IAF Mandatory Document

IAF Mandatory Document For The Audit and Certification of a Management System operated by a Multi-Site Organization (where application of site sampling is not appropriate)

Issue 1

(IAF MD 19:2016)

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The IAF MLA is structured in five levels: Level 1 specifies mandatory criteria that apply to all ABs, ISO/IEC 17011. The combination of Level 2 activity(ies) and the corresponding Level 3 normative document(s) is called the main scope of the MLA, and the combination of Level 4 (if applicable) and Level 5 relevant normative documents is called a sub-scope of the MLA.

- The main scope of the MLA includes activities e.g. product certification and associated mandatory documents e.g. ISO/IEC 17065. The attestations made by CABs at the main scope level are considered to be equally reliable.

- The sub scope of the MLA includes conformity assessment requirements e.g. ISO 9001 and scheme specific requirements, where applicable, e.g. ISO TS 22003. The attestations made by CABs at the sub scope level are considered to be equivalent.

The IAF MLA delivers the confidence needed for market acceptance of conformity assessment outcomes. An attestation issued, within the scope of the IAF MLA, by a body that is accredited by an IAF MLA signatory AB can be recognized worldwide, thereby facilitating international trade.

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Introduction to IAF Mandatory Documents

The term “should” is used in this document to indicate recognised means of meeting the requirements of the standard. A Conformity Assessment Body (CAB) can meet these in an equivalent way provided this can be demonstrated to an Accreditation Body (AB). The term “shall” is used in this document to indicate those provisions which, reflecting the requirements of the relevant standard, are mandatory.

IAF MANDATORY DOCUMENT FOR THE AUDIT AND CERTIFICATION OF A MANAGEMENT SYSTEM OPERATED BY A MULTI-SITE ORGANIZATION (where application of site sampling is not appropriate)

0 INTRODUCTION

This document is for the audit and, if appropriate, the certification of management systems of organizations with a network of sites within certification schemes which do not permit site sampling. The aim is to ensure that the audit provides adequate confidence in the implementation of the management system to the relevant standard across all sites listed and that the audit is both practical and feasible in economic and operative terms.

1. SCOPE

This document is mandatory for Certification Bodies (CBs) of Management Systems for the consistent application of Clause(s) 8.2 and 9 of ISO/IEC 17021-1: 2015, for all situations involving the audit and certification of Management Systems operated by organizations with a network of sites where application of site sampling is not appropriate. All clauses of ISO/EC 17021-1 continue to apply and this document does not supersede any of the requirements in that standard. However, relevant standards may provide specific requirements for multi-site auditing and certification (e.g. ISO/IEC 27006, ISO/TS 22003).

2. DEFINITIONS

2.1 Organization

Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives.

(Source: Definition 3.1 of Annex SL of ISO Directives)

2.2 Permanent site

Location (physical or virtual) where a client organization performs work or provides a service on a continuing basis.

(Source: ISO/IEC TS17023: 2013)

2.3 Temporary site

Location (physical or virtual) where a client organization performs specific work or provides a service for a finite period of time and which is not intended to become a permanent site.

(Source: ISO/IEC TS17023: 2013)

2.4 Multi-site organization

An organization covered by a single management system comprising of an identified central function (not necessarily the headquarters of the organization) at which certain activities are planned, controlled, and a network of sites (permanent, temporary or virtual) at which such activities are fully or partially carried out.

2.5 Central function

The function that is responsible for and centrally controls the management system.

Note: The Central function is where control and authority from the top management of the organization is exerted over every site.

2.6 Virtual site

On-line environment allowing persons from different physical locations to execute processes.

Note 1: An example of such a virtual site is a design & development organization with all employees performing work located remotely, working in a Cloud environment.

Note 2: A site cannot be considered a virtual site where the processes must be executed in a physical environment, e.g., warehousing, manufacturing, physical testing laboratories, installation or repairs to physical products.

Note 3: A virtual site is considered a single site for the purpose of calculating of audit time.

2.7 Primary Process

Process directly related to products or activities, where any failure impacts directly the conformity regarding the objective of the applicable normative documents

Note: Such processes are sometimes referred to as “core or value creating processes”, normally addressed in the Annex SL under Clause 8.

2.8 Secondary Process

Supporting process which does not have a direct impact on the conformity regarding the objective of the applicable normative documents.

3. RATIONALE FOR THE PROPOSED APPROACH

This document deals with the auditing (for 3rd Party certification purposes) of an organization performing activities which are planned, controlled, and realized by a network of sites, regardless of whether they are permanent, temporary or virtual.

Any one site may perform fully or partially the activities covered by the scope of the Management system.

However, this document is addressing the situation where the application of site sampling is not appropriate during the planning and conduct of the audit. There may be many reasons for this, such as;

- all the sites perform significantly different activities;
- the client requests each site to be audited;
- there is a sector scheme or regulatory requirement stipulating that each site is to be audited systematically.

Any legal considerations concerning the organization’s management system extending over a single legal entity or multiple legal entities is generally irrelevant to the auditing of the management system, and unless otherwise stated are not covered in the present document.

It is the organization's **Management System** which must be audited and certified; furthermore, by definition, a Management System audit is only based on a limited sample of the information available.

If we take the example of a QMS audit of a manufacturing organization with 4 different production lines. All 4 will need to be audited irrespective of the fact that they are on a single site or in locations hundreds of kilometers apart; even if the logistics of the audit need to be appropriate to the geographical distances, the on-site auditing time should not vary significantly.

Prior to the audit, the CB is responsible for obtaining the correct understanding of where and how the organization is performing the different activities under the scope of the management system in order to plan and to perform efficient and effective audits.

Key criteria to ensure effective planning and implementation of an audit program include:

- obtaining knowledge at the planning stage of what Management System elements/ processes/activities are performed at which site;
- determining the critical factors to be evaluated for an efficient and effective audit, depending on the type of Management System being audited;
- selecting the audit team members // taking account of the above;
- allocating sufficient on-site audit time.

4 METHODOLOGY FOR AUDIT AND CERTIFICATION

4.1 General

4.1.1 All appropriate requirements of ISO/IEC 17021-1 shall apply in addition to the methodologies set out below.

4.2 Eligibility for Certification

4.2.1 The organization shall identify its central function responsible for the management system.

4.2.2 The central function shall have organizational authority to define, establish and maintain the management system.

4.2.3 The organization's management system shall be subject to a centralized management review.

4.2.4 All sites shall be subject to the organization's internal audit program.

4.2.5 The central function shall be responsible for ensuring that data // is collected and analyzed from all sites and shall be able to demonstrate its authority and ability to initiate organizational change as required in regard, but not limited, to:

(i) system documentation and system changes;

(ii) management review;

(iii) complaints;

(iv) evaluation of corrective actions;

(v) internal audit planning and evaluation of the results;

(vi) statutory and regulatory requirements pertaining to the applicable standard(s).

4.3 Application Review and Audit Programme

4.3.1 The CB shall obtain relevant information concerning the organization in order to:

- determine the scope of the management system being operated and the requested scope of certification;

- understand the legal and contractual arrangements linking the different sites implementing the Management System;

- understand "what happens where" i.e. determine interfaces between the different sites and activities and identify any duplication of activities on separate sites;

- take into consideration other relevant factors (see also IAF MD5, ISO/IEC TS 17023);

- determine the audit time and determine audit team(s) competence required;

- determine the audit program.

4.3.2 When determining the audit program, the CB shall allow sufficient additional time for activities which are not part of the calculated audit time, such as travelling, communicating between audit team members, local on-site opening and closing

meetings, post-audit meetings, etc. due to the specific configuration of the organization to be audited.

Note: Remote auditing techniques may be used, provided that the processes to be audited are of such a nature that remote auditing is appropriate (see ISO/IEC 17021-1).

4.3.3 The CB shall consider the need to perform Stage 1 on more than one site, in order to obtain the information required by Clause 9.3.1.2.2 of 17021-1.

4.3.4 The CB, in collaboration with the organization, shall identify all the processes of the Management System implemented at each site (based on the scope of certification) including primary processes, performance evaluation and improvement processes and secondary processes.

In each certification cycle, the audit program shall:

i. include during each audit all the primary processes, as performed on each site;
ii. include all the Performance Evaluation and Improvement processes during each initial and recertification audit and at least one other time in each certification cycle during a surveillance audit;
iii. include the secondary processes in the following manner:
    a. Audit of all the secondary processes in each initial audit and recertification audit, but similar secondary processes carried out at different sites can be checked on sampling basis;
    b. During surveillance audits, the secondary processes shall be checked on sampling basis and depending on the result of the preceding audits. This sampling shall be designed to ensure a significant sample size to achieve an evaluation of conformity with the requirements of the management system, and shall ensure that the selection of processes audited over the 3 year cycle are reasonably representative of the management system.

4.3.5 Where audit teams consisting of more than one member are used at any point, it shall be the responsibility of the CB, in conjunction with the Team Leader, to identify the technical competence required for each part of the audit and for each site and to allocate appropriate team members for each part of the audit.

4.4 Initial Audit: Stage 1

4.4.1 During Stage 1, the audit team shall complete the information to:

- confirm the audit program;

- plan Stage 2, taking into account the processes/ elements/activities to be audited in each site. In addition to any Primary processes implemented on each site, the audit team shall select at which sites the implementation of non-primary processes needs to be audited to ensure an effective and complete audit of the Management system; and

- confirm that the Stage 2 audit team has the requisite competence.

Note: The non-primary processes referred to here mean the Performance Evaluation and Improvement processes as well as the Secondary processes.

4.5 Initial Audit: Stage 2

At the outcome of the initial audit, the Audit team shall document which processes were audited on each site. This information will be used to amend audit plans for subsequent surveillance audits.

4.6 Surveillance Audits

4.6.1 The CB shall allocate sufficient on-site time to audit all the primary processes as well as other processes on each site (see 4.5). The secondary processes can be sampled provided a significant sample size is achieved to ensure an evaluation of conformity with the requirements of the Management System (see also the requirements in Clause 9.6.2.2 of ISO/IEC 17021-1: 2015). The CB shall ensure that the selection of processes audited over the 3 year cycle are reasonably representative of the Management System.

4.6.2 The amount of audit time allocated to each site shall depend on whether that site is performing primary processes or not.

4.7 Recertification Audits

The CB shall audit the complete management system similarly to the initial audit. The CB shall take into account which processes have been audited on which site during the current cycle.

5. CALCULATION OF AUDIT TIME

5.1 The relevant ISO Standards, IAF documents (principally IAF MD5) and, where necessary, any applicable Sector Scheme requirements in conjunction with the requirements in this document shall be used to calculate the total audit time for the Management System, irrespective of the number of sites.

This audit time shall never be less than that which would have been calculated for the size and complexity of the operation if all the work had been undertaken at a single site (i.e. with all the employees of the company in the same site).

Note: It is unlikely that the “one-third” approach for surveillance audit time and the “two-thirds” approach for recertification audit time on single sites will be adequate, and consideration must be made for adding time needed for local opening & closing meetings, duplicated processes, the variety of primary processes to be audited, etc, as indicated in IAF MD5 for complicated logistics.

6. CERTIFICATION DOCUMENTS

6.1 The Certification document shall reflect the scope of certification and the sites/legal entities audited and certified by the CB.

End of IAF Mandatory Document for the Audit and Certification of a Management System operated by a Multi-Site Organization (where application of site sampling is not appropriate)

Further Information:

For further Information on this document or other IAF documents, contact any member of IAF or the IAF Secretariat.

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