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IAF Mandatory Document for Duration of QMS and EMS Audits

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IAF Mandatory Document

IAF Mandatory Document For Duration of QMS and EMS Audits

Issue 1

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Name for Enquiries: John Owen, IAF Corporate Secretary

Contact: Phone: +612 9481 7343;

Email: secretary1@iaf.nu

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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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Contents

Clause	Topic	Page
0	INTRODUCTION	5
1	DEFINITIONS	5
2	APPLICATION	6
3	METHODOLOGY FOR DETERMINING AUDIT DURATION	7
4	INITIAL AUDIT DURATION (STAGE 1 PLUS STAGE 2)	8
5	SURVEILLANCE	9
6	RECERTIFICATION	9
7	INDIVIDUALIZED SECOND AND SUBSEQUENT CERTIFICATION CYCLES	9
8	FACTORS FOR ADJUSTMENTS OF AUDIT DURATION (QMS AND EMS)	9
9	TEMPORARY SITES	10
10	MULTI-SITE AUDIT DURATION	11
Annex A – Quality Management Systems		12
Annex B – Environmental Management Systems		14

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IAF Mandatory Document for Duration of QMS and EMS Audits

This document is mandatory for the consistent application of Clause 9.1.4. of ISO/IEC 17021:2006 for audits of quality and environmental management systems and is based upon guidance previously provided in IAF GD2:2005 Annex 2 and GD6: 2006 Annex 1. All clauses of ISO/IEC 17021:2006 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 audit duration, this is not the sole consideration and account shall be taken of other factors affecting audit duration.

0 INTRODUCTION

0.1 This document provides mandatory provisions and guidance for CABs to develop their own documented procedures 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 audit duration between CABs, as well as between similar clients of the same CAB.

0.2 CABs shall identify the audit duration for the stage 1 and stage 2 initial audit, surveillance audits, and re-certification audits for each applicant and certified client.

0.3 This mandatory document does not stipulate minimum/maximum times but provides a framework that shall be utilized within a CAB's documented procedures to determine appropriate audit duration, taking into account the specifics of the client to be audited.

0.4 For accreditation purposes, it should be noted that nonconformity with this document (and/or the included tables) in individual instances does not automatically lead to nonconformity against ISO/IEC 17021. However, this situation could be grounds for further investigation into the completeness of the audit. Special consideration should be given to investigating the grounds for deviation from this mandatory document.

0.5 If inconsistencies to this mandatory document are found on a more regular basis, this could form the basis for nonconformity against ISO/IEC 17021 on the grounds that the CAB cannot give a reasonable assurance that it gives its audit teams the time to perform a sufficiently complete audit as part of the certification process.

1 DEFINITIONS

1.1 Audit Duration

Audit duration for all types of audits is the effective time measured in auditor days required to carry out auditing activity.

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1.2 Auditor Day

The duration of an auditor day is normally 8 hours and may or may not include travel time or lunch depending upon local legislation.

1.3 Effective Number of Personnel

The effective number of personnel consists of all full time personnel involved within the scope of certification including those working on each shift. Non-permanent (seasonal, temporary and contracted personnel) and part time personnel who will be present at the time of the audit shall be included in this number.

1.4 Temporary Site

A temporary site is one set up by an organization in order to perform specific work or a service for a finite period of time and which will not become a permanent site. (eg. a construction site).

1.5 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 auditor time.

2 APPLICATION

2.1 Audit Duration

Audit duration for all types of audits includes on site time at a client's premises and time spent off-site carrying out planning, document review, interacting with client personnel and report writing.

It is expected that the audit duration involved in such planning and report writing combined should not typically reduce the total on-site audit duration to less than 80% of the time shown in the Tables QMS 1 and EMS 1. This applies to initial, surveillance and recertification audits. Where additional time is required for planning and/or report writing, this will not be justification for reducing on-site audit duration for any audit.

2.2 Auditor Day

Tables QMS 1 and EMS 1 present audit durations calculated in auditor days on the basis of 8 hours per day. 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 hours of auditing of Tables QMS 1 and EMS 1.

The number of auditor days allocated shall not be reduced at the planning stages by programming longer hours per working day.

2.3 Effective Number of Personnel

The effective number of personnel is used as a basis for the calculation of audit duration. Dependent upon the hours worked, part time personnel numbers may be reduced and converted to an equivalent number of full time personnel. Appropriate reduction should be made to the

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temporary unskilled personnel who may be employed in considerable numbers in some countries due to low level of technology and automation. Appropriate reduction of number of personnel also should be made where significant proportion of staff carry out a similar simple function for instance: transport, line work, assembly lines, etc"

A CAB shall agree with the organization to be audited the timing of the audit which will best demonstrate the full scope of the client activities.

3 METHODOLOGY FOR DETERMINING AUDIT DURATION

3.1 The methodology used as a basis for the calculation of audit duration of an initial audit (stage 1 + stage 2) involves the interpretation of tables and figures in Annex A and Annex B for QMS and EMS audits respectively. Annex A (QMS) is based solely upon the effective number of personnel (see clause 2.3 for guidance on the calculation of the effective number of personnel) but does not provide minimum or maximum duration. 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 duration.

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

3.3 The CAB shall have procedures 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 contract review process for their potential impact on the audit duration 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. These tables and figures provide the framework for further audit planning and for making adjustments to audit duration for all types of audits.

3.5 For QMS audits, Figure QMS 1 provides a visual guide to making adjustments from the basic audit times 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. 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. The justification for not auditing each shift shall be documented.

3.6 For an EMS audit it is appropriate to base audit duration 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. The audit duration should then be adjusted based on any significant factors that uniquely apply to the organization to be audited. The CAB should exercise discretion to ensure that any variation in audit duration does not lead to a compromise on the effectiveness of audits.

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3.7 The starting point for determining audit duration 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 duration including adjustments made shall be recorded.

3.8 Audit duration determinations using the tables or figures in Annexes A and B shall not include the time of "auditors-in-training" or the time of technical experts.

3.9 It would be unlikely that the reduction of audit duration would exceed 30% of the times established from Tables QMS 1 or EMS 1.

4 INITIAL AUDIT DURATION (STAGE 1 PLUS STAGE 2)

4.1 Audit duration involved in planning and preparation and report writing combined should not reduce the total on-site audit duration to less than 80 % of the time shown in Tables QMS 1 or EMS 1. Where additional time is required for planning and/or report writing, this will not be justification for reducing on-site audit duration.

4.2 Table QMS 1 and Figure QMS 1 and Tables EMS 1 and EMS 2 provide a starting point for estimating the duration of an initial audit (Stage 1 + Stage 2) for QMS and EMS audits respectively.

4.3 Where a CAB has applied a reduction to the times established in Tables QMS 1 or EMS 1, it shall make the justification available to their accreditation body for review during accreditation body assessments and on request from the accreditation body.

4.4 Certification audit duration 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 "on-site audit duration". If the CAB plans an audit for which the remote auditing activities represent more than 30% of the planned on-site audit duration, the CAB shall justify the audit plan and maintain the records of this justification which shall be available to an accreditation body for review. It is unlikely that the remote auditing activities represent more than 50% of the total on-site auditor time.

NOTES: 1. On-site auditor time refers to the on-site auditor 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 organization's premises.

2. Regardless of the remote auditing techniques used, the client shall be physically visited at least annually.

3. It is unlikely that duration of Stage 2 audit will be less than 1 auditor/day.

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5 SURVEILLANCE

5.1 During the initial three year certification cycle, surveillance audit duration for a given organization should be proportional to the time spent on initial certification audit (stage 1 + stage 2), with the total amount of time spent annually on surveillance being about 1/3 of the time spent on the initial certification audit. An update of client data related to certification shall be available for the planning of each surveillance audit. The planned surveillance audit duration shall be reviewed from time-to-time, at least at every surveillance audit and always at the time of recertification, to take into account changes in the organization, system maturity, etc. The evidence of review including any adjustments to audit duration shall be recorded.

6 RECERTIFICATION

6.1 The duration of the recertification audit should be calculated on the basis of the updated information of the client and is normally approximately 2/3 of the 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 initial certification audit duration). The audit duration shall take account the outcome of the review of system performance (ISO/IEC 17021 cl. 9.4.1.2).

7 INDIVIDUALIZED SECOND AND SUBSEQUENT CERTIFICATION CYCLES

7.1 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). If an ASRP approach is not chosen the audit duration should be calculated as indicated in clauses 5 and 6.

8 FACTORS FOR ADJUSTMENTS OF AUDIT DURATION (QMS AND EMS)

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

Increase in audit duration:

- Complicated logistics involving more than one building or location where work is carried out. e.g., a separate Design Centre must be audited;
- Staff speaking in more than one language (requiring interpreter(s) or preventing individual auditors from working independently);
- Very large site for the number of personnel (e.g., a forest);
- High degree of regulation (eg. food, drugs, aerospace, nuclear power etc);
- System covers highly complex processes or relatively high number of unique activities;
- Activities that require visiting temporary sites to confirm the activities of the permanent site(s) whose management system is subject to certification.

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- **For EMS Only**
  - Higher sensitivity of receiving environment compared to typical location for the industry sector;
  - Views of interested parties;
  - Indirect aspects necessitating increase in auditor time;
  - Additional or unusual environmental aspects or regulated conditions for the sector.

Decrease in audit duration:

- Client is not "design responsible" or other standard elements are not covered in the scope (QMS only);
- Low risk products or processes (for EMS, this is captured in Table EMS 1);
- Very small site for number of personnel (e.g. office complex only);
- Maturity of management system;
- Combined audit of an integrated system of two or more compatible management systems;
- Prior knowledge of the client management system (e.g., already certified to another standard by the same CAB);
- Client preparedness for certification (e.g., already certified or recognized by another 3rd party scheme);
- Low complexity activities, e.g.
  - Processes involve a single generic activity (e.g., Service only);
  - Identical activities performed on all shifts with appropriate evidence of equivalent performance on all shifts based on prior audits (internal audits and CAB audits);
  - Where a significant proportion of staff carry out a similar simple function.
- 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.

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 auditor time for an effective audit. Additive factors may be off-set by subtractive factors.

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 programmes.

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

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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 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.

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.

- Interviews or progress meetings with the client and/or its customer in person or by teleconference;
- Document review of temporary site activities;
- 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);
- 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 MULTI-SITE AUDIT DURATION

10.1 In the case of multi-site audits, the starting point for calculating audit duration for each site shall be consistent with Table QMS 1, and Figure QMS 1 for quality management systems and Table EMS 1 for environmental management systems. However reductions can be made taking into account situations where certain management system processes are not relevant to the site and are the primary responsibility of the controlling site. Requirements for multi site audits are covered in more detail in IAF MD 1 for Certification of Multiple Sites based on Sampling.

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Annex A – Quality Management Systems

Table QMS 1 - Quality Management Systems

Relationship between effective number of personnel and audit duration (Initial Audit only)

Effective Number of Personnel	Audit Duration Stage 1 + Stage 2 (days)	Effective Number of Personnel	Audit Duration 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 employees in Table QMS 1 should be seen as a continuum rather than a stepped change.

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

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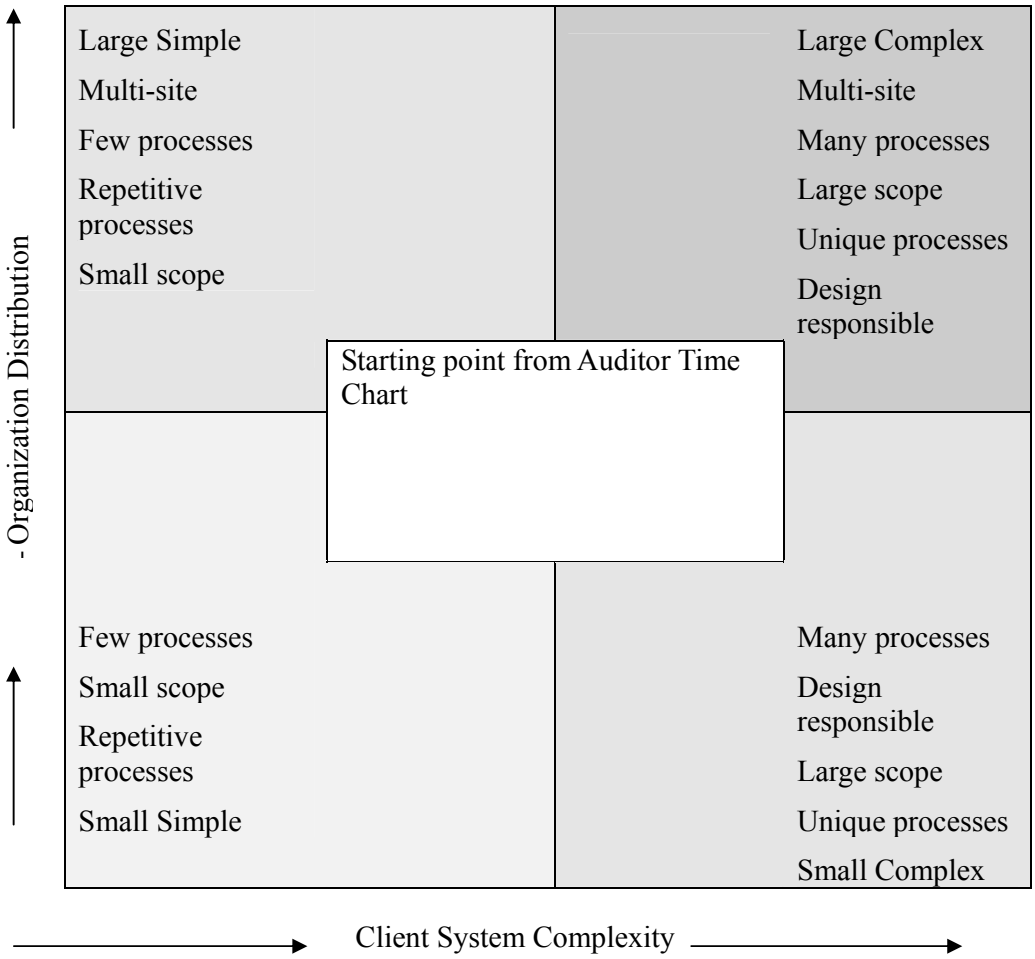
Figure QMS 1- Relationship between complexity and audit duration



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Annex B – Environmental Management Systems

TABLE EMS 1 - Relationship between effective number of personnel, complexity and audit duration (Initial Audit only)

Effective Number of Personnel	Audit Duration Stage 1 + Stage 2 (days)				Effective Number of Personnel	Audit Duration 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 duration 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

Note 3: The CAB's procedure may provide for audit duration for a number of personnel exceeding 10700. Such audit duration 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 excludes primary production 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 whole sale 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)

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Complexity category	Business sector
	technical testing and laboratories healthcare/hospitals/veterinary leisure services and personal services excludes hotels/restaurants
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 - excludes manufacturing of rubber and plastic raw materials which 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 CASES	nuclear nuclear electricity generation storage of large quantities of hazardous material public administration local authorities organizations with environmental sensitive products or services financial institutions

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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 auditor 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 contract 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 duration shall be developed and justified on an individual basis in these cases.

End of IAF Mandatory Document for Duration of QMS and EMS Audits

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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 - IAF Web Site - <http://www.iaf.nu>

Secretariat -

John Owen,

IAF Corporate Secretary,

Telephone +612 9481 7343

email <secretary1@iaf.nu>

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