



ISAB MD 12:2023: Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries

Document Title	Issue & Version	Issue Date	Application Date
ISAB MD 12:2023	Issue 2, Version 2	14 June 2023	07 January 2016

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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



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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. 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.

1. Introduction

1.1 This document is mandatory for the consistent application of Clause 7 of ISO/IEC 17011:2004 regarding an Accreditation Body (AB)'s assessment of Conformity Assessment Bodies (CAB)'s that provide certification in countries outside the country in which their head office is located. Aspects of accreditation relating to cooperation between ISAB Multilateral Recognition Arrangement (MLA) AB's are covered by ISAB ML 4.

1.2 Clauses 7.5.7 and 7.5.8 of ISO/IEC 17011 prescribe requirements for ABs assessment of locations from which key activities are performed. Key activities are defined in ISAB/ILAC A5 Clause 7.5. This document takes account of the AB's responsibility for establishing that all of the CAB's activities, within its scope of accreditation with that AB, not only key activities, conform to all requirements of the relevant conformity assessment standards, irrespective of where in the world these activities are performed.

1.3 This document takes account of the fact that some activities may not be performed at fixed



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office locations, but by remote personnel using the CAB Information Technology (IT) system.

2. Definitions

2.1 Accreditation Body

An accreditation body that is a member of ISAB.

2.2 Fixed Office Location

The permanent premises where certification activities are performed and/or managed for the CAB, regardless of location and relationship with the CAB.

2.3 Other Activities

Certification functions that are not key activities.

2.4 Remote Personnel

The individuals, who may be internal or external that perform certification activities for a CAB and do not work at a fixed office location.

3. Implementation

3.1 Data Collection

The AB shall require its accredited CAB's to identify:

- i. Countries into which accredited certificates are issued and the number of certificates issued in each country;
- ii. Countries in which the CAB operates from a fixed office location that performs any certification activities;
- iii. Countries in which the CAB has remote personnel that perform any certification activities;
- iv. Which fixed office locations are responsible for performing and/or managing key activities as defined in ISAB/ILAC A5, or from where remote personnel performing key activities are managed; and
- v. The CAB's arrangements for managing all activities that are performed from a foreign fixed office location or by remote personnel.

Note: The recording of this information is not for the purpose of granting prior permission to the CAB to issue certificates in a particular country, but to enable the AB to plan its assessment program for the CAB based on up-to-date knowledge of the full geographic scope of the CAB's accredited activities.

3.2 Assessment Program



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The AB shall have an assessment program, covering the current accreditation period that enables it to confirm the CAB's conformity with the requirements of the relevant conformity assessment standard(s), within the CAB's scope of accreditation, irrespective of where certification activities are performed.

Note: As a consequence of the assessment output, the AB may decide to limit or restrict the scope of a CAB's accreditation to certain geographical areas or fixed office locations.

The program shall be developed to identify the activities and key activities to be assessed and the countries where these are performed and/or managed, taking account of the following:

- i. The relationship between the CAB and its foreign entities and subsidiaries;
- ii. The CAB's arrangements for managing its foreign certification activities;
- iii. Whether the CAB holds accreditation from the local AB;
- iv. The number of fixed office locations, undertaking certification activities, in each country;
- v. The number of remote personnel, undertaking certification activities, in each country;
- vi. Where key activities are performed and managed or from where remote personnel performing key activities are managed;
- vii. The range of certification activities performed, where they are performed and from where remote personnel are managed;
- viii. The effectiveness of the CAB's management controls of its certification activities;
- ix. The accessibility of the CAB's records;
- x. The availability of selected CAB personnel (internal and external) for interview;
- xi. The number of certificates issued through a particular fixed office location;
- xii. Schemes for which certification is granted through a particular fixed office location;
- xiii. Where a fixed office location manages other fixed office locations or remote personnel outside of their national boundaries;
- xiv. The number of different countries covered by remote personnel and how they are managed;
- xv. The risks posed by the activities performed and/or managed and where they are performed and/or managed (Note: these may be non-key activities);
- xvi. The capability of the AB to conduct remote assessments;
- xvii. Social and cultural aspects of each country;
- xviii. The number and type of complaints;
- xix. The effectiveness of the CAB's oversight in controlling its foreign certification activities, including internal audits it performs on fixed office locations; and
- xx. Where there is evidence of malpractice, such as misrepresentation by sales personnel, inappropriate relationships with consultants or ineffective oversight by the CAB.

The AB's assessment program shall be reviewed annually to take account of changes to the



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information in 3.1 and changes to the above factors.

The personnel performing and managing certification activities are more important than where they are performed. The assessment program should include provision for interviews with a representative sample of the CAB's personnel (internal and external) to enable the AB to confirm that the CAB's certification activities, irrespective of where they are performed, meet the requirements of the relevant conformity assessment standard(s).

Remote assessment can be utilised instead of conducting on-site assessments, provided the outcomes of such assessments are equivalent to those of on-site assessments.

3.3 Initial Assessment

The initial assessment of the CAB shall include assessment of all fixed office locations, whatever the relationship with the CAB, where key activities are performed and/or managed, or from which remote personnel performing key activities are managed, and/or where records are maintained.

Where appropriate, the initial assessment shall also include assessment of selected fixed office locations, whatever the relationship with the CAB, where other activities covered by the requirements of the relevant conformity assessment standard(s) are performed, or from which personnel performing these activities are managed.

For extensions of scope, the AB shall determine an assessment program taking account of the factors in 3.2 and whether the extension is for a new main scope, a new sub-scope or within an accredited sub-scope. The assessment program does not necessarily need to include visits to each fixed office location.

3.4 Surveillance and Reassessment

For surveillance and reassessment, each fixed office location, whatever the relationship with the CAB, at which key activities are performed and/or managed or from which remote personnel performing key activities are managed and/or records are maintained, shall be assessed at least once in each accreditation cycle and in accordance with the AB's assessment program.

The AB shall have the procedure for sampling fixed office locations, including remote personnel, where other activities are performed or from which personnel performing these activities are managed. The procedure shall ensure that a representative number of these locations are assessed within a defined timeframe.

Annex A - Informative



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This informative Annex provides some examples of the type of relationships a CAB may have with its foreign entities and subsidiaries:

- A wholly or majority (partly) owned regional subsidiary which controls and manages a number of subsidiaries;

Note: This may be a separate entity which is wholly or majority (partly) owned by the CAB.

- A wholly or majority (partly) owned subsidiary or branch of the CAB, either in its own country or in another country;

Note: This may be a separate entity which is wholly or majority (partly) owned by the CAB.

- A joint venture company, in which the CAB is a partner;

- A wholly or majority (partly) owned subsidiary of a joint venture company;

Note: This may be a separate entity which is wholly or majority (partly) owned by the joint venture company.

- A representative, agency, franchisee or sales office of the CAB, a wholly or majority (partly) owned subsidiary of the CAB or a joint venture company;

- Any separate entity that has contractual relationship with the CAB for performing certification activities.

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>.

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