Title	***Regulation for the accreditation of multisite Testing Laboratories, Medical Laboratories and Proficiency Testing Providers***
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NOTE: The present document is the English version of the document under reference at the specified revision. In case of difference the Italian version prevails. To identify the revised parts reference must be made to the version in Italian only.

Preparation	Approval	Authorization	Application date
The Director of Department of Testing Laboratories	The Directive Council	The President	05-02-2019

CONTENTS

0. SCOPE AND FIELD OF APPLICATION

The present regulation describes the Requirements and specific procedural modalities for the accreditation of Testing Laboratories, Medical Laboratories, Proficiency Testing Providers (PTPs) whose activities are performed in a number of sites.

In accordance with the General Regulations RG-02 and RG-14 the applicant laboratory/PTP shall be a single legal entity, therefore this regulation is not applicable to groups of laboratories/PTPs where all empowerments and responsibilities are delegated to remote units such as holding or franchising companies or associations.

The present Regulation shall not be applied separately from regulation RG-02 for Testing Laboratories and Medical Laboratories and from RG-14 for PTPs.

1. TERMS AND DEFINITIONS

The terms and definitions contained in Regulations RG-02 and RG-14 are applicable for the purposes of this Regulation.

The terms and definitions specifically regarding this document are given below.

Conformity Assessment Body (CAB): a body performing conformity assessment activities, including calibrations, tests, certifications and inspections (Reg. EC 765/2008, Ch. 1, Art. 2, paragraph 13). For the purposes of this regulation a CAB is a testing laboratory, a medical laboratory or a PTP.

Multisite: a CAB with a single legal entity, consisting of one or more remote units or branch sites and a central structure where a series of activities take place. All activities – both central and branch/secondary – come within a single quality management system.

Central site: the site where personnel with legal responsibilities of the multisite carry out their tasks and it is the center of the quality management system, coordinating the other sites.

For Testing Labs and Medical Labs, there may be a lab at the central site and therefore also an operative site, and in such cases:

- if the lab of the central site coordinates the work of the other laboratories, the central location is always assessed with regard to the applicable management requirements and accredited tests;
- if the lab of the central location does not coordinate the work of the other laboratories, the lab is deemed to be a secondary site.

Secondary location: operative site, permanent or temporary[1], not situated at the central site. All secondary sites shall be indicated in the documents attesting the CAB's legal identity (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 CAB in question.

[1] Temporary site: fixed site operative for a limited, predefined period of time. Tests done at such sites are considered Category 1 (See RG-02).

Sites situated near to the central site are considered secondary where activities are undertaken which are limited compared with the entire field of application of the accreditation or they do not operate continuously (e.g. testing or instrument sections or storage areas). These sites come within the central site's management system and do not possess full management independence.

Below are examples of activities which may be undertaken at secondary sites:

For testing labs:

- tests;
- storage, warehouse;
- preservation of samples;
- data processing.

For medical labs:

- exams;
- collection of samples;
- receipt, storage, preservation of samples, review of exam results;
- performance of exams nearby the point of care and assistance of patients (POCT), managed by the medical lab in compliance with the requirements of UNI EN ISO 22870.

For PTPs:

- tests;
- tests for the evaluation of the sufficiency, homogeneity/stability;
- storage, warehouse;
- preservation of samples;
- data processing.

2. NORMATIVE REFERENCES

The following regulations and standards are applicable for areas not explicitly covered by the present regulation:

- UNI CEI EN ISO/IEC 17011 "Requirements for accreditation bodies accrediting CABs";
- UNI CEI EN ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories";
- UNI EN ISO 15189 "Medical Laboratories - Requirements for quality and competence";
- UNI CEI EN ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing;
- UNI EN ISO 22870 Point-of-care testing (POCT) - Requirements for quality and competence;
- RG-02 "Regulation for the accreditation of Testing and Medical Laboratories";
- RG-14 "Regulation for the accreditation of Proficiency Testing Providers";

- RG-09 "Regulation for the use of the ACCREDIA Mark";
- PG-12 "Management of "Cross Frontier" Accreditations";
- Other applicable ACCREDIA Technical Regulations.

For the ACCREDIA documents the latest revision is applicable, downloadable in ACCREDIA's website from the area of corporate documents and proceedings and/or the area for testing labs.

3. PROCEDURE AND REQUIREMENTS FOR THE ACCREDITATION OF MULTISITE CABS

3.1. APPLICATION FOR ACCREDITATION

If the CAB seeking accreditation has more than one operative location it may submit a single application. If one of these sites is already accredited it can submit an application for the other sites using the procedure for extension of accreditation. The application involves completing the module DA-00, entering the data for each site, and for each site it is also necessary to complete a copy of the modules DA-02/DA-06/DA-08 with the attachments requested.

In cases of the accreditation/extension of sample collection facilities and of POCTs, Medical Labs shall use the modules DA-08, DA-08 Annex 2 and DA-08 Annex 3.

If the management activities are managed by another site which does not carry out technical activities (tests, exams), this shall also be indicated in the application as the central location and it will be the object of assessment of the management requirements.

If the preliminary phases of the test or exam (e.g. conditioning of the sample/extract) are conducted at different sites frm the site doing the determination, and considering that it is not possible to request accreditation for the test or exam phases, the tests/exams to be accredited shall be included in the application for accreditation of the site doing the determining phase. The application shall include specification of the sites where the preliminary phases (if any) are performed.

It is not possible to apply for accreditation for POCTs only against ISO 22870. Accreditation for these exams may be issued to a Medical Lab only jointly with the standard ISO 15189.

It is not possible to apply for accreditation against ISO 15189 only for sample collection facilities.

If a multisite CAB has sites out of Italy, the procedure PG-12 is applicable for acceptance of the application and issue of accreditation or extension, granted accordance with this regulation.

3.2. SPECIFIC REQUIREMENTS

In order to use the procedures for a multisite CAB, the central site shall:

- demonstrate that it has full and continuous control of the activities of secondary sites;
- prepare and make available, using the ACCREDIA modules (MD-09-15/37/38-DL respectively for the LAB/MED/PTP schemes) for each requirement of the reference standard and of ACCREDIA's documents, a description of the activities managed at the central location which are taking place at the various secondary sites and the traceability of all

records produced at the various sites. This document shall be attached to the application for accreditation during the phase of first accreditation and/or renewal and shall be sent if there are any variations;

- appoint QMS staff for all activities in the various sites. If it considers it to be necessary, the CAB may appoint references for quality at the multisite locations in order to ensure that the QMS is implemented at all times at the individual locations;
- specify 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 central location as long as it is demonstrated that the operative and management conditions exist to ensure fulfillment of the accreditation requirements;
- prepare and make available a quality manual (or self-assessment in cases of accreditation to UNI CEI EN ISO/IEC 17025:2018) which responds to the requirements of the reference standard and those of ACCREDIA, and which includes all the activities performed in the various sites. This document 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 for the performance of the necessary activities, including records, transport, retention, issue of testing reports etc.;
- consider, amongst the input elements of the QMS review, all the activities performed in the various sites. The CAB, if it considers it necessary, may carry out specific QMS reviews at the secondary sites, the results of which shall be an input element for the CAB's general multisite review.
  A POCT accredited as a secondary site of a medical lab, in order to conduct the QMS review, shall also consider the requirements of § 4.15 of UNI EN ISO 22870;
- send, at least 10 calendar days before the visit, to ACCREDIA-DL, the module MD-19 "Information relating to specific risks in the workplace and protection measures", completed with the information concerning the place where the assessment is performed, as envisaged by Reg.s RG-02 and RG-14. According to its staff structure and organization, the CAB may send a single MD-19 containing the information for all the multisite CAB, or send a specific MD-19 for each site.

Every secondary site shall also:

- prepare and make available (if necessary) its management procedures in line with the provisions contained in the main MS of the multisite CAB, as well as procedures/operative instructions deriving from the specificity of the site in terms of staff, means and organization. Such documentation shall be retained under controlled management.
- Provide details in its documents and test reports of any preliminary phases of tests/exams carried out at other sites of the multisite CAB.

3.3. ACTIVATION OF THE PROCEDURE AND SELECTION OF SITES TO BE VISITED

The initial accreditation assessment or the extension assessment shall be performed at every accredited site or site seeking extension.

For each site, including POCTs and sample collection facilities, a sampling shall be performed of activities undertaken (e.g. of tests/exams, collection of samples, acceptance of samples) and also of the authorized personnel.

If activities are performed in the secondary sites which are different from tests/exams (e.g. storage, preservation of samples or records, acceptance of samples) the assessment shall evaluate the specific requirements for these activities.

In secondary sites where technical activities take place but in a partial manner (e.g. conditioning of the sample/extraction phase), the assessment shall regard the evaluation of the specific requirements for the specific activities and shall permit the assessment of the entire process of sampled tests/exams.

If the CAB has more than one secondary site, where necessary, the surveillance of the secondary sites will be planned applying the following criteria:

- the central location is always assessed;
- during each cycle of accreditation, each secondary site shall be assessed at least twice (including the accreditation/re-accreditation visit);
- at every surveillance, the sampled sites shall, taken altogether, enable an assessment of tests which are representative of all the accreditation scope (e.g. sampling, typology of collection of samples, of tests/exams);
- for sample collection facilities, taken altogether, the sampled facilities shall be representative of the typology of sample collection (venous, swab testing), the nature of the sampling taken (e.g. urine, feces, swab etc.);
- for POCTs, taken altogether, the sampled POCTs shall be representative of the typology of diagnostic systems used;
- if a nonconformity is raised, it shall be submitted for sampling on the occasion of the next surveillance visit unless sanctions are imposed;

if the multisite CAB's organizational and management system permit it, it is possible that:

- the technical assessors/experts perform a remote assessment of the activities performed also at the other sites even if not sampled, as well as the programmed on-site assessments;
- during the surveillances the systems assessor may assess parts of the requirements by remote system, without going to all the sampled sites in question.

ACCREDIA only issues accreditation/extension to multisite CABs after approval by the Sector Accreditation Committee of the DL department (CSA DL). The CSA DL, following approval of the accreditation and taking into consideration the outcome of the assessment and the risk analysis conducted by the CAB, also sets out the 4-yearly sampling program for the surveillances at the head and secondary sites. 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 activities performed at the CAB's secondary sites do not maintain conformity with all the applicable requirements of the reference standard and the applicable ACCREDIA documents, which may happen after a complaint, the results of PYs or the outcome of a surveillance visit. The reviewed sampling of a site is subsequently submitted to the CSA DL for approval.

When re-accreditation is due to be performed, an assessment visit will be performed at all the sites in question.

3.4. ASSESSMENT VISIT

The plan for the assessment visit at the multisite CAB should be organized so that the closing meeting can take place at the central location.

The formalization of the results of the assessment at the multisite CAB will be presented during the closing meeting following review by the assessment team of the results of the assessments at each site.

3.5. SUSPENSION REDUCTION AND WITHDRAWAL OF ACCREDITATION

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

With regard to the management of the suspension, reduction or withdrawal, Regulation RG-02 is applicable for Testing Labs and Medical Labs, and RG-14 is applicable for PTPs.

3.6. CERTIFICATE OF ACCREDITATION

Following the granting of accreditation ACCREDIA issues a single accreditation certificate for the CAB's registered office containing also the list of the accredited sites. The lists of activities for each accredited site will be attached to the certificate.

Changes made to the number of sites involved in the accreditation (extension/reduction) involve revision of the certificate of accreditation and the lists of accredited activities.

The certificate of accreditation and the lists of accredited activities are sent by ACCREDIA to the central location.

3.7. ACCREDITATION CONTRACTUAL AGREEMENT

The present regulation is an integral part of the accreditation agreement (CO) to be signed by ACCREDIA and by the legal representative of the multisite CAB. All of the CAB's obligations towards ACCREDIA laid down in the contractual agreement shall include secondary sites, for which the central location retains responsibility.