

ISAF In-House Certification



Audit Plan

1. Introduction

Accountability is the main element of control within the ISAF In-house Certification Programme and accountability is achieved primarily through a regime of audits, formal and routine. This paper sets out an overview of a formal audit plan typically implemented by an IHC licensed manufacturer to measure their accountability. Within the Programme other, less formal or routine audits will be necessary. Details of these will be included in the appropriate documentation.

2. Audit Outline Plan

	Type	Authority	Objective	Time plan
Pre-issue of IHC License				
1	CS Internal	Manufacturer	To establish the viability of their intended CS	Set by the Manufacturer
2	CS External	AA	To establish the viability of the intended CS (pre audit)	At the time requested by the Manufacturer
3	CS External	AA	To establish the viability of the intended CS (final audit)	Not before 1 month after pre audit
Issue of IHC License				
4	Surveillance Internal	Manufacturer	To check CS is achieving objectives	1 month after achieving License
5	Surveillance Internal	Manufacturer	To check CS is achieving objectives	3 months after achieving License
6	Surveillance External	AA	To check CS is achieving objectives	6 months after achieving License
7	Surveillance Internal	Manufacturer	To check CS is achieving objectives	Every 3 months
8	Surveillance External	AA	To check CS is achieving objectives	Every 12 months
9	Non-conformity Internal	Manufacturer	To check corrective actions achieving objective	After change to CS
10	Non-conformity External	AA	To check corrective actions achieving objective	After change to CS
11	Non-conformity External	AA	To check corrective actions achieving objective	1 month after change to CS
12	CS External	AA	To establish the continued viability of the CS	Every 3 years

The CS (Certification System) audits will thoroughly ascertain that the system that the manufacturer has set up ensures control of the procedure leading to equipment certification and avoids the certification of non conformities.

During a Surveillance audit, the auditor will sample the system's documentation to ensure that this confirms the compliance of certificated equipment and demonstrates adequate traceability.

A non-conformity audit is to ascertain that changes to a CS made subsequent to detection of non-conforming certificated equipment ensure that such certification does not re-occur.

3. Minimum Criteria for Auditors

An ISAF IHC auditor shall, as a minimum:-

- 1) Have updated knowledge of:
 - a) The ISAF IHC Programme, it's purpose and documents
 - b) Relevant applicable ISO 9001:2000 chapters according to the records listed in Appendix 1, to be kept by the Manufacturer
- 2) Be independent and have no vested interest and have declared such with an AA
- 3) Be able to demonstrate at least 1 year of previous auditing activity.

An auditor with ISO 9001:2000 standard knowledge and certified by an internationally accreditation Certification Body would be suitable for appointment.

Appendix 1

Cross reference of ISO 9001 sections to sections in the ISAF IHC Minimum Certification System Criteria (MCSC)

ISO 9001*	Description	MCSC
6.6.2	Competence, awareness and training	1, 2
5.5.1	Responsibility and authority	1, 2
4.2.3	Control of documents	3
4.2.4	Control of records	3
7.4	Purchasing	4, 5
7.5.1	Control of production and service provision	7, 10
7.5.3	Identification and traceability	6, 7, 11
7.5.5	Preservation of product	8
7.6	Control of measuring and monitoring	9
8.2.4	Monitoring and measurement of product	10, 11
8.3	Control of Non-Conforming product	12
8.5.2	Corrective action	13, 14

* Where applicable according to the MSCS