IAF Informative Document

GUIDANCE ON THE DETERMINATION OF AUDIT TIME FOR INTEGRATED AUDIT OF MULTI-SITE MANAGEMENT SYSTEMS

Issue 1, Version 2

(IAF ID 14:2023)

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International Accreditation Forum, Inc.

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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 a 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 mandated standards 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 22003-1. 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 INFORMATIVE DOCUMENTS

This IAF Informative Document reflects the consensus of IAF members on this subject and is intended to support the consistent application of requirements. However, being a document for information purposes only, IAF Accreditation Body Members, and the Conformity Assessment Bodies they accredit, are not under any obligation to use or comply with anything in this document.

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Guidance on the Determination of Audit Time for Integrated Audit of Multi-Site Management Systems

1. INTRODUCTION

The growth in the number of management systems and respective reference standards for certification has led to the increase of different methodologies for determining the audit time, that include requirements partially or significantly different from those of the document IAF MD 5 that was basically designed for Quality Management Systems (QMS), Environmental Management Systems (EMS) and Occupational Health and Safety Management Systems (OH&SMS).

Furthermore, the determination of audit time becomes more complicated in the case of the combination of multi-site management systems and integrated audits of two or more different management systems.

This complex situation has highlighted the need to provide a guide to ensure that the combination of all the main factors of each methodology contributing to the determination of the total audit time is correctly considered.

2. SCOPE

This informative document provides guidance for achieving a basic level of consistency for determining the audit time according to the application of the relevant requirements of ISO/IEC 17021-1 for audits of different management systems, such as:

- Quality Management Systems (QMS)

- Environmental Management Systems (EMS)

- Occupational Health and Safety Management Systems (OH&SMS)

- Energy Management Systems (EnMS)

- Food Safety Management Systems (FSMS)

- Information Security Management Systems (ISMS)

- Information Technology Service Management Systems (ITSMS)

- Medical Devices Management Systems (MDMS)

The same approach may also be extended to any other ISO/IEC 17021-1 based certification schemes.

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3.   TERMS AND DEFINITIONS

3.1.   Management Systems Certification Scheme

Conformity assessment system related to management systems to which the same specified requirements, specific rules and processes apply.

[Source: clause 1.1, IAF MD5:2019]

3.2.   Client Organization

Entity or defined part of an entity operating a management system.

[Source: clause 1.2, IAF MD5:2019]

3.3.   Central Function

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

Note: Descriptions and requirements of "central function" are provided in clause 5 of IAF MD1:2018.

[Source: clause 2.5, IAF MD1:2018]

3.4.   Permanent Site

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

Note: Descriptions and requirements of "site" are provided in clauses 3.1.1 and 3.1.2 of IAF MD1:2018.

[Source: clause 1.3, IAF MD5:2019 and clause 2.2, IAF MD1:2018]

3.5.   Virtual Site

Virtual location where a client organization performs work or provides a service using an online environment allowing persons irrespective of 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, manufacturing, physical testing laboratories, installation or repairs to physical products.

Note 2: An example of such a virtual site is a design & development organisation with all employees performing work located remotely, working in a cloud environment.

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Note 3: A virtual site (e.g. an organisation's intranet) is considered a single site for the calculation of audit time.

[Source: clause 1.4, IAF MD5:2019 and clause 2.6, IAF MD1:2018]

3.6. 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: clause 1.5, IAF MD5:2019 and clause 2.3, IAF MD1:2018]

3.7. Audit Time

Time needed to plan and accomplish a complete and effective audit of the client organization's management system.

[Source: clauses 3.16, ISO/IEC 17021-1:2015 and 1.6, IAF MD5:2019]

3.8. Duration of Management System Certification Audits

Part of audit time spent conducting audit activities from the opening meeting to the closing meeting, inclusive.

Note 1 to entry: Audit activities normally include:

- *conducting the opening meeting*

- *performing document review while conducting the audit*

- *communicating during the audit*

- *assigning roles and responsibilities of guides and observers*

- *collecting and verifying information*

- *generating audit findings*

- *preparing audit conclusions*

- *conducting the closing meeting*

[Source: clauses 3.17, ISO/IEC 17021-1:2015 and 1.7, IAF MD5:2019]

3.9. Audit Day

The duration of an audit day is normally 8 hours and may or may not include a lunch break depending upon local legislation.

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[Source: clause 1.8, IAF MD5:2019]

3.10. Effective Number of Personnel

The effective number of personnel consists of all personnel (permanent, temporary, and part-time) involved within the scope of certification including those working on each shift. When included within the scope of certification, it shall also include non-permanent (e.g. contractors') personnel.

It shall also include personnel from contractors and subcontractors performing work or work-related activities that are under the control or influence of the organization, that can have impact on the organization's management system performance.

Note: Certain scheme(s) may have a different definition for "Effective Number of Personnel" than the one in MD5, e.g. for ISO 50003:2021, clause 3.5.

[Source: clause 1.9, IAF MD5:2019 modified]

3.11. Integrated Management System

A single management system managing multiple aspects of organizational performance to meet the requirements of more than one management standard, at a given level of integration. A management system may range from a combined system adding separate management systems for each set of audit criteria/standard, to an Integrated Management System, sharing in single system documentation, management system elements, and responsibilities.

[Source: clause 1.2, IAF MD11:2013]

3.12. Level of Integration

The level to which an organization uses one single management system to manage multiple aspects of organizational performance to meet the requirements of more than one management system standard. Integration relates to the management system being able to integrate documentation, appropriate management system elements and responsibilities in relation to two or more sets of audit criteria/standards.

Note: Audit criteria are intended to mean management system standards used as a basis for conformity assessment and certification (e.g. ISO 9001, ISO 14001, ISO/IEC 20000, ISO 22000, ISO/IEC 27001, etc.).

[Source: clause 1.3, IAF MD11:2013]

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3.13. Audit of Integrated Management System

An audit of an organization's management system against two or more sets of audit criteria/standards conducted at the same time.

[Source: clause 1.1, IAF MD11:2013]

3.14. Organization

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

[Source: clause 2.1, IAF MD1:2018]

3.15. 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.

[Source: clause 2.4, IAF MD1:2018]

4.   METHODOLOGY FOR DETERMINING THE TOTAL AUDIT TIME

4.1.   General Requirements

The determination of the audit time for the certification of management systems should be based on the information obtained from the client organization and established before the preparation of the audit plan.

The certification body should periodically review the effectiveness of the process to establish the audit time.

The methodology for determining the total audit time is based on the general requirements of the relevant clauses of ISO/IEC 17021-1:2015:

- 9.1.4 "Determining audit time"
- 9.1.5 "Multi-site sampling"
- 9.1.6 "Multiple management systems standards"

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4.2.   Specific Requirements

The specific requirements applicable to each management system are included in the IAF MLA Level 4 standards and IAF mandatory documents, to be used alone or in combination, listed in clauses 5.1 and 5.2 and reported in Tables 1 and 2 with details of the application.

4.3.   Methodological Approach

The certification body should use the framework provided in Level 3 and Level 4 MLA documents to develop a process to determine the time of the management system certification audit specific to the client organization.

The methodological approach is structured as a sequence of steps organized according to the process flow reported in Figure 1 and described in detail in Table 2:

1. Check whether one or more management systems are applicable and determine the applicable standards (see Table 1).
2. Evaluate whether the organization is eligible for multi-site certification.
3. Evaluate whether sampling is appropriate or not.
4. Determine the number of sampled sites.
5. Determine the Effective Number of Persons (ENP) for each management system at each site (when relevant based on the applicable scheme requirements).
6. Determine the complexity level for each management system at each site (when applicable).
7. Determine the audit time for each management system at each site (as applicable).
8. Determine the adjustment factors in reduction or increase for each management system at each site (when applicable).
9. In case of multi-site determine a further reduction in audit time for each site (when applicable).
10. In case of multiple management systems check whether there are the conditions for conducting an integrated audit.
11. Determine the starting point for the total audit time of the integrated management system (IMS).
12. Adjust the integrated audit time by considering factors that may increase or reduce the required audit time.
13. Calculate the on-site audit duration.

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14. Consider how to split the audit time between Stage 1 and Stage 2.

15. Determine the audit time for surveillance and recertification audits.

16. Confirm audit time or make adjustments as needed during the certification cycle.

Note: Steps from 6 onwards are required per sampled site (where relevant), considering the relevant factors for that site.

4.4. Additional Considerations

4.4.1 Main Factors

Different factors should be used for the determination of the audit time for the certification of specific management systems. The main factors to be taken into account should depend on the type and scope of audit:

- Effective number of personnel

- Risk and complexity categories associated with the products, processes or activities of the client organization (when relevant based on the applicable scheme requirements and site-specific conditions)

- Management system standard

- Number of sites to be audited

- Single or integrated management systems

- Level of integration in an integrated management system

- Other factors specific for each management system (see Table 2)

The certification body should identify the applicable factors which can contribute to the adjustment of the audit time for a particular client organization.

4.4.2 Relevant Management System Standard(s) and Other Requirements

The duration of management system certification audits can depend on relevant management system standard(s) and certification scheme requirements and the type of audit (e.g. initial audit, surveillance, recertification, special audit):

a) *When an audit is done in two stages (e.g. initial audit and recertification audit), the duration of management system certification audits is the sum of stage one and stage two.*

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b) The time spent travelling (en-route or between sites) and any breaks are not included in the determination of the duration of management system certification audits.

c) The audit time for all types of audits includes the total time spent on site at a client's location (physical or virtual) and the time spent off site carrying out planning, document review, interacting with client personnel and report writing.

d) The total time spent on site at a client's location (physical or virtual) is the duration of a management system certification audit. This is the time from the start of the opening meeting to the end of the closing meeting (3.8).

e) Other audits (e.g. special audits, transfer audits) can be performed and the duration of such audits is usually established on a case-by-case basis depending on the objectives of the audits.

5. APPLICABLE DOCUMENTS

5.1. ISO Standards

5.1.1 IAF MLA Level 3 Standard Applicable to Management Systems

- ISO/IEC 17021-1:2015 *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

5.1.2 IAF MLA Level 4 Standards Applicable to Management Systems

Standards containing criteria supplementary to those contained in ISO/IEC 17021-1:2015 to be used in conjunction with ISO/IEC 17021-1:2015 for specific management systems:

- ISO 50003:2021 *Energy management systems — Requirements for bodies providing audit and certification of energy management systems*

- ISO/IEC 27006:2015 *Information technology — Security techniques — Requirements for bodies providing audit and certification of information security management systems -* "Amendment 1:2020"

- ISO/IEC -20000-6:2017 *Information technology — Service management — Part 6: Requirements for bodies providing audit and certification of service management systems*

- ISO/TS 22003:2013 *Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems*

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5.1.3 IAF MLA Level 5 Standards Applicable to Management Systems

Standards used by the accredited conformity assessment body to deliver an accredited conformity assessment field:

- ISO 9001:2015 *Quality management systems — Requirements*

- ISO 14001:2015 *Environmental management systems — Requirements*

- ISO 45001:2018 *Occupational health and safety management systems — Requirements with guidance for use*

- ISO 50001:2018 *Energy management systems — Requirements with guidance for use*

- ISO/IEC 27001:2013 *Information technology — Security techniques — Information security management systems — Requirements*

- ISO/IEC 20000-1:2018 *Information technology — Service management — Part 1: Service management system requirements*

- ISO 22000:2018 *Food safety management systems — Requirements for any organization in the food chain*

- ISO 13485:2016 *Medical devices — Quality management systems — Requirements for regulatory purposes*

5.2.   IAF Mandatory Documents

Documents containing additional mandatory requirements to those contained in ISO/IEC 17021-1:2015 for determining the audit time when conducting separate or integrated audits in case of single-site or multi-site management systems:

- IAF MD 1:2018 *IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization*

- IAF MD 5:2019 *Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems*

- IAF MD 9:2022 *Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)*

- IAF MD 11:2013 *IAF Mandatory Document for Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS)*

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TABLE 1 – APPLICABLE DOCUMENTS AND REQUIREMENTS

	QMS	EMS	OH&SMS	EnMS	ISMS	ITSMS	FSMS	MDMS
Level 5 std.	ISO 9001:2015	ISO 14001:2015	ISO 45001:2018	ISO/50001:2018	ISO/IEC 27001:2013	ISO/IEC 20000-1:2018	ISO 22000:2018	ISO 13485:2016
Level 4 std.	-	-	-	ISO 50003:2021[1]	ISO/IEC 27006:2015 - Amd.1:2020)[2]	ISO/IEC 20000-6:2017[3]	ISO/TS 22003:2013[4]	-
DETERMINATION OF AUDIT TIME ISO/IEC 17021-1:2015 clause 9.1.4 "Determining audit time"	IAF MD5: 2019	IAF MD5: 2019	IAF MD5: 2019	ISO 50003:2021: • cl.9.1.4 "Determining audit time" [5] Annex A "EnMS audit time" • A.1 "General" • A.2 "Determination of the EnMS effective personnel" • A.3 "Determination of energy types" • A.4 "Determination of an EnMS complexity" • A.5 "Determination of EnMS audit time" • A.6 "Factors for adjustment of the audit time" Annex D "Examples of audit calculations" (informative): • D1 Audit time calculation • D2 Single permanent site • D3 Multi-site organization	ISO/IEC 27006:2015-Amd.1:2020): • cl.9.1.4 "Determining audit time" Annex B "Audit time" (normative) • B.3.3 "Audit time calculation" • B.3.4 "Factors for adjusting audit time" • B.3.5 "Limitation of deviation of audit time" • B.3.6 "On-site audit time" • B.4 "Audit time for surveillance" • B.5 "Audit time for re-certification" • B.6 "Audit time of multi-site" Annex C "Methods for audit time calculation" (informative)[6] • C1 "General" • C2 "Classification of factors for calculating audit time" • C3 "Example for audit time calculation"	ISO/IEC 20000-6:2017: • cl.9.1.4"Determining audit time"	ISO/TS 22003:2013: • cl.9.1.2 Annex B "Minimum audit time" • B1 "General" • B2 "Calculation of minimum initial certification audit time"	IAF MD9:2022[7]: • cl.MD 9.1.4 "Determining audit time" refers to IAF MD5:2019 as applicable with exception of table D.1 in Annex D, of IAF MD9:2022 which replaces table QMS1 of MD5:2019 • Annex D, Table D.1 "Determination of Audit Time"

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[1] ISO 5003:2021 mentions IAF MD11 as applicable in Note of cl.A.6.3, in examples of audit calculation (clauses D.2 andD.3) and Bibliography. IAF MD1 and MD5 are never mentioned

[2] ISO/IEC 27006:2015 (Amendment 1:2020) does not mention IAF MD1, MD5 and MD11 – It is mentioned by IAF MD1, cl.1, mentioned by IAF MD11, cl.2.1.5.1, and not mentioned by IAF MD5

[3] ISO/IEC 20000-6:2017 does not mention IAF MD1, MD5 and MD11 – it is not mentioned by IAF MD1, IAF MD5 and IAF MD11

[4] ISO/TS 22003:2013 does not mention IAF MD1, MD5 and MD11 – it is mentioned by IAF MD1, cl.1, mentioned by IAF MD11, cl.2.1.5.1, and not mentioned by IAF MD5

[5] ISO 50003:2021 factors to be included in determining the audit time:
  a) the number of EnMS effective personnel;
  b) the number of energy types;
  c) the annual energy consumption (TJ);
  d) the number of significant energy uses (SEUs).

[6] ISO/IEC 27006:2015 (integrated by Amendment 1:2020) - Audit time calculation sequence:
  • Step 1 - determination of factors related to business and organization (other than IT): Identify the suitable grade for each of the categories given in Table C.2 and sum up the results.
  • Step 2 - determination of factors related to IT environment: Identify the suitable grade for each of the categories given in Table C.3 and sum up the results.
  • Step 3 - based on the results of step 1 and 2 above, identify the impact of factors on audit time by selecting the appropriate entry in Table C.4.
  • Step 4 - final calculation: the number of days determined by applying the audit time chart (Table B.1) is multiplied by the factor resulting from Step 3. Where multi-site sampling is utilized, the audit days calculated are increased based on the efforts needed to execute the multi-site sampling plan.

[7] IAF MD9:2022 refers to the application of IAF MD5 and IAF MD11 in cl.9.1.4. Does not mention IAF MD1

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	QMS	EMS	OH&SMS	EnMS	ISMS	ITSMS	FSMS	MDMS
MULTISITE AUDIT ISO/IEC 17021-1:2015 clause 9.1.5 "Multi-site sampling"	**IAF MD1: 2018**	**IAF MD1: 2018**	**IAF MD1: 2018** **IAF MD22:2019** cl.9.1.4 cl.9.1.5	**ISO 50003:2021:** • cl.9.1.5 "Multi-site sampling" Annex B "Multi-site sampling" • B.1 "General" • B.2 "Sites in a multi-site organization" • B.3 "Eligibility of an organization for sampling" • B.4 "Sampling methodology" • B.5 "Audit and certification" Annex D "Examples of audit calculations": • D1 Audit time calculation • D2 Single permanent site • D3 Multi-site organization	**ISO/IEC 27006:2015 - Amd.1:2020)** • cl.9.1.5 "Multi-site sampling" Annex B "Audit time" (normative) • cl.B6 "Audit time of multi-site" Annex C "Methods for audit time calculation" (informative) • C3 "Example for audit time calculation", step 4	**ISO/IEC 20000-6:2017:** • cl.9.1.5 "Multi-site sampling" • cl.9.2.3.1-SM9.3.3.1 "Sampling accuracy"	**ISO/TS 22003:2013:** • cl.9.1.5 "Certification of multi-site organizations"	**IAF MD9:2022:** • cl.MD 9.1.5 "Multi-site sampling" • *(IAF MD1 not mentioned)*

INTEGRATED AUDIT
ISO/IEC 17021-1:2015 clause 9.1.6 "Multiple management systems standards"
	IAF MD11: 2013
	
	(also see new draft MD11, issue 2, nov.2021 with no major changes)
		IAF MD11: 2013
		
		(also see new draft MD11, issue 2, nov.2021 with no major changes)
			IAF MD11: 2013
			
			(also see new draft MD11, issue 2, nov.2021 with no major changes)
				ISO 50003:2021:
				• cl. 9.1.6 "Multiple management system standards"
				• A.6 "Factors for adjustment of the audit time"
				Annex D "Examples of audit calculations":
				• D1 Audit time calculation
				• D2 Single permanent site
				• D3 Multi-site organization
					ISO/IEC 27006:2015 - Amd.1:2020):
					• cl.9.1.5.1-IS 9.1.5 "Multiple sites"
					• cl.9.1.6 "Multiple management systems standards"
						ISO/IEC 20000-6:2017:
						• cl.9.1.6 "Multiple management systems standards"
						  • cl.9.1.6.1 SM9.1.6.1 Combining management system audits
						  • cl.9.1.6.2 SM9.1.6.2 Combining management system audits for ISO/EC 20000-1 and ISO/IEC 27001
						• cl.9.1.4.3-SM9.1.4.3 "Adjustment for other management systems standard certification"
							ISO/TS 22003:2013:
							• B.1 "Minimum audit time"
							• D.2 "Application review"
								IAF MD9:2022:
								• cl.MD 9.1.4 "Determining audit time" refers to the application of IAF MD11 for integrated audit for standards other than ISO 9001

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TABLE 2 – PROCESS FLOW FOR THE DETERMINATION OF THE TOTAL AUDIT TIME

Steps from 6 onwards are required per each sampled site (where relevant), considering the relevant factors for that site.

N	Process flow step	QMS	EMS	OH&SMS	EnMS	ISMS	ITSMS	FSMS	MDMS
1.	**Check whether one or more management systems are applicable and determine the applicable standards**	see table 1 above	see table 1 above	see table 1 above	see table 1 above	see table 1 above	see table 1 above	see table 1 above	see table 1 above

2.	**Evaluate whether the organization is eligible for multi-site certification**	**IAF MD1:2018:**
		• cl.5 "Eligibility of a multi-site organization for certification"
			IAF MD1:2018:
			• cl.5 "Eligibility of a multi-site organization for certification"
				IAF MD1:2018:
				• cl.5 "Eligibility of a multi-site organization for certification"
					ISO 50003:2021:
					• cl.B.3 "Eligibility of an organization for sampling"
					  • Table B.1 Mgmt. system data
					  • Table B.2 Energy performance data
						ISO/IEC 27006:2015-Amd.1:2020:
						• cl.9.1.5 "Multi-site sampling"
						• cl.9.1.5.1-IS 9.1.5 "Multiple sites"
							ISO/IEC 20000-6:2017:
							• cl.9.1.5 "Multi-site sampling"
							• cl.9.1.5.1-SM 9.1.5 "Criteria for multi-site sampling"
								ISO/TS 22003:2013:
								• cl.9.1.5.1
								• cl. 9.1.5.2
									IAF MD9:2022:
									• cl.MD 9.1.5 "Multi-site certification eligible"

3.	**Evaluate whether site sampling is appropriate or not**	**IAF MD1:2018:**
		• cl.6.1: site sampling is appropriate
		• cl.6.2: site sampling is not appropriate
		• cl.6.3: combination of sites that can and cannot be sampled
			IAF MD1:2018:
			• cl.6.1: site sampling is appropriate
			• cl.6.2: site sampling is not appropriate
			• cl.6.3: combination of sites that can and cannot be sampled
				IAF MD1:2018:
				• cl.6.1: site sampling is appropriate
				• cl.6.2: site sampling is not appropriate
				• cl.6.3: combination of sites that can and cannot be sampled
				
				IAF MD22:2019
				  • cl.9.1.4
				  • cl.9.1.5
					ISO 50003:2021:
					• B.5.4.1... eligibility criteria may consist of sites that can be sampled, sites that cannot be sampled or a combination of both
					• cl.B.4 "Sampling methodology"
					  • cl.B.4.1 General
					  • cl.B.4.2 Conditions
					  • cl.B.4.3 Site selection
					  • cl.B.4.4 Selection of temporary sites
						ISO/IEC 27006:2015-Amd.1:2020:
						• cl.9.1.5.1-IS 9.1.5 "Multiple sites": CBs may consider using a sample-based approach to multiple-site certification audit
							ISO/IEC 20000-6:2017:
							• cl.9.1.5.1-SM 9.1.5 "Criteria for multi-site sampling": CBs may consider using a sample-based approach to multiple-site certification audit
								ISO/TS 22003:2013:
								• cl.9.1.5.3 and table A.1 "Food chain categories":
								  • multi-site sampling is possible for cat. A, B, E, F and G and companies with > 20 sites operating similar processes within these categories.
								  • multi-site sampling is not possible for cat. C, D
									IAF MD9:2022
									• cl.MD 9.1.5 "Multi-site sampling":
									• *"Sites involved in design, development and manufacturing of medical devices (Table A.1.1-1.6 "Finished medical devices") cannot be sampled"*
									• *sites involved in associated activities or manufacturing of parts (table A1.7 "Parts and services") can be sampled*

N	Process flow step	QMS	EMS	OH&SMS	EnMS	ISMS	ITSMS	FSMS	MDMS
4.	Determine the number of sampled sites[8][9]	**IAF MD1:2018**: • cl.6.1.2 "Sampling" • cl.6.1.3: "Size of sampling": ⇒ *Initial audit: y=√x* ⇒ *Surveillance: y=0.6√x* ⇒ *Recertification: y=√x or y=0.8√x where MS has proved to be effective*	**IAF MD1:2018**: • cl.6.1.2 "Sampling" • cl.6.1.3: "Size of sampling": ⇒ *Initial audit: y=√x* ⇒ *Surveillance: y=0.6√x* ⇒ *Recertification: y=√x or y=0.8√x where MS has proved to be effective*	**IAF MD1:2018**: • cl.6.1.2 "Sampling" • cl.6.1.3: "Size of sampling": ⇒ *Initial audit: y=√x* ⇒ *Surveillance: y=0.6√x* ⇒ *Recertification: y=√x or y=0.8√x where MS has proved to be effective*	**ISO 50003:2021**: • cl.B.4 "Sampling methodology" • cl.B.4.5 "Size of the sample": ⇒ *Initial: y=√x* ⇒ *Surveillance: y=0.6√x* ⇒ *Recertification: y=√x or y=0.8√x where MS has proved to be effective* • cl.4.6 "Risk"	**ISO/IEC 27006:2015 - Amd.1:2020**: • cl.9.1.5.1-IS 9.1.5 "Multiple sites" *Note: IAF MD1 not mentioned, but its rationale, related to e.g. sample size and site selection may be applied since ISO 27006 explicitly allows a sampling-based approach (IAF MD1 mentions ISO/IEC 27006)*	**ISO/IEC 20000-6:2017**: cl.9.1.5.1-SM 9.1.5 "Criteria for multi-site sampling" *Note: IAF MD1 not mentioned, but its rationale, related to e.g. sample size and site selection may be applied since ISO 20000-6 explicitly allows a sampling-based approach (IAF MD1 mentions ISO/IEC 20000-6)*	**ISO/TS 22003:2013**: • cl.9.1.5.4 and table 1 "Examples of the number of sites to be audited when multi-site sampling is used": • < =20 sites: no sampling • > 20 sites: 1 sampled site per 5 sites above 20	**IAF MD9:2022**: • cl.MD 9.1.5 *Note: IAF MD1:2018 is not mentioned, but its rationale may be applied in case of table A.1.7*
5.	Determine the Effective Number of Persons (ENP) for each management system at each site (when relevant)	**IAF MD5:2019**: • cl.1.9 (definition of ENP) • cl. 2.3 (calculation of ENP)	**IAF MD5:2019**: • cl.1.9 (definition of ENP) • cl. 2.3 (calculation of ENP)	**IAF MD5:2019**: • cl.1.9 (definition of ENP) • cl. 2.3 (calculation of ENP)	**ISO 50003:2021**: • cl. 9.1.4.4 EnMS "Effective number of personnel" • A.2 "Determination of the EnMS effective personnel"	**ISO/IEC 27006:2015-Amd.1:2020)**: • cl.B.2.1 "Number of persons doing work under the organization's control"	**ISO/IEC 20000-6:2017**: • cl.9.1.4.1-SM9.1.4.1 "Determining the audit time", Note	**ISO/TS 22003:2013**: • Annex B "Minimum audit time"	**IAF MD5:2019**: • cl.1.9 (definition of ENP) • cl. 2.3 (calculation of ENP)
6.	Determine the complexity level for each management system at each site (when applicable)	**IAF MD5:2019**: • table QMS2: complexity level based on the business sector of the organization)	**IAF MD5:2019**: • table EMS2: complexity level based on the business sector of the organization	**IAF MD5:2019**: • table OH&SMS2: complexity level based on the business sector of the organization	**ISO 50003:2021**: • A.3 "Determination of energy types • A.4 "Determination of EnMS complexity[10]": • table A.1 "Energy complexity factors for determination of audit time" • table A.2 "Level of the EnMS complexity" • *cl.A.4.2 Complexity formula*[11]:	**ISO/IEC 27006:2015 Amd.1:2020**: • C.3 "Example for audit time calculation" • table C1 "Classification of factors for calculating audit time" • table C.2 "Factors related to business & organization (other than IT)"	**ISO/IEC 20000-6:2017**: *Note: complexity is not needed for entering into Table 1 "Relationship between effective number of personnel and audit time before adjustments (initial audit)"*	**ISO/TS 22003:2013**: *Note: complexity is not needed for entering into Table B.1 "Minimum initial certification audit time"*	**IAF MD5:2019**: • *Not applicable for entering Table D1, Annex D*

[8] IAF MD1 cl.6.1.3.4: "The central function … shall be audited during the initial certification and every recertification audit and at least once a calendar year as part of surveillance"

[9] from IAF MD1: y = number of sites to be sampled; x = total number of sites.

[10] ISO 50003:2021: The EnMS complexity is based on three criteria: annual energy consumption, number of energy types, number of significant energy uses (SEUs)

[11] ISO 50003:2021: clause A.4 and Table A.1: complexity factors: F_{EC} for the annual energy consumption, F_{ET} for the number of energy types, F_{SEU} for the number of significant energy uses

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N	Process flow step	QMS	EMS	OH&SMS	EnMS	ISMS	ITSMS	FSMS	MDMS
					$C = (F_{EC}×0,25) + (F_{ET}×0,25) +(F_{SEU}×0,50)$	• table C.3 "Factors related to IT environment" • table C.4 "Impact factors on audit time" • B3.4 "Factors for adjustment of audit time"			
7.	Determine the audit time for each management system at each site (as applicable)	**IAF MD5:2019**: • table QMS 1 *Note: Table output is "audit time"*	**IAF MD5:2019**: • table EMS 1 *Note: Table output is "audit time"*	**IAF MD5:2019**: • table OH&SMS 1 *Note: Table output is "audit time"*	**ISO 50003:2021**: • A.5 Determination of EnMS audit time • table A.3 "Initial certification minimum audit time (audit days)"	**ISO/IEC 27006:2015 Amd.1:2020**[12]: • cl.B.3.3 "Audit time calculation" • cl. B6 "Audit time of multi-site" • table B.1 "Audit time chart" • C.3 "Example for audit time calculation"	**ISO/IEC 20000-6:2017**: • cl.9.1.4.1-SM9.1.4.1 "Determining the audit time" • Table 1 "Relationship between effective number of personnel and audit time before adjustments (initial audit)" *Note: Table output is "audit time"*	**ISO/TS 22003:2013**: • cl.B.2 "Calculation of minimum initial certification audit time" and table B.1 • minimum audit time[13] for a single site: • $Ts = TD+TH+TMS+TFTE$ *Note: Table output is "audit time"*	**IAF MD9:2022**: • cl.MD 9.1.4 • Annex D, table D.1
8.	Determine the adjustment factors in reduction or increase for each management system at each site (when applicable)	**IAF MD5:2019**: • cl.8 "Factors for adjustment of audit time": ⇒ *reduction: 30% max* ⇒ *increase not quantified*	**IAF MD5:2019**: • cl.8 "Factors for adjustment of audit time": ⇒ *reduction: 30% max* ⇒ *increase not quantified*	**IAF MD5:2019**: • cl.8 "Factors for adjustment of audit time": ⇒ *reduction: 30% max* ⇒ *increase not quantified*	**ISO 50003:2021**: • cl.A.6 "Factors for adjustment of audit time": ⇒ *max reduction: 30% of audit time from Table A.3 (A.6.2)* ⇒ *max increase not quantified*	**ISO/IEC 27006:2015-Amd.1:2020**: • cl.B.3.4 "Factors for adjustment of audit time" • cl.B.3.5 "Limitation of deviation of audit time": *30% max reduction* • C.3 "Example for audit time calculation"	**ISO/IEC 20000-6:2017**: • cl.9.1.4.2-SM9.1.4.2 "Adjustment to audit time": • table 2 "Factors which can decrease audit time": max. reduction 30% • table 3 "Factors which can increase audit time": increase not quantified	**ISO/TS 22003:2013**: • table B.1 (last column): possible <u>reduction</u> 50% of minimum on-site audit time for each additional site visited • clause B.1 (last sentence): … other factors may necessitate <u>increasing</u>	**IAF MD9:2022,** Annex D, table D.1, Factors used to adjust the audit time from Table D.1: • a) increase not quantified • b) reduction 20% max • c) reduction 50% max solely for the certification scope of "Distribution or

[12] ISO/IEC 27006:2015 (integrated by Amendment 1:2020) - Audit time calculation sequence:
- Step 1 - determination of factors related to business and organization (other than IT): Identify the suitable grade for each of the categories given in Table C.2 and sum up the results.
- Step 2 - determination of factors related to IT environment: Identify the suitable grade for each of the categories given in Table C.3 and sum up the results.
- Step 3 - based on the results of step 1 and 2 above, identify the impact of factors on audit time by selecting the appropriate entry in Table C.4.
- Step 4 - final calculation: the number of days determined by applying the audit time chart (Table B.1) is multiplied by the factor resulting from Step 3. Where multi-site sampling is utilized, the audit days calculated are increased based on the efforts needed to execute the multi-site sampling plan.

[13] For FSMS minimum audit time: T_D = basic on-site audit time (days); T_H = n° of audit days for additional HACCP studies; T_{MS} = n° of audit days for absence of relevant management system; T_{FTE} = n° of audit days per number of employees

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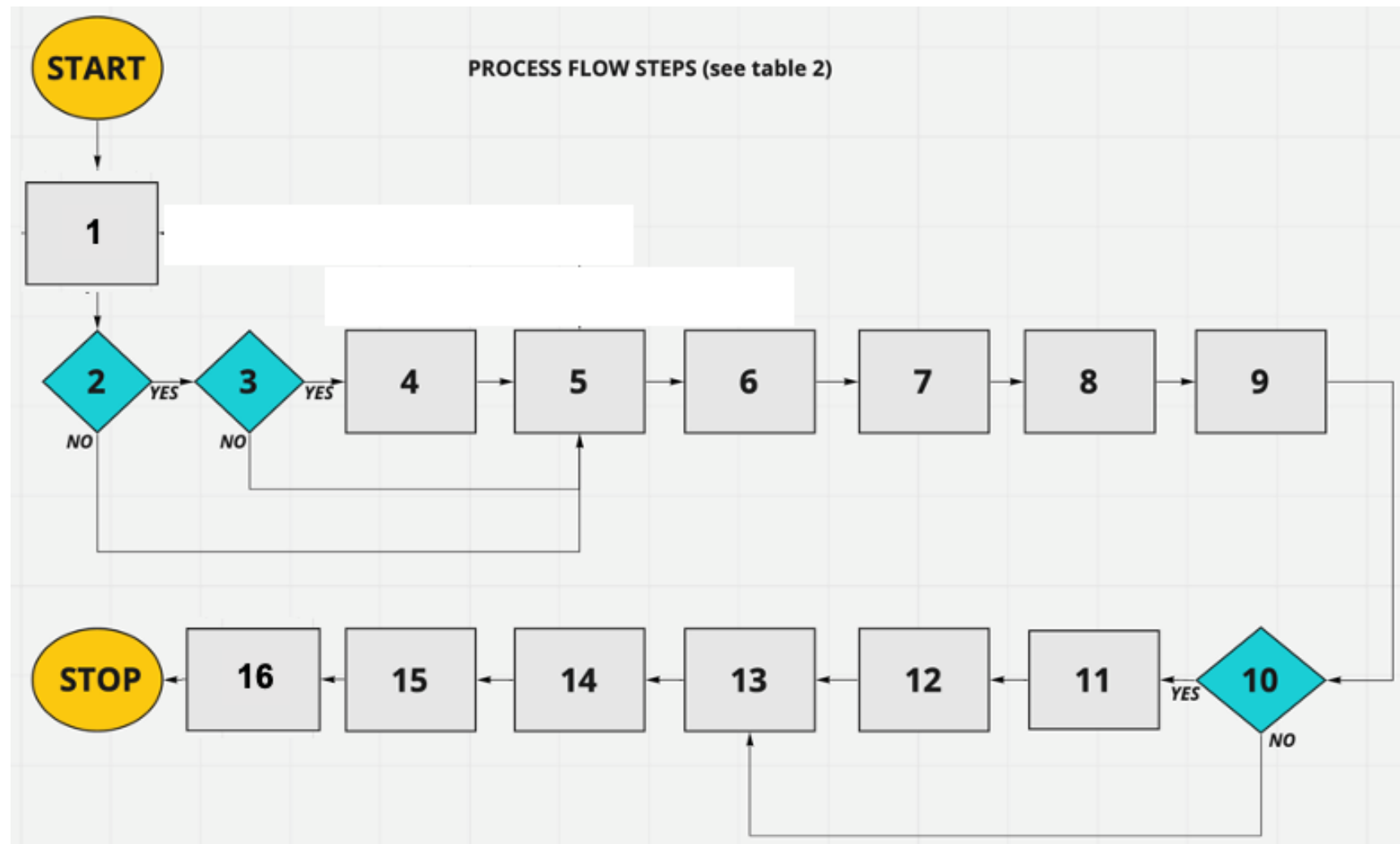| N	Process flow step	QMS	EMS	OH&SMS	EnMS	ISMS	ITSMS	FSMS	MDMS
						• table C.1 classification of factors) *• table C.4: increase / reduction depending on the business and IT complexity*		the minimum audit time…	*transportation Services"*
9.	**In case of multi-site determine further reduction in audit time for each site (when applicable)**	**IAF MD1:2018**: • cl.7.3 "Calculation of audit time": unless precluded by specific schemes, the reduction of audit time per sampled site shall not be greater than 50%.	**IAF MD1:2018**: • cl.7.3 "Calculation of audit time": unless precluded by specific schemes, the reduction of audit time per sampled site shall not be greater than 50%.	**IAF MD1:2018**: • cl.7.3 "Calculation of audit time": unless precluded by specific schemes, the reduction of audit time per sampled site shall not be greater than 50%.	**ISO 50003:2021**: • cl.B.5.4.2: *further site reduction not mentioned*	**ISO/IEC 27006:2015 Amd.1:2020**: • "Further site reduction not mentioned"	**ISO/IEC 20000-6:2017** *Note: IAF MD1 not mentioned: "Further site reduction not mentioned"*	*IAF MD1 not mentioned, but its rationale may be applied since IAF MD1 mentions ISO TS 22003 (See also above)*	**IAF MD9:2022**: • cl.MD 9.1.5 *Note: IAF MD1:2018 is not mentioned, but its rationale may be applied in case of table A.1.7*
10.	**In case of multiple management systems check whether there are the conditions for conducting an integrated audit**	**IAF MD11:2013**: • cl.2 "Application"	**IAF MD11:2013**: • cl.2 "Application"	**IAF MD11:2013**: • cl.2 "Application"	**ISO 50003:2021** • cl.9.1.6 "Multiple management systems standards" cl. A.6.3 Note refers to IAF MD11	**ISO/IEC 27006:2015 Amd.1:2020**: • cl.9.1.6 "Multiple management systems" *Note: IAF MD11 not mentioned, but its rationale may be applied since IAF MD11 mentions ISO/IEC 27006 (cl.1.3, cl.2.1.5.1)*	**ISO/IEC 20000-6:2017**: • cl. 9.1.6 "Multiple management systems" *Note: IAF MD11 not mentioned, but its rationale may be applied since IAF MD11 mentions ISO/IEC 20000 (cl.1.3)*	**ISO/TS 22003:2013**: • cl.B.1 "General": in case of a combined audit involving FSMS, a reduction of the audit time can be implemented • Annex D "Guidance on generic certificate functions" *Note: IAF MD11 not mentioned, but its rationale may be applied since IAF MD11 mentions ISO/TS 22003 (clauses 2.1.5.1)*	**IAF MD9:2022**: • cl.MD 9.1.4 states the applicability of IAF MD11 for integrated audit for standards other than ISO 9001 • Annex D: when conducting an ISO 9001 and ISO 13485 audit together, a minimum of 25% will be added to audit time calculated per Annex D.
11.	**Determine the starting point for the total audit time of the integrated management system (IMS)**	**IAF MD11:2013**: • cl.2.1.5.1b: determine the starting point for calculating the total audit time of an IMS by adding the audit times calculated for each management system that is part of it	**IAF MD11:2013**: • cl.2.1.5.1b: determine the starting point for calculating the total audit time of an IMS by adding the audit times calculated for each management system that is part of it	**IAF MD11:2013**: • cl.2.1.5.1b: determine the starting point for calculating the total audit time of an IMS by adding the audit times calculated for each management system that is part of it	**IAF MD11:2013**: • cl.2.1.5.1b: determine the starting point for calculating the total audit time of an IMS by adding the audit times calculated for each management system that is part of it **ISO 50003:2021**	**IAF MD11:2013**: • cl.2.1.5.1b: determine the starting point for calculating the total audit time of an IMS by adding the audit times calculated for each management system that is part of it	**IAF MD11:2013**: cl.2.1.5.1b: determine the starting point for calculating the total audit time of an IMS by adding the audit times calculated for each management system that is part of it	**IAF MD11:2013**: cl.2.1.5.1b: determine the starting point for calculating the total audit time of an IMS by adding the audit times calculated for each management system	**IAF MD9:2022**: • cl.MD 9.1.4 states the applicability of IAF MD11 for integrated audit for standards other than ISO 9001 **IAF MD11:2013**: • cl.2.1.5.1b: add the audit time of MDMS to

N	Process flow step	QMS	EMS	OH&SMS	EnMS	ISMS	ITSMS	FSMS	MDMS
					• cl.A.6.3, Note • cl.B.5.4.2				the sum of the audit time of other schemes
12.	**Adjust the starting point figure by considering factors that may increase or reduce the required audit time**	**IAF MD11:2013**: • cl.2.1.5.1c: take into account factors that may increase or reduce the time required for the audit • cl.2.1.5.2: reduction ranges from 0% to 20% based on the integration level of the organization MS and of the competence of the CB audit team • Annex 1 "Reduction of audit time"	**IAF MD11:2013**: • cl.2.1.5.1c: take into account factors that may increase or reduce the time required for the audit • cl.2.1.5.2: reduction ranges from 0% to 20% based on the integration level of the organization MS and of the competence of the CB audit team • Annex 1 "Reduction of audit time"	**IAF MD11:2013**: • cl.2.1.5.1c: take into account factors that may increase or reduce the time required for the audit • cl.2.1.5.2: reduction ranges from 0% to 20% based on the integration level of the organization MS and of the competence of the CB audit team • Annex 1 "Reduction of audit time"	**ISO 50003:2021** cl.A.6.3 "An audit of an integrated management system can result in increased audit time, but where it results in reduction it shall not exceed 20%"	**ISO/IEC 27006:2015 - Amd.1:2020**: • cl.9.1.6 "Multiple management systems" *Note: IAF MD11 not mentioned, but its rationale may be applied since IAF MD11 mentions ISO/IEC 27006 (cl.1.3, 2.1.5.1)*	**ISO/IEC 20000-6:2017**: • cl. 9.1.6 "Multiple management systems" *Note: IAF MD11 not mentioned, but its rationale may be applied since IAF MD11 mentions ISO/IEC 20000 (cl.1.3)*	**ISO/TS 22003:2013**: • clause B.1"General": in the case of a combined audit involving the FSMS, a reduction of the audit time can be implemented if justified and documented *Note: IAF MD11 not mentioned, but its rationale may be applied since IAF MD11 mentions ISO/TS 22003 (clauses 2.1.5.1)*	**IAF MD9:2022**: • cl.MD 9.1.4 states the applicability of IAF MD11 for integrated audit for standards other than ISO 9001 **IAF MD 11:2013**: • cl.2.1.5.2: reduction ranges from 0% to 20% based on the integration level of the organization MS and of the competence of the CB audit team • Annex 1 "Reduction of audit time"

13.	**Calculate the on-site audit duration**	**IAF MD5:2019**:
		• cl.4.1: should not be less than 80% of the audit time
			IAF MD5:2019:
			• cl.4.1: should not be less than 80% of the audit time
				IAF MD5:2019:
				• cl.4.1: should not be less than 80% of the audit time
					ISO 50003:2021
					cl.9.1.4.2: shall not be less than 80% of the audit time
						ISO/IEC 27006:2015 - Amd.1:2020:
						cl. B.3.6 "On-site audit time": minimum 70% of the audit time
							ISO/IEC 20000-6:2017:
							• cl.9.1.4.1-SM9.1.4.1 "Determining the audit time": minimum 80% of the audit time
								ISO/TS 22003:2013:
								• cl.B.1"General":
								  • The minimum time for on-site auditing of the product and/or service realization of the organization shall be 50% of the total minimum audit time (applies to all type of audits).
								  • Note 2: Product and service realization processes do not include activities related to FSMS development, training, control, audit, review and improvement.
									IAF MD9:2022:
									• cl.MD 9.1.4 states the applicability of IAF MD5
									IAF MD5:2019:
									• cl.4.1: should not be less than 80% of audit time)

14.	**Consider how to split the audit time**	**IAF MD5:2019**:	**IAF MD5:2019**:	**IAF MD5:2019**:	*Note: IAF MD5 not mentioned, but same rationale may be applied*	*Note: IAF MD5 not mentioned, but same rationale may be applied*	*Note: IAF MD5 not mentioned, but same rationale may be applied*	*Note: IAF MD5 not mentioned, but same rationale may be applied*	**IAF MD9:2022**:

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	between Stage 1 and Stage 2 [14]	• cl 3.1, *Note: Normal practice is that time spent for Stage 2 exceeds time spent for Stage 1.*	• cl 3.1, *Note: Normal practice is that time spent for Stage 2 exceeds time spent for Stage 1.*	• cl 3.1, *Note: Normal practice is that time spent for Stage 2 exceeds time spent for Stage 1.*					• cl.MD 9.1.4 states the applicability of IAF MD5 **IAF MD5:2019**: • cl 3.1, *Note: Normal practice is that time spent for Stage 2 exceeds time spent for Stage 1.*
15.	Determine the audit time for surveillance and recertification audits	**IAF MD5:2019:** • cl.5 "Surveillance": about 1/3 of the audit time spent on the initial certification audit (should not be less than 1 md) • cl.6: "Recertification": about 2/3 of the audit time that would be required for an initial certification audit, if such an initial audit were to be carried out at the time of recertification (should not be less than 1 md)	**IAF MD5:2019:** • cl.5 "Surveillance": about 1/3 of the audit time spent on the initial certification audit (should not be less than 1 md) • cl.6: "Recertification": about 2/3 of the audit time that would be required for an initial certification audit, if such an initial audit were to be carried out at the time of recertification (should not be less than 1 md)	**IAF MD5:2019:** • cl.5 "Surveillance": about 1/3 of the audit time spent on the initial certification audit (should not be less than 1 md) • cl.6: "Recertification": about 2/3 of the audit time that would be required for an initial certification audit, if such an initial audit were to be carried out at the time of recertification (should not be less than 1 md)	**ISO 50003:2021** • A.5 Determination of EnMS audit time • table A.4 Surveillance and recertification audit time (audit-days)	**ISO/IEC 27006:2015 - Amd.1:2020:** • cl.B4 "Audit time for surveillance audit": about 1/3 of the audit time spent on the initial certification audit • cl.B5 "Audit time for re-certification audit": at least 2/3 of the time that would be required for initial certification audit of the same organization at the time that it is to be audited for re-certification	**ISO/IEC 20000-6:2017:** • cl.9.1.4.4-SM9.1.4.4 "Determining audit time for surveillance and recertification audits" • surveillance: min. 1/3 of the audit time for the initial audit (min. 1 day) • recertification: min. 2/3 of the audit time for the initial audit (min. 2 days)	**ISO/TS 22003:2013:** • cl.B.3 "Calculation of minimum surveillance and recertification audit time" • surveillance: in.1/3 of the audit time for the initial audit (min. 1 day, min 0,5 day for cat.A and B) • recertification: min. 2/3 of the audit time for the initial audit (min.1 day, min 0,5 day for cat.A and B)	**IAF MD9:2017:** • cl.MD 9.1.4 states the applicability of IAF MD5 **IAF MD5:2019:** • cl.5 "Surveillance": about 1/3 of the audit time spent on the initial certification audit. • cl.6: "Recertification": about 2/3 of the audit time that would be required for an initial certification audit, if such an initial audit were to be carried out at the time of recertification
16.	Confirm audit time or make adjustments as needed during the certification cycle	The audit time can be furtherly adapted considering the results of any prior audit • cl.9.1.4.2 of ISO/IEC 17021-1:2015 • cl.5 and 6 of IAF MD5:2019 • cl.4 of IAF MD11:2013	The audit time can be furtherly adapted considering the results of any prior audit • cl.9.1.4.2 of ISO/IEC 17021-1:2015 • cl.5 and 6 of IAF MD5:2019 • cl.4 of IAF MD11:2013	The audit time can be furtherly adapted considering the results of any prior audit • cl.9.1.4.2 of ISO/IEC 17021-1:2015 • cl.5 and 6 of IAF MD5:2019 • cl.4 of IAF MD11:2013	The audit time can be furtherly adapted considering the results of any prior audit • cl.9.1.4.2 of ISO/IEC 17021-1:2015 • cl.4 of IAF MD11:2013	• cl.B4 "Audit time for surveillance audit" • cl.B5 "Audit time for re-certification audit"	The audit time can be furtherly adapted considering the results of any prior audit • cl.9.1.4.2 of ISO/IEC 17021-1:2015 cl.4 of IAF MD11:2013	The audit time can be furtherly adapted considering the results of any prior audit • cl.9.1.4.2 of ISO/IEC 17021-1:2015 cl.4 of IAF MD11:2013	The audit time can be furtherly adapted considering the results of any prior audit • cl.9.1.4.2 of ISO/IEC 17021-1:2015 • cl.5 and 6 of IAF MD5:2019 • cl.4 of IAF MD11:2013

[14] For a multisite the Stage 1 could be normally limited to the central function and possibly some other site(s)s as deemed useful.

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FIGURE 1 – PROCESS FLOW CHART FOR THE DETERMINATION OF THE TOTAL AUDIT TIME

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PROCESS FLOW STEPS (see table 2)

START

1

2 — YES → 3 — YES → 4 → 5 → 6 → 7 → 8 → 9

2 NO

3 NO

STOP ← 16 ← 15 ← 14 ← 13 ← 12 ← 11 ← 10 — YES

10 NO

Note: Steps from 6 onwards are required per each sampled site (where relevant), considering the relevant factors for that site.

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End of IAF Informative Document Guidance on the Determination of Audit Time for Integrated Audit of Multi-Site Management Systems

Further Information

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