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Classification and identification of documents

Document classification
ACCREDIA documentation is classified into three levels: I, II, III.

The Level I includes all those documents that define the basic structure of the system Management and delivery processes and supply of services, which are generally approved by the statutory bodies responsible (eg. CD, etc.)

This includes:
- statute
- Rules of operation of the Statutory Bodies,
- General Regulations for the accreditation,
- Technical Regulations;
- Quality Management System;
- Application for Accreditation / Accreditation Extension;
- Price Accreditation;
- Convention of accreditation;
- Conventions Inspectors

Classification and identification of documents

Level II includes all those documents that constitute the documentation prescriptive used to implement the operational activities (internal and external). They cover the organizational processes, the responsibilities associated, reference documentation, and one to be used for record what has been done. This documentation is made up of the management procedures (PG) and the Operating Instructions (IO).

Level III includes all those documents detail including the forms:
Forms varies expected to record activities, for contractual issues, etc;
Lists: consist of lists, logs, etc.; Format for Letters, Standard Communications consist Circular, Internal Communications,etc ..
Amendments to those documents do not involve the modification / revision of documents one level because they do not affect the content.

Regulation for the accreditation of testing and medical laboratories RG 02

0.2 SCOPE AND FIELD OF APPLICATION

The present document applies to:

- testing laboratories;
- medical laboratories.

The aim of the present document is to describe the procedure that must be followed:

a) **by the laboratory** in:

• submitting the application for accreditation; according to UNI CEI EN ISO/IEC 17025 (for testing laboratories)

and/or UNI EN ISO 15189 (for medical laboratories);

• collaborating in the performance of the assessment visit by ACCREDIA and in all related activities;

• implementing corrective actions following the results of the accreditation procedure and all related activities;

• signing the accreditation agreement;

• cooperating in subsequent accreditation surveillance and maintenance activities;

• submitting applications for extension, modification and renewal of accreditation;

• implementing the ACCREDIA rules in cases of suspension, reduction, renunciation and withdrawal.

Regulation for the accreditation of testing, food safety and medical laboratories RG 02

b) **by ACCREDIA** in administering the following activities

- accreditation,
- surveillance ,
- extension,
- modification,
- suspension,
- reduction, renunciation, revocation of accreditation,
- renewal of accreditation.

Regulation for the accreditation of multisite laboratories RG-02-01

1. SCOPE AND FIELD OF APPLICATION

The present Regulation describes the requirements and specific procedural modalities for the accreditation of testing labs and multisite medical labs.

The requirements of this regulation are not applicable to groups of labs where authority and responsibilities are delegated to external units, as is the case with holding organizations, laboratories or franchising associations.

Regulation for the accreditation of multisite laboratories RG-02-01

2. TERMS AND DEFINITIONS

Multisite laboratory: a lab with a single legal entity, consisting of a number of secondary (or branch) locations where testing activities take place, and a central structure where, as well as testing activities, other activities are undertaken. All activities – both central and branch – come within a single quality management system.

Head office: the site where personnel with legal responsibilities of the multisite lab work, and it is the center of the quality management system, coordinating the other sites.

There may be a testing lab at the site of the head office, and in such cases:

- If the lab of the head office coordinates the work of the other labs, the head office is assessed with regard to the applicable management requirements and accredited tests;
- If the lab of the head office does not coordinate the work of the other labs, the lab is deemed to be a secondary, site.

Secondary site: operative site, permanent or temporary, generally not situated at the head office. All secondary sites shall be indicated in the documents attesting the lab's legal entity (e.g. chamber of commerce profile), with the exception of temporary sites for which a contract is acceptable making the site available for use by the lab.

Regulation for the accreditation of multisite laboratories RG-02-01

3 ADDITIONAL REQUIREMENTS

In order to apply these procedures, the head office shall:

- demonstrate that it has full and continuous control of the activities of secondary sites;
- prepare, a description of the activities managed at the head office, taking place at the various secondary sites, and also of the traceability of all records they produce;
- set up staff at the head office responsible for the QMS also for the secondary sites;
- define the responsibilities concerning the issue of testing reports at secondary sites and provide for personnel for QMS. These responsibilities may be assigned to staff of the head office as long as it is demonstrated that the operative and management conditions exist to ensure fulfillment of AB's requirements;
- prepare and make available a quality manual which responds to the requirements of the reference standard and those of AB, for both the head office and for all the activities undertaken by the secondary sites. The manual shall also contain the modalities of coordination and surveillance of the QMS of the secondary sites;
- prepare and make available, as part of the QMS, appropriate written instructions to ensure control with regard to any transfer of materials or samples for testing between the various sites, including records, transport, conservation, issue of testing reports etc..

Regulation for the accreditation of multisite laboratories RG-02-01

Every secondary site shall also:

- carry out periodical reviews of its own QMS, the results of which will be verified during the management review at the head office. The review can be partial, referring to specific activities carried out in the secondary site.
- prepare and make available (if necessary) its management procedures in line with the provisions contained in the quality manual of the head office, as well as procedures/ operative instructions deriving from the specificity of the site in terms of staff, means and organization. Such documentation shall be under controlled management.

Regulation for the accreditation of multisite laboratories RG-02-01

IMPLEMENTATION OF PROCEDURE AND SELECTION OF SITES TO BE VISITED

The initial accreditation or the extension assessment will be performed at every accredited site or site seeking extension. If the lab has more than one secondary site, where necessary, the surveillance of the secondary sites will be planned applying the following criteria:

5. the head office is always assessed;
6. during each cycle of accreditation, each secondary site shall be assessed at least twice;
7. at every surveillance, the aggregate of the sampled sites shall enable an assessment of tests which are representative of all the accredited tests;
8. if a nonconformity is raised, the site will be submitted for sampling on the occasion of the next surveillance visit;
9. during the surveillance the systems assessor may, if the lab's management system permits it, assess parts of the requirements by remote system, without going to all the sampled sites in question.

Regulation for the accreditation of multisite laboratories RG-02-01

AB sets out the 4-yearly sampling program for the surveillances at the head and secondary offices. This sampling may be subject to changes if an application for extension of accreditation is made by accredited secondary sites or if an application for extension is made by new secondary sites. It may also be changed if there are reasons to doubt that the secondary sites do not maintain conformity with all the applicable requirements which may happen after a complaint, the results of tests or the outcome of a surveillance visit. When re-accreditation is due to be performed, all the interested sites will be assessed.

Regulation for the accreditation of multisite laboratories RG-02-01

SUSPENSION AND WITHDRAWAL OF ACCREDITATION

In the case of suspension or withdrawal of accreditation, also of just one lab which is part of the multisite system, AB, depending upon the criticality and specificity of the causes, decides whether or not such sanctions will be imposed on all of the labs belonging to the system.

This is also true if AB decides suspension of use of its mark on testing reports following a negative outcome surveillance visit, until the verification of the implementation of corrective actions on the part of the lab has been completed.

If the head office requests the suspension of accreditation for one or more sites, the suspension regards exclusively the site(s) in question. If the head office requests the suspension of accreditation for itself, this will involve the suspension of all the sites in the multisite system

Sampling of tests RG-02

The sample test is carried out in accordance with the following criteria:

- ✓ the tests for accreditation are divided into homogeneous groups, for example: the equipment used, the test methodology, the matrix / product which is the object of the test, the location of the test, the frequency of controls, the sanitary importance, where applicable;

- ✓ for each group of tests the sampling is performed on the number of tests considered sufficient to determine the technical competence of the lab, to guarantee the reliability of the operators to carry out satisfactorily all the tests in the same group using adequate equipment;

- ✓ c) using appropriate checklists, at least one tests shall be vertically assessed on all the applicable requirements, while the others shall be conducted assessing one or more of the following requirements:
  - personnel qualification, including PT performance (scope: check of the competence of an adequate number of technicians);
  - equipment calibration, including measurement traceability
  - uncertainty of measurement and repeatability (always, where applicable)
  - sampling of archived test reports, check of the technical records for evidence of the traceability of the test from the sampling of the approval of the results
  - PT results or the results of other quality guarantee activities (always)
  - other requirements: limit of determination (LOD), limit of qualification (LOQ), recovery etc and conformity with mandatory requirements

Sampling of tests RG-02

- records regarding the validation of test methods and/or the assessment of laboratories in the application of standardized methods
- in the case of accreditation of tests with ***flexible scope*** it is necessary to assess the records and validations of the methods where modifications have taken place with respect to the previous visit
- for stack emissions assessment must be performed for conformity with the requirements of CEN/TS 15675

See also the requirements contained in ILAC G18:2010

As a rule, the laboratory will not be notified in advance of the assessment, exception made when a lack of notification might make it impossible to perform the tests; some cases that need notification in advance are listed below:

- necessity to prepare for the assessment
- necessity of particular environmental conditions such as long conditioning of the specimen
- test of samples which may not be available in the lab

Sampling of tests

The technical assessor shall also indicate whether or not each sampled test has to be carried out in duplicate

In the event that execution of a test involves sequence of steps separated by long intervals of time (e.g. for conditioning of test samples, corrosion tests or growth of cell/microbe cultures), to shorten the assessment time, the technical assessor may request a set of repeats of the same test started at appropriate intervals on different samples, so as to be able to check the relevant phases within a restricted period of time and/or present other requests focused to ascertain the laboratory' s capability to perform requested tests

Interruption of the assessment

When in the course of the assessment a serious failure on the part of the laboratory arises with respect to the standards or the AB documents, the coordinating assessor, in agreement with other assessors and the Department Director, may propose to the laboratory manager to interrupt the assessment. If this is done, the assessors hold meetings to formalize the findings until the interruption takes place and to record the interruption in the summary report of the assessment.

AB shall reimburse the laboratory for the cost of the days not spent and the accreditation process will be closed.

If the laboratory requests that the visit shall continue, the assessors will take care to record the laboratory decision in the brief visit report form, and they shall continue with their activities

Proficency tests

2. DEFINITIONS

Inter-laboratory or Proficiency tests (PTs): evaluation of the performance of a participant in accordance with pre-established criteria using inter-laboratory comparisons (UNI CEI EN ISO/IEC 17043 sub-section 3.7).

Inter-laboratory comparison (ILC): organisation, performance and evaluation of measurements or tests on the same, or similar, materials by two or more laboratories In compliance with preestablished conditions (UNI CEI EN ISO/IEC 17043 sub-section 3.4).

3. DIFFERENT TYPES OF INTER-LABORATORY COMPARISON

Inter-laboratory comparisons can be identified in certain main types:

1. Evaluation tests proposed by independent organisers
2. Proficiency tests organised by EA or by APLAC or offered as part of international cooperation
3. Measurement audits
4. Evaluation tests based on bilateral comparisons

Proficency tests

Type 1: In the case of PTs proposed by independent organisers, the participating laboratory has the responsibility of verifying the competence of the organiser who shall give proof of operating in compliance with the requirements of UNI CEI EN ISO/IEC 17043, or to be accredited in conformity with such requirements. Apart from information which can be obtained on AB's Website, the database (www.eptis.bam.de) offers information on the organisers of PTs.

Type 2:AB will select one or more laboratories for participation according to the field of application of the accreditation tests. The laboratories shall send the results to AB or directly to the organisation depending upon specific instructions given by the organisation or by AB.

Type 3: Audits on measurements can be performed by technical inspectors during evaluations when certified reference materials are available, in order to verify the technical competence of a single laboratory.

Type 4: Other types of ILC can be accepted when no other type of inter-laboratory comparison is available. In such cases, as a statistical processing of the data is not possible due to such data being insufficient and not representative, the results are considered to be of little importance

Proficency tests

ILCs are frequently used for different scopes and their use is also increasing on an international level. Typical scopes for ILCs include as follows:

a) evaluations of the performances of laboratories for specific tests or measurements and the monitoring of the performance of laboratories on a continuous basis;

b) the identification of problems in the laboratories and the activation of improvement actions for related problems such as inadequate testing or measurement procedures, or training effectiveness and personnel supervision or the calibration of equipment.

c) description of the effectiveness and comparability of testing or measurement methods;

d) guarantee of extra trust by the laboratories' clients;

e) identification of inter-laboratory differences;

f) training for participant laboratories on the basis of comparison results;

g) validation of uncertainty declarations

Proficency tests

Inter-laboratory evaluation tests do not generally entail use of the following points owing to the fact that the competence of the laboratories in these applications is an a priori requirement. These applications can also be used for giving independent evidence of the competence of the Laboratories

h) validation of the performance characteristics of a method;

i) allocation of values to materials of reference and verification of their suitability for use in procedures of testing or measurement;

j) support for equivalence declarations by the Istituti Nazionali di Metrologia through “key comparisons” and supplementary comparisons carried out on behalf of the International Bureau of Weights and Measurements (BIPM) and of the associated regional metrology bodies.

Proficency tests

4 PARTICIPATION IN INTER-LABORATORY COMPARISONS

In order to demonstrate technical competence and compliance with the requirements of point 5.9 of standard UNI CEI EN ISO/IEC 17025, the laboratories must participate in a sufficient number of inter-laboratory comparisons, the results of which must be taken into account by the accreditation bodies, in both initial assessment and for maintenance of accreditation.

The laboratories shall communicate to AB, using the relevant modules of the accreditation body, upon application for accreditation and in the subsequent documents related to the update or variation of the test list or test extension request, the results of participation at inter-laboratory comparisons indicating, apart from the organising body, the dates of the performance of such program and the type of test, specifying the matrix, the parameter, the testing method, the regulations and sub-regulations, the year of participation and the identification data of the ILC

Frequency of participation at inter-laboratory comparisons – as for other activities related to assurance of quality of results apart from those which are mandatory requirements – shall be established by the laboratory based upon risks connected with non-valid results for real samples and results which are not in compliance with inter-laboratory comparisons, statistically evaluated (ISO 13528)

Proficency tests

Participation at inter-laboratory comparisons, where applicable, shall include all accredited tests, in terms of materials/matrices, measured and testing methods.

Participation cannot be limited only to the more common tests and it shall always guarantee the inclusion of all the laboratory's testing techniques, both quantitative and qualitative.

The minimum requirements requested by ACCRDIA for participation are as follows

- At least one analytical activity for each regulation before assessment for accreditation;
- At least one analytical activity related to each of the more important sub-regulations after accreditation and before assessment for renewal of accreditation.

If there are no PTs available for the sector of competence, the laboratory shall provide evidence of the research carried out and of the quality assurance activities (such as internal quality control, see also UNI CEI EN ISO/IEC 17025 sub-section 5.9 and UNI EN ISO 15189 sub-section 5.6.4

Proficency tests

5 Negative results of participation at ILCs

In the case of results which are not in accordance with the criteria of acceptability given by the officer in charge of the inter-laboratory comparison, or by the laboratory itself, the laboratory shall provide evidence of having reviewed the entire analytical process to identify the causes of the nonconformity and that the corrective actions have been implemented.

Following verification of the corrective actions, the laboratory shall make an immediate request to the organisation body, if this has not already been taken care of in the plan, to carry out a fresh research regarding the nonconformity in the subsequent sending of samples. If it is technically possible, it is advisable that the laboratory repeats the test on the same sample (re-sending of a sample identical to the one already examined and object of the non-conformity). If it is not possible for organisational and technical reasons, it will be possible to repeat the test (with the same measured and method) also using another sample

The laboratory shall communicate to AB the tests with a negative result which has not been resolved at the second recurrence, requesting suspension of use of the mark for that specific test. In case of failure of communication found by AB or during the audit or following a specific request made by AB to the organising body, AB reserves the right to suspend accreditation of the laboratory

Proficency tests

6 IDENTIFICATION OF THE SECTORS AND OF THE TESTING TECHNIQUES

In order to satisfy the requirements of the procedure, the laboratory shall, first and foremost, classify each of its accredited tests according to the materials/products, regulations and sub-regulations.

This classification leads to selecting the inter-laboratory comparison involving all the tests which are part of a sub-regulation.

To define the regulations and sub-regulations it is necessary to identify the products/ matrices/materials, measureds/measured properties and the size and technique of test or measurement.

For example, if the products are taken into consideration, it is possible to include different products in the same sub-regulation as long as the matrices are of an equivalent nature (regulation: foods; sub-regulation: milk, meat, cheese....).

If the property to be measured is taken into consideration, more than one property can be included in the sub-regulation (regulation: pollutants; sub-discipline: residue of pesticides in foods, IPA, dioxins etc.).

When principles of measurement are taken into consideration, however, it is not possible to include different measurement principles in the same sub-regulation (for example: Hg determined with ICPMS cannot cover the use of the AA technique with cold vapours).

Each laboratory can have its own classification in regulations or sub-regulations which it shall document and justify

Flexible scope

INTRODUCTION

The description of the competence of a laboratory, attested by accreditation is contained in the scope of accreditation, which must be available to the client, to other interested parties and to the market in general.

The scope of accreditation shall be defined clearly and precisely in order to identify the activities covered by it.

The scope of accreditation is set out by AB as an attachment to the accreditation certificate (the list of tests or calibration template).

This way of defining the scope presents a certain restriction in the scope handling because, for any change or extension to the scope the laboratory has to present a specific application to AB entailing a subsequent assessment and approval.

This procedure may be especially onerous for certain sectors such as agri-food, the environmental and medical sectors where the rapid technical and scientific evolution of the applicable methods is not always compatible with the conformity assessment process or where health warnings or technological changes require a rapid response from labs performing controls. Exceptional situations may occur in the field of accreditation regarding calibration labs, requiring the calibration of complex multi-quantity and/ or multifunction systems or measuring devices which are unique or rare for which a fixed accreditation scope would be difficult to implement.

The adoption of a flexible scope of accreditation allows labs, within the accredited sector of competence, to respond to the requests of clients and of authorities to define new measurands or properties measured on new materials/products/matrices/tools/samples by the laboratory and to carry out calibrations of devices which are not specifically provided for.

Flexible scope

With regard to labs performing tests or calibrations in line with the requirements of technical or product standards, flexible scope accreditation enables an increase, within the activities of competence, in the application of new technical or product standards or calibration procedures (e.g. product or calibration testing of devices in the sector of electromagnetic compatibility and electrical safety)

4. TERMS AND DEFINITIONS

Scope of accreditation: specific conformity assessment services for which accreditation is required or has been granted (UNI CEI EN ISO/IEC 17011, point 3.17).

> Note: With reference to testing laboratories, the accreditation scope consists of the list of tests with attested technical competence of the lab. The tests are recorded in a list which is attached to the accreditation certificate and it contains the testing materials/matrices/products, the parameters or quantities and ranges to be to be determined (and the measurands) and the test methods used.
>
> With regard to calibration labs, the scope consists of the accreditation template which contains the CMCs (Calibration and Measurement Capabilities).

Fixed scope of accreditation: A fixed accreditation scope for testing labs means a description of the scope, detailing the testing materials/matrices/products, the quantities to be determined and the test methods used.

A fixed accreditation scope for calibration labs means a description of the measurement range under calibration, quantities or physical parameters, reference to the technical standards (when appropriate and applicable), reference to internal procedures and CMCs in terms of quantities, measurement range and relative uncertainty

Flexible scope

Flexible scope of accreditation: flexible accreditation scope means a more generic description of the scope of accreditation as concerns testing materials/and/or matrices and/or products or quantities to be ascertained, including the possibility for the laboratory on the basis of assessed capabilities to modify testing or calibration methods developed by an accredited laboratory and to extend the range of application, to use new revisions of standardized methods (where the testing technique is the same as previous revisions) or to add new methods based on the same techniques as those already accredited. For calibration laboratories it means that beside the limits of the fixed scope the acceptable flexibilities are indicated. The flexible accreditation must comply with the limitations associated to the CMCs granted to the Laboratory

For example:

- to implement updates and amendments of standardized methods such as the use of UNI EN ISO 3960:2010 instead of UNI EN ISO 3960:2009 for determining the number of peroxides in animal and vegetable oils and fat;
- to add other standardized methods issued by different standardization bodies with the same field of application (chlorides in conformity with APAT CNR IRSA 4020 Man 29 2003 and chlorides in conformity with UNI EN ISO 10304-1:2009) and the same testing or calibration technique;

Flexible scope

- to add other measurers associated with different testing methods from those accredited with the fixed scope but similar in terms of the measuring or instrument technique used (e.g. electromagnetic compatibility tests with EN and MIL-STD standards) – not applicable for calibration labs;
- for calibration labs to prepare and apply calibration methods with hybrid measuring systems which include a number of physical quantities amongst those accredited
- for labs carrying out tests in line with the requirements of product technical standards to add new products (and the applicable standards) where the testing technique is the same for other products (and the applicable standards) already covered by the accreditation

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