Guideline for the Formulation of Scopes of Accreditation for Laboratories

ILAC-G18:04/2010

The ILAC Secretariat
PO Box 7507
Silverwater NSW 2128
Australia
Fax: +61 2 9736 8373
Email: ilac@nata.com.au

TABLE OF CONTENTS

PREAMBLE

The scope of accreditation of a laboratory is the formal and precise statement of the activities which the laboratory is accredited for. It is as such the result of a combination of information (scope parameters) concerning the field of activity (e.g. testing, calibration), the product/object tested or calibrated and the methods and procedures used. The assessment (and reassessment) of the scope of accreditation represents the core of the accreditation process and may be defined as the set of operations carried out by the Accreditation Body in order to ensure, with an adequate degree of confidence, that the laboratory has the competence to provide reliable services within the defined scope.

Accredited laboratories may be allowed to modify their own laboratory-developed methods or to use up-dated versions of standard methods and standards they are accredited for and to introduce similar new methods without having to report to the Accreditation Body in advance, provided that these modifications and up-dated versions or new methods do not incorporate new measurement principles that are not covered by the original description of the scope. The flexibility of a laboratory in this respect is described by a flexible scope. The concept of flexible scope according to ISO/IEC 17025, Clauses 5.4.3 and 5.4.4, and Clauses 5.5.1 to 5.5.3 of ISO 15189 has found broad acceptance all over the world. There are many benefits of this concept. For the Accreditation Body, it provides a means for better service to the laboratory, less administrative work, more time to concentrate on technical aspects of accreditation, and fewer unexpected surveillance visits for enlarging or modifying the scope of accreditation. For the laboratory, it allows in-time adaptation of their methods to the needs of new products, manufacturers and conformity procedures, as well as to the technology involved.

Accreditation bodies around the world are offering accreditation of flexible scope according to ISO/IEC 17025, Clauses 5.4.3 and 5.4.4, and Clauses 5.5.1 to 5.5.3 of ISO 15189. There are however still differences between interpretations of the term “flexible scope” and the way it is implemented in different countries. For example, a number of Accreditation Bodies apply flexible scope in specific fields only. Laboratories and their customers may therefore have difficulties understanding the concept of flexible scope and there is also a need to ensure that this concept is applied consistently at an international level.

PURPOSE

The purpose of this publication is to provide information on how to define the scope of accreditation (fixed and flexible) and to identify criteria and ways of assessing the scope in order to allow an effective and harmonised application among Accreditation Bodies in relation to the relevant international Standards.

AUTHORSHIP

ILAC G18:2002 *The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing* was developed by the then ILAC committee on Technical Accreditation Issues, and approved for publication by the ILAC General Assembly in 2001. ILAC G18:2002 was revised in 2008/9 by the ILAC Accreditation Committee (AIC) to produce this publication.

1. GENERAL

1.1 Scope of accreditation

The scope of accreditation of a testing, calibration or medical laboratory is the official and detailed statement of the activities for which the laboratory is accredited. In ISO/IEC 17011:2004 Clause 7.9.4 it is required that the accreditation body shall provide an accreditation certificate to the accredited laboratory which shall provide a brief indication of, or reference to, the scope of accreditation while Clause 7.9.5 requires that the accreditation certificate or an annex to it shall identify:

- the tests or types of tests performed and materials or products tested and, where appropriate, the methods used (for testing laboratories)
- the calibrations, including the types of measurements performed, the Calibration and Measurement Capability (CMC) [historically and used by ISO/IEC 17011: Best Measurement Capability (BMC)] or equivalent (for calibration laboratories)

In addition ISO/IEC 17011 Clause 8.2.1 requires that the accreditation body shall make publicly available information about the current status of the accreditations, which shall be updated regularly. The information shall include scopes of accreditation, condensed and/or in full. If only condensed scopes are provided, information shall be given on how to obtain full scopes.

The formulation and assessment of the scope of accreditation represents the core of the accreditation process. The role of the Accreditation Body is to ensure (to an adequate degree of confidence) that the laboratory has the competence to offer the service defined in the scope.

According to Clauses 5.4.3 and 5.4.4 of ISO/IEC 17025 and Clauses 5.5.1 to 5.5.3 of ISO 15189 accredited laboratories may modify methods. In the context of accredited laboratories, such modifications require the laboratory to have a flexible scope of accreditation. The basic consequence of a flexible scope and the benefit to the laboratory has the acknowledged flexibility, to modify methods, validate the changes and apply them without having to ask the Accreditation Body for extensions to the scope. Such modifications to methodology must not incorporate new measurement principles not previously covered in the scope of accreditation.

1.2 References

ISO/IEC 17011:2004	*General requirements for accreditation bodies accrediting conformity assessment bodies*
ISO/IEC 17025:2005	*General requirement for the competence of testing and calibration laboratories*
ISO 15189:2007	*Medical laboratories - Particular requirements for quality and competence*

2. THE DEFINITION OF THE SCOPE OF ACCREDITATION

2.1 Scope description

The scope of accreditation can be clearly defined by parameters such as described in Table 1.

Table 1: Typical parameters for description of the scope of accreditation

Testing laboratory	**Calibration laboratory**	**Medical laboratory**
Testing field *(e.g. environmental testing or mechanical testing)*	Calibration field *(e.g. dimensional measurements)*	Medical field *(e.g. clinical chemistry, hematology)*
Type of test *(e.g. mass spectrometry or hardness testing)*	-	Examination technique *(e.g. IR spectrometry)*
Test object or product *(e.g. automotive components); Matrices (e.g. tap water)*	Calibration objects *(e.g. gauge blocks)*	Biological samples *(e.g. whole blood, serum, body fluid)*
Test parameter (when appropriate) *(e.g. Shore hardness)*	Quantity, property *(e.g. length)*	Components / Analytes *(e.g. CO_2) or related groups of analytes (e.g. liver function)**
Reference to standardised method *(e.g. ISO 14577-1:2003)*	Reference to standardised procedure (when appropriate and applicable)	Reference to standardised procedure (when appropriate and applicable)
Internal method reference	Internal calibration procedure reference	Internal examination procedure reference
-	Calibration and Measurement Capability (CMC)	-

* If the laboratory has flexible scope, test parameters/components/analytes may not be specified.

"-" Indicates that this scope parameter is not relevant in the specific field

The methods/calibration or examination procedures is usually an important reference to give in the scope and may be specific or generic and can be based on standard methods or laboratory-developed methods:

- Non standard or laboratory-developed methods are developed by the laboratory itself or other parties, or adapted from standard methods and validated.
- Standard methods are developed by a standardisation body or other well-established organisations whose methods are generally accepted by the technical sector in question.

In describing the scope of the laboratory it is relevant in some cases to give both a reference to a standardised method as well as an internal method reference (in the quality management system). In other cases this is not relevant.

Depending on the type of laboratory activity, more emphasis can be given to one or more of the scope parameters described in Table 1. If, for example, range and uncertainty is omitted in the description of the scope this does not mean that the laboratory shall not answer for those details. It is only not needed in order to characterise the scope of the laboratory. This will have an impact on the way the scope will be presented and assessed.

Conventionally, the scope of accreditation is described using a fixed list of all methods/ calibration or examination procedures which the laboratory can use when referring to accredited status. This list is usually an annex to the certificate of accreditation and gives the details in the scope of accreditation.

Granting a laboratory a flexible scope provides the possibility of describing major sub disciplines of the laboratory activities in a more general form. The laboratory must anyway retain a current list of methods covered by accreditation including newly modified, introduced or developed methods.

The fact that a laboratory is entitled to introduce new or modified methods shall be made clear to the market and to the customer through reference in the scope. This reference should avoid any potential impression that this is a form of classification of laboratories.

2.2 Flexible scope

When a laboratory is granted a flexible scope, it is allowed to include additional activities in its scope of accreditation on the basis of its own validations without evaluation by the accreditation body prior to operation of the activity. The possibility of introducing new, modified or developed methods under flexible scope does not include introduction of new measurement principles of testing, calibration or examination not previously covered by the scope of accreditation. Flexible scope can be established based on degrees of freedom for flexibility such as:

- *Flexibility concerning object/matrix/sample*
  This means flexibility that allows for changes with respect to various products (e.g. change in matrices) within a product area. For example this covers HGA atomic absorption spectroscopy which is extended from determination of cadmium in fruit, jams and other fruit products for the determination of cadmium in cereals and bakery products. Another example is mechanical testing of various components (e.g. wheels, suspensions) for automotive applications.
- *Flexibility concerning parameters/components/analytes*
  This means flexibility that allows for changes with respect to parameters. An example is the extension of cadmium determination in food to other trace metals by HGA atomic absorption spectroscopy.
- *Flexibility concerning the performance of the method*
  This means flexibility that allows for changes in the performance of the method for a given specimen type and a given parameter. This includes for example, the modification of measuring range and uncertainty.
- *Flexibility concerning the method*
  This means flexibility which allows adoption of methods that are equivalent to methods already covered by accreditation. An example is the extension of in-plane displacement field measurement by 2D-ESPI (electronic speckle pattern interferometry) to three dimensional distribution of the displacement by 3D-ESPI.

In formulating the flexible scope it is important that accreditation is not granted for a specific measurement procedure and that the limits of the flexibility are clearly set. It is understood that a flexible scope and a fixed scope can be separately described or combined within one accreditation whatever is the most convenient. In all cases, the laboratory must retain an updated list of all methods for which accreditation is held, including newly modified, introduced or developed methods for review by the Accreditation Body.

In calibration, possibilities for flexible scopes are more limited than in testing. It is thus not possible to have a flexible scope in calibration, which concerns the performance of the method in relation to the CMC. It is also not possible in calibration to have flexibility concerning parameters (quantities) as different quantities require completely different measurement techniques. The possibility for flexibility with respect to objects is in some cases generically included and need not be specified as such in the scope of accreditation. This is the case in electrical calibration where scopes usually are specified in quantities and apply to any instrument which can be connected to the measurement set-up. In calibration most methods are also self developed measurement procedures and as far as changes to those makes no change to the CMC and use the same techniques, then those procedures can be updated as other documents in the laboratory's quality management system. This inherent flexibility does not need to be specified in the scope of accreditation as it applies to all calibration laboratories.

3. ASSESSMENT OF SCOPES

3.1 Staff competence

Evaluation of the technical competence at all hierarchical levels and for all functions of a laboratory is one of the core responsibilities of Accreditation Bodies when assessing laboratories' competence. The competence of staff can be obtained and demonstrated in various ways such as:

- General knowledge in the domain which the clients of the laboratory are working in.
- Knowledge about risks the clients are dealing with and how they intend to use the results.
- Knowledge about the procedures applied, about their reliability, including the associated uncertainties. The individual components contributing to the uncertainty of these procedures.
- Formal education and the years of experience in the respective field.
- Training courses in the past years and the effect of these training courses.
- Cooperation with scientific organisations, standardisation organisations, national and international organisations contributing to the development of the techniques and application of conformity assessments' procedures and its use in the field.
- Internal learning and improvement processes due to audits, reviews, cooperation with clients.

When a laboratory develops a new or a modified method special attention must be given to the competence of the staff. The staff who undertake development and modification of methods shall have the necessary technical understanding of the test method and the technology used. They shall be able to judge the suitability of methods and the quality of the results obtained. This competence can be obtained and demonstrated in various ways such as:

- Formal education and training received,
- Experience within the field,

- Participation in research or development projects,
- Participation in standardisation committees,
- Participation in scientific or authoritative committees.

Accreditation Bodies should assess staff who are authorised to develop and validate methods in order to assess them for this capability. The evaluation should be more comprehensive if the laboratory operates a flexible scope and should include documented evidence that the laboratory operates all steps involved in the development and operation of methods within the flexible scope.

3.2 Method development and modification

The laboratory that undertakes development and modification of methods should meet criteria such as:

- Procedures that cover development and approval of methods,
- Authorisation of experienced staff who are responsible for development and validation of new and modified methods,
- Records covering the full process from development, validation and verification,
- Management commitment to sustain a flexible scope if accredited for this.

Procedures and responsibilities for development, implementation and validation of modified, updated or introduced methods shall be described in detail within the quality documentation. The responsible staff will have to state the minimum quality requirements before starting the process of validation and implementation, or even better, before starting the whole development process.

An experienced person should be authorised by the management for each designated technical sector to take the overall responsibility for modification, development and implementation of new or revised methods.

Modifications and up-dates of test methods or development activities including all the underlying results and other relevant data must be controlled and maintained on record. This data shall be available to the Accreditation Body which has to check it during a surveillance visit, a reassessment or on request.

The responsible staff (including those responsible for quality management) shall regularly review the modified, revised or newly developed methods. Procedures and responsibilities linked to the development or revision of accredited methods shall be reviewed periodically by the responsible management taking into account the results of internal and external quality control. Records of these review activities must be made available to the Accreditation Body.

3.3 Validation

New and modified methods must be validated and the laboratory’s capability to perform the method verified before it can be included in the scope of accreditation. Where the method is a standard method, validation is not required but verification must be undertaken.

In the case of free selection of standard methods or its equivalent method within a defined field or area of testing validation does not apply, when the use of the standard method or its equivalent methods is unchanged. However this rule does not hold, when the standard method is combined and used for a new test objective.

3.4 Documentation

Laboratories maintaining a flexible scope of accreditation must have, where it is applicable, fully documented procedures for the validation of method modifications (incl. modifications of parameters and matrices) and for the verification of additional methods to be covered under the flexible accreditation scope. The appropriateness and robustness of these procedures will be assessed by the Accreditation Body prior to accreditation being granted for a flexible scope.

Complete records of validation and verification of additional methods and the data obtained must be retained and made available for review at assessment. This would normally be in the form of a validation and/or verification report.

The laboratory must also retain a current list of methods for which it is accredited, including those that are modified, newly introduced or developed.

3.5 Responsibilities

The responsible staff must regularly review the modified, revised or newly developed methods, in order to ensure that they continue to meet specified or implied requirements. Procedures and responsibilities relevant to the development or revision of methods covered by accreditation must be reviewed periodically by the responsible management and take into account the results of internal and external quality control. Records must be available for review by the Accreditation Body.

4. SPECIFIC GUIDELINES FOR THE ON-SITE ASSESSMENT

4.1 General

Assessment activities may be grouped in two practical elements which inter-relate and whose complexity and importance depend on the extent of the scope, namely:

- the assessment of the quality management system;
- assessment of technical competence.

With regard to the technical aspects, the assessment and the surveillance visits should cover all the fields of activity mentioned in the scope over a full assessment cycle. For a given field of activity, the Accreditation Body should ensure that it assesses the key methods in the scope and the associated personnel, that it selects tests that can be witnessed during the assessment and surveillance visits and that the selected methods are suitable to provide confidence in the competence of the laboratory to perform all the tests and measurements proposed for the scope of accreditation at an appropriate quality level.

Possible criteria for the selection of these methods, from both quantitative and qualitative points of view, may be:

- evidence of the implementation of the quality management system, experience, capability, if any, of modification/development of methods
- technical complexity
- consequence of errors (possible risks)
- balance between standard methods and nonstandard methods

- balance between complete observations of performance and checks of reports and/or validation records and/or quality control records and/or inspection of laboratory facilities

During the initial assessment or reassessment the number of methods to be assessed must be sufficiently large so that the key or principal methods in each field of activity can be drawn upon and be adequately assessed. In each field of activity in any case, at least one key or principal method must be assessed.

During every surveillance visit, methods that the laboratory has modified, newly introduced, or developed since the last assessment visit must be explicitly assessed.

4.2 Flexible scope

When assessing flexible scopes of accreditation, the focus of the assessment of the laboratory's management system should be on the implementation of the validation and/or verification procedures required under 3.3 above, and the monitoring activities related to their implementation e.g. review of requests, tenders and contracts, management review, internal audits, personnel competence and authorities, measurement uncertainty estimations, equipment and measurement traceability, proficiency testing activities and internal quality control. Particular attention should also be given to the appropriateness of claims of accreditation status with regard to previously un-assessed activities under the flexible scope of accreditation.