IAF Mandatory Document

Determination of Audit Time of Quality and Environmental Management Systems

Issue 3

(IAF MD 5: 201X)

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The International Accreditation Forum, Inc. (IAF) details criteria for the accreditation of bodies that provide conformity assessment services, and such accreditation facilitates trade and reduces demands for multiple conformity assessment activities.

Accreditation reduces risk for business and its customers by assuring that accredited Conformity Assessment Bodies (CABs) are competent to carry out the work they undertake within their scope of accreditation. Accreditation Bodies (ABs) that are members of IAF and the CABs they accredit are required to comply with appropriate international standards and the applicable IAF application documents for the consistent application of those standards.

ABs that are signatories to the IAF Multilateral Recognition Arrangement (MLA) are evaluated regularly by an appointed team of peers to provide confidence in the operation of their accreditation programs. The structure and scope of the IAF MLA is detailed in IAF PR 4 - Structure of IAF MLA and Endorsed Normative Documents.

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.

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

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

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INTRODUCTION TO IAF MANDATORY DOCUMENTS

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

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Prepared by: IAF Technical Committee

Approved by: IAF Members Date: dd mm yy

Issue Date: dd mm yy

Application Date: dd mm yy

Name for Enquiries: Elva Nilsen

IAF Corporate Secretary

Telephone: +1 613 454-8159 Email: secretary@iaf.nu

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This document is mandatory for the consistent application of the relevant clauses of ISO/IEC 17021-1 for audits of quality and environmental 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 certification, a number of elements may be used for other 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.

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1 DEFINITIONS

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.

ISO 17021:1 3.16 Audit time - tempo complessivo dell'audit

3.17 Durata degli audit di certificazione del sistema di gestione

parte del tempo complessivo dell'audit (3.16) spesa a condurre attività di audit a partire dalla riunione di apertura sino a quella di chiusura, comprese

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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 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) and part time personnel. Refer to 2.3 for calculation of effective number of personnel.

Bisogna contare TUTTO il personale che lavora su tutti i turni e i subcontractor se ricadono nello scopo del certificato

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

<u>Novità importante</u>: per aziende ad alto rischio è MOLTO MOLTO difficile non applicare aumenti del 30%

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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)

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 and EMS 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 and EMS 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).

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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 and EMS1.

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.

Accredia potrà chiedere di fare una media degli sconti applicati per tutte o un gruppo di aziende. Il totale dovrebbe essere vicino al valore medio (salvo eccezioni giustificate)

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, repetitive processes and the employment of large numbers of unskilled personnel in some countries.

 Per l'outsorcing c'è adesso un punto specifico
- 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

Punto importante TRASPARENZA

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 Repetitive process within scope

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.

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

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activities, including the need to audit outside normal working hours and various shift patterns. This shall be agreed with the client.

2.3.6 Temporary unskilled personnel

Non in Italia, Assolutamente!!!

This issue normally only applies in countries with a low level of technology where temporary unskilled personnel may be employed in considerable numbers to replace automated processes. Under these circumstances a reduction in effective personnel may be made, but the consideration of processes is more important than employee numbers. This reduction is unusual and the justification for doing so shall be recorded and made available to the AB at assessment.

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 and Annex B for QMS and EMS 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, Appendix B (EMS) is based also on the environmental complexity of the organization and does not provide minimum or maximum audit time.

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 both QMS and EMS. 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 both QMS and EMS which demonstrate the relationship between effective number of personnel and complexity, **cannot** be used in isolation.

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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.
- 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. 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.
- 3.8 The audit time of management systems determined using the tables or figures in Annexes A and B 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 or EMS 1.

Note: Clause 3.9 may not apply to the situations described in IAF MD1 for the individual sites in multi-site operations where sampling of sites is permitted. 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)

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- 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 and Table EMS 1 provide a starting point for estimating the audit time of an initial audit (Stage 1 + Stage 2) for QMS and EMS 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 upon request.

 Importantissimo
- 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 (see 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. If the CAB plans an audit for which the remote auditing activities represent more than 30% of the planned on-site duration of management systems audits, the CAB shall justify the audit plan and maintain the records of this justification which shall be available to an Accreditation Body for review (see MD4).
- Note 1: Duration of management system certification audits refers to the audit time allocated for individual sites. Electronic audits of remote sites are considered to be remote audits, even if the electronic audit is physically carried out on the client organization's location (physical or virtual).
- Note 2: Regardless of the remote auditing techniques used, the client organization shall be physically visited at least annually where such a physical location exists.
- Note 3: It is unlikely that the duration of a Stage 2 audit will be less than one (1) audit day.



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

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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 will take 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 will be less than one (1) audit day.

A volte ritornano...! INDIVIDUALIZED SECOND AND SUBSEQUENT CERTIFICAT 7

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.

FACTORS FOR ADJUSTMENTS OF AUDIT TIME OF MANAGEMENT 8 SYSTEMS (QMS AND EMS)

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

- i) Increase in audit time of 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).

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- 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.
- g. Outsourced functions or processes.

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).
- 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.
- iv) 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).
 - e. Client preparedness for certification (e.g., already certified or recognized by another 3rd party 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.

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f. High level of automation.

- 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.
- h. Activities considered to be of low risk (see Annex A, Table QMS 2 for examples and Table EMS 1). Low complexity activities, e.g.:
 - Processes involving similar and repetitive activities (e.g., Service only).
 - o Identical activities of low complexity performed on all shifts with appropriate evidence of equivalent performance on all shifts.
 - Where a significant proportion of staff carry out a similar simple function. Repetitive process within scope (when employees perform repetitive activities).

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.

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 associated with the client's operations. 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.

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- 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.
- 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.
- 10.2 For certification of multiple sites where sampling is not permitted, detailed requirements will be covered in more detail in a new IAF MD when it is available. The starting point for calculating audit time of the management system is the total involved on all of the sites, consistent with Table QMS 1 and Table QMS 2 for quality management systems and Table EMS 1 and Table EMS 2 for environmental management systems.

The proportion of the total time spent on each site shall take into account situations where certain management system processes are not relevant to the site.

10.4 For certification of multiple sites where sampling is permitted, detailed requirements are covered in more detail in IAF MD1. The starting point for calculating audit time of the management system is the total involved on each of the sampled sites. MD1 shall be used to select sites to be sampled prior to applying MD5 to each selected site. The total time should never be less than that which would have been calculated for the size and complexity of the operation if all the work had been undertaken at a single site (MD1 – clause 5.3.4).

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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 and commitments to compliance with legal requirements.
- 11.2 The CB 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.

Dipende dallo scopo!! Se lo scopo dice "controllo" delle attiività svolte in oursourcing non occorre verificare l'outsourcer.
Se invece l'ttività è inclusa dello scopo certificato bisogna valutarlo, e quindi contare le persone in subappalto

End of IAF Mandatory Document for determination of audit time of QMS and EMS audits

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		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

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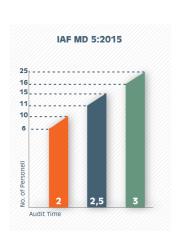
Note 1: The numbers of personnel in Table QMS 1 should be seen as a continuum rather than a stepped change. I.e. if drawn as a graph, the line should start with the values in the lower band and end with the endpoints of each band. The starting point of the graph should be personnel of 1 attracting 1.5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

Non sono blocchi fissi, ma un grafico con una linea spezzata!!!

Es: Azienda di 6 persone si applica 2, non 1,6!!!



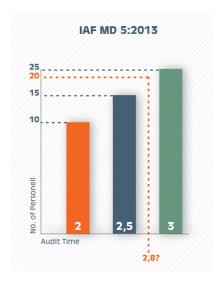
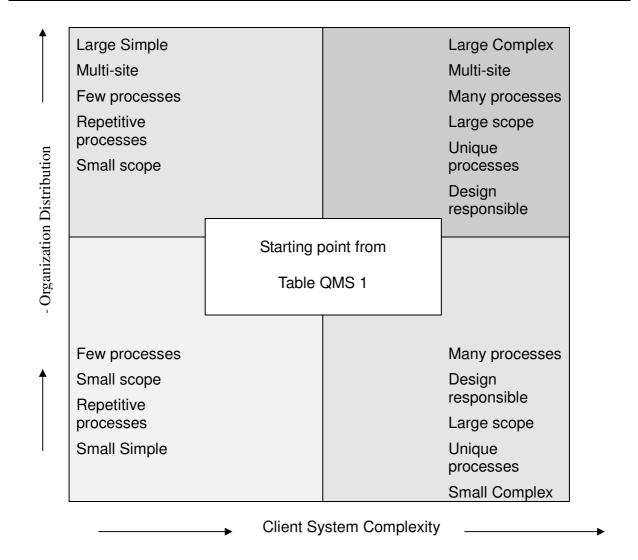


Figure QMS 1 – Relationship between Complexity and Audit Time

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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:

Esempio

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 QMS1, 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 (eg: 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.

<u>Novità importante</u>: per aziende ad alto rischio è MOLTO MOLTO MOLTO difficile non applicare aumenti del 30% IAF MD 5:2013

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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	Stage		Time age 2 (d	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.

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

Complexity Category	Business Sector
High	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	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

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Complexity Category	Business Sector
	 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 (note: extraction is graded high)
	 water abstraction, purification and distribution, including river management (note: commercial effluent treatment is graded as high)
	 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

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Complexity Category	Business Sector
Low	- 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
	 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	 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	- nuclear
Special Cases	nuclear electricity generation
	storage of large quantities of hazardous material
	 storage of large quantities of nazardous material public administration
	public duffillibitation

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Complexity Category	Business Sector
	 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.

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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.

Further Information

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

For contact details of members of IAF see the IAF website: http://www.iaf.nu.

Secretariat:

IAF Corporate Secretary Telephone: +1 613 454-8159 Email: secretary@iaf.nu