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IAF MD1:2018 – SCOPO E CONTENUTI

IAF Mandatory Document

IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization

Issue 2

(IAF MD 1:2018)

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Issue No 2
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SCOPO

1 Scopo

IAF MD1 **si applica** nei casi di:

- Organizzazioni composte da **più siti che operano sotto lo stesso sistema di gestione**

IAF MD1 **non si applica** nei casi di:

- situazioni in cui **organizzazioni indipendenti sono raccolte insieme da un'altra organizzazione indipendente** (ad esempio società di consulenza o un'organizzazione artificiale) sotto l'egida di un unico sistema di gestione
- organizzazioni multi-sito in cui sono distribuiti più sistemi di gestione all'interno dell'organizzazione, **quando ciascun sito deve essere considerato come singola organizzazione del sito** e verificato di conseguenza

SCHEMI CON SPECIFICI REQUISITI MULTISITO

	Calcolo Mdays	Multi-site	Audit of Integrated MS		
QMS	IAF MD5:2019	IAF MD1	IAF MD11		
EMS	IAF MD5:2019	IAF MD1	IAF MD11		
OH&SMS	IAF MD5:2019	IAF MD1	IAF MD11		
EnMS	ISO 50003	ISO 50003	IAF MD11		
ISMS	ISO/IEC 27006	ISO/IEC 27006	IAF MD11		
FSMS	ISO/TS 22003	ISO/TS 22003	IAF MD11		

0 INTRODUCTION

It is intended **that certification of single-site organizations will continue to implement IAF MD 5**, but in the event of any conflict between MD 1 and MD 5 for multi-site organizations, MD 1 requirements take precedence ~~until such times as MD 5 is revised~~.

La parte della frase evidenziata in giallo è ormai superata dalla pubblicazione del IAF MD5:2019, che ha rimosso ogni conflitto.

2. DEFINITIONS

2.2 Permanent Site

Site (physical or virtual) where a client organization performs work or from which a service is provided on a continuing basis.

- *(Source: Adapted from ISO/IEC TS 17023:2013 Conformity assessment -- Guidelines for determining the duration of management system certification audits)*

2.3 Temporary Site

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

- *(Source: ISO/IEC TS 17023:2013)*

3.2 TEMPORARY SITE

3.2.1

- Temporary sites that are covered by the organization's management system **shall be subject to audit on a sample basis** to provide evidence of the operation and effectiveness of the management system.
- They **may**, however **be included within the scope of a multi-site certification and included on the certification document**, **subject to agreement between the CB and the client organization**.
- When temporary sites are shown on the certification documents, such **sites shall be identified as temporary.**

2. DEFINITIONS

2.6 Virtual Site

Virtual location where a client organization performs work or provides a service **using an on-line environment** allowing persons from different physical locations to execute processes**.**

- *Note 1: A virtual site cannot be considered as such where the processes must be executed in a physical environment e.g. warehousing, physical testing laboratories, installation or repairs to physical products.*
- *Note 2: 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 3: A virtual site (e.g. an organization's intranet) is considered a single site for the purpose of calculating of audit time.*
- *Note 4: For further information, see also IAF MD 4: Use of Computer Assisted Auditing Techniques ("CAAT") for Accredited Certification of Management Systems.*

2. DEFINITIONS

2.4 Multi-site Organization

An organization:

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

2. DEFINITIONS

2.5 Central Function

The function that **is responsible for and centrally controls** the management system (refer to Section 5).

2.8 Top Management

Person or group of people **who directs and controls an organization** at the highest level.

2.7 Sub-scope

The **scope of a single site**.

- *Note: The scope of a single site might be the same as the full scope of the multi-site organization but may also be only a small part of the multi-site organization's scope.*
- *Note: The above definition of "sub-scope" is to be used for the purposes of implementing the requirements of this document (in contrast with the use of the term on page 2 of this document, where reference is made to "sub-scope" in the context of accreditation and not certification).*

3.3 MULTI-SITE ORGANIZATION

3.3.1 A multi-site organization **need not be a unique legal entity,** but **all sites shall have a legal or contractual link with the central function** of the organization and **be subject to a single management system**, which is laid down, established and subject to **continuous surveillance and internal audits by the central function**.

- This means that the central function has rights to require that the sites implement corrective actions when needed in any site.
- Where applicable this should be set out in the formal agreement between the central function and the sites.

4. RATIONALE FOR THE PROPOSED APPROACH

4.2 Any one site **may perform fully or partially the processes/activities covered by the scope** of the MS, and different sites **may belong to the same legal entity or not**.

4.4 It is the organization's MS which must be audited and certified; … it must be demonstrated that **the MS is capable of achieving its intended results for all sites involved**.

4.6 SITE SAMPLING APPROPRIATE OR NOT?

- **Site sampling is appropriate** in the case of a multi-site organization where each site is performing very similar processes/activities, such as:
  - a chain of franchise stores or a bank branch network).
- **Site sampling is not appropriate** in cases there may be many reasons for this, such as:
  - all the sites perform significantly different processes/activities in connection with the management system scope;
  - the client requests each site to be audited; or
  - there is a sector scheme or regulatory requirement stipulating that each site is to be audited systematically.
- **Part of the sites** perform similar processes/activities while other sites perform very specific processes not performed elsewhere in the organization.
  - Therefore **site sampling is limited** only to those sites which are performing very similar processes/activities, which are part of the organization's scope.

5. ELIGIBILITY OF A MULTI-SITE ORGANIZATION

- single management system
- central function part of the organization resposible to maintain the single MS:
  i. system documentation and system changes;
  ii. centralized management review;
  iii. complaints;
  iv. evaluation of corrective actions;
  v. internal audit planning and evaluation of the results; and
  vi. statutory and regulatory requirements pertaining to the applicable standard(s)
- all sites subject to the organization's internal audit programme.

6.1. CONDITIONS FOR SITE SMPLING

- 6.1.1.1 Sampling of a set of sites is permitted where the **sites are each performing very similar processes/activities**
- 6.1.1.2 Not all «multi-site organizations» are eligible for sampling.
- 6.1.1.3 Specific MS standard do not allow multisite sampling (e.g. aereospace or automotive IATF 16949)

6.1 CA SES FOR RESTRICTION OF SITE SMPLING

- 6.1.1.4 CBs shall have documented procedures to restrict sampling where site sampling is inappropriate with respect to:
  - **assessment of risks or complexity** associated with that sector or processes/activities);
  - **size of sites** eligible for multi-site audit;
  - **variations in the local implementation of the** management system to address different processes/activities or **different contractual or regulatory systems**;
  - **use of temporary sites** that operate under the management system of the organization even if they are not listed in the certification documents.

6.1.2 FACTORS FOR SITE SAMPLING

Select a **representative range** of different sites for ensuring auditing **all processes covered by the scope of certification:**

- at least 25% of the sample selected at random.
- results of internal site audits and management reviews;
- Complaints, corrective and preventive action;
- significant variations in the size of the sites;
- variations in shift patterns and work procedures;
- complexity of the MS and processes conducted at the sites;
- modifications since the last certification audit;
- maturity of the MS and knowledge of the organization;
- aspects/impacts for EMS / hazard/risks for OH&SMS
- culture, language and regulatory requirements
- whether the sites are permanent, temporary or virtual.

6.1.3 SIZE OF SAMPLE

The minimum number of sites to be visited per audit is:

- **Initial audit**: **$y=\sqrt{x}$**
- **Surveillance audit**: **$y=0.6\ \sqrt{x}$**,
- **Re-certification audit**:
  - **$y=\sqrt{x}$** as for an initial audit or
  - **$y=0.8\ \sqrt{x}$** where the MS has proved to be effective over the certification cycle,

x = total number of sites

y = number of sites to be sampled (rounded up to the next whole number)

The central function to be audited during

- initial certification
- every recertification audit
- at least once a calendar year as part of surveillance

6.1.3 HIERACHICAL LEVELS OF SAMPLE

6.1.3.6 When the organization has a **hierarchical system of levels** (e.g. head (central) office, national offices, regional offices, local branches), the **sampling model** for initial audit as defined above **applies to each level**.

6.1.3.7 The sampling process shall be part of the management of **audit programme to be reviewed and adjusted** by the CB whenever necessary:

- before planning the surveillance audit,
- in case of organization change in site and structure (e.g., acquisition of new sites to be be added into the certification boundary

6.1.3 HIERACHICAL LEVELS OF SAMPLE

Example:

- 1 head office: visited at each audit cycle (initial or surveillance or recertification)
- 4 national offices: sample = 2: minimum 1 at random
- 27 regional offices: sample = 6: minimum 2 at random
- 1700 local branches: sample = 42: minimum 11 at random
  - The sample of regional offices should include at least one regional office controlled by each national office.
  - The sample of local branches should include at least one local branch controlled by each regional office.
  - This may result in the sample size at each level exceeding the minimum sample size calculated

6.1.3 INCREASE OF SIZE AND FREQUENCYE OF SAMPLE

Increase size or frequency of the sample where the CB **risk analysis of the process/activity** covered by the MS subject to certification indicates special circumstances in respect of factors such as:

- **size of the sites** and **number of employees**;
- **complexity/risk level** of the process/activity/MS
- **changes** in working practices (e.g. shift working);
- **variations in process/activities** undertaken;
- **complaints** and **corrective and preventive actions**;
- any **multinational aspects**; and
- results of **internal audits** and **management review**.

6.1.4 ADDITIONAL SITES (SAMPLING APPROPRIATE)

On the application of **inclusion of new sites or a new group of sites** to join an already certified multi-site organization, the CB shall:

- **determine the required activities to be performed** before including the new site(s) in the certificate**.**
- make consideration of **whether or not to audit the new site(s)**.
- determine the **sample size for future** surveillance or recertification audits.

6.2 WHEN SITE SAMPLING IS NOT APPROPRIATE

6.2.1 The audit programme shall audit in:

- **initial audit**: **100% of sites**
- **recertification audit**: **100% of sites**
- **surveillance audits**: **30% of sites / year** (rounded up to the whole number)
    - Each audit will include the central function.
    - The sites selected for the second surveillance audit will normally be different from the sites selected for the first surveillance audit.

6.2.2 The audit programme shall be designed to ensure that **all processes covered by the certification scope are audited over each cycle**

6.2 ADDITIONAL SITES (SAMPLING NOT APPROPRIATE)

On the application of a new site to join an already certified multi-site organization:

- **the site shall be audited before being included in the certificate**, in addition to the planned surveillance in the audit programme.
- after inclusion of the new site in the certificate, **it shall be cumulated with the previous ones** for determining the audit time for future surveillance or recertification audits.

6.3 COMBINATION OF SITES (SAMPLED/NOT SAMPLED)

The audit programme shall be established using:

- **section 6.1** for those sites that can be sampled and
- **section 6.2** for the remaining part of the organization where sampling is not appropriate

7.1 APPLICATION AND APPLICATION REVIEW

The CB shall obtain necessary information to:

- confirm that a single MS is deployed across the organization;
- determine the scope of the MS and, if applicable, sub-scopes;
- understand the legal and contractual arrangements for each site;
- understand processes/activities performed at each site
- identify the central function;
- determine the degree of centralization of process/activities which are delivered to all sites (e.g. purchasing);
- determine interfaces between the different sites;
- determine which sites may be applicable for sampling (i.e. where very
- similar processes/activities are provided) and those that are not eligible;
- take into consideration other relevant factors (see also IAF MD 4, IAF MD 5, IAF MD 11, ISO/IEC TS 17023);
- determine the audit time for the organization;
- determine the audit team(s)' competence required; and
- identify the complexity and scale of the processes/activities (e.g. one or many) covered by the MS

7.2 AUDIT PROGRAMME

In addition to the requirement in ISO/IEC 17021-1:2015 clause 9.1.3, the audit programme shall at least include or refer to the following

- **processes/activities** provided **on each site**;
- identification of those **sites** which are **liable to be sampled**, and which are **not**;
- identification of **sites** which are **covered by sampling**, and which are **not**.

7.2 AUDIT PROGRAMME

7.2.2 The CB shall **allow sufficient additional time for activities which are not part of the calculated audit time**, such as:

- travelling,
- communicating among audit team members,
- post-audit meetings, etc. due to the specific configuration of the organization to be audited

7.2.3 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.

7.3 CALCULATION OF AUDIT TIME

7.3.1 An organization that satisfies the eligibility criteria may consist of:

- sites that can be sampled,
- sites that cannot be sampled or
- a combination of both.

The audit time must be **sufficient to undertake an effective audit** irrespective of the makeup of the organization.
Unless precluded by specific schemes, the reduction of audit time per sampled site shall not be greater than 50%.
Example:

- 30% is the maximum reduction allowed by IAF MD 5
- 20% is the maximum reduction allowed for the single MS processes performed by the central function and any potential centralised processes (e.g. purchasing)

7.3 CALCULATION OF AUDIT TIME

The audit time per selected site, including elements of the central function if applicable, whether it comes from:

- **sampling** as in 6.1,
- **non- sampling** as in 6.2 or
- **mixed methodology** as in 6.3,

shall be calculated for each site using the applicable documents:

- **IAF MD 5 for QMS, EMS and OH&SMS**
- **IAF MD 11 for integrated management systems**,
- any **applicable sector scheme requirements** for the calculation of man-days

7.4 AUDIT PLAN

In addition to the requirement in ISO/IEC 17021-1:2015 clause 9.2.3, the CB shall at least consider the following :

- **general certification scope**
- **certification sub-scopes for each site**;
- MS **standard for each site**, if multiple MS standards are being considered;
- **processes/activities** to be audited;
- **audit time for each site**;
- allocated **audit team**.

7.7 NONCONFORMITIES AND CERTIFICATION

7.7.1 **When NCs are found** at any individual site, either through the organization's internal auditing or from auditing by the CB, **investigation shall take place to determine whether the other sites may be affected**.

The CB shall require the organization to review the NCs to determine **whether or not they indicate an overall system deficiency** applicable to other sites.

- **If they are found to do so**, CAs shall be performed and verified both at the central function and at the individual affected sites.
- **If they are found not to do so**, the organization shall be able to demonstrate to the CB the justification for limiting its follow-up corrective action.

7.7 NONCONFORMITIES AND CERTIFICATION

7.7.3 At the time of the **decision-making process**, **if any site has a major NC, certification shall be denied to the whole multi-site organization** of listed sites pending satisfactory corrective action.

7.7.4 **It shall not be admissible that, to overcome the obstacle raised by the existence of a nonconformity at a single site**, the organization seeks to exclude from the scope the "problematic" site during the certification process.

7.8 CERTIFICATION DOCUMENTS

The certification document **shall:**

- **reflect the scope of certification and the sites and /legal entities** covered by the multi-site certification (7.8.1)
- **contain the name and address of all the sites**, reflecting the organization to which the certification documents relate (7.8.2).

7.8.2 The scope shall make it clear that the **certified activities are performed by the sites on the list**.

- If a site's activities only include a subset of the organization's scope, **the certification document shall include the site's sub- scope**.
- When temporary sites are shown on the certification documents, **such sites shall be identified as temporary**.

7.8 CERTIFICATION DOCUMENTS

7.8.3 Where certification documents for one site are issued, they shall include:

- that it is the **MS of the whole organization** which is certified;
- the **activities performed for that specific site / legal entity** which are covered by this certification;
- **traceability with the main certificate**, e.g. a code; and
- a statement saying "the validity of this certificate depends on the validity of the main certificate".

The certification document:

- **cannot be issued to the name of the site/legal entity** or
- **suggest that this site/legal entity is certified** (the one certified is the client organization),
- **shall include a declaration of conformity of the site processes/activities** to the normative document.

7.8 CERTIFICATION DOCUMENTS

7.8.4 The certification documentation **will be withdrawn in its entirety if any** of the sites does not fulfil the necessary provisions for the maintenance of the certification

7.9 SURVEILLACE AUDITS

7.9.1 Surveillance in **case of «sampling»**:

- **sampling**: determined in accordance with Clause 7.1
- **audit time**: calculated in accordance with Clause 7.3.

7.9.2 Surveillance of in case of **«non sampling»**: **:**

- **number of sites**: auditing 30% of the sites plus the central function
- **2nd surveillance:** not to include any sites sampled as part of the 1st surveillance audit
- **audit time**: calculated in accordance with Clause 7.3

7.10 RECERTIFICATION AUDITS

7.9.1 Recertification audit in **case of «sampling»**:

- **sampling**: determined in accordance with Clause 7.1
- **audit time**: calculated in accordance with Clause 7.3.

7.9.2 Recertification audit in **case of «non sampling»**:

- **number of sites**: 100% of the sites plus the central function
- **audit time**: calculated in accordance with Clause 7.3