The Scope of Accreditation & Consideration of Methods & Criteria for the Assessment of the Scope in Testing

ILAC-G18:2002

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PREAMBLE

The scope of accreditation of a testing 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 testing field, the type of test (describing the measurement principle), the product/object tested and the methods and procedures used for the test (see chapter 2.1). 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 test 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 laboratory must inform the Accreditation Body about modifications in an agreed time interval.

Introduction of substantially new methods represents a separate topic to this document. They may normally be added to the scope of accreditation only with prior consent and, whenever necessary, an assessment by the Accreditation Body. An assessment of such a new method and technique may include an evaluation of the related documentation, or even a comprehensive assessment at the laboratory premises.

The need for laboratories to be allowed to introduce new methods or standards or modify their own laboratory-developed methods within their scope of accreditation (flexible scope) became apparent because in practice sometimes the development or modification of test methods has to be done in shorter times than the normal assessment times of accreditation bodies and in several cases (like e.g. NDT and EMC) the standards are so generic, that laboratories have to develop procedures and testing concepts for almost each new contract.

The prior assessment of laboratories would be simply impractical and to expensive in these areas. When laboratories have shown in the past that they were able to implement new methods or modify laboratory-developed methods properly so that the accreditation bodies can have confidence in that ability also in future, formulation of accreditation scopes on a more general basis should be considered.

Laboratories applying for a scope of accreditation which allows the possibility for a continuous development of services covered by accreditation must demonstrate their technical capability to validate new developed or modified methods in accordance to § 5.4 of ISO/IEC 17025.

It is understood that the capability to modify methods does not mean the freedom to choose modified methods without the agreement of the customer.

This document is applicable to all laboratories regardless of the number of personnel or the extent of scope. It is written in general terms in order to encourage more accreditation bodies to develop their national schemes of accreditation for laboratories which modify methods or develop new ones. Based on broad experience at a later stage a more specific guidance document may be agreed upon by the international organisations of accreditation bodies and laboratories.

PURPOSE

The purpose of this publication is to provide information on how to define the scope of accreditation and to identify some criteria and ways of assessing the scope in order to provide practical guidance for an effective and harmonised application of the relevant international Standards.
The major parts concern the implementation of the state of practice of describing the scope for laboratories accredited to modify methods or design new methods as foreseen in ISO/IEC 17025, § 1.6, 5.4.3 and 5.4.4.

AUTHORSHIP

This publication was developed by the ILAC committee on Technical Accreditation Issues, and approved for publication by the ILAC General Assembly in 2001.

1 THE DEFINITION OF THE SCOPE OF ACCREDITATION

1.1 Scope Parameters

The testing field should be clearly defined (e.g. electrical, chemical, mechanical). The products considered may be specific or generic (e.g. seat belt, polymeric materials, metals and alloys).

The tests are normally identified in terms of

- quantities or properties to be measured (e.g. voltage, elemental composition of substances, tensile strength, presence or absence of microorganism);
- range of measurements (where applicable);
- associated uncertainties (were applicable);
- product standards where applicable.

The test methods and procedures may be specific or generic and can be based on standard methods or laboratory-developed methods:

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

1.2 Interpretation

Depending on the type of laboratory activity, more emphasis can be given to one or more of the scope parameters above. This will have an impact on the way the scope will be presented and assessed.

Laboratories may also have some flexibility in updating and/or modifying generic methods and procedures or in implementing new ones, in order to take into account technological progress or to satisfy the changing needs of their clients, provided such changes will not imply any significant deviation from the defined scope and are made with proper notification to the Accreditation Body.

The description of the scope should be sufficiently precise. Either methods applied or technologies (equipment) operated may be set out as well as application related types of tests (describing the measurement principle). It must be made clear that the possibility of introducing new, modified or developed methods does not include introduction of new principles of measurement.

In all cases the laboratory has to keep an updated list of accredited test methods including newly modified, introduced or developed methods available for the accreditation body.

The fact that a laboratory is allowed to introduce new or modified methods may be made clear to the market by mentioning it in the accreditation certificate in a way not leading to classification of laboratories.

2 THE ASSESSMENT OF THE SCOPE

The following paragraphs show elements and criteria to be considered during the assessment of a laboratory applying for a scope including the modification of existing or the development of new methods, considering the above interpretations. Requirements of ISO/IEC 17025 which are repeated, or additional guidance for laboratories in the following paragraphs are meant at the same time as guidance for assessors with regard to the assessment of a flexible scope.

2.1 General Aspects

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

(a) the assessment of the quality management system;
(b) the assessment of the technical competence.

As for the technical aspects, the assessment and the surveillance visits should cover all the fields of activity mentioned in the scope. For a given testing field, 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 tests, 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 testing methods
- technical complexity
- consequence of errors (possible risks)

- balance between standard methods and non-standard methods (e.g. clients specification, laboratory-developed methods,etc)
- balance between complete observations of test performance and checks of test reports and/or validation records and/or quality control records and/or inspection of test facilities

The number of selected test methods must be large enough to allow drawing reliable conclusions out of the assessment for each testing field but must not put the testing laboratory to unreasonable costs.

Laboratories given the possibility of a continuous development of aspects of their scope covered by accreditation will have to develop a specific approach for this purpose, which should also be reflected in the quality policy.

ISO/IEC 17025 states in §1.6: "If testing and calibration laboratories comply with the requirements of this International Standard they will operate a quality system for their testing and calibration activities that also meets the requirements of ISO 9001 when they engage in the design/development of new methods, and/or develop test programmes combining standard and non-standard test and calibration methods, and ISO 9002 when they only use standard methods." This correspondence may be mentioned in the accreditation certificate or in its relevant annexes. The qualification and experience of the staff shall match their responsibilities and tasks especially concerning the introduction of new or modified methods.

The laboratories shall be able to judge the suitability of the methods they use and the quality of the results obtained particularly according to the needs of their clients. If the laboratory develops new or modifies methods, this requires a thorough technical understanding of the testing procedures and of the technologies applied. This understanding can be achieved by participating in relevant research or development projects, in method development projects or by a broad experience within the relevant testing field.

2.2 Specific Aspects Concerning the Introduction, Evaluation, Verification and Validation of New or Modified Methods

Once a method is modified, updated or introduced as a new one within the given scope, it must be validated before it can be considered as being included in the scope of accreditation, unless it is a standardised method.

Procedures and responsibilities for development, implementation and validation of such methods should be described in detail within the quality documentation. Flow charts are useful tools to achieve these goals. For complex methods such procedures may, at least to some extent, end up in project management schemes. 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.

The assessment of the method validation procedures established by an applicant may be one of the most difficult parts of a laboratory assessment. Assessors must be able to judge whether the applied procedures will provide the results needed to define the quality of an individual method with view to its field of application and the kind of products tested.

Modifications and up-dates of test methods or development activities including all the underlying results and other relevant data (e.g. results of validation) must be controlled and maintained on record. This data shall be available on request for 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 available to the Accreditation Body.

The assessment programme must be explained to and discussed with the applicant laboratory. The laboratory must clearly know the criteria used to establish the programme.

3 REFERENCES

ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories” (1999)

ISO 9001 “Quality systems – Model for quality assurance in design/development, production, installation and servicing” (1994)

ISO 9002 “Quality systems – Model for quality assurance in production, installation and servicing” (1994)

APPENDIX A

Examples of Annex to Accreditation Certificate.

The following examples show the state of practice for the expression of the scope for laboratories, which are accredited for the design and for modification of test methods. More detailed informations had been given on a common workshop of EUROLAB and EAL (European Accreditors) in Interlaken 1995. The Proceedings are available from the EUROLAB secretariat (eurolab@bam.de).

The expression of the scope of accreditation for the fixed and the flexible accreditation will vary from country to country and from sector to sector depending on the tradition in the respective sector and country and depending on the requirements and needs of important customers of the laboratory. Eventually sectoral guidelines may be necessary. A common requirement is however that the limits of flexibility are clear to the laboratory and the accreditation body based on lists of methods and test objects available, even if these are not published. Apart from a few exceptions, the scope will contain flexible parts and fixed lists of test methods for the same laboratory. The following examples show the possibilities, without being complete or even prescriptive. Accreditation bodies and laboratories are encouraged to develop, if needed, their own description of scope according to the recommendations of this paper.

Example No. 1:
The laboratory may have for certain test areas the fixed accreditation or two types of flexibility. Footnotes or other signs indicate the degree of flexibility for each part of the scope,e.g.

1.1 No modification of the list of accredited methods allowed
1.2 Optimisation of given test methods allowed (adaptation to clients needs, new edition of test standards)
1.3 Development of additional test methods within the accredited types of tests allowed

The examples of the scope show no significant difference, apart from the footnote referred to.

Example 1.1: Fixed Scope

Products of materials, type of activity	**Measurement principle [1)] (measurand, range, types of tests)**	**Test method (method, international standard, validated laboratory-developed methods)**
Materials testing . .	"Vickers" hardness measurement . .	ISO 4516, 1980 ISO 6507-2, 1983 ISO 6507-03, 1989

1. No modification of the list of accredited methods allowed
2. Optimisation of given test methods allowed (adaptation to clients needs, new editions of test standards)
3. Development of additional test methods within the accredited types of tests allowed

Example 1.2: Flexible Scope (Optimisation of given test methods allowed)

Products of materials, type of activity	**Measurement principle [1] (measurand, range, types of tests) methods)**	**Test method (method, international standard, validated laboratory-developed**
Electrical, electronical and mechanical equipment and objects filled with explosives	Thermal / climatic tests Heat tests: Chamber up to +180° C Size 300 - 1800 ltrs	ISO 4516, 1980 ISO 6507-2, 1983 ISO 6507-03, 1989 MIL STD 810 E, Meth 501 MIL STD 331 A, Test 112, Proc. III MIL STD 331 B, Test C6 IEC 68-2-2 EN 60 068-2-2 V 009 100 Directive USP of GRD, P-No.101

1. No modification of the list of accredited methods allowed
2. Optimisation of given test methods allowed (adaptation to clients needs, new editions of test standards)
3. Development of additional test methods within the accredited types of tests allowed

Example 1.3: Flexible Scope (development of additional test methods allowed)

Products of materials, type of activity	**Measurement principle [1] (measurand, range, types of tests)**	**Test method (method, international standard, validated laboratory-developed methods)**
Metals and plastics	Non-destructive Testing Radiography Diverse X-ray units (stationary and mobile) Isotopes (lr 192) (stationary and mobile)	DIN EN 462-1, 462-4 DIN 54111 T1, T2 SVDB 507 ASME, Section V .

1. No modification of the list of accredited methods allowed
2. Optimisation of given test methods allowed (adaptation to clients needs, new editions of test standards)
3. Development of additional test methods within the accredited types of tests allowed

Example No.2:

Fixed scope parts are indicated by lists of accredited methods, flexible scope parts are indicated by reference to documented laboratory-developed methods and procedures

Example 2.1: Fixed Scope

Products of materials, type of activity	**Measurement principle [1] (measurand, range, types of tests)**	**Test method (method, international standard, validated laboratory-developed methods)**
Polymeric and composite materials .	Mechanical tests Tear strength .	BS 2782, 3, 360 B:1980 . .

Example 2.2: Flexible Scope

Products of materials, type of activity	**Measurement principle [1] (measurand, range, types of tests)**	**Test method (method, international standard, validated laboratory-developed methods)**
Electrotechnical products containing polymers and other insulating materials	Electrical tests Surface resistivity	Documented Laboratory-developed Methods and Procedures and standard methods using: IEC 93:1980 BS 6233:1982 ASTM D257-92 CENELEC 429SI:1984 BS 2782:Part 2:Method 231 A:1991

Example No.3:

Fixed parts of the scope are given by lists of test methods. Flexible parts are indicated by reference to types of tests. The rules of the accreditation body require the competence in a minimum number of testing techniques for the accreditation of "type of tests".

Example 3.1: Fixed Scope

Excerpt from the Annex of the Accreditation certificate:
"Environmental chemical analysis – single test methods for analysis of water

Chloride	DIN 38405-D1 1985-07	DEV – Determination of chloride ions"

Example 3.2: Flexible Scope

Excerpt from the Annex of the Accreditation certificate:
"Types of tests in spectroscopy

- NMR-spectroscopy
- UV/VIS Fluorescence spectroscopy
- IR spectroscopy
- Mass spectroscopy"

In addition a table relates the types of tests to the testing objects for which testing competence is confirmed.

	NMR	UV/VIS	IR	MS
Inorganic Chemicals	X			X
Organic Chemicals	X	X	X	X
Plant protection products, Pet food, Fertilisers				X
Pharmaceuticals, Cosmetics	X		X	X
Polymers, Rubber	X		X	X

The sector specific rules of the accreditation body give additional guidance on the methods the laboratory has to be competent for. The complete updated list of methods is at each time available for customers and the accreditation body.

Example No. 4:

Fixed parts of the scope are given by lists of test methods. Flexible scopes are given by short lists of standards and laboratory-developed methods followed by the sentence:

"Within the indicated test area the laboratory may modify, improve and newly develop test methods without prior information and consent of the accreditation body. The test methods given are examples only."

Example 4.1: Flexible Scopes

"**SOP – pp. 11-24 Testing of repel-elasticity test equipment**

in connection with:

ISO 4662 1986-08 *Rubber Determination of rebound resilience of vulcanizates*

DIN 53512 1988-12 *Testing of rubber – Determination of rebound resilience (Schob pendulum)*

The International Laboratory Accreditation Cooperation (ILAC) is the principal international forum for the exchange of ideas and information on laboratory accreditation.

Established in the late 1970s, ILAC membership has grown rapidly and includes representatives from the world's major laboratory accreditation systems in Europe, Asia, North America, Australia and the Pacific. Countries that are developing their own laboratory accreditation systems are also welcome to participate and contribute.

ILAC operates a series of committees which investigate issues such as the harmonisation of international laboratory accreditation practices, the effectiveness of mutual recognition agreements in facilitating trade and the promotion of the aims and awareness of laboratory accreditation around the world.

There are regular meetings of individual ILAC committees as well as a major plenary meeting of all ILAC members.

The activities of ILAC affect a diverse range of areas including standardisation, accreditation, certification, testing, calibration, and regulation in both the public and private sectors.

ILAC has a comprehensive website at www.ilac.org which contains a wealth of information regarding accreditation, testing, trade related publications and other information of interest to industry, regulators, government, trade bodies, laboratories, accreditation bodies, and users of testing and calibration services.

The following ILAC publications are available free of charge on the ILAC website at www.ilac.org:

Brochures
ILAC Information Brochure
Why Use An Accredited Laboratory?
Why Become An Accredited Laboratory?
How Does Using an Accredited Laboratory Benefit Government & Regulators?
The Advantages of Being An Accredited Laboratory

Information Documents (I Series)

ILAC-I1:1994	Legal Liability in Testing
ILAC-I2:1994	Testing, Quality Assurance, Certification and Accreditation
ILAC-I3:1996	The Role of Testing and Laboratory Accreditation in International Trade
ILAC-I4:1996	Guidance Documents for the Preparation of Laboratory Quality Manuals

Guidance Documents (G Series)

ILAC-G2:1994	Traceability of Measurement
ILAC-G3:1994	Guidelines for Training Courses for Assessors
ILAC-G4:1994	Guidelines on Scopes of Accreditation
ILAC-G7:1996	Accreditation Requirements and Operating Criteria for Horseracing Laboratories
ILAC-G8:1996	Guidelines on Assessment and Reporting of Compliance with Specification
ILAC-G9:1996	Guidelines for the Selection and Use of Certified Reference Materials
ILAC-G10:1996	Harmonised Procedures for Surveillance & Reassessment of Accredited Laboratories
ILAC-G11:1998	Guidelines on Assessor Qualification and Competence
ILAC-G12:2000	Guidelines for the Requirements for the Competence of Reference Material Producers
ILAC-G13:2000	Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes
ILAC-G14:2000	Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status
ILAC-G15:2001	Guidance for Accreditation to ISO/IEC 17025
ILAC-G17:2002	Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025
ILAC-G18:2002	The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing
ILAC-G19:2002	Guidelines for Forensic Science Laboratories

Secretariat Documents (S Series)

ILAC-S1:2000	Guidelines for the Proposal, Drafting, Approval and Publication of ILAC Documents
ILAC-S2:1998	Rules

Procedural Documents (P Series)

ILAC-P1:2000	ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies
ILAC-P2: 2000	ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Regional Cooperation Bodies for the Purpose of Recognition
ILAC-P3: 2002	ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Unaffiliated Bodies for the Purpose of Recognition
	ILAC Mutual Recognition Arrangement (Arrangement): Terms of Reference and Composition of the Arrangement Management Committee
	ILAC Mutual Recognition Arrangement (Arrangement)
	ILAC Mutual Recognition Arrangement (Arrangement): Policy Statement