




INTERNATIONAL ACCREDITATION SERVICE®

**Class Exercises and Discussion
for
IAF MD Training**

IAF MD 1




Class Exercise / Discussion # 1:

Identify the correct answer below:

IAF MD 1 is applicable to the CAB involved in audit and certification of Management Systems operated by the organization:

- with one site and one management system
- with one site and multiple management systems
- with a multiple operating sites with several management systems
- with a number of sites with a single management system
- with collection of independent organizations in association with another independent organization under the umbrella of a single management system.
- All of above
- None of above

IAF MD 1




Class Exercise / Discussion # 2:

Scenario:

The scope of a management system certification of an organization includes three manufacturing sites and 3 certificates are issued specific to each site. However, certain processes / activities within the scope of certification (such as: HR management, account & finance control, top management decision, sales & marketing, and purchasing) are solely carried out at the head office (i.e. central function). The head office is not yet cover under management system certification. The organization has requested to issue a single certificate under a multi-site certification scheme considering only those three sites, but without having head office location been certified.


Is it acceptable to consider the request of above organization for multi-site certification as per IAF MD 1?

IAF MD 1 

Class Exercise / Discussion # 3:


In which of the following conditions a site sampling requirements will be appropriate:

- a multi-site organization where each site is performing very similar processes/activities.
- all the sites perform significantly different processes/activities in connection with the management system scope.
- the client requests each site to be audited.
- there is a sector scheme or regulatory requirement stipulating that each site is to be audited systematically.
- a multi-site organization with part of their sites performing similar processes/activities while other sites are dedicated to very specific processes not performed elsewhere in the organization.
- all of above

IAF MD 1 

Class Exercise / Discussion # 4: (Identify whether the statements below are True or False)

- For multi-site sampling, at least 25% of the sample shall be selected at random.
- The selection of multi-site samples must be done at the start of the audit process.
- The Certification Body will have a policy for determining the sample size.
- For inclusion of new sites or a new group of sites to join an already certified multi-site organization, the CB shall determine the required activities to be performed before including the new site(s) in the certificate.
- A justification and recording of the rationale for proceeding with any approach to the auditing and certification of a multi-site organization is not mandatory.
- Unless precluded by specific schemes, the reduction of audit time per sampled site shall not be > 50%.
- If the nonconformities are found at any individual site under the f multi-site certification, the investigation shall be limited to that specific site for its resolution.
- if any site within the scope of multi-site certification has a major nonconformity, a certification decision can be made to the whole multi-site organization of listed sites pending satisfactory corrective action.
- The certification documentation will be withdrawn in its entirety if any of the sites does not fulfil the necessary provisions for the maintenance of the certification.
- The sites selected for the second surveillance of a certification cycle shall normally not include any sites sampled as part of the first surveillance audit.

IAF MD 2 


Class Exercise / Discussion # 1:

Identify the correct answer below:

Eligibility of a certification by CAB for transfer includes:

- a certification which is covered by an accreditation of an IAF or Regional MLA signatory at level 3 and where applicable level 4 and 5.
- a suspended certification which has appropriate corrective action plan that is already accepted by a previous certification body.
- Organization bearing certificate with expiration date overdue by one week.
- where certification has been granted by a certification body which has ceased trading or whose accreditation has expired, been suspended or withdrawn over 9 months period
- all of above
- none of above


IAF MD 2



Class Exercise / Discussion # 2: (Identify whether the statements below are True or False)

- a) if there are outstanding major nonconformities identified by issuing CB then the accepting CB shall conduct a full on-site audit of the transferring client.
- b) After receiving a notification that the organization is transferring to another CB, the issuing certification body should quickly suspend or withdraw the organization's certification, although the client continues to satisfy the requirements of certification.
- c) the accepting certification body shall not issue certification to the transferring client until:
 - it has verified the implementation of corrections and corrective actions for all outstanding major nonconformities; and
 - it has accepted the transferring client's plans for correction and corrective action for all outstanding minor nonconformities.
- d) Upon identification of issues that prevent the completion of transfer during pre-transfer review stage, the accepting CB can ask transferring organization to submit an adequate corrective action plan and accept it for transfer based on the previous certification cycle.
- e) If the most recent audit reports are not available or if the surveillance audit or recertification audit has not been completed as per issuing CB's audit programme, then the organisation shall be treated as a new client
- f) Once the accepting CB has issued the certification it shall inform the issuing CB.

IAF MD 3




Class Discussion:

What are the pre-requisite for CB to utilize ASRP ?

What are the eligibility criteria for CB to utilize ASRP ?

IAF MD 4




Class Exercise / Discussion :

Identify whether the statements below are True or False:

1. For the effective application of ICT, the security and confidentiality measures shall be maintained throughout audit/assessment activities.
2. When using ICT the increase in total audit/assessment time is not required.
3. When using ICT, persons involved in auditing/assessment (e.g. drone pilots, technical experts etc) can depend upon the competency and ability of auditors/assessors for utilization of ICT.
4. Audit/assessment reports and related records shall indicate the extent to which ICT has been used in achieving the audit/assessment objectives.
5. It is not necessary to identify virtual sites in the certification documentation.

IAF MD 5



Class Exercise / Discussion:

Case Study # 1:


For ISO 9001 certification, the XYZ certification LLC has determined the effective number of employees based on the following factors:
 Temporary/Permanent Unskilled workers = 10% reduction
 Performing same type of Job = 50 % reduction
 Part time Employee = 50 % reduction
 Full Time Different Job = 70 % reduction

After determining the effective number of employees, the audit time (audit duration) has been calculated in aggregate considering 30 % of further reduction as per IAF MD 5.

QTN: Is the reduction applied in calculating the effective number of personnel justifiable?

QTN: Has the intent and objectives of IAF MD 5 been fulfilled?

IAF MD 5




Case Study # 2:

The QMS of Goodies Enterprises has been certified to ISO 9001 since 2 certification cycles. The CB has estimated audit duration of 5 days for stage 1 and sage 2 based on total 15 numbers of employees.

The actual audit time was determined as 3.5 days (stage 1 + stage 2) equivalent to a 30% reduction. Justification record indicates 20 % reduction is given for No design and No outsourcing, 5 % reduction for single shift operations with low complexity and 5 % reduction for QMS maturity.

Is the audit time determination as per IAF MD 5 ?

IAF MD 5



Case Study # 3:


The CB audit time determination for Initial Audit shows 7 man-days (i.e. stage 1 + stage 2) for ISO 9001 and ISO 13485 certification of Hands-on Limited. The client under certification has total of 125 employees. The audit time determination and justification document of CB shows that the man-days (audit time) calculation has considered 20% reduction for No Design. The stage 1 has been completed within 1.5 days and stage 2 has been completed with 4 days of audit.

The CB calculation detail is recorded as follows:
 20% reduction of 7 days = 5.6 days = **5.5 days** (round figure)
 Initial audit = 1.5 days for stage 1 + 4 days for stage 2 = 5.5 days
 Surveillance audit = 5.5 x 0.33 = 1.815 days = 2 days (rounded up)
 Re-certification audit = 5.5 x 0.67 = 3.685 days = 3 days (rounded figure)

Note: IAF MD 5 requires 7 days for IA.

Is it appropriate audit time determination ?

IAF MD 5



Case Study # 4:
 Superior Chemical Manufacturing Ltd (an EMS – ISO 14001 certified client) has total 438 employees. The breakdown of employee count includes:

- Full time employee (Management and Administrative) = 84
- Employee performing same type of job at shop floor (skilled worker full time) = 156
- Temporary / unskilled workers = 198


The Express Certification Inc. (a MSCB) has calculated effective No of employees = 244
 (Note: CB has considered 20 % reduction for Management / admin staff as they are not affected by EMS operations, 50% reduction on repetitive work and 50 % reduction for unskilled employees)

Total initial audit duration determined considering medium risk / complexity category = 10 days (i.e. stage one = 2 days, stage two = 6 days and off-site activities = 2 days).

The justification recorded by CB indicates:
 The man-days reduction is as per established procedure (PR 005, rev.6) and further 20 % reduction is given for off-site site activities as per IAD MD 5.

Question: Does this scenario satisfy IAF MD 5 requirements?

IAF MD 5



Case Study # 5:
 StandHogs Pulp & Paper Industries Ltd. is certified to ISO 14001 and ISO 45001 Standards. The CB audit time calculation shows:


Total No. of Employees = 35
 Risk / complexity category = Medium
 Stage 1 = 3.5 man-days
 Stage 2 = 6 man-days
 Total audit duration determined = 9.5 man-days.

As per audit plan executed by CB, based on the audit report, there was total of 10 days utilized (i.e. for stage 1 = 3.5 man-days, and for stage 2 = 6.5 man-days). The audit time calculation and justification record shows that there was no reduction applied for this audit.

Note:
 For EMS and DH&SMS the IAF MD 5 requires total of 5.5 days each of audit time for IA (Stage 1 + Stage 2) respectively.

Does above satisfy IAF MD 5 requirements ?

IAF MD 11



Case Study # 1:
 ABC Manufacturing Ltd is certified to ISO 9001, ISO 14001 and ISO 13485 standards. Their scope of certification includes manufacturing of printed circuit boards (PCBs) for use in nonactive, non-implantable medical device industries. ABC has set up its manufacturing facility 25 kilometer outside of central town near to Hangs River. It has total of 34 production employees, 5 management team and 7 office staffs. It operates 24/7 with 3 shifts and high demand of supply products to renowned customers in country.


Excellent Certification Services (a MSCB) has determined to deploy Standard Audit Approach based on its advance planning system. The initial audit time determination by ECS includes:

- QMS initial audit = 5 days (as per IAF MD 5)
- EMS initial audit = 6 days (as per IAF MD 5)
- MD-QMS initial audit = 7 days (as per IAF MD 9)
- Starting point = 5+6+7 = 18 days
- Reduction of 20 % = 18 x 20% = 3.6 days

Total audit time for initial audit of IMS = 18 – 3.6 = 14.4 days = 14.5 days (rounded figure)

Advance planning system output resulted in assigning 3 auditors qualified to ISO 9001, ISO 14001 and ISO 13485 standards. ESC conducted 2.5 days of stage one audit, and 12 days (3 auditors x 4 days) of on-site audit.

IAF MD 11



Continue..... Case Study # 1:


Note:
Justification recorded for reduction in audit time states:

- The management system of ABC Manufacturing Ltd is 80% integrated
- ABC Manufacturing has integrated MS with an IMS manual, common high level procedures / work instruction with shared responsibilities among the employees, in exception of separate SOPs for operational control specific to each management system
- Employees are trained to IMS and able response to more than one management systems
- All ESC auditors are qualified to perform IMS based on ISO 9001, ISO 14001 and ISO 13485 standards

Does above scenario satisfy the intent and objectives of IAF MD 11?

(Please see the handouts given to each participant)

IAF MD 11



Case Study # 2:
Platinum Registrar Inc (a CB) has certified the Elk Civil Construction Co. (ECCC) for ISO 9001, ISO 14001 and ISO 45001 standard. ECCC has total 45 employee counts. The CB has determined to apply **Extended Audit Approach (EAA)** for IMS audit, and their initial audit advanced planning system shows the following:


QMS initial audit = 4 days (as per IAF MD 5) / High risk category
 EMS initial audit = 7 days (as per IAF MD 5) / High risk category
 OHSMS initial audit = 7 days (as per IAF MD 22) / High risk category
 IMS initial audit time = 4 + 3.5 (50% of 7) + 3.5 (50% of 7) = 11 days

Reduction in accordance with IAF MD 11 (Annex 2):

As per Vertical	= 60% integration of management systems
As per Horizontal	= $100 \frac{(X1-1) + (X2-1)}{2(Y-1)}$
	= $100 \frac{(3-1) + (2-1)}{2(3-1)}$
	= $300 / 4 = 75%$ (ability to perform IMS audit)

Note:
X1 and X2 are the number of standards for which an auditor is qualified relevant for the scope of the integrated audit; Y is the number of management system standards to be covered by integrated audit; and Z is the number of auditors.

IAF MD 11



Continue..... Case Study # 2:
Total audit time reduction as per Annex 2 table (Figure 1) for IMS audit = 15%
(i.e. 11 days x 15% = 1.65 = 1.5 days rounded figure)

Total audit time required for initial IMS audit = 11 - 1.5 = 9.5 days
Stage 1 = 1.5 days (performed by Lead Auditor)
Stage 2 = 8 days (performed by 2 auditors x 4 days)

Justification recorded for reduction states:

- The management system of ECCC is 60% integrated
- ECCC has integrated MS with an IMS manual, common high level procedures / work instruction with shared responsibilities among the employees, in exception of separate SOPs for operational control specific to each management system
- Employees are trained to IMS and able response to more than one management systems
- PRI Lead auditor is qualified for all three standards (ISO 9001, ISO 14001 and ISO 45001) and PRI auditor is qualified for two standards (ISO 9001 and ISO 14001) to perform IMS audit.
- Audit time saved while conducting the audit is as per IAF MD 11 (page 13/14).

Is it appropriate audit time determination as per IAF MD 11 ?
 (Please see the handouts given to each participant)

Thank You !

Q & A

