



ISAB MD 16:2024: Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies

Document Title	Issue	Issue Date	Application Date
ISAB MD 16:2024	Issue 2	21 May 2024	21 May 2024

© International Standards & Accreditation Board 2024

Foreword

The International Standards & Accreditation Board (ISAB) 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 ISAB 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 ISAB and their accredited CABs are required to comply with appropriate international standards and ISAB mandatory documents for the consistent application of those standards.

ABs that are signatories to the ISAB 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 ISAB MLA is detailed in ISAB PL 3 - Policies and Procedures on the ISAB MLA Structure and for Expansion of the Scope of the ISAB MLA. The scope of the ISAB MLA is detailed in the ISAB MLA Status document.

The ISAB MLA is structured in five levels: Level 1 specifies mandatory criteria that apply to all



INTERNATIONAL STANDARDS & ACCREDITATION BOARD

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 ISAB MLA delivers the confidence needed for market acceptance of conformity assessment outcomes. An attestation issued, within the scope of the ISAB MLA, by a body that is accredited by an ISAB MLA signatory AB can be recognized worldwide, thereby facilitating international trade.

Introduction to ISAB Mandatory Documents

The term "should" is used in this document to indicate recognised means of meeting the requirements of the standard. An Accreditation Body (AB) can meet these in an equivalent way. 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 for scoping the accreditation of Food Safety Management System (FSMS) Certification Bodies. All clauses of ISO/IEC 17011 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 (CABs).

0.2 The objective of this document is to enable Accreditation Bodies (ABs) to harmonize their



INTERNATIONAL STANDARDS & ACCREDITATION BOARD

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 organisations' food safety management systems.

0.3 This document follows the structure of ISO/IEC 17011. ISAB 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 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 22003-1:2022 - Food Safety Part 1: 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 Certification Bodies that provide audit and certification of FSMS, in addition to the requirements contained within ISO/IEC 17011. It is also appropriate as a requirements document for the peer evaluation process for the ISAB 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.

- i. ISO/IEC 17011 - Conformity Assessment - Requirements for Accreditation Bodies accrediting conformity assessment bodies;
- ii. ISO 22003-1 - Food safety - Part 1: 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 17000, ISO/IEC 17021-1, ISO 22000, and ISO 22003-1 apply. No additional terms are defined in this document.



4. General Requirements

4.1 Legal entity

No additional requirements.

4.2 Accreditation agreement

No additional requirements.

4.3 Use of accreditation symbols and other claims of accreditation

No additional requirements.

4.4 Impartiality requirements

No additional requirements.

4.5 Financing and liability

No additional requirements.

4.6 Establishing accreditation schemes

No additional requirements.

5. Structural Requirements

No additional requirements.

6. Resource Requirements

6.1 Competence of personnel

6.1.1 General

No additional requirements.

6.1.2 Determination of competence criteria

MD 6.1.2 ISO/IEC 17011 Clause 6.1.2 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.



INTERNATIONAL STANDARDS & ACCREDITATION BOARD

Competency (Note 1)	Document review	Office 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 17021-1 and ISO 22003-1	X	X+	X+	X	X
Knowledge of Certification Body's certification processes	X	X+	X	X	X
Knowledge of and ability to apply ISO 22000 or other applied	X	X+	X+	X	



INTERNATIONAL STANDARDS & ACCREDITATION BOARD

Competency (Note 1)	Document review	Office Assessment	Witness assessment	Accreditation decisions (Note 3)	Scheme management
FSMS certification standards					
Knowledge of and ability to apply the following in relation to food safety management systems: hazard analysis and critical control points (HACCP) principles	X	X+	X+	X	
food safety management including prerequisite programs (PRPs) legal framework					



INTERNATIONAL STANDARDS & ACCREDITATION BOARD

Competency (Note 1)	Document review	Office Assessment	Witness assessment	Accreditation decisions (Note 3)	Scheme management
Knowledge of and ability to apply (in the food chain sector being assessed): current principles of HACCP, relevant PRPS			X+		
identification of food safety hazards					
control measures					
products, processes and practices related legal requirements (Note 2)					



INTERNATIONAL STANDARDS & ACCREDITATION BOARD

Competency (Note 1)	Document review	Office Assessment	Witness assessment	Accreditation decisions (Note 3)	Scheme management
Knowledge of Certification Body's Client business sector			X		
Knowledge of cultural and social customs related to the categories and geographic areas to be assessed		X	X		

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.

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.

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.

6.1.3 Competence management



No additional requirements.

6.2 Personnel involved in the accreditation process

No additional requirements.

6.3 Personnel records

No additional requirements.

6.4 Outsourcing

No additional requirements.

7. Process Requirements

7.1 Accreditation requirements

MD 7.1.1 Accreditation assessments shall be against ISO/IEC 17021-1 including the requirements of ISO 22003-1. The accreditation documents (e.g. certificate or schedule) shall explicitly state that the accreditation is against ISO/IEC 17021-1 and ISO 22003-1.

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 22003-1.

7.3 Resource review

No additional requirements.

7.4 Preparation for assessment

MD 7.4.5 Witnessing

MD 7.4.5.1 In Table A.1 in Annex A in ISO 22003-1 the food chain categories are grouped into the following clusters¹:

1. Primary production (A+B)
2. Processing food for humans and animals (C+D)



INTERNATIONAL STANDARDS & ACCREDITATION BOARD

3. Catering/food service (E)
4. Retail, Transport and Storage (F+G)
5. Auxiliary services (H)
6. Packaging material (I)
7. Auxiliary equipment (J)
8. Bio/chemical (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 7.4.5.2 The Accreditation Body shall not grant accreditation for a given food chain category without at least one witness assessment performed in the cluster.

MD 7.4.5.3 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 7.4.5.4 These requirements are minimum requirements (except for the cases described in MD 7.4.5.11). 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 7.4.5.5 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 7.4.5.6 A single witness assessment could encompass different categories if the activities of the witnessed company and of the Certification Body justify it.

MD 7.4.5.7 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 stage 2 audit or recertification audit.

MD 7.4.5.8 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 7.4.5.9 It is preferable that the Accreditation Body witnesses an audit team that has not been witnessed previously in that particular food chain category.

MD 7.4.5.10 Witness assessments should avoid the repeated witnessing of the same Certification Body client company. Accreditation Bodies shall take into account previous results of witnessing to establish their witness strategy.

MD 7.4.5.11 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



INTERNATIONAL STANDARDS & ACCREDITATION BOARD

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 7.4.5.2 to MD 7.4.5.6. This should be based on the certification activity of clients and distribution of the Certification Body's auditors. These cases shall be fully documented and justified by the Accreditation Body.

7.5 Review of documented information

No additional requirements.

7.6 Assessment

MD 7.6.1 Accreditation for one or more food chain categories (ISO 22003-1 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 7.6.2 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 the Certification Body:

- i. Has competent personnel to perform the contract review and select the correct food chain category and sub-category (see Annex C in ISO 22003-1).
- ii. Has established technical criteria to describe the competence for personnel in each sub-category defined.
- iii. Has competent personnel in at least one sub-category of the food chain category.
- iv. Has established a process giving assurance that accredited certification will be offered only in sub-categories where the Certification Body has competent personnel.
- v. 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.
- vi. 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.

7.7 Accreditation decision-making

No additional requirements.

7.8 Accreditation information



No additional requirements.

7.9 Accreditation cycle

No additional requirements.

7.10 Extending accreditation

No additional requirements.

7.11 Suspending, withdrawing or reducing accreditation

No additional requirements.

7.12 Complaints

No additional requirements.

7.13 Appeals

No additional requirements.

7.14 Records on conformity assessment bodies

No additional requirements.

8. Information Requirements

8.1 Confidential information

No additional requirements.

8.2 Publicly available information

No additional requirements.

9. Management System Requirements



9.1 General

No additional requirements.

9.2 Management system

No additional requirements.

9.3 Document control

No additional requirements.

9.4 Records control

No additional requirements.

9.5 Nonconformities and corrective actions

No additional requirements.

9.6 Improvement

No additional requirements.

9.7 Internal audits

No additional requirements.

9.8 Management reviews

No additional requirements.

End of ISAB Mandatory Document Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies.



INTERNATIONAL STANDARDS & ACCREDITATION BOARD

Further Information

For further information on this document or other ISAB documents, contact any member of ISAB or the ISAB Secretariat.

For contact details of members of ISAB see the ISAB website: <https://www.isab.global>.

Secretariat:

ISAB Corporate Secretary

Email: info@isab.global