# IAF MD 10:2013 IAF Mandatory Document for Assessment of CB Management of Competence in Accordance with ISO/IEC 17021:2011

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#### 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

- 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
- 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 & 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 & 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 the following:
- (a) Application review;
- (b) Establishing the audit program;
- (c) Scheduling of audits;
- (d) Allocation of audit teams;
- (e) Auditing and reporting;
- (f) Report reviews and certification decisions;
- (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.

- 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.

# IAF MD 10 - Intended Results - Example

#### **Application Review**

- the scope falls within the competence of the CB;
- the proposed scope is accurately defined;
- the technical area(s) correctly identified and allocated;
- sufficient auditors have been assigned;
- the assigned auditors have the required competence for:
  - 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 & justified for the audit, in line with specified requirements based on the review of information provided by applicant.
- applications for transfer of certification are processed in line with the requirements of IAF MD 2.

#### 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 EA 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.
- (b) In some cases, a single technical area may relate to more than one scope of accreditation i.e.:
- the manufacture of plastic bags for use in packaging could relate to both QMS scope 9 printing companies & QMS scope 14 rubber & 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 (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.

#### 03 Food Products, Beverages and Tobacco DA

- Production, processing & preserving of meat & meat products
- Processing & preserving of fish & fish products
- Processing and preserving of fruit and vegetables
- Manufacture of vegetable and animal oils and fats
- Manufacture of dairy products
- Manufacture of grain mill products, starches and starch products
- Manufacture of prepared animal feeds
- Manufacture of other food products
- Manufacture of beverages
- Manufacture of tobacco products

#### • 12 Chemicals, Chemical Products and Fibres DG

- Manufacture of basic chemicals
- Manufacture of pesticides & other agro-chemical products
- Manufacture of paints, varnishes & similar coatings, printing ink and mastics
- Manufacture of soap and detergents, cleaning & polishing preparations, perfumes and toilet preparations
- Manufacture of other chemical products including: explosives, glues and gelatines,
- essential oils, photographic chemical material, prepared unrecorded media, and other chemical products n.e.c.
- Manufacture of man-made fibres
- 13 Pharmaceuticals DG
- Manufacture of pharmaceuticals, medicinal chemicals and botanical products

#### 17 Basic Metals and Fabricated Metal Products (DJ)

- Manufacture of basic iron and steel and ferro-alloys
- Manufacture of tubes (cast iron and steel)
- Other first processing of iron & steel & production of ferro-alloys
- Manufacture of basic precious and non-ferrous metals
- Casting of metals
- Manufacture of structural metal products
- Manufacture of tanks, reservoirs and containers of metal;
   manufacture of central heating radiators and boilers
- Manufacture of steam generators, except above
- Forging, pressing, stamping and roll forming of metal; powder metallurgy
- Treatment & coating of metals; general mechanical eng
- Manufacture of cutlery, tools and general hardware
- Manufacture of other fabricated metal products

#### 19 Electrical and Optical Equipment DL

- Manufacture of office machinery and computers
- Manufacture of electric motors, generators and transformers
- Manufacture of electricity distribution and control apparatus
- Manufacture of insulated wire and cable
- Manufacture of accumulators, primary cells and primary batteries
- Manufacture of lighting equipment and electric lamps
- Manufacture of other electrical equipment n.e.c. (including for engines and vehicles n.e.c.)
- Manufacture of electronic valves and tubes and other electronic components
- Manufacture of television and radio transmitters and apparatus for line telephony and line telegraphy

- Manufacture of television and radio receivers, sound or video recording or reproducing apparatus and associated goods
- Manufacture of instruments and appliances for measuring, checking, testing, navigating and other purposes, except industrial process control equipment Manufacture of industrial process control equipment
- Manufacture of optical instruments & photographic equipment
- Manufacture of watches and clocks
- Manufacture of medical and surgical equipment and orthopedic appliances
- Manufacture of active medical devices (ISO 13485/13488)
- Manufacture of active implantable medical devices (ISO 13485/13488)
- Manufacture of implantable medical devices (ISO 13485/13488)
- Sterilization of medical devices

#### 36 Public Administration L

- Administration of the State and the economic and social policy of the community
- Provision of services to the community as a whole
- Compulsory social security activities

#### 39 Other Social Services

- Sewage and refuse disposal, sanitation and similar activities
- Activities of business, employers and professional organizations
- Activities of trade unions
- Activities of other membership organizations
- Motion picture and video activities
- Radio and television activities
- Other entertainment activities
- News agency activities

# 5. DETERMINATION OF COMPETENCE CRITERIA

- 5.1 The AB shall verify that the CB has documented the expertise needed to establish & 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 & for each MS standard.

- (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.

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

#### Clause 5.2 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.

Clause 5.2 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 evaluation & evaluating the continued competence of all personnel involved in the management & 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, has specified some methods for evaluation, but any others can also be used. The AB shall verify that the CB can demonstrate that these methods are effective in demonstrating competence.

#### Clause 6.1 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.
- Evaluation by another accredited CB may be taken in to account, but not solely rely on it, when complete records of evaluation are available.

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.