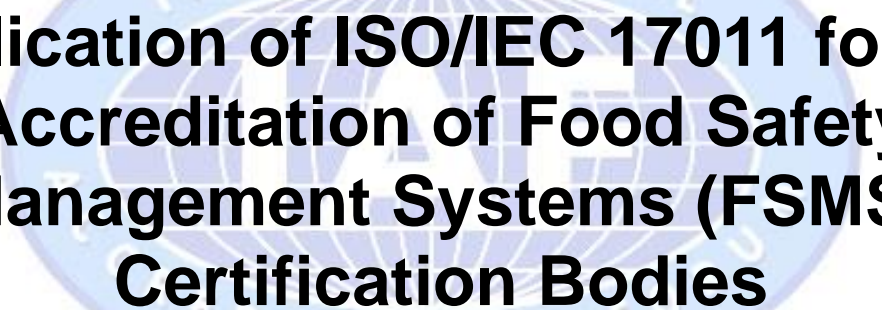




IAF Mandatory Document



Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies

Issue 1, Version 3

(IAF MD 16:2023)

The International Accreditation Forum, Inc. (IAF) facilitates trade and supports industry and regulators by operating a worldwide mutual recognition arrangement among Accreditation Bodies (ABs) in order that the results issued by Conformity Assessment Bodies (CABs) accredited by IAF members can be accepted globally.

Accreditation reduces risk for business and its customers by assuring them that accredited CABs are competent to carry out the work they undertake within their scope of accreditation. ABs that are members of IAF and their accredited CABs are required to comply with appropriate international standards and IAF mandatory 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 of the IAF MLA is detailed in IAF PL 3 - Policies and Procedures on the IAF MLA Structure and for Expansion of the Scope of the IAF MLA. The scope of the IAF MLA is detailed in the IAF MLA Status document.

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 mandated standards e.g. ISO/IEC 17065. 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 22003-1. 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.

TABLE OF CONTENTS

| | |
|--|-----------|
| 0. INTRODUCTION | 6 |
| 1. SCOPE | 6 |
| 2. NORMATIVE REFERENCES | 7 |
| 3. TERMS AND DEFINITIONS | 7 |
| 4. ACCREDITATION BODY | 7 |
| 4.1 Legal responsibility | 7 |
| 4.2 Structure | 7 |
| 4.3 Impartiality | 7 |
| 4.4 Confidentiality | 7 |
| 4.5 Liability and financing | 7 |
| 4.6 Accreditation activity | 8 |
| 5. MANAGEMENT | 8 |
| 5.1 General | 8 |
| 5.2 Management system | 8 |
| 5.3 Document control | 8 |
| 5.4 Records | 8 |
| 5.5 Nonconformities and corrective actions | 8 |
| 5.6 Preventive actions | 8 |
| 5.7 Internal audits | 8 |
| 5.8 Management reviews | 8 |
| 5.9 Complaints | 8 |
| 6. HUMAN RESOURCES | 9 |
| 6.1 Personnel associated with the Accreditation Body | 9 |
| 6.2 Personnel involved in the accreditation process | 9 |
| 6.3 Monitoring | 10 |
| 6.4 Personnel records | 10 |
| 7. ACCREDITATION PROCESS | 11 |
| 7.1 Accreditation criteria and information | 11 |
| 7.2 Application for accreditation | 11 |

| | | |
|-----------|---|-----------|
| 7.3 | Resource review | 11 |
| 7.4 | Subcontracting the assessment | 11 |
| 7.5 | Preparation for assessment | 11 |
| 7.6 | Document and record review | 13 |
| 7.7 | On-site assessment | 13 |
| 7.8 | Analysis of findings and assessment report | 14 |
| 7.9 | Decision-making and granting accreditation | 14 |
| 7.10 | Appeals | 14 |
| 7.11 | Reassessments and surveillance | 14 |
| 7.12 | Extending accreditation | 14 |
| 7.13 | Suspending, withdrawing or reducing accreditation | 14 |
| 7.14 | Records on CABs | 14 |
| 7.15 | Proficiency testing and other comparisons for laboratories | 14 |
| 8. | RESPONSIBILITIES OF THE ACCREDITATION BODY AND THE CAB | 14 |
| 8.1 | Obligations of the CAB | 14 |
| 8.2 | Obligations of the Accreditation Body | 15 |
| 8.3 | Reference to accreditation and use of symbols | 15 |

Issue No 1, Version 3

Approved by IAF Technical Committee

Date: 21 August 2012

Approved by IAF Members

Date: 02 July 2014

Issue Date: 14 June 2023

Application Date: 15 December 2016

Name for Enquiries: Elva Nilsen, IAF Corporate Secretary

Contact: Phone: +1 (613) 454-8159

Email: secretary@iaf.nu

Introduction to IAF Mandatory Documents

The term “should” is used in this document to indicate recognized 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.

Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies

This document is mandatory for the consistent application of ISO/IEC 17011:2004 for scoping the accreditation of Food Safety Management System (FSMS) Certification Bodies. All clauses of ISO/IEC 17011:2004 continue to apply and this document does not supersede any of the requirements in that standard.

0. INTRODUCTION

0.1 ISO/IEC 17011 is an International Standard that sets out the requirements for bodies operating accreditation systems for Conformity Assessment Bodies.

0.2 The objective of this document is to enable Accreditation Bodies to harmonize their application of ISO/IEC 17011 for the accreditation of bodies providing audit and certification of Food Safety Management Systems (FSMS). This document provides normative criteria on the application of ISO/IEC 17011 for the accreditation of bodies providing certification of organization's food safety management systems.

0.3 This document follows the structure of ISO/IEC 17011. IAF normative criteria are identified by the letters "MD" followed with a reference number that incorporates the related requirements clause in ISO/IEC 17011. In all cases a reference in the text of this document to "clause XXX" refers to a clause in ISO/IEC 17011 unless otherwise specified.

0.4 This document is intended to provide direction for the consistent assessment of the scope of competence of an FSMS Certification Body by Accreditation Bodies (ABs). The document identifies the activities that an AB will undertake to assess the competence of a CAB in each of the food chain categories identified in Annex A of *ISO/TS 22003:2013 – Food Safety Management Systems – Requirements for bodies providing audit and certification of food safety management systems*.

1. SCOPE

1.1 This document specifies normative criteria for Accreditation Bodies assessing and accrediting CABs which provide audit and certification of FSMS, in addition to the requirements contained with ISO/IEC 17011. It is also appropriate as a requirements document for the peer evaluation process for the IAF Multilateral Recognition Arrangement (MLA) among Accreditation Bodies.

2. NORMATIVE REFERENCES

2.1 For the purposes of this document, the normative references given in ISO/IEC 17011 and the following apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- a) ISO/IEC 17011 – Conformity Assessment – general requirements for Accreditation Bodies accrediting conformity assessment bodies;
- b) IAF/ILAC A5 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004;
- c) ISO/TS 22003:2013 – Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems;

3. TERMS AND DEFINITIONS

MD 3.1 The terms and definitions in ISO/IEC 17021 and ISO/TS 22003 apply. No additional terms are defined in this document.

4. ACCREDITATION BODY

4.1 Legal responsibility

No additional requirements.

4.2 Structure

No additional requirements.

4.3 Impartiality

No additional requirements.

4.4 Confidentiality

No additional requirements.

4.5 Liability and financing

No additional requirements.

4.6 Accreditation activity

No additional requirements.

5. MANAGEMENT

5.1 General

No additional requirements.

5.2 Management system

No additional requirements.

5.3 Document control

No additional requirements.

5.4 Records

No additional requirements.

5.5 Nonconformities and corrective actions

No additional requirements.

5.6 Preventive actions

No additional requirements.

5.7 Internal audits

No additional requirements.

5.8 Management reviews

No additional requirements.

5.9 Complaints

No additional requirements.

6. HUMAN RESOURCES

6.1 Personnel associated with the Accreditation Body

No additional requirements.

6.2 Personnel involved in the accreditation process

MD 6.2.1 ISO/IEC 17011 Clause 6.2.1 requires an Accreditation Body to identify the competencies required for each accreditation activity. The following table specifies the knowledge and skills that an Accreditation Body shall apply for specific accreditation activities in the accreditation of an FSMS Certification Body. X means the Accreditation Body personnel shall have a general level of knowledge and skills. X+ indicates a need for the Accreditation Body personnel to have a deeper level of knowledge and skills gained through practical experience or other approaches.

| Accreditation functions Competency (Note 1) | Document review | On-Site Assessment | Witness assessment | Accreditation decisions (note 3) | Scheme management |
|--|-----------------|--------------------|--------------------|----------------------------------|-------------------|
| Knowledge of and ability to apply assessment principles, practices and techniques | | X+ | X+ | X | X |
| Knowledge of and ability to apply the requirements of ISO/IEC 17021 and ISO/TS 22003 | X | X+ | X+ | X | X |
| Knowledge of CAB certification processes | X | X+ | X | X | X |
| Knowledge of and ability to apply ISO 22000 or other FSMS certification standards | X | X+ | X+ | X | |
| Knowledge of and ability to apply the following in relation to food safety management systems: – HACCP principles – food safety management including PRPs – legal framework | X | X+ | X+ | X | |
| Knowledge of and ability to apply (in the food chain sector being assessed); – current principles of HACCP | | | X+ | | |

| Accreditation functions | Document review | On-Site Assessment | Witness assessment | Accreditation decisions (note 3) | Scheme management |
|---|-----------------|--------------------|--------------------|----------------------------------|-------------------|
| Competency (Note 1) | | | | | |
| <ul style="list-style-type: none"> - relevant PRPs - identification of food safety hazards - control measures - products, processes and practices - related legal requirements (note 2) | | | | | |
| Knowledge of CAB's Client business sector. | | | X | | |
| Knowledge of cultural and social customs related to the categories and geographic areas to be assessed. | | X | X | | |
| <p>Note 1: Where a team is conducting the assessment, the competencies required are to be held within the team as a whole and not by every individual member of the team. However where an individual is undertaking the assessment that person must have all competencies listed.</p> <p>Note 2: Legal requirements identified here is an understanding of those regulations that the organisation that is the subject of the witness would be expected to comply with for either the food industry sector or country/state/province within which they operate.</p> <p>Note 3: When a group reviews assessment reports and makes accreditation decisions, the knowledge required is to be held within the group as a whole and not by each individual member of the group.</p> | | | | | |

6.3 Monitoring

No additional requirements.

6.4 Personnel records

No additional requirements.

7. ACCREDITATION PROCESS

7.1 Accreditation criteria and information

MD 7.1.1 Accreditation assessments shall be against ISO/IEC 17021 including the requirements of ISO/TS 22003. The accreditation documents (e.g. certificate or schedule) shall explicitly state that the accreditation is against ISO/IEC 17021 and ISO/TS 22003.

7.2 Application for accreditation

MD 7.2.1 The Scope of accreditation shall be expressed using the food chain categories detailed in Annex A Table A.1 of ISO/TS 22003.

7.3 Resource review

No additional requirements.

7.4 Subcontracting the assessment

No additional requirements.

7.5 Preparation for assessment

MD 7.5.6 Witnessing

MD 7.5.6.1 In Table A.1 in Annex A in ISO/TS 22003 the food chain categories are grouped into the following clusters ¹:

1. Farming (A+B)
2. Food and Feed Processing (C+D)
3. Catering (E)
4. Retail, Transport and Storage (F+G)
5. Auxiliary Industries (H+I+J)
6. (Bio) Chemicals (K)

¹ These clusters are established only for the accreditation process and are not appropriate to be used by Certification Bodies in their certification processes

MD 7.5.6.2 The Accreditation Body shall not grant accreditation for a given food chain category without at least one witness assessment performed in the cluster.

MD 7.5.6.3 This criteria is also applicable to extension of scopes. For extensions inside a cluster, witnessing is not mandatory. Witnessing is mandatory for extensions to categories in a new cluster.

MD 7.5.6.4 These requirements are **minimum** requirements (except for the cases described in MD 7.5.6.11). The Accreditation Body shall assess every individual case and decide if more witnessing is needed in specific situations based on the outcome of the office assessment, existing food safety management schemes accreditations and process risks.

MD 7.5.6.5 The Accreditation Body shall witness at least one audit in cluster 2 (if covered by the accredited scope of the Certification Body) each year and at least one audit in each of the other clusters during the accreditation cycle.

MD 7.5.6.6 A single witness assessment could encompass different categories if the activities of the witnessed company and of the Certification Body justify it.

MD 7.5.6.7 A witness of an initial certification audit, including stage 1, should be undertaken as part of the initial accreditation. At least one of the witness audits per accreditation cycle should include an initial certification audit.

MD 7.5.6.8 Wherever feasible, throughout its accreditation cycle, the Accreditation Body should ensure that witness assessments are performed in those sub-categories (from those covered by the Certification Body scope) with the higher risks of food safety hazards.

MD 7.5.6.9 It is preferable that the Accreditation Body witnesses an audit team that has not been witnessed previously in that particular food chain category.

MD 7.5.6.10 Witness assessments shall avoid the repeated witnessing of the same Certification Body client company. Accreditation Bodies shall take into account previous results of witnessing to establish its witness strategy.

MD 7.5.6.11 The Accreditation Body may take into account accreditations granted to the Certification Body in other food safety standards or schemes (either management system or product certification schemes) for categories in the same cluster when deciding which witness assessments need to be performed. In these cases the Accreditation Body may use witnessing performed in one of such schemes to substitute some but not the majority, of the witness assessment activity required in MD 7.5.6.2 to MD 7.5.6.6. This should be based on the certification activity of clients and distribution of the CB's auditors. These cases shall be fully documented and justified by the Accreditation Body.

7.6 Document and record review

No additional requirements.

7.7 On-site assessment

MD 7.7.1 Accreditation for one or more food chain categories (ISO/TS 22003 Annex A Table A.1) confirms that the Certification Body has demonstrated competence to deliver certification for FSMS (e.g. ISO 22000) in those food chain categories.

MD 7.7.2 However, it does not mean that the Certification Body has auditors with the competence needed in all the sub-categories that may be included in such food chain categories. For this reason before granting accreditation for a specific food chain category, the Accreditation Body shall assess that:

- a) The Certification Body has competent personnel to perform the contract review and select the correct food chain category and sub-category (see Annex C in ISO/TS 22003).
- b) The Certification Body has established technical criteria to describe the competence for personnel in each sub-category defined.
- c) The Certification Body has competent personnel in at least one sub-category of the food chain category.
- d) The Certification Body has established a process giving assurance that accredited certification will be offered only in sub-categories where the Certification Body has competent personnel.
- e) The Certification Body keeps an updated list of the sub-categories in which it has competent personnel. This list shall be available to the Accreditation Body on demand.

- f) The Certification Body is able to demonstrate that it has at least one active or potential application in the food chain category for which it is seeking accreditation.

7.8 Analysis of findings and assessment report

No additional requirements.

7.9 Decision-making and granting accreditation

No additional requirements.

7.10 Appeals

No additional requirements.

7.11 Reassessments and surveillance

No additional requirements.

7.12 Extending accreditation

No additional requirements.

7.13 Suspending, withdrawing or reducing accreditation

No additional requirements.

7.14 Records on CABs

No additional requirements.

7.15 Proficiency testing and other comparisons for laboratories

No additional requirements.

8. RESPONSIBILITIES OF THE ACCREDITATION BODY AND THE CAB

8.1 Obligations of the CAB

No additional requirements.

8.2 Obligations of the Accreditation Body

No additional requirements.

8.3 Reference to accreditation and use of symbols

No additional requirements.

End of IAF Mandatory Document Scoping of Accreditation of Certification Bodies Offering Certification of Food Safety Management Systems.

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