

International Accreditation Forum, Inc.



IAF Mandatory Document

IAF Mandatory Document for Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021:2011

Issue 1

(IAF MD 10:2013)

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 program. 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.

- The main scope of the MLA includes activities e.g. product certification and associated mandatory documents e.g. ISO/IEC Guide 65. 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.

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INTRODUCTION TO IAF MANDATORY DOCUMENTS

The term “shall” is used throughout this document to indicate those provisions which, reflecting the requirements of the relevant standard, are mandatory. The term “should” is used to indicate recognised means of meeting the requirements; a Certification Body (CB) can meet these criteria in an equivalent way provided this can be demonstrated to an Accreditation Body (AB).

Table of Contents

1. INTRODUCTION.....	5
2. DEFINITIONS.....	5
3. GENERAL.....	5
4. TECHNICAL AREAS.....	8
5. DETERMINATION OF COMPETENCE CRITERIA.....	9
6. EVALUATION PROCESSES.....	10
ANNEX A - INFORMATIVE.....	12

ASSESSMENT OF CERTIFICATION BODY MANAGEMENT OF COMPETENCE IN ACCORDANCE WITH ISO/IEC17021:2011

1. INTRODUCTION

The aim of this document is to provide a harmonised approach to how Accreditation Bodies assess a Certification Body (CB)'s management of competence in accordance with ISO/IEC 17021:2011.

2. DEFINITIONS

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

- 2.1 Certification process: the entirety of functions relating to certification from receipt of application to the granting and maintenance of certification
- 2.2 Certification function: a stage of the certification process, for example, application review, audit, certification decision (ref; ISO/IEC 17021:2011 Annex A)
- 2.3 Intended results the outputs of a certification function that comply with the requirements of ISO/IEC 17021:2011 and the objectives of the CB's certification process

3. GENERAL

- 3.1 The AB shall verify that the CB can demonstrate that all personnel involved in performing certification functions have the required competence.
- 3.2 The AB shall verify that the CB has defined its certification process and the intended results to be achieved for each certification function. The AB's evaluation of the CB's competence shall be based on:
- (a) the CB's documented process for determining competence criteria;
 - (b) the outcomes of the process for determining competence criteria;
 - (c) the CB's evaluations of its personnel; and
 - (d) taking account of the intended results of each certification function and whether, or not, these have been achieved.

3.3 The certification functions for which the AB shall verify that the CB has determined competence criteria, include, but are not limited to, the following:

- (a) Application review (see example in 3.5 below);
- (b) Establishing the audit program;
- (c) Scheduling of audits;
- (d) Allocation of audit teams;
- (e) Auditing and reporting;
- (f) Report reviews and certification decisions; and
- (g) Maintenance of certification.

Annex A of this document is informative and provides examples of intended results from the above certification functions. The CB may identify other intended results from these certification functions.

3.4 The AB shall verify that the CB has determined competence criteria for:

- (a) Management overseeing the certification process;
- (b) Members of its committee for safeguarding impartiality;
- (c) Personnel performing internal audits; and
- (d) Personnel responsible for evaluating and monitoring the competence and performance of personnel performing certification functions.

3.5 The AB shall regard objective evidence of the CB achieving the intended results for all certification functions (see Annex A of this document) as an indication of the effectiveness of its processes for determining and evaluating competence. The AB shall regard objective evidence of the CB failing to achieve intended results for any certification functions as an indication that the processes for determining and evaluating competence may be ineffective.

Note: The failure of the CB to achieve the intended results for a particular certification function could also be an indication that the CB's procedures for that function are ineffective or have not been implemented.

For example, in the case of the application review, to determine that the CB has competent audit team members, it can allocate and to determine the audit time, the AB shall verify that the CB:

- a) has defined the intended results (see (d) below) for this function of the certification process;
- b) has defined effective competence criteria for the personnel performing this function;
- c) can provide objective evidence that the staff performing this function have demonstrated that they meet the competence criteria; and
- d) that the output from this function of the certification process has achieved the intended results, by:
 - i) providing evidence that the technical area(s) of the organisation to be audited has/have been correctly allocated;
 - ii) providing evidence that the assigned auditors have the required competence for the appropriate technical area(s); and
 - iii) providing evidence that adequate time has been allocated for the audit, based on the review of information provided by the applicant/certified client and from previous audits.

3.6 The AB shall assess the process and procedures established by the CB to determine competence criteria and to evaluate competence to verify that personnel evaluated as competent consistently achieve the intended results for all certification functions.

3.7 The AB shall verify that the CB has appropriate records of the implementation of its processes for determining and evaluating competence and that the CB can demonstrate its evaluation methods are effective and achieve intended results consistently.

4. TECHNICAL AREAS

4.1 The AB shall verify that the CB has defined the technical areas for which it provides accredited certification and that these cover the total scope of the CB's accreditation. It is the responsibility of the CB to determine the technical areas in which it operates, based on commonality of processes, environmental impacts and aspects, risk, etc.

- (a) Technical areas do not necessarily need to be defined using scopes of accreditation. It is possible that a single scope of accreditation may comprise more than one technical area, for example QMS scope 38* Health and Social Work could comprise:

Veterinary services
Hospital services
Medical and dental practices
Care services
Social work

Similarly, QMS scope 28* Construction may need to take account that it comprises activities ranging from painting and decorating to major construction and civil engineering projects.

* See IAF ID1:2010 Informative Document for QMS Scopes of Accreditation

- (b) In some cases, a single technical area may relate to more than one scope of accreditation. For example, the manufacture of plastic bags for use in packaging could relate to both QMS scope 9 printing companies and QMS scope 14 rubber and plastics products.

4.2 The AB shall verify whether the documented technical area competence criteria of the CB:

- (a) have been formulated in terms of competence (i.e. what are the required knowledge and skills for that technical area);

Note: In certain instances, for example in the case of a medical doctor, evidence of qualification and professional registration with the relevant national authority may be considered as part of the evidence of technical area competence.

- (b) cover all the relevant aspects of that technical area; i.e. has all relevant knowledge (for example, legal requirements, processes, products, control techniques) for that technical area been identified.

4.3 The AB shall seek evidence that the CB is able to demonstrate competence in all certification functions across the whole of a technical area, by achieving the intended results for each certification function. The AB shall seek evidence that the CB has processes in place to ensure it can do so consistently.

5. DETERMINATION OF COMPETENCE CRITERIA

5.1 The AB shall verify that the CB has documented the expertise needed to establish and maintain the competence criteria for each technical area. This expertise may be provided by an external resource.

5.2 The AB shall verify that the CB's process for determining competence criteria identifies the knowledge and skills necessary for personnel performing all certification functions in each of its technical areas and for each management system standard or specification.

- (a) For some certification functions allocated to particular individuals, competence may be embedded in the design of the process. For example, the CB's IT system may contain details of auditors and the technical areas for which they have been evaluated as competent and can nominate which auditors are competent to perform an audit of a particular organisation. Where this is the case, the AB shall verify that the CB's process is appropriately controlled and capable of achieving intended results.

Note: Appropriate controls may include defining authority levels, password control etc.

- (b) It is not necessary for personnel involved in reviewing applications, selecting audit teams, determining audit times, reviewing reports and making certification decisions to have the same depth of competence, in all areas, as auditors. For example, referring to Annex A of ISO/IEC 17021, personnel reviewing reports and making certification decisions are required to have equivalent competence to that of auditors in knowledge of the CB's processes, but not in knowledge of the client's business sector or knowledge of audit principles, practices and techniques.

- (c) Individuals assigned to perform certification functions need not necessarily each have all the required competencies, providing the CB can demonstrate that it has the collective competence to perform those functions. For example, the certification decision maker may not be competent in all of the client's business sector, but if the report has been reviewed by an independent technical expert the collective competence may be evident.
- (d) The competence required in an audit team may differ depending on the scope of the audit. For example, the scope of a surveillance visit may be narrower than that for an initial assessment. The AB shall verify that the CB has a process which ensures audit teams have the collective competence necessary to audit for particular visits.

6. EVALUATION PROCESSES

6.1 The AB shall verify that the CB has documented processes for initially evaluating the competence and evaluating the continued competence of all personnel involved in the management and performance of all certification functions. The AB shall seek objective evidence that the CB has evaluated these personnel in accordance with its own documented processes.

- (a) Annex B of ISO/IEC 17021, being informative and not normative, provides useful guidance on some methods that may be used by a CB to evaluate competence. However, the CB is free to use other methods of evaluating competence. Whichever methods the CB uses to evaluate competence, the AB shall verify that the CB can demonstrate that these methods are effective in demonstrating competence.
- (b) The CB may take into account, but not solely rely on, a history of proven ability of personnel achieving intended results for the tasks they have been assigned. The AB shall verify that this proven ability is based on the CB performing an evaluation of the outputs from the appropriate certification function, for example, records, reports or other information, which can contribute to the evidence that personnel have the knowledge and skills required by the documented competence criteria.

6.2 The AB shall verify that where the CB employs external and new personnel who may have been evaluated as competent by another accredited CB, it performs its own evaluation of those personnel against its own competence criteria. However, the CB may take the evaluation (when the complete records of the evaluation are available) by the other accredited CB into account, but not solely rely on it, when performing its own evaluation.

6.3 Certification in a personnel certification scheme, accredited to ISO/IEC 17024 may be used as demonstrating the competence of personnel, to the extent covered by the scope of the scheme. The AB shall seek evidence that the CB has determined which of its competence criteria are not covered by the scope of the personnel certification scheme and that the CB has performed its own evaluation against these criteria.

6.4 Where a personnel certification scheme is not accredited it may be used only as an indication that personnel have certain knowledge and skills, and the AB shall verify that the CB has performed its own evaluation of competence against the criteria covered by the scheme.

6.5 The AB shall verify the CB is able to identify where an individual ceasing to be available to the CB has an impact on the overall competence of the CB. For example, it is possible that an auditor, competent in a specific technical area, leaving the employment of a CB could result in it no longer being able to demonstrate competence in a particular technical area. Under such circumstances the AB shall seek evidence that the CB has identified the limitations to its overall competence and the effect on existing certifications.

End of IAF Mandatory Document for Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021:2011.

ANNEX A - INFORMATIVE

Examples of intended results from certification functions.

CERTIFICATION FUNCTION	INTENDED RESULTS
Application review	<ul style="list-style-type: none"> • the scope falls within the competence of the CB; • the proposed scope is accurately defined consistent with the products/service of the applicant and the management system; • the technical area(s) of the organisation to be audited has/have been correctly identified and allocated; • sufficient auditors have been assigned; • the assigned auditors have the required competence for: <ul style="list-style-type: none"> i) the audit functions they are assigned, e.g. audit team leader; ii) the processes and operations they are assigned; iii) the relevant management system standard(s); iv) the certification scheme, where appropriate. • adequate time has been allocated and justified for the audit, in line with IAF MD1 and IAF MD5 (for QMS and EMS) or other specific requirements for particular certification schemes, based on the review of information provided by the applicant/certified client. • applications for transfer of certification are processed in line with the requirements of IAF MD 2.
Establishing the audit programme	<ul style="list-style-type: none"> • the schedule for surveillance and recertification audits is in line with ISO/IEC 17021; • correct application of IAF MD 1 for multiple sites.
Scheduling of audits	<ul style="list-style-type: none"> • the audit program complies with ISO/IEC 17021; • audit duration and dates have been agreed with the client.
Allocation of audit teams	<ul style="list-style-type: none"> • the collective competence of the audit team is consistent with the products and processes of the client.

CERTIFICATION FUNCTION	INTENDED RESULTS
Audit planning	<ul style="list-style-type: none"> • the audit plan is consistent with the proposed scope of certification and the type of audit and reflects the client's organisation, processes and operation; • the audit plan allocates sufficient time for a thorough audit; • the audit team members are allocated tasks appropriate to their competence.
Auditing and reporting	<ul style="list-style-type: none"> • audit execution is performed effectively: <ul style="list-style-type: none"> ○ opening and closing meetings are held; ○ audit evidence collection techniques are effective; ○ audit team members take adequate notes of audit evidence; ○ sampling techniques are used effectively; ○ audit team members reach conclusions consistent with the audit evidence. • the content of the audit report fulfils the requirements of ISO/IEC TS 17022:2012. • reaudits are performed when necessary. • the certification recommendation is consistent with the audit findings, the audit scope and the scope of certification.
Report reviews and certification decisions	<ul style="list-style-type: none"> • checking for any changes since the application review; • confirming that the audit duration was correct; • confirming that audit team members have been allocated audit tasks appropriate to their competence; • confirming that the audit report fulfils the requirements of ISO/IEC TS 17022:2012; • confirming that the recommendation is consistent with the audit findings; • documentary evidence is available where the independent reviewer has had cause to discuss/clarify any aspect of the report content or associated recommendation.

CERTIFICATION FUNCTION	INTENDED RESULTS
Maintenance of certification	<ul style="list-style-type: none">• the audit program has been followed and surveillance and recertification functions have been performed in a timely manner;• adequate sampling of surveillance reports for review;• any changes have been reviewed and verified as not adversely affecting the certification;• demonstrated escalation in the event of non-conformities that could lead to suspension or withdrawal of certification;• timely recertification audits and recertification decisions prior to expiry.

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>.

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