



IAF Mandatory Document

DETERMINATION OF AUDIT TIME OF QUALITY, ENVIRONMENTAL, AND OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEMS

Issue 4, Version 2

(IAF MD 5:2019)

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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 documents 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.

TABLE OF CONTENTS

0. INTRODUCTION	6
1. DEFINITIONS	7
1.1. Management Systems Certification Scheme.....	7
1.2. Client Organization.....	7
1.3. Permanent Site.....	7
1.4. Virtual Site.....	7
1.5. Temporary Site	7
1.6. Audit Time	7
1.7. Duration of Management System Certification Audits	7
1.8. Audit Day.....	8
1.9. Effective Number of Personnel.....	8
1.10. Risk Category (QMS only).....	8
1.11. Complexity Category (EMS only)	8
1.12. Complexity Category (OH&SMS only).....	9
2. APPLICATION	9
2.1. Audit Time	9
2.2. Audit Day(s).....	9
2.3. Calculation of the Effective Number of Personnel	10
3. METHODOLOGY FOR DETERMINING AUDIT TIME OF MANAGEMENT SYSTEMS	12
4. INITIAL MANAGEMENT SYSTEMS CERTIFICATION AUDITS (STAGE 1 PLUS STAGE 2).....	14
5. SURVEILLANCE	14
6. RECERTIFICATION.....	15
7. INDIVIDUALIZED SECOND AND SUBSEQUENT CERTIFICATION CYCLES.....	15
8. FACTORS FOR ADJUSTMENTS OF AUDIT TIME OF MANAGEMENT SYSTEMS (QMS, EMS, and OH&SMS)	15
9. TEMPORARY SITES.....	18
10. AUDIT TIME OF A MULTI-SITE MANAGEMENT SYSTEM.....	18
11. CONTROL OF EXTERNALLY PROVIDED FUNCTIONS OR PROCESSES (OUTSOURCING).....	19

ANNEX A – QUALITY MANAGEMENT SYSTEMS 21

ANNEX B – ENVIRONMENTAL MANAGEMENT SYSTEMS 24

ANNEX C – OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEMS 29

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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.

DETERMINATION OF AUDIT TIME OF QUALITY, ENVIRONMENTAL, AND OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEMS

This document is mandatory for the consistent application of the relevant clauses of ISO/IEC 17021-1 for audits of quality, environmental and occupational health and safety management systems. All clauses of ISO/IEC 17021-1 continue to apply and this document does not supersede any of the requirements in that standard. Although personnel numbers (permanent, temporary, and part time) of the client are used as the starting point when considering the determination of audit time of management systems, this is not the sole consideration and account shall be taken of other factors affecting the audit time, including all those listed in ISO/IEC 17021-1.

0. INTRODUCTION

- 0.1. The correct determination of the audit time for an initial audit (Stage 1 plus Stage 2) is an integral part of the application review for any client organization.
- 0.2. This document provides mandatory provisions and guidance for CABs to develop their own processes for determining the amount of time required for the auditing of clients of differing sizes and complexity over a broad spectrum of activities. It is intended that this will lead to consistency of the determination of audit time of management systems between CABs, as well as between similar clients of the same CAB.
- 0.3. CABs shall identify the audit time of the Stage 1 and Stage 2 initial audit and of surveillance and re-certification audits for each applicant and certified client.
- 0.4. This mandatory document provides a framework that shall be utilized within a CAB's processes to determine appropriate audit time of management systems, taking into account the specifics of the client to be audited.
- 0.5. Although this document is set up for EMS/QMS/OH&SMS certification, a number of elements may be used for other ISO/IEC 17021-1 based certification schemes. Examples of these elements are the application of audit time duration or audit day and effective personnel.
- 0.6. Notwithstanding the guidance provided by this document, the time allocated for a specific audit should be sufficient to plan and accomplish a complete and effective audit of the client's management system.

1. DEFINITIONS

For the purposes of this document, the following definitions apply:

1.1. Management Systems Certification Scheme

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

1.2. Client Organization

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

1.3. Permanent Site

Location (physical or virtual) where a client organization (1.2) performs work or provides a service on a continuing basis.

1.4. Virtual Site

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

Note 1: A virtual site cannot be considered 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: A virtual site (e.g. company intranet) is considered a single site for the calculation of audit time.

1.5. Temporary Site

Location (physical or virtual) where a client organization (1.2) performs specific work or provides a service for a finite period of time and which is not intended to become a permanent site (1.3).

1.6. Audit Time

Time needed to plan and accomplish a complete and effective audit of the client organization's management system (ISO/IEC 17021-1).

1.7. Duration of Management System Certification Audits

Part of audit time (1.6) spent conducting audit activities from the opening meeting to the closing meeting, inclusive.

Note: 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*

1.8. 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.

1.9. 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.

For OH&SMS 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 OH&SMS performance.

Refer to 2.3 for calculation of effective number of personnel.

1.10. Risk Category (QMS only)

For QMS, the provisions in this document are based on three categories, dependant on the risks posed by failure of the product or service of the client organization. These categories can be considered as high, medium or low risk. High risk activities (e.g. nuclear, medical, pharmaceutical, food, construction) normally require more audit time. Medium risk activities (e.g., simple manufacturing) are likely to require the average time to carry out an effective audit and low risk activities less time. (See Annex A, Table QMS 2).

1.11. Complexity Category (EMS only)

For environmental management systems, the provisions specified in this document are based on five primary complexity categories of the nature, number and gravity of the environmental aspects of an organization that fundamentally affect the audit time. (See Annex B, Table EMS 2).

1.12. Complexity Category (OH&SMS only)

For OH&SMS, the provisions specified in this document are based on three primary complexity categories based on the nature, number and severity of the OH&S risks of an organization that fundamentally affect the audit time (See Annex C, Table OH&SMS 2).

2. APPLICATION

2.1. Audit Time

2.1.1. The audit time for all types of audits includes the **total** time **on-site** at a client's location (physical or virtual) (1.7) and time spent **off-site** carrying out planning, document review, interacting with client personnel and report writing.

2.1.2. The duration of a management system certification audit (1.7) should typically not be less than 80% of the audit time calculated following the methodology in Section 3. This applies to initial, surveillance and recertification audits.

2.1.3. Travel (en-route or between sites) and any breaks are not included in the on-site duration of management system certification audits.

Note: See 1.8. There may be a local legal requirement to include lunch breaks.

2.2. Audit Day(s)

2.2.1. Tables QMS 1, EMS 1, and OH&SMS 1 present the **average** audit time of management systems certification audits calculated in audit days. National adjustments on the number of days may be needed to comply with local legislation for travel, lunch breaks and working hours, to achieve the same total number of days of auditing from Tables QMS 1, EMS 1, and OH&SMS 1.

2.2.2. The number of audit days allocated shall not be reduced at the planning stages by programming longer hours per working day. Consideration can be made to allow efficient auditing of shift activities which may require additional hours in a working day.

2.2.3. If after the calculation, the result is a decimal number, the number of days should be adjusted to the nearest half day (e.g.: 5.3 audit days becomes 5.5 audit days, 5.2 audit days becomes 5 audit days).

2.2.4. To help ensure the effectiveness of the audit, the CAB should also consider the composition and size of the audit team (e.g. ½ day with 2 auditors may not be as effective as a one day audit with 1 auditor or 1 audit day with one lead auditor and one technical expert is more effective than 1 auditor day without the technical expert).

Note 1: ABs may require a CAB to demonstrate that the average audit time of specified clients is neither significantly more nor less than the audit time calculated from tables QMS1, EMS1, and OH&SMS1.

Note 2: CABs that work primarily in high risk or complex industries are likely to have an average higher than the tables and CABs that work primarily in low risk industries are likely to have an average lower than the tables.

2.3. Calculation of the Effective Number of Personnel

2.3.1. The effective number of personnel as defined above is used as a basis for the calculation of audit time of management systems. Considerations for determining the effective number of employees include part-time personnel and employees partially in scope, those working on shifts, administrative and all categories of office staff, similar or repetitive processes (see 2.3.4) and the employment of large numbers of unskilled personnel in some countries.

In case of seasonal operations (e.g. harvesting activities, holiday villages and hotels, etc.) the calculation of the effective number of personnel shall be based on the personnel typically present in peak season operations.

Reductions due to employment of large numbers of unskilled personnel shall not be made without consideration of the associated OH&S risk (see 2.3.6).

2.3.2. The justification to determine the effective number of personnel shall be available to the client organization and to the Accreditation Body for review during their assessments and on request from the Accreditation Body.

2.3.3. Part time personnel and employees partially in scope

Dependent upon the hours worked, part time personnel numbers and employees partially in scope may be reduced or increased and converted to an equivalent number of full time personnel. (e.g. 30 part time personnel working 4 hours/day equates to 15 full time personnel.)

2.3.4. Similar or repetitive process within scope

For QMS and EMS, when a high percentage of personnel perform certain activities/positions that are considered repetitive (e.g. cleaners, security, transport, sales, call centers, etc.) a reduction to the number of personnel which is coherent and consistently applied on a company to company basis within the scope of certification is permitted. The methods incorporated for the reduction shall be documented to include any consideration of the risk of the activities/positions.

For OH&SMS:

- a) When a high percentage of personnel perform certain activities/positions that are considered similar or identical because they expose personnel to similar OH&S risks (e.g. cleaners, security, sales, call centers, etc.) a reduction in the number of personnel which is coherent and consistently applied on a company to company basis within the scope of certification is permitted. The methods incorporated for the reduction shall be documented to include any consideration of the risk of the activities/positions.
- b) For groups of workers performing repetitive jobs which can reduce attention, and raise the associated level of OH&S risk (e.g. mounting, assembling, packaging, sorting, etc.), the methods incorporated for possible reductions shall be documented to include the assessment of the OH&S risk of any activities/positions of workers.

2.3.5. Shift work employees

The CAB shall determine the duration and timing of the audit which will best assess the effective implementation of the management system for the full scope of the client activities, including the need to audit outside normal working hours and various shift patterns. This shall be agreed with the client.

The CAB should ensure that any variation in audit time does not compromise the effectiveness of audits (see also clause 3.7).

2.3.6. Temporary unskilled personnel

This issue normally only applies for organizations with a low level of technology where temporary unskilled personnel may be employed in considerable numbers to replace automated processes.

For QMS and EMS, under these circumstances, a reduction in effective personnel may be made. Being the consideration of processes more important than employee number, this reduction is unusual and the justification for doing so shall be recorded and made available to the AB.

For OH&SMS this reduction is in principle to be regarded as not applicable since the employment of temporary unskilled personnel can be a source of OH&S risks. If, in exceptional cases, a reduction is made, the justification for doing so shall be recorded and made available to the AB.

3. METHODOLOGY FOR DETERMINING AUDIT TIME OF MANAGEMENT SYSTEMS

3.1. The methodology used as a basis for the calculation of audit time of management systems for an initial audit (Stage 1 + Stage 2) involves the understanding of tables and figures in Annex A for QMS, Annex B for EMS, and Annex C for OH&SMS audits respectively. Annex A (QMS) is based upon the effective number of personnel (see Clause 2.3 for guidance on the calculation of the effective number of personnel) and the level of risk, but does not provide minimum or maximum audit time. In addition to effective number of personnel, Annex B (EMS) is based also on the environmental complexity of the organization and does not provide minimum or maximum audit time, Annex C (OH&SMS) is based upon the effective number of personnel and the complexity category of OH&S risk associated with the business sector of the organization and does not provide a minimum or maximum audit time. Table OH&SMS 2 shows the linkage between business sectors and OH&S complexity categories based on OH&S risks.

Note: Normal practice is that time spent for Stage 2 exceeds time spent for Stage 1.

3.2. Using a suitable multiplier, the same tables and figures may be used as the base for calculating audit time for surveillance audits (Clause 5) and recertification audits (Clause 6).

3.3. The CAB shall have processes that provide for the allocation of adequate time for auditing of relevant processes of the client. Experience has shown that apart from the number of personnel, the time required to carry out an effective audit depends upon other factors for QMS, EMS, and OH&SMS. These factors are explored in more depth in Clause 8.

3.4. This mandatory document lists the provisions which should be considered when establishing the amount of time needed to perform an audit. These and other factors need to be examined during the CAB's application review process and after Stage 1 and throughout the certification cycle and at recertification for their potential impact on the determination of audit time regardless of the type of audit. Therefore, the relevant tables, figures, and diagrams for QMS, EMS, and OH&SMS which demonstrate the relationship between effective number of personnel and complexity, **cannot** be used in isolation. These tables and figures provide the framework for audit planning and therefore required adjustments for the determination of audit time for all types of audits.

3.5. For QMS audits, Figure QMS 1 provides a visual guide to making adjustments from the audit time calculated from Table QMS 1 and provides the framework for a process that should be used for audit planning by identifying a starting point based on the total effective number of personnel for all shifts.

3.6. For an EMS audit, it is appropriate to base audit time on the effective number of personnel of the organization and the nature, number and gravity of the environmental aspects of the typical organization in that industry sector. Tables EMS 1 and EMS 2 provide the framework for the process that should be used for audit planning. The audit time of management systems should then be adjusted based on any significant factors that uniquely apply to the organization to be audited.

For an OH&SMS audit, it is appropriate to base audit time on the effective number of personnel of the organization and nature, number and severity of the OH&S risks of the typical organization in that industry sector. Tables OH&SMS 1 and OH&SMS 2 provide a framework for the process that should be used for planning. The audit time of management systems should then be adjusted based on any significant factors that uniquely apply to the organization to be audited.

3.7. The starting point for determining audit time of management systems shall be identified based on the effective number of personnel, then adjusted for the significant factors applying to the client to be audited, and attributing to each factor an additive or subtractive weighting to modify the base figure. In every situation, the basis for the establishment of audit time of management systems including adjustments made shall be recorded. The CAB should ensure that any variation in audit time does not lead to a compromise on the effectiveness of audits.

For QMS and EMS, where product or service realization processes operate on a shift basis, the extent of auditing of each shift by the CAB depends on the processes done on each shift, and the level of control of each shift that is demonstrated by the client. To audit effective implementation, at least one of the shifts shall be audited. The justification for not auditing the other shifts (e.g. those outside of regular office hours) shall be documented.

For OH&SMS, where product or service realization processes operate on a shift basis, the extent of auditing of each shift by the CAB depends on the processes done on each shift, taking into consideration the associated OH&S risks, and the level of control of each shift that is demonstrated by the client. To audit effective implementation, at least one of the shifts inside and one outside of regular office hours shall be audited during the first cycle of certification. During surveillance audits of the subsequent cycles, the CB may decide not to audit the second shift based on the recognised maturity of the organization's OH&SMS. Adjustments for delaying the starting time of audit are recommended whenever possible, in order to cover both shifts within the audit day. The justification for not auditing the other shifts shall be documented taking into account the risk for not doing so.

3.8. The audit time of management systems determined using the tables or figures in Annexes A, B, and C shall not include the time of "auditors-in-training", observers or the time of technical experts.

3.9. The reduction of audit time of management systems shall not exceed 30% of the times established from Tables QMS 1, EMS 1, or OH&SMS 1.

Note: Clause 3.9 may not apply to the situations as described in IAF MD1 for the individual sites in multi-site operations. In this situation, a limited number of processes may be present in such sites and the implementation of all relevant requirements of the management system standards(s) can be verified.

4. INITIAL MANAGEMENT SYSTEMS CERTIFICATION AUDITS (STAGE 1 PLUS STAGE 2)

4.1. Determination of audit time of management systems involved in combined offsite activities (Clause 2.1) should not reduce the total **on-site** duration of management systems audits to less than 80% of the audit time calculated from the tables following the methodology in Section 3. Where additional audit time is required for planning and/or report writing, this will not be justification for reducing the on-site duration of management systems certification audits.

4.2. Table QMS 1, Table EMS 1, and Table OH&SMS 1 provide a starting point for estimating the audit time of an initial audit (Stage 1 + Stage 2) for QMS, EMS, and OH&SMS respectively.

4.3. The audit time determined by the CAB and the justification for the determination shall be recorded. This calculation shall include details on the time to be allocated to cover the entire scope of certification.

4.4. The CAB shall provide the audit time determination and the justification to the client organization as part of the contract and make it available to its Accreditation Body.

4.5. Certification audits may include remote auditing techniques such as interactive web-based collaboration, web meetings, teleconferences and/or electronic verification of the client's processes. If the CAB plans an audit for which the remote auditing activities are utilised, it shall apply the requirements defined in IAF MD4. These activities shall be identified in the audit plan, and the time spent on these activities may be considered as contributing to the total duration of management systems audits.

For OH&SMS, these activities shall be limited to reviewing documents/records and to interviewing staff and workers. In addition for OH&SMS, processes control and OH&S risk control cannot be audited using remote audit techniques.

5. SURVEILLANCE

During the initial three-year certification cycle, audit time for surveillance audits for a given organization should be proportional to the audit time spent on the initial certification audit (Stage 1 + Stage 2), with the total amount of time spent annually on

surveillance being about 1/3 of the audit time spent on the initial certification audit. The CAB shall obtain an update of client data related to its management system as part of each surveillance audit. The planned audit time of a surveillance audit shall be reviewed at least at every surveillance and recertification audit to take into account changes in the organization, system maturity, etc. The evidence of review including any adjustments to the audit time of management systems audits shall be recorded.

Note: It is unlikely that a surveillance audit duration will be less than one (1) audit day.

6. RECERTIFICATION

The audit time for the recertification audit should be calculated on the basis of the updated information of the client and is normally approximately 2/3 of the audit time that would be required for an initial certification audit (Stage 1 + Stage 2) of the organization if such an initial audit were to be carried out at the time of recertification (i.e. **not** 2/3 of the original time spent on the initial audit). The audit time of management systems shall take account the outcome of the review of system performance (ISO/IEC 17021-1). The review of system performance does not itself form part of the audit time for recertification audits.

Note: It is unlikely that a recertification audit duration will be less than one (1) audit day.

7. INDIVIDUALIZED SECOND AND SUBSEQUENT CERTIFICATION CYCLES

For the second and subsequent certification cycles, the CAB may choose to design an individualized surveillance and recertification program (see IAF MD3 for Advanced Surveillance and Recertification Procedures – ASRP) with approval by the Accreditation Body. If an ASRP approach is not chosen, the audit time of management systems should be calculated as indicated in Clauses 5 and 6.

For OH&SMS these requirements are not applicable.

8. FACTORS FOR ADJUSTMENTS OF AUDIT TIME OF MANAGEMENT SYSTEMS (QMS, EMS, and OH&SMS)

The additional factors that shall be considered include but are not limited to:

- i) Increase in audit time of all management systems:
 - a. Complicated logistics involving more than one building or location where work is carried out, e.g. a separate Design Centre must be audited.
 - b. Staff speaking in more than one language (requiring interpreter(s) or preventing individual auditors from working independently).
 - c. Very large site for the number of personnel (e.g. a forest).

- d. High degree of regulation (e.g. food, drugs, aerospace, nuclear power, etc.).
 - e. System covers highly complex processes or relatively high number of unique activities.
 - f. Activities that require visiting temporary sites to confirm the activities of the permanent site(s) whose management system is subject to certification.
- ii) Increase in audit time of management systems for QMS only:
- a. Activities considered to be of high risk (see Annex A, Table QMS 2).
 - b. Outsourced functions or processes.
- iii) Increase in audit time of management systems for EMS only:
- a. Higher sensitivity of receiving environment compared to typical location for the industry sector.
 - b. Views of interested parties.
 - c. Indirect aspects necessitating increase in audit time.
 - d. Additional or unusual environmental aspects or regulated conditions for the sector.
 - e. Risks of environmental accidents and impacts arising, or likely to arise, as consequences of incidents, accidents and potential emergency situations, previous environmental problems that the organization has contributed to.
 - f. Outsourced functions or processes.
- iv) Increase in audit time of management systems for OH&SMS only:
- a. Views of interested parties,
 - b. Rate of accidents and occupational diseases higher than average for the business sector,
 - c. If the members of the public are present on the organization's site (e.g. hospitals, schools, airports, ports, train stations, public transport),
 - d. The organization is facing legal proceedings related to OH&S (depending on the severity and impact of risk involved),
 - e. The temporary large presence of many (sub)contractors' companies and their employees causing an increase in complexity or OH&S risks (e.g. periodical shutdowns or turnaround of refineries, chemical plants, steel manufacturing plants, and other large industrial complexes),
-

- f. Where dangerous substances are present in quantities exposing the plant to the risk of major industrial accidents, in accordance with the applicable national regulations, and/or risk assessment documentation,
 - g. Organization with sites included in the scope in other countries than the mother site country (if legislation and language are not well known).
- v) Decrease in audit time of management systems:
- a. Client is not "design responsible" or other standard elements are not covered in the scope (QMS only).
 - b. Very small site for number of personnel (e.g. office complex only).
 - c. Maturity of management system.
 - d. Prior knowledge of the client management system (e.g. already certified to another standard by the same CAB). For OH&SMS this means already certified in another voluntary OH&SMS scheme.
 - e. Client preparedness for certification (e.g. already certified or recognized by another 3rd party scheme). For OH&SMS this means already subject to periodical audits by the National Authority for a mandatory governmental OH&SMS scheme.
Note: if audit is conducted in accordance with IAF MD 11 this justification is invalid as reduction will be calculated from the level of integration.
 - f. High level of automation (not applicable for OH&SMS).
 - g. Where staff include a number of people who work "off location" e.g. salespersons, drivers, service personnel, etc. and it is possible to substantially audit compliance of their activities with the system through review of records (not applicable for OH&SMS).

Activities considered to be of low risk (not applicable for OH&SMS): For QMS see Annex A, Table QMS 2 for examples and for EMS see Annex B Table EMS 2. All attributes of the client's system, processes, and products/services should be considered and a fair adjustment made for those factors that could justify more or less audit time for an effective audit. Additive factors may be off-set by subtractive factors.

Any decision taken in relation to the requirements of this clause shall be justified and recorded.

Note 1: Subtractive factors may be used once only for each calculation for each client organization.

Note 2: Additional factors to consider when calculating the audit time of integrated management systems are addressed in IAF MD 11.

9. TEMPORARY SITES

9.1. In situations where the certification applicant or certified client provides their product(s) or service(s) at temporary sites, such sites shall be incorporated into the audit programs.

9.2. Temporary sites could range from major project management sites to minor service/installation sites. The need to visit such sites and the extent of sampling should be based on an evaluation of the risks of the failure of the QMS to control product or service output or the EMS to control environmental aspects and impacts or the OH&SMS to control OH&S risks associated with the client's operations.

For QMS and EMS the sample of sites selected should represent the range of the client's scope of certification, competency needs and service variations having given consideration to sizes and types of activities, and the various stages of projects in progress and associated environmental aspects and impacts.

For OH&SMS the sites included in sampling should represent the client's scope of certification, sizes and types of activities and processes, type of hazards involved and associated OH&S risks, and stages of projects in progress.

9.3. Typically on-site audits of temporary sites would be performed. However, the following methods could be considered as alternatives to replace some on-site audits:

- i) Interviews or progress meetings with the client and/or its customer in person or by teleconference.
- ii) Document review of temporary site activities.
- iii) Remote access to electronic site(s) that contains records or other information that is relevant to the assessment of the management system and the temporary site(s).
- iv) Use of video and teleconference and other technology that enable effective auditing to be conducted remotely.

For OH&SMS the above methods could be considered as alternatives to replace only those parts of on-site audits not related to witness the process control and other OH&SMS risk control.

9.4. In each case, the method of audit should be fully documented and justified in terms of its effectiveness.

10. AUDIT TIME OF A MULTI-SITE MANAGEMENT SYSTEM

10.1. In the case of a management system operated over multiple sites it is necessary to establish if sampling is permitted or not.

For OH&SMS, the decision if site sampling is permitted or not, shall be based on the evaluation of the level of OH&S risks associated with the activities and processes carried out in each site included in the scope of certification. Records of such evaluations and rationale of decisions taken shall be made available to the AB.

10.2. The requirements for multiple site management system certification are covered by IAF MD 1 "IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization".

11. CONTROL OF EXTERNALLY PROVIDED FUNCTIONS OR PROCESSES (OUTSOURCING)

11.1. If an organization outsources part of its functions or processes, it is the responsibility of the CAB to obtain evidence that the organization has effectively determined the type and extent of controls to be applied in order to ensure that the externally provided functions or processes do not adversely affect the effectiveness of the MS, including the organization's ability to consistently deliver conforming products and services to its customers or to control its environmental aspects or to control its OH&S risks, and commitments to comply with legal requirements.

11.2. For QMS and EMS the CAB will audit and evaluate the effectiveness of the client's management system in managing any supplied activity and the risk this poses to the delivery of objectives, customer and conformity requirements. This may include gathering feedback on the level of effectiveness from suppliers. However, auditing the supplier's management system is not required, considering that it is included in the scope of the organization's management system only the control of the supplied activity, and not the performance of the activity itself. From this understanding of risk any additional audit time shall be determined.

11.3. For OH&SMS the CAB will audit and evaluate the effectiveness of the organization's OH&SMS in managing any supplied activity and the risk this poses to OH&S performance of its own activities and processes and conformity requirements.

- a) This may include gathering feedback on the level of effectiveness from suppliers, based:
- on the criteria applied by the organization for the evaluation, selection, monitoring of performance, and re-evaluation of these external providers based on their ability to provide functions or processes in accordance with specified requirements, in compliance with the legal requirements; and
 - on the risk that the external providers can adversely affect the organization's ability to control its own OH&S risks.

- b) Although the provider's management system is not required to be audited, the CAB shall audit those controls that the organization has implemented for the processes or functions included within the scope of the organization's OH&SMS, which have been outsourced to external providers to plan and complete an effective audit.

The contractor's personnel who operate at the organization's premises, on processes included in the scope of the organization's OH&SMS, shall be interviewed to evaluate their OH&S awareness.

- c) The CAB should be able to establish this during the preparation of the certification programme and further verify it during the initial audit, and before every surveillance and recertification audit.

ANNEX A – QUALITY MANAGEMENT SYSTEMS
Table QMS 1 – Quality Management Systems
**Relationship between Effective Number of Personnel and Audit Time
(Initial Audit only)**

Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)	Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)
1-5	1.5	626-875	12
6-10	2	876-1175	13
11-15	2.5	1176-1550	14
16-25	3	1551-2025	15
26-45	4	2026-2675	16
46-65	5	2676-3450	17
66-85	6	3451-4350	18
86-125	7	4351-5450	19
126-175	8	5451-6800	20
176-275	9	6801-8500	21
276-425	10	8501-10700	22
426-625	11	>10700	Follow progression above

Note 1: The numbers of personnel in Table QMS 1 should be seen as a continuum rather than a stepped change. I.e. if drawn as a graph, the line should start with the values in the lower band and end with the endpoints of each band. The starting point of the graph should be personnel of 1 attracting 1.5 days. See clause 2.2 for dealing with parts of a day.

Note 2: The CAB's procedure may provide for calculation of audit time for a number of personnel exceeding 10700. Such time should follow the progression in Table QMS 1 in a consistent fashion.

Note 3: See also clause 1.9 and 2.3.

Figure QMS 1 – Relationship between Complexity and Audit Time

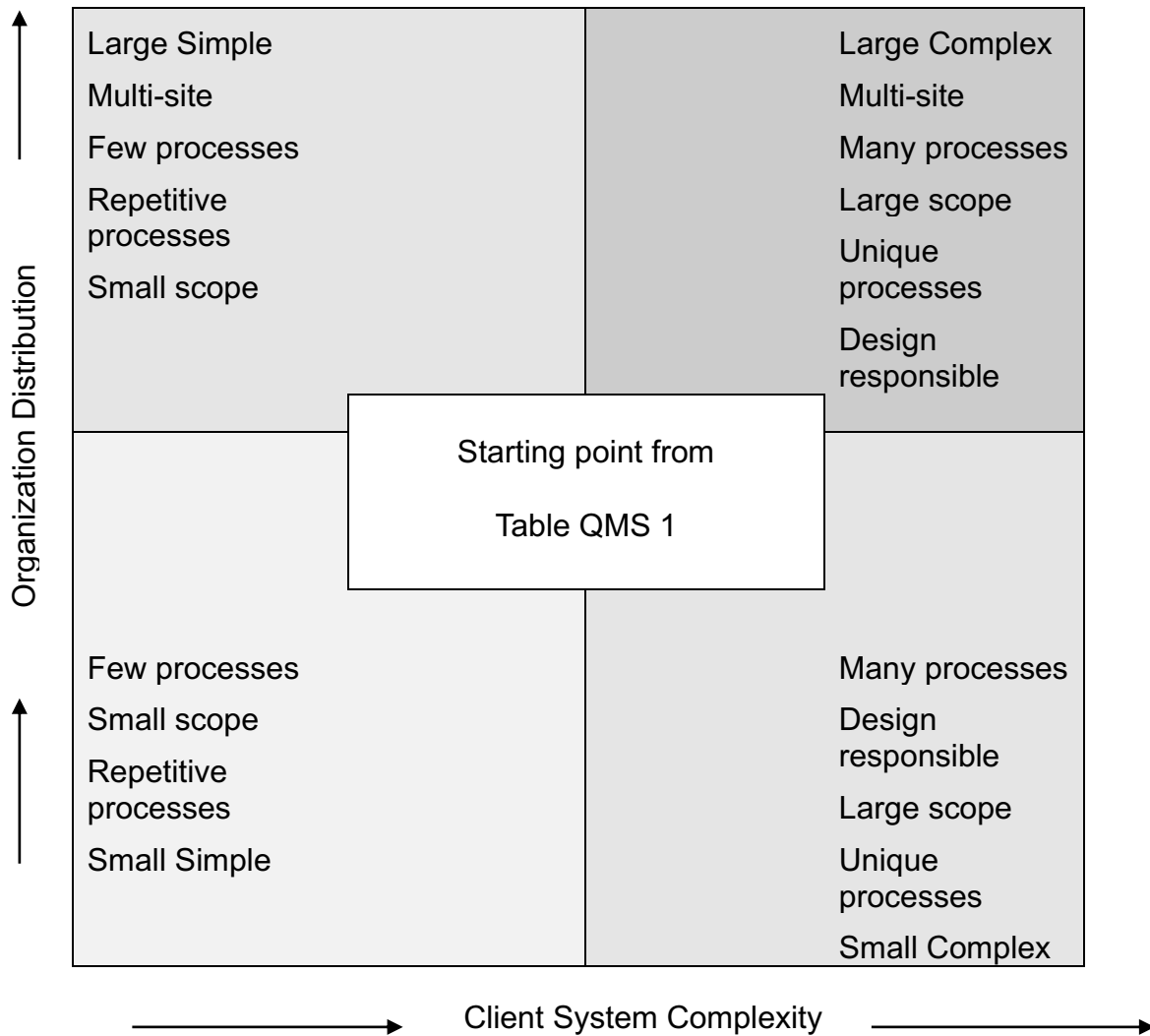


Table QMS 2 – Examples of Risk Categories

These risk categories are not definitive, they are examples only that could be used by a CB when determining the risk category of an audit.

High Risk

Where failure of the product or service causes economic catastrophe, or puts life at risk. Examples include but are not limited to:

Food; pharmaceuticals; aircraft; shipbuilding; load bearing components and structures; complex construction activity; electrical and gas equipment; medical and health services; fishing; nuclear fuel; chemicals, chemical products and fibres.

Medium Risk

Where failure of the product or service could cause injury or illness. Examples include but are not limited to:

Non load bearing components and structures; simple construction activities; basic metals and fabricated products; non-metallic products; furniture; optical equipment; leisure and personal services.

Low Risk

Where failure of the product or service is unlikely to cause injury or illness. Examples include but are not limited to:

Textiles and clothing; pulp, paper and paper products; publishing; office services; education; retailing, hotels and restaurants.

Note 1: It is expected that business activities defined as low risk may require less audit time than the time calculated using Table QMS 1, activities defined as medium risk will take the time calculated using Table QMS 1, and activities defined as high risk will take more time.

Note 2: If a company is providing a mixture of business activities (e.g.: construction company that builds simple construction – medium risk - and bridges – high risk), it is up to the CAB to determine the correct audit time, taking into consideration the number of personnel involved in each of the activities.

ANNEX B – ENVIRONMENTAL MANAGEMENT SYSTEMS

**Table EMS 1 – Relationship between Effective Number of Personnel,
Complexity and Audit Time
(Initial Audit only- Stage 1 + Stage 2)**

Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)				Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)			
	High	Med	Low	Lim		High	Med	Low	Lim
1-5	3	2.5	2.5	2.5	626-875	17	13	10	6.5
6-10	3.5	3	3	3	876-1175	19	15	11	7
11-15	4.5	3.5	3	3	1176-1550	20	16	12	7.5
16-25	5.5	4.5	3.5	3	1551-2025	21	17	12	8
26-45	7	5.5	4	3	2026-2675	23	18	13	8.5
46-65	8	6	4.5	3.5	2676-3450	25	19	14	9
66-85	9	7	5	3.5	3451-4350	27	20	15	10
86-125	11	8	5.5	4	4351-5450	28	21	16	11
126-175	12	9	6	4.5	5451-6800	30	23	17	12
176-275	13	10	7	5	6801-8500	32	25	19	13
276-425	15	11	8	5.5	8501-10700	34	27	20	14
426-625	16	12	9	6	>10700	Follow progression above			

Note 1: Audit time is shown for high, medium, low and limited complexity audits.

Note 2: The numbers of personnel in Table EMS 1 should be seen as a continuum rather than a stepped change. I.e. if drawn as a graph, the line should start with the values in the lower band and end with the endpoints of each band. The starting point of the graph should be personnel of 1 attracting 2.5 days. See clause 2.2 for dealing with parts of a day.

Note 3: The CAB's procedure may provide for calculation of audit time for a number of personnel exceeding 10700. Such time should follow the progression in Table EMS 1 in a consistent fashion.

Table EMS 2 – Examples of Linkage between Business Sectors and Complexity Categories of Environmental Aspects

Complexity Category	Business Sector
High	<ul style="list-style-type: none"> – mining and quarrying – oil and gas extraction – tanning of textiles and clothing – pulping part of paper manufacturing, including paper recycling processing – oil refining – chemicals and pharmaceuticals – primary productions – metals – non-metallics processing and products covering ceramics and cement – coal-based electricity generation – civil construction and demolition – hazardous and non-hazardous waste processing, e.g. incineration, etc. – effluent and sewerage processing
Medium	<ul style="list-style-type: none"> – fishing/farming/forestry – textiles and clothing except for tanning – manufacturing of boards, treatment/impregnation of wood and wooden products – paper production and printing, excluding pulping – non-metallics processing and products covering glass, clay, lime, etc. – surface and other chemically-based treatment for metal fabricated products, excluding primary production

Complexity Category	Business Sector
	<ul style="list-style-type: none"> – surface and other chemically-based treatment for general mechanical engineering – production of bare printed circuit boards for electronics industry – manufacturing of transport equipment – road, rail, air, ships – non-coal-based electricity generation and distribution – gas production, storage and distribution (<i>note: extraction is graded high</i>) – water abstraction, purification and distribution, including river management (<i>note: commercial effluent treatment is graded as high</i>) – fossil fuel wholesale and retail – food and tobacco processing – transport and distribution by sea, air, land – commercial estate agency, estate management, industrial cleaning, hygiene cleaning, dry cleaning normally part of general business services – recycling, composting, landfill (of non-hazardous waste) – technical testing and laboratories – healthcare/hospitals/veterinary – leisure services and personal services, excluding hotels/restaurants
Low	<ul style="list-style-type: none"> – hotels/restaurants – wood and wooden products, excluding manufacturing of boards, treatment and impregnation of wood – paper products, excluding printing, pulping, and paper making – rubber and plastic injection moulding, forming and assembly, excluding manufacturing of rubber and plastic raw materials that are part of chemicals

Complexity Category	Business Sector
	<ul style="list-style-type: none"> – hot and cold forming and metal fabrication, excluding surface treatment and other chemical-based treatments and primary production – general mechanical engineering assembly, excluding surface treatment and other chemical-based treatments – wholesale and retail – electrical and electronic equipment assembly, excluding manufacturing of bare printed circuit boards
Limited	<ul style="list-style-type: none"> – corporate activities and management, HQ and management of holding companies – transport and distribution management services with no actual fleet to manage – telecommunications – general business services, except commercial estate agency, estate management, industrial cleaning, hygiene cleaning, dry cleaning – education services
Special Cases	<ul style="list-style-type: none"> – nuclear – nuclear electricity generation – storage of large quantities of hazardous material – public administration – local authorities – organizations with environmental sensitive products or services, financial institutions

Complexity Categories of Environmental Aspects

The provisions specified in this document are based on five primary complexity categories of the nature and gravity of the environmental aspects of an organization that fundamentally affect the audit time. These are:

High – environmental aspects with significant nature and gravity (typically manufacturing or processing type organizations with significant impacts in several of the environmental aspects);

Medium – environmental aspects with medium nature and gravity (typically manufacturing organizations with significant impacts in some of the environmental aspects);

Low – environmental aspects with low nature and gravity (typically organizations of an assembly type environment with few significant aspects);

Limited – environmental aspects with limited nature and gravity (typically organizations of an office type environment);

Special – these require additional and unique consideration at the audit planning stage.

Table EMS 1 covers the above four top complexity categories: high, medium, low, and limited. Table EMS 2 provides the link between the five complexity categories above and the industry sectors that would typically fall into that category.

The CAB should recognise that not all organizations in a specific sector will always fall in the same complexity category. The CAB should allow flexibility in its application review procedure to ensure that the specific activities of the organization are considered in determining the complexity category. For example, even though many businesses in the chemical sector should be classified as “high complexity”, an organization which would have only a mixing free from chemical reaction or emission and/or trading operation could be classified as “medium” or even “low complexity”. The CAB shall document all cases where they have lowered the complexity category for an organization in a specific sector.

Table EMS 1 does not cover the “special complexity” category and the audit time of management systems audits shall be developed and justified on an individual basis in these cases.

ANNEX C – OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEMS
Table OH&SMS 1 – Occupational Health and Safety Management Systems

**Relationship between Effective Number of Personnel,
Complexity Category of OH&S Risk and Audit Time
(Initial Audit only – Stage 1 + Stage 2)**

Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)			Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)		
	High	Med	Low		High	Med	Low
1-5	3	2.5	2.5	626-875	17	13	10
6-10	3.5	3	3	876-1175	19	15	11
11-15	4.5	3.5	3	1176-1550	20	16	12
16-25	5.5	4.5	3.5	1551-2025	21	17	12
26-45	7	5.5	4	2026-2675	23	18	13
46-65	8	6	4.5	2676-3450	25	19	14
66-85	9	7	5	3451-4350	27	20	15
86-125	11	8	5.5	4351-5450	28	21	16
126-175	12	9	6	5451-6800	30	23	17
176-275	13	10	7	6801-8500	32	25	19
276-425	15	11	8	8501-10700	34	27	20
426-625	16	12	9	>10700	Follow progression above		

Note 1: Audit time is shown for audits at high, medium and low complexity category of OH&SM risk.

Note 2: The numbers of personnel in Table OH&SMS 1 should be seen as a continuum rather than a stepped change. If drawn as a graph, the line should start with the values in the lower band. The starting point of the graph should be personnel of one attracting 2,5 days. See clause 2.2 for dealing with parts of a day.

Note 3: See also clause 1.9 and 2.3.

TABLE OH&SMS 2 - Examples of Linkage between Business Sectors and Complexity Categories of OH&S Risks

Complexity category of OH&S risk	Business Sector
<p align="center">High</p>	<ul style="list-style-type: none"> • fishing (offshore, coastal dredging and diving) • mining and quarrying • manufacture of coke and refined petroleum products • oil and gas extraction • tanning of leather and leather products • dyeing of textiles and clothing • pulping part of paper manufacturing including paper recycling processing • oil refining • chemicals (including pesticides, fabrication of batteries and accumulators), and pharmaceuticals • manufacturing of fibreglass • gas production, storage and distribution • electricity generation and distribution • nuclear • storage of large quantities of hazardous material • non-metallic processing and products covering ceramics, concrete, cement, lime, plaster, etc. • primary productions of metals • hot and cold forming and metal fabrication • manufacturing and assembly of metal structures • shipyards (depending on the activities could be medium) • aerospace industry • automotive industry • manufacturing of weapons and explosives • recycling of hazardous waste • hazardous and non-hazardous waste processing e.g. incineration etc. • effluent and sewerage processing • industrial and civil construction and demolition (including building completion with electrical, hydraulic and air conditioning installation activities) • slaughter houses • transport and distribution of dangerous goods (by land, air and water) • defence activities/crisis management • healthcare/hospitals/veterinary/social works

Complexity category of OH&S risk	Business Sector
<p>Medium</p>	<ul style="list-style-type: none"> • aquaculture (breeding, rearing, and harvesting of plants and animals in all types of water environments) • fishing (offshore fishing is high) • farming/forestry (depending on the activities could be high) • food, beverage and tobacco – processing • textiles and clothing except for dyeing • leather and leather product except for tanning • manufacturing of wood and wooden products including manufacturing of boards, treatment/impregnation of wood • paper production and paper products excluding pulping • non-metallic processing and products covering glass, ceramics, clay, etc. • general mechanical engineering assembly • manufacturing of metallic products • surface and other chemically based treatment for metal fabricated products excluding primary production and for general mechanical engineering (depending on the treatment and the size of the component could be high) • production of bare printed circuit boards for electronics industry • rubber and plastic injection moulding, forming and assembly • electrical and electronic equipment assembly • manufacturing of transport equipment and their repairs - road, rail and air (depending on the size of the equipment, could be high) • recycling, composting, landfill (of non-hazardous waste) • water abstraction, purification and distribution including river management (note commercial effluent treatment is graded as high) • fossil fuel wholesale and retail (depending on the amount of fuel, could be high) • transport of passengers (by air, land and sea) • transport and distribution of non-dangerous goods (by land, air and water) • industrial cleaning, hygiene cleaning, dry cleaning normally part of general business services • research & development in natural and technical sciences (depending on the business sector could be high). Technical testing and laboratories • hotels, leisure services and personal services excludes restaurants • education services (depending on the object of teaching activities could be high or low)

Complexity category of OH&S risk	Business Sector
Low	<ul style="list-style-type: none"> • corporate activities and management, HQ and management of holding companies • wholesale and retail (depending on the product, could be medium or high, e.g. fuel) • general business services except industrial cleaning, hygiene cleaning, dry cleaning and education services). • transport and distribution - management services with no actual fleet to manage • engineering services (could be medium depending on type of services) • telecommunications and post office services • restaurants and campings • commercial estate agency, estate management • research & development on social sciences and humanities • public administration, local authorities • financial institutions, advertising agency

Complexity Categories of OH&S Risks

The provisions specified in this document are based on three primary complexity categories of OH&S risks based on the nature and severity of the OH&S risks of an organization that fundamentally affect the auditor time. These are:

- **High** – OH&S risks with significant nature and severity (typically the construction industry, heavy manufacturing or processing type organizations),
- **Medium** – OH&S risks with medium nature and severity (typically light manufacturing organizations with some significant risks), and
- **Low** – OH&S risks with low nature and severity (typically office based organizations).

Table OH&SMS 1 covers the above three complexity categories of OH&S risks.

Table OH&SMS 2 provides the link between the three complexity categories of OH&S risks above and the industry sectors that would typically fall into that category.

The CAB should recognize that not all organizations in a specific sector will always fall in the same OH&S risk category. The CAB should allow flexibility in its contract review procedure to ensure that the specific activities of the organization are considered in determining the complexity categories of OH&S risks.

For example, even though many businesses in shipbuilding should be classified as “high risk”, an organization which would have only small boats of carbon fiber with lower complexity activities could be classified as “medium”.

The CAB shall document all cases where they have lowered the complexity category of OH&S risks of an organization in a specific business sector.

Note: The complexity category of OH&S risk of an organization may also be associated with the consequences of a failure of the OH&SMS to control the risk:

- High – where failure to manage the risk could put life at risk or result in serious injury or illness,
- Medium – where failure to manage the risk could result in injury or illness, and
- Low – where failure to manage the risk may result in minor injury or illness.

End of IAF Mandatory Document for determination of audit time of QMS, EMS, and OH&SMS audits.

Further Information:

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