progresses. Please comment on the format and utility of this material.
- Please comment on whether it would be useful to develop a new, combined Intermediate Phase PAG considering all exposure pathways to potentially simplify decision making.

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#### *Chapter 4 – Late Phase:*

- A brief planning guidance on the cleanup process is included. Please comment on the usefulness of this information, as well as how it might best be implemented in state, tribal and local plans. It should be noted that the extent and scope of contamination as a result of an NPP, RDD or IND incident may be at a much larger scale than a site or facility decommissioning or remedial cleanup normally experienced under established regulatory frameworks. Lesser radiological incidents may be well addressed under existing emergency response and environmental cleanup programs.
- A suggested process and organization for approaching the late phase cleanup is provided from the 2008 RDD-IND Planning Guidance. Please comment on the merging of that guidance with the 2013 PAG Manual.
- Basic planning guidance on approaching radioactive waste disposal is included. Please comment on this material and how it should be implemented in emergency response and recovery plans at all levels of government.

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After considering public comments as appropriate, EPA intends to issue a final PAG Manual which will supersede the 1992 PAG Manual and the 2008 RDD-IND Planning Guidance.

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Dated:

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Bob Perciasepe,  
Acting Administrator.