



Guideline for describing Scopes of Accreditation

ILAC-G18:01/2024

About ILAC

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement - among Accreditation Bodies (ABs). The data and test results issued by laboratories, and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally via this Arrangement. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of “accredited once, accepted everywhere”.

In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

Accreditation Bodies that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent implementation of those standards.

Accreditation Bodies having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at www.publicsectorassurance.org.

For more information, please contact:

The ILAC Secretariat

PO Box 635

Newton SA 5074

Australia

Phone: +61 (0) 870 922 655

Email: secretariat@ilac.org

Website: www.ilac.org



[@ILAC_Official](https://twitter.com/ILAC_Official)



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PREAMBLE

The scope of accreditation of a Conformity Assessment Body (CAB) is the formal statement issued by an Accreditation Body (AB) of the specific conformity assessment activities which a CAB is accredited for and hence competent to perform. The minimum information (scope parameters) needing to be included in the scope of accreditation is detailed in ISO/IEC 17011 Sub-clause 7.8.3.

Scopes of accreditation are specific when defining the conformity assessment activities for which a CAB is accredited. Accordingly, a CAB cannot modify the activities covered without advising the AB and undergoing some level of assessment.

When a CAB requests an extension to its scope of accreditation, the assessment approach will be dependent on whether the scope is flexible or not and on the AB's procedures.

Flexible scopes of accreditation may allow a CAB to claim accreditation for changed methodologies or other scope parameters in accordance with the procedure(s) defined by the AB.

PURPOSE

The purpose of this publication is to provide guidance to ABs in how to describe scopes of accreditation in order to allow an effective and harmonised application among ILAC signatories in relation to the relevant International Standards.

AUTHORSHIP

This publication was developed by the 'Scopes' Working Group within the ILAC Accreditation Committee (AIC) with specific input to the annexes from the relevant Working Groups of the AIC.

TERMS AND DEFINITIONS

1.1 Scope of Accreditation (ISO/IEC 17011 Clause 3.6)

Specific conformity assessment activities for which accreditation is sought or has been granted.

1.2 Flexible Scope of Accreditation (ISO/IEC 17011 Clause 3.7)

Scope of accreditation expressed to allow Conformity Assessment Bodies to make changes in methodology and other parameters which fall within the competence of the Conformity Assessment Body as confirmed by the Accreditation Body.

SCOPE OF ACCREDITATION

ISO/IEC 17011 Sub-clause 7.8.1 requires that the AB shall provide information about the scope of accreditation to the accredited CAB and make that information publicly available as required by Sub-clause 8.2.2. The information that is to be identified as a minimum is covered in Sub-clause 7.8.3 Items a) - h).

For each type of CAB listed in Sub-clause 7.8.3 Items c) - f), a separate Appendix to this document provides additional information.

While ISO/IEC 17011 Sub-clause 7.8.3 Item h) specifies the minimum content that must be identified on a scope of accreditation for other conformity assessment bodies not covered by items a) - g), further guidance is offered for biobanking in Appendix F.

NOTE: Appendices for CABs listed in Sub-clause 7.8.3 Items a) and g) have not been provided as these relate to conformity assessment activities not covered under the ILAC Arrangement. Guidance on how to describe scopes of accreditation for Inspection Bodies (Sub-clause 7.8.3 Item b)) is covered by ILAC-G28.

The description and assessment of the scope of accreditation represents the core of the accreditation process. The role of the AB is to ensure (to an adequate degree of confidence) that the CAB has the competence to perform all the services defined in the scope of accreditation.

FLEXIBLE SCOPE OF ACCREDITATION

The main feature of a flexible scope of accreditation is the manner in which grouped items are described. The grouping of items recognises common competencies required to perform the conformity assessment activities relating to these items.

It is not mandatory for ABs to offer flexible scopes of accreditation and the guidance provided within this document only applies where the AB chooses to allow this service to CABs.

The level of detail included in the scope of accreditation will depend on the degree of flexibility that is offered by the AB. When an AB has granted a flexible scope of accreditation, this should be clear from the information that is publicly available as required by ISO/IEC 17011 Sub-clause 8.2.2 and the AB's procedure(s) for how it manages flexible scopes of accreditation.

The benefit of a flexible scope of accreditation is that the CAB has the recognised ability to modify methodology or other parameters, validate or verify the changes and apply them without having to

request the AB for an extension to its scope of accreditation. Such modifications to methodology or other scope parameters, however, are not to cover new competencies which have not previously been assessed by the AB and hence not covered by the scope of accreditation. It is expected that the AB defines what is considered a new competency.

ISO/IEC 17011 Sub-clause 7.8.4 states when the AB uses a flexible scope of accreditation, it shall have documented procedures on how it addresses and manages flexible scopes. The procedure(s) is to include how the AB addresses Sub-clause 7.8.3 Items a) to h) including specifying how the information required for Items a) to h) will be maintained and made available on request.

The AB's procedure(s) for the management of flexible scopes of accreditation can be based on the degree(s) of flexibility associated with the scope parameters required by ISO/IEC 17011 Sub-clause 7.8.3. The degree of flexibility awarded can vary between technical disciplines and conformity assessment activities and the approach should be controlled by the AB taking into consideration the level of risks associated with the activity.

When granting a flexible scope of accreditation the following requires consideration:

- a) Retention of information of the specific conformity assessment activities conducted by a CAB under its flexible scope.

The information is to be kept current in order to provide transparency of the conformity assessment activities covered by the flexible scope.

The process on how this information is to be kept current and available to interested parties is to be determined by the AB (e.g., the CAB may be responsible for maintaining an up-to-date listing or the AB maintains the listing which is updated following notification by the CAB).

- b) Established responsibilities for the management of the flexible scope.
- c) The CAB's competency to perform and manage modifications including but not limited to the following:
 - i) access to all the necessary resources (e.g., personnel and authorisations, equipment, facilities);
 - ii) handling and processing requests for activities not undertaken before but within the boundaries of the flexible scope;
 - iii) robustness of validation and/or verification procedures.

The more detailed application and limitation of a flexible scope of accreditation for each type of CAB mentioned in Items c) - f) and h) of ISO/IEC 17011 Sub-clause 7.8.3 is described in the Appendices to this document.

REFERENCES

- [1] ISO/IEC 17011 *Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies*
- [2] ILAC G-28:07/2018 *Guideline for the formulation of scopes of accreditation for inspection bodies*
- [3] ISO/IEC 17025 *General requirement for the competence of testing and calibration laboratories*
- [4] JCGM 200:2012 *International vocabulary of metrology - Basic and general concepts and associated terms (VIM) (ISO/IEC Guide 99:2007)*
- [5] ILAC P-14:09/2020 *ILAC policy for measurement uncertainty in calibration*
- [6] ISO 15189 *Medical laboratories - Requirements for quality and competence*
- [7] ISO 22870 *Point-of-care testing (POCT) - Requirements for quality and competence*
- [8] ISO 17034 *General requirements for the competence of reference material producers*
- [9] ISO/IEC 17043 *Conformity assessment - General requirements for the competence of proficiency testing providers*
- [10] ISO 20387 *Biotechnology - Biobanking - General requirements for biobanking*

APPENDIX A

Scope of Accreditation for ISO/IEC 17025 – Calibration Laboratories

ISO/IEC 17011 Sub-clause 7.8.3 Item c) requires the identification of the calibration or measurement method or procedure. This may be done by reference to a specific procedure or a generic description of a logical organization of operations used in a measurement (e.g., ‘direct measurement against a reference’). (Refer to JCGM 200 Clause 2.5).

The measurement range and expanded measurement uncertainty may be expressed in many different ways (see ILAC P-14).

A1.1 Flexible Scopes in Calibration

In calibration, possibilities for flexible scopes are more limited than in testing. The examples provided below cannot be or do not have to be addressed by means of a flexible scope policy.

- *Flexibility concerning the performance of the method*
Changes in methodology and other parameters which could affect the Calibration and Measurement Capability (CMC) (e.g., the calibration method, the measurement range or the measurement uncertainty) would be considered to fall outside of the calibration laboratory’s existing competency and can therefore not be allowed under a flexible scope of accreditation.
- *Flexibility concerning instruments/material*
The possibility for flexibility with respect to the type of instrument or material to be calibrated or measured can be limited or extended by the detail in which the device or the material is described within the CMC. In technical fields where a broad variety of devices can be calibrated by the specified calibration method, e.g., in electrical calibrations, a generic description such as “DC source” or “DC meter” would be sufficient.
- *Flexibility concerning the method*
In calibration, the use of in-house measurement procedures to specify the calibration methods included in the CMCs of the laboratory is common. As long as changes to the in-house measurement procedures do not contradict the topics described above in “Flexibility concerning the performance of the method”, these procedures can be updated.

APPENDIX B

Scope of Accreditation for ISO/IEC 17025 – Testing Laboratories

Product testing and type/pattern approval

In product testing and/or type/pattern approval, product or test standards may include a larger number of (often multidisciplinary) tests and each separate test is usually not specified. For example, International Organization of Legal Metrology (OIML) recommendations may contain a large number of different tests (e.g., physical, mechanical and electrical or electromagnetic compatibility tests) for the same measuring instruments. If all tests required cannot be performed by the CAB, then this should be clear from the scope of accreditation. Usually the applicable tests may be specified or the exempted tests may be specified (i.e. included or excluded from the scope of accreditation).

Sampling activities

ISO/IEC 17011 Sub-clause 7.8.3 does not provide specific requirements for the scope of accreditation of a CAB performing sampling activities. Sub-clause 7.8.3 Item d) applies regardless of whether sampling is done as a stand-alone activity or is associated with subsequent testing, however, the parameters, components or characteristics may be defined more generically. The scope of accreditation should be clear in regard to the objective of the sampling (e.g., sampling for subsequent physico-chemical and microbiological analysis of waters) and the type of sampling (e.g., grab, composite, membrane filtration, etc.).

B1.1 Flexible Scopes in Testing Laboratories

The possibility of adopting new standard methods, developing new in-house methods and modifying existing methods under a flexible scope does not include introduction of new measurement principles. A flexible scope can be established based on degrees of freedom for flexibility such as:

- *Flexibility concerning materials/products*
This may cover testing using the same measurement principle which is extended from determination of the mass fraction of cadmium in fruit, jams and other fruit products to the determination of the mass fraction in vegetable products. Another example is electromagnetic compatibility (EMC) tests for a wide variety of electric equipment.
- *Flexibility concerning components/parameters/characteristics*
An example is the extension of the determination of the mass fraction of cadmium in food to the determination of the mass fractions of trace elements in food by the same measurement principle.
- *Flexibility concerning the performance of the method*
This flexibility allows for changes in the performance of a method for a given material or product type and a given parameter. This includes for example, the modification of measurement range and measurement uncertainty.
- *Flexibility concerning the method*
This flexibility allows adoption of methods that are equivalent to methods already covered by accreditation. An example is ultrasonic testing of welds performed to similar methods from different standardization organizations.

APPENDIX C

Scope of Accreditation for ISO 15189 – Medical Testing Laboratories

The scope of accreditation for medical examinations based on ISO 15189 follows the same principles as the scope of accreditation of an ISO/IEC 17025 testing laboratory and as required by ISO/IEC 17011 Sub-clause 7.8.3 Item d).

The scope of accreditation may be supplemented with ‘medical laboratory fields’ (e.g., clinical chemistry, anatomical pathology, medical microbiology and other pathology disciplines) and if needed also with ‘medical laboratory sub-fields’.

Test /technique /equipment

Examinations are often determined by the instrument (analyser) used and in accordance with the manufacturer’s instructions/protocol. Thus, a reference to the instrument (name of manufacturer and version/type) may provide unique identification of the method in the scope of accreditation. Adding the measurement principle could also be considered.

Point Of Care Testing (POCT)

For those POCT laboratories accredited to ISO 22870 in combination with ISO 15189, the scope of accreditation is to follow the same principles as for testing laboratories (including medical laboratories) as required by ISO/IEC 17011 Sub-clause 7.8.3 Item d).

C1.1 Flexible Scopes in Medical Testing

A flexible scope of accreditation in medical testing follows the same principles defined for an ISO/IEC 17025 testing laboratory flexible scope.

APPENDIX D

Scope of Accreditation for ISO 17034 – Reference Material Producers

Approach used to assign property values

ISO/IEC 17011 Sub-clause 7.8.3 Item f) requires that the type of reference material is identified (certified reference material, reference material, or both), as well as the identification of the reference material matrix or artefact and the approach used to assign the property value.

The approach used to assign property values should be aligned with Clause 7.12 of ISO 17034 (e.g., whether it is using a single reference measurement procedure in a single laboratory, characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories, etc.).

Range and property value capability

For certified reference materials (CRMs) supporting the Joint Committee for Traceability in Laboratory Medicine (JCTLM) or the Key Comparison Database (KCDB) managed by the Bureau International des Poids et Mesures (BIPM, *English: International Bureau of Weights and Measures*) or being equivalent to such materials, the AB may consider specifying the measurement range and measurement capability (CMC).

D1.1 Flexible Scopes in Reference Material Producers

As the need for accredited reference materials is growing, ABs are encouraged to allow a degree of flexibility for scopes to not restrict access to such materials.

If the Reference Material Producer (RMP) performs its own measurements needed for characterization, changes to the manner in which property values are assigned would be considered to fall outside the RMP's existing competency and can therefore not be permitted under a flexible scope of accreditation.

APPENDIX E

Scope of Accreditation for ISO/IEC 17043 – Proficiency Testing Providers

Schemes offered by the Proficiency Testing Providers

The scope of accreditation may be supplemented with an identification of each particular Proficiency Testing (PT) scheme that has been accredited, this might take the form of a number or a particular name or some other distinct identifier.

Type of PT items

The type of PT item may be specific but may also be described by indicating a particular technical field or broken down into sub-fields which includes the PT item/matrix(ices). The degree of detail will depend on the specific nature of the PT scheme, along with the degree of flexibility that has been granted to the PT provider by the AB (see E1.1).

Measurands or characteristics

Whether the measurand(s) or characteristic(s) are grouped together in a generic group or not (e.g., as residues in fruits in contrast to a specific residue) will depend on the specific nature of the PT scheme.

E1.1 Flexible Scopes in Proficiency Testing Providers

To ensure that PT schemes can continue to develop in order to meet laboratory needs, it is strongly encouraged that all PT providers are granted a certain level of flexibility.

A flexible scope of a PT provider requires that the AB specifies the activities that fall within the competence of the PT provider. This includes the AB establishing the boundaries regarding groups of items and the measurements and characteristics performed.

The degrees of flexibility may include the PT schemes offered by the PT provider, type of PT items and measurands or characteristics to be identified, measured or tested. The degree of flexibility afforded should take into account the technical competence of the PT provider to obtain or produce suitable homogeneous and stable PT items with well-established and sufficiently accurate values of the targeted measurand as well as the technical competence for the test procedures used for analysis of these PT items.

APPENDIX F

Scope of Accreditation for ISO 20387 – Biobanks

Biobanking as defined by ISO 20387 Clause 3.6 is the process of acquisition and storing together with some or all of the activities related to collection, preparation, preservation, testing, analysing, and distributing defined biological material as well as associated data.

Therefore, any biobanking scope of accreditation should also include, as a minimum, acquisition, storing and one or more among collection, preparation, preservation, testing, analysing, and distributing defined biological material as well as associated data. Any other identified activity in a scope of accreditation should be traceable to one of the biobanking activity categories listed in the definition. The scope of accreditation should also define the biological material and its source (e.g. human, animal, plant, microbial, fungal biological material), the storage conditions under which it is held (e.g. cold storage -80 °C to -190 °C) and the standards, normative documents and/or regulatory requirements containing the requirements against which the conformity assessment activity is performed, as applicable. The biological material may be further categorized into sub-categories (e.g., saliva, plasma, serum, tissues, DNA, spores).

F1.1 Flexible Scopes in Biobanking

The degrees of flexibility may relate to specific aspects of the biobanking activities, where the same acquisition and storage techniques are applied.

REVISION TABLE

The table provides a summary of the key changes to this document from the previous version.

Section	Amendment
SCOPE OF ACCREDITATION; APPENDIX F	Additional guidance provided on scopes of accreditation for biobanking.