

TITLE **REGULATION FOR THE ACCREDITATION OF INTERLABORATORY PROFICIENCY TESTING PROVIDERS (PTPs)**

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NOTE *The present document is the English version of the document under reference at the specified revision. In case of conflict, the Italian version will prevail. To identify the revised parts reference must be made to the Italian version only.*

PREPARATION

THE DIRECTOR OF THE TESTING LABORATORIES DEPARTMENT

APPROVAL

THE DIRECTIVE COUNCIL

AUTHORIZATION

THE PRESIDENT

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FOREWORD

The objective of ACCREDIA's Department of Testing Laboratories (ACCREDIA-DL), is to contribute towards the creation of trust in the conformity assessment system for attesting the conformity of interlaboratory proficiency testing providers in accordance with the applicable national and international technical requirements of the standards, as well as ensuring an effective and consistent approach by operators of the system, enhancing growth and competitiveness in the national economy and improvement in the well-being of its citizens.

For this purpose, ACCREDIA's Department of Testing Laboratories accredits:

- Proficiency Testing Providers – PTPs – operating in conformity with the provisions and requirements of the standard UNI CEI EN ISO/IEC 17043 and with the applicable ACCREDIA, EA and ILAC documents

ensuring that the PTPs possess and maintain fulfillment of the organizational, procedural, technical and professional requirements such as to foster, among all interested parties and, in particular, users and consumers, a high level of trust in their operations and in the value of the declarations of conformity which they issue.

In line with the above aims and with the policies of its statutory bodies and with the objective of better ensuring the effectiveness of the accreditation process, ACCREDIA-DL has defined rules and criteria for the application of the normative references, formalized by means of this Regulation and other applicable documentation to be used jointly.

This Regulation also takes into account the changes introduced to the reference standards as well as the experience gained by ACCREDIA and the suggestions expressed by ACCREDIA's corporate bodies for improving the accreditation system.

1 INTRODUCTION

The application of the reference standard UNI CEI EN ISO/IEC 17043 and other applicable documents is intended to benefit the creation and maintenance of the trust of clients in PTPs and the impartiality and integrity of their associated technical and commercial operations.

Accreditation attests the technical competence of PTPs to design, provide and manage proficiency tests in the scope of accreditation.

PTPs with ACCREDIA accreditation are considered competent to undertake these activities also in support of the activities of the Testing Laboratories and Calibration Laboratories and accredited certification, inspection, verification and validation activities bodies.

For promoting the effectiveness and credibility of the accreditation process it is necessary to introduce specific rules which, without transcending the spirit and the letter of the standard, favor their full application by accredited bodies, constituting unequivocal, objective and impartial references for the assessments conducted by the Accreditation Body.

These objectives can be attained through the proper and effective application of this Regulation.

General note: it should be noted that the timelines indicated in this Regulation may not be respected during corporate periods of closure which are communicated on the ACCREDIA website.

1.1 SCOPE AND FIELD OF APPLICATION

This Regulation applies to the accreditation of organizations which design, perform and organize interlaboratory proficiency testing and to their suppliers of services relating to the management and implementation of each accredited test.

This Regulation is not applicable for organizations limited to marketing interlaboratory proficiency testing entirely managed and operated by different entities from those which market them.

This Regulation establishes the conditions and procedures for the granting, surveillance, extension, renewal, reduction, self-reduction, suspension, self-suspension, resumption and withdrawal of accreditation of the PTP, with respect to the applicable standards and other documents, introducing suitable specifications in cases where the reference standard provides only general requirements.

The specific procedural modalities for the accreditation of multi-site PTPs are defined in Regulation RG-02-01.

This General Regulation constitutes a contractual obligation between ACCREDIA-DL and the accredited and applicant bodies, whereby:

- ACCREDIA-DL shall undertake, with competence, objectivity, diligence, impartiality and professional integrity, the assessment of the adequacy of the PTP's system to the requirements of the standards and reference documents and, if the outcome is positive, ACCREDIA-DL shall grant accreditation, maintenance, extension and renewal of accreditation and shall place the PTP and the relative data in the ACCREDIA database of accredited bodies;
- the PTP shall conform with the requirements of this Regulation and maintain conformity throughout the cycle of accreditation which is fixed at 4 years.

The circulars/provisions that are issued by ACCREDIA must also be considered as contractual obligations in the relationship between ACCREDIA-DL and the accredited and applicant CABs, including the clarifications and specifications illustrated in the presentations of the annual congresses, pending implementation in appropriate documents.

On the basis of the specialty criterion, a technical circular/provision issued by ACCREDIA integrates the general requirements of the applicable regulations.

ACCREDIA-DL considers the following to be obligatory:

- a) the mandatory EA/ILAC documents and the documents issued by standardization bodies;
- b) any applicable requirements deriving from resolutions adopted by the general assemblies of EA and ILAC (see the document EA-INF/17 in the current version);
- c) the accreditation documents issued by the European Commission (CERTIF year-xx);
- d) any applicable provisions issued by the Public Administration Authorities;
- e) any applicable provisions issued by ACCREDIA's corporate bodies.

With regard to the application of points b), c), d), and e) ACCREDIA-DL shall inform PTPs regarding the issuance by means of circulars/notifications.

In cases of disputes, ACCREDIA-DL considers as points of reference:

- the FAQ issued by the EA Laboratories Committee and by the ILAC Technical Committee and the relative WGs;
- the interpretations provided by the ISO CASCO *maintenance group*.

ACCREDIA-DL shall not accept any a priori obligations concerning a positive outcome of assessments and, therefore, regarding the issuance/maintenance/extension/renewal of accreditation.

ACCREDIA-DL shall verify – within the limits of assessments usually performed by sampling – that the PTP possesses the competence required (in terms of organization, procedures and documents, human and instrument resources) for the performance of its testing/exam activities in compliance with this Regulation and all other applicable requirements.

This Regulation clarifies the modalities on the basis of which ACCREDIA-DL determines whether a PTP is competent, impartial and consistent, concerning its own rules in carrying out conformity assessment activities.

It is the responsibility of the PTP to ensure and maintain full and systematic conformity with the above requirements, at all times and for all aspects of its activities.

This General Regulation is submitted to the ACCREDIA Directive Council (article 14 of the ACCREDIA statute), following a favorable opinion of the Committee for Accreditation Activities and is issued with the authority of the ACCREDIA President. The Steering and Control Committee is also involved in the process in a consulting capacity.

1.2 NORMATIVE REFERENCES

The normative references for the application of this Regulation are given in the document of ACCREDIA-DL, LS-04 “Standards and reference documents for the accreditation of testing laboratories, medical laboratories and interlaboratory proficiency testing providers”, in the current version, including all the applicable ISO, ILAC and EA documents.

It follows that – within the ambit of a determined accreditation scheme – the use of this Regulation is additional to the requirements of the technical regulations (RT) / technical documents (DT) / technical circulars which may be applicable to the scheme, where such exist.

This Regulation also refers, when applicable, to the following ACCREDIA documents and regulations:

- ACCREDIA Statute (ST-00);
- General Regulation for the application of the Statute (ST-01);
- Regulation for the proceedings of the Accreditation Committee (RG-04);
- Regulation for the proceedings of the Sector Accreditation Committee of the Department of Testing Laboratories (RG-04-DL);
- Regulation for the proceedings of the Steering and Guarantee Committee (RG-05);
- Regulation for the proceedings of the Commission of Appeals (RG-06);
- Regulation for the use of ACCREDIA mark (RG-09);

- ACCREDIA accreditation pricelist (TA-00);
- Contractual accreditation agreement (CO-00);
- Application for accreditation (DA-00);
- Application for accreditation for PTPs (DA-06);
- Applicable ACCREDIA Technical Regulations;
- Applicable technical documents (DT);
- EA, ILAC and other documents applicable to PTPs;
- Mandatory normative documents, as applicable;
- Informative/technical circulars.

Each of the above documents is applicable in the current revision. ACCREDIA's documents are freely downloadable from the documents area and/or reserved area of ACCREDIA's website.

1.3 TERMS AND DEFINITIONS

Accreditation: an attestation by a national accreditation body that certifies that a conformity assessment body meets the requirements set by harmonized standards and, where applicable, any additional requirements including those set out in relevant sector programs, to carry out a specific conformity assessment activity in compliance with Reg. (EC). 765/2008 section 1, article 2, par. 10 and subsequent additions and amendments);

NOTE: accreditation consists of a declaration of adequacy (an adequacy audit and therefore not a compliance or conformity audit) of the organization and procedures employed by the CAB in providing a competent, consistent and impartial service, consequent to complete fulfillment of the reference standards and regulations.

Accreditation certificate: declaration issued by the National Accreditation Body, based on a decision attesting the compliance of a CAB with the requirements of a specific accreditation standard.

National Accreditation Body: the sole body in a Member State authorized by the Government to perform accreditation activities in compliance with Reg. (EC) 765/2008 section 1, article 2, paragraph 11 and subsequent additions and amendments.

Conformity Assessment Body (CAB): a body that performs conformity assessment activities including calibrations, tests, certifications and inspections in compliance with Reg. (EC) 765/2008 section 1, article. 2, par. 13 and subsequent additions and amendments. For the purpose of this Regulation a CAB is intended as a PTP.

Proficiency Testing Provider - PTP: an organization which takes the responsibility for all tasks relating to the development and performance of an interlaboratory proficiency testing scheme [UNI CEI EN ISO/IEC 17043, § 3.9].

Interlaboratory comparisons: the organization, performance and evaluation of measurements or tests on the same or similar objects by one or more labs in conformity with the established conditions [UNI CEI EN ISO/IEC 17043, § 3.4].

Proficiency Testing - PT: an evaluation of the performance of a participant against the established criteria by means of interlaboratory comparisons [UNI CEI EN ISO/IEC 17043, § 3.7].

Interlaboratory proficiency testing scheme: interlaboratory proficiency testing designed and operated in one or more cycles for a specific sector of testing, measurement, calibration or inspection [UNI CEI EN ISO/IEC 17043 point 3.11].

Scope of accreditation or field of application of accreditation: specific conformity activities for which accreditation is sought or issued [ISO/IEC 17011 §3.6].

NOTE: in the case of PTPs, the scope of accreditation consists of the list of accredited schemes. The list, which is attached to the certificate of accreditation, describes: the proficiency testing sector materials/matrices/products/matrices/objects of testing activities/measurands/properties/quantities to determine, and the scheme typology (e.g. quantitative/qualitative).

Fixed scope of accreditation or fixed field of application of accreditation: description of the scope of accreditation giving full details, clearly and unambiguously of the sector of the proficiency test, the measurands/properties/quantities to determine, and the scheme typology.

For the PTPs, some clarifications are given below with respect to some points of ISO/IEC 17043:

- Preparation of the sample (§ 4.2 ISO/IEC 17043): it is permitted to improve its performance without changing the principle of preparation or the nature of the sample;
- homogeneity/stability test (§ 4.3 ISO/IEC 17043): it is permitted to improve the process without changing the evaluation principle;
- assigned value (§ 4.5 ISO/IEC 17043): it is not permitted to change the methods of determining the assigned value (change of statistical techniques);
- subcontracting (§ 5.5 ISO/IEC 17043): it is not permitted to outsource activities or internalize previously subcontracted activities if the organization has not been assessed for its competence;
- performance evaluation (§ 7.2 ISO/IEC 17043): it is not permitted to change the performance evaluation methods (e.g. change of statistical model);
- definition of the type of scheme (§ 3.1.8 ISO/IEC 17043): it is not permitted to change the type of scheme if this involves different competences (e.g. qualitative, quantitative, interpretative scheme, etc.).

Changes outside these limits must be subject to verification by ACCREDIA, before updating the fixed field of accreditation.

Flexible scope of accreditation or flexible field of application of accreditation: more general description of the scope of accreditation, regarding the testing of materials/products/matrices/objects to be tested and measurands/properties/quantities to determine. The possibility of introducing new activities within the flexible accreditation field is limited to those activities that require the same competences already included within the boundaries delimited by the scope of accreditation.

Site: facility where the PTP's activities are carried out. A site can be a permanent or temporary facility. The sites where PTP's activities are carried out are reported on the accreditation certificate and in the relative attachments.

Assessment: process undertaken by ACCREDIA-DL to determine the competence of a CAB, based on one or more standards and/or other normative documents, for a specific scope of accreditation [ISO/IEC 17011 § 3.22].

Assessment program: the set of assessments consistent with a specific accreditation scheme which ACCREDIA-DL performs with respect to a CAB during the cycle of accreditation.

Assessment techniques: the methods used by ACCREDIA-DL to conduct assessments.

NOTE: the assessment techniques for this Regulation, may include, but are not limited to:

- on-site assessments;
- document reviews;
- unannounced assessments;
- interviews;
- mystery audits.

All the above assessment techniques can also be carried out in remote or mixed mode, according to the rules and limits of applicability defined by ACCREDIA-DL.

Assessments (VI): assessments performed by ACCREDIA-DL (initial, supplementary, surveillance, programmed and non-programmed, extension, renewal) for the purpose of the process of the granting, maintenance, extension and renewal of accreditation.

Remote assessments: remote assessments performed by ACCREDIA-DL assessors not physically present at the site of the PTP. This is an assessment of a physical or virtual site of a PTP or an organization (in the case of external activities), using communication techniques/electronic means (IT systems).

NOTE: A virtual site is a virtual place where a PTP conducts its activities or provides a service, using an online environment that enables people, regardless of physical locations, to perform processes.

Mixed mode assessments: assessments carried out partly in presence and partly remotely.

Unannounced assessments: assessments performed by ACCREDIA-DL, without prior knowledge of the PTP at its head office or, if applicable, at a branch location.

Assessment plan: description of the activities and rules concerning an assessment.

Cycle of accreditation: period of validity of the accreditation. An accreditation cycle begins after the date of the decision to grant initial accreditation or renewal of accreditation and it has a duration of 4 years and, in the event of any postponements¹, it must not nevertheless exceed 5 years.

Accreditation decision: decision regarding the granting, maintenance, extension, reduction, suspension or withdrawal of accreditation.

Granting of accreditation: the issuance of accreditation for a specific scope of accreditation.

Maintenance of accreditation: confirmation of the continuity of accreditation for a specific scope.

¹ In the cases provided by this Regulation.

Reassessment: assessment conducted for the renewal of the cycle of accreditation. For the purpose of this Regulation, reassessment is indicated as renewal.

Extension: enlargement of the scope of accreditation which may regard:

- a) the inclusion new matrices/parameters;
- b) request for the accreditation of a new PT scheme;
- c) modification of a scheme in line with Annex A of UNI CEI EN ISO/IEC 17043 (e.g. the addition of qualitative, quantitative schemes or interpretative);
- d) relocation and/or addition of new activities from one site to another;
- e) the introduction of tests with flexible scope accreditation.

Variation of accreditation: modification to the scope of accreditation which may regard:

- a) the reduction of the number of accredited schemes
- b) the updating of legal identity (organization or name of organization).
- c) change to the name of the matrices/parameters.

Reduction of accreditation: a sanction whereby a part of a PTP's scope of accreditation is eliminated.

Suspension of accreditation: a sanction whereby a part of a PTP's scope of accreditation is suspended.

Withdrawal of accreditation: a sanction whereby the accreditation of a PTP is withdrawn.

Renunciation of accreditation: a request presented by the PTP to renounce accreditation for any reason (e.g. non-acceptance of changes to the pricelist or of any changes to the rules governing accreditation activities etc.).

Transfer of accreditation: procedure for the transfer of accreditation of a CAB, by means of assessments by an Accreditation Body, signatory to the EA, IAF MLA or ILAC MRA, to ACCREDIA.

Transfer of ownership of accreditation: procedure for the transfer of accreditation of a CAB, by means of assessments, to another legal entity through the ceding of a company or branch of a company, merger or other operation involving modification of the fiscal code or of the VAT number.

Finding: result of an evaluation formalized by ACCREDIA-DL and graded as a NC, Concern or Comment.

Nonconformity (NC): a finding raised due to the presence of a deviation or failure which:

- a) jeopardizes the reliability of the results, performances, services of the CAB, and/or
- b) compromises the capacity of the CAB's quality management system to maintain the quality level required for the performance of conformity assessments or indicates a malfunction in the functioning of the QMS, and/or
- c) poses a threat to the credibility of the accreditation procedure or to the integrity of ACCREDIA, and/or
- d) reveals a failure to respect the mandatory requirements of the scope of accreditation, and or

- e) may derive from repeated failure to effectively resolve a previous finding raised against the CAB.

ACCREDIA-DL will also issue a NC in cases where it becomes aware that the CAB established in Italy does not comply with ACCREDIA circular n. 3/2016 issued in relation to the application of EU Regulation 765/2008 and subsequent amendments, with specific reference to Article 7 (Cross Frontier accreditation). It is forbidden for a CAB established in Italy to request accreditation in a scheme/sector from another Accreditation Body, whether residing in Europe or outside Europe, if the same accreditation can be provided by ACCREDIA. If the CAB is already covered by ACCREDIA accreditation in this scheme/sector, it is possible for this CAB to request further accreditation, but only from a non-European accreditation body.

The identification of non-compliance with the legal requirements is highlighted as a NC only if relevant with respect to the requirements of the management system and/or the applicable technical requirements, regardless of the controls and sanctions of the competent authorities.

NOTE 1: A NC is formulated by ACCREDIA-DL's assessors by means of a clear identification of the finding and it shall report the evidence for the finding as well as the reference to the specific requirement which has not been respected.

NOTE 2: A NC can lead to the imposition of sanctions in accordance with § 7.

Concern: a finding which is caused by the partial implementation of a requirement (of a standard or regarding accreditation regulations/documents) which does not or may not impact directly or immediately on the quality of the CAB's performance and results.

NOTE 1: A Concern is formulated by ACCREDIA-DL's assessors by means of a clear identification of the finding and it shall report the evidence for the finding as well as the reference to the specific requirement which has not been respected.

NOTE 2: A Concern which is not closed at the time of the next due assessment may become graded as a NC.

Comment: a Comment is raised by ACCREDIA-DL against a CAB when there is not objective evidence of a failure to meet the requirements, but its aim is to prevent such a situation from occurring (when such a possibility really exists) and/or to provide an indication for improvement of documents and/or operative modalities on the part of the CAB.

Management of findings by the CAB: activities to be undertaken by the CAB against findings raised by ACCREDIA-DL.

All findings raised by ACCREDIA-DL as NCs or Concerns, on the basis of the above criteria, shall be reviewed by the CAB, which shall send to ACCREDIA-DL, **within 15 working days** from receipt of the communication confirming the findings, an adequate plan for their management which includes:

For Nonconformities: the correction (where applicable), an analysis of the extent and of the root causes and the CAs related to the identified causes, with indication of the timeline for implementation. Evidence of closure for this type of finding shall be evaluated with positive outcome by ACCREDIA-DL before the decision of the CSA regarding the granting, renewal or extension of the accreditation.

For maintenance and renewal the CSA may issue a positive decision on the basis of sufficient information showing that the response to the findings is satisfactory.

An on-site assessment may be necessary to ensure effective implementation of the CAs.

For Concerns: the correction (where applicable), an analysis of the root causes and, when established by the PTP regarding the causes identified, the CAs, together with the implementation timeline.

The implementation is verified during the next surveillance assessment.

If considered necessary by ACCREDIA, the evidences with regard to the correction and/or CAs are submitted to a document review by ACCREDIA before the next assessment. Depending on the nature and number of Concerns, ACCREDIA may decide that, for this type of finding, the evidence of closure must be evaluated before the decision for granting or extension by the CSA DL.

For Comments: Comments may be managed with the opening of an improvement action or they may not be implemented. For comments it is not mandatory (but recommended) to formulate the plan for the management of the finding in the ACCREDIA forms, as the implementation or the reasons for failed implementation are verified by ACCREDIA at the first due assessment.

If a CAB fails to send to ACCREDIA-DL the plan for the management of findings or the documented evidence requested within the agreed time, the DDL may send the file to the CSA DL for the imposition of sanctions (see § 7 below).

The findings formalized at the end of assessments may be reclassified by ACCREDIA-DL following a review of the results.

Appeal: request by a CAB for the reconsideration of a decision concerning its status of accreditation.

Complaint: dissatisfaction requiring a response expressed by a person or organization towards ACCREDIA-DL or an accredited CAB.

Impartiality: presence of objectivity and absence of conflicts of interest.

Accreditation scheme: the defined rules, procedures and activities performed by ACCREDIA for the issuance, extension and maintenance of accreditation in conformity with the standards (e.g. ISO/IEC 17043).

Risk: the effect on an activity which may derive from certain processes/activities performed by the CAB, including the work done by its internal staff and collaborators.

The CAB should identify the risk indicators proportionally to the expected effect and the probability of occurrence of a certain situation.

Technical Officer: a person appointed by ACCREDIA-DL to manage the phases of assessment, surveillance, maintenance, renewal, extension, reduction, suspension or withdrawal of accreditation, coordinating the activities of system and technical assessors.

System assessor: a person qualified and appointed by ACCREDIA-DL, either individually or as an audit group member, to assess the conformity of the QMS of a PTP with the applicable reference standard and with ACCREDIA-DL's regulations.

Technical assessor: a person qualified and appointed by ACCREDIA to assess the technical competence of a laboratory in conformity with the applicable reference standard and with ACCREDIA's regulations and technical standards applicable to the testing methods for which the laboratory is accredited or has applied for accreditation.

Technical expert: person qualified and appointed by ACCREDIA-DL, who does not carry out assessment activities independently but works under the responsibility of an assessor, providing specific knowledge or experience regarding particular technical activities to be assessed. For the purposes of this document, the activities envisaged for a technical assessor are also intended to be applicable for a technical expert, unless otherwise indicated.

Implementation time: period between the date of issuance (first issue or revision) of any ACCREDIA regulatory document and the date of entry into force of such documents.

1.4 ACRONYMS

- **ACCREDIA-DL:** ACCREDIA Testing Laboratories Department
- **CSA:** Sector Accreditation Committee
- **CdA:** Committee of Accreditation Activities
- **DDL:** Director of the Testing Laboratories Department
- **FT:** Technical officer
- **SGQ (QMS):** Quality Management System
- **CAB:** Conformity Assessment Body²
- **LAB:** Testing Laboratory
- **MED:** Medical Laboratory

2 REQUIREMENTS AND INFORMATION FOR ACCREDITATION

2.1 INFORMATIVE PHASE

Any PTP may send to ACCREDIA-DL a request – written, verbal or by email - to have information concerning the accreditation process.

Upon receipt of the request, ACCREDIA-DL sends ACCREDIA's website address www.accredia.it to the CAB from which it can download ACCREDIA's documents, including those for accreditation.

Unless otherwise indicated, ACCREDIA's contact address is:

Registered Head Office: Via G. Saliceto, 7/9 - 00161 – ROMA;

² For the purpose of this Regulation a CAB is intended as a testing or medical laboratory.

Operative location of the Department of Testing Laboratories: Via G. Saliceto, 7/9 - 00161 - ROMA.

For sending emails use the appropriate addresses or numbers given in the website www.accredia.it.

When necessary, it is possible to organize a preliminary meeting at ACCREDIA-DL's offices (or by remote mode) with a maximum duration of half a day in order to clarify the process of accreditation to the applicant PTP. Such meetings, to which experts in the tests in question may be invited, do not involve any reciprocal commitment and they shall not take on the character of a consultancy (also unintended).

If the applicant PTP requests a preliminary meeting, this shall be specified in the quotation, invoiced in person-days in accordance with the conditions of the ACCREDIA pricelist and the duration shall not be greater than that of an initial accreditation assessment.

The activities shall be conducted in such a way as to signal failures without giving indications of the correction modalities. ACCREDIA-DL does not require corrections or CAs for any failures to emerge during the preliminary visit and it does not provide consultancy to the PTP.

In all cases the conclusions of this visit do not influence the outcome or duration of any subsequent request for accreditation. Only one preliminary assessment can be conducted for one PTP. A preliminary assessment cannot be an initial assessment.

2.2 COST QUOTATION

In order to receive an estimate for the cost of accreditation, the PTP shall send by email the application for accreditation (DA-00 and DA-06) with the list of tests for which it applies for accreditation (DA-06 Annex 1, section 2), duly completed, to the email address info@accredia.it.

Estimates are calculated on the basis of the ACCREDIA pricelist TA-00, available on the website.

3 PROCESS OF ACCREDITATION

3.1 PRESENTATION OF THE APPLICATION FOR ACCREDITATION AND RELATIVE REVIEW

Following a careful reading of the documents as set out in § 2.1, the PTP prepares the application for accreditation to be sent to ACCREDIA.

The application for accreditation of a PTP shall be presented to ACCREDIA-DL by means of the modules available in ACCREDIA's website, DA-00 and DA-06, together with the necessary documentation. The application shall be completed carefully and fully, with all the data and information requested. Any failure to do this shall be motivated or it will not be accepted. The application shall be signed by the legal representative of the PTP or authorized person. In cases of a delegation, for the purposes of the validity of the signing, ACCREDIA-DL reserves the right to ask the CAB for the document certifying the authorized powers of the delegated person (e.g. power of attorney, executive decision, decision of the Directors).

The application for accreditation must include, in addition to the key figures of the PTP, the name of the person who ensures the contact and the email address of the PTP for official communications with ACCREDIA. For reasons of confidentiality and information property, it is recommended to indicate the PTP references (e.g. email addresses on the PTP's domain), and not personal ones. A similar request is made for the choice of credentials for accessing the online applications/ACCREDIA reserved areas.

The application for accreditation and its attachments can be submitted in Italian or English. If the requesting PTP uses different languages, it must provide for the translation of the relevant documentation. For internal PTP documents that do not need to be presented to ACCREDIA for document examination (pre/post-assessment), a written translation in Italian or English is not required, but an instant translation must be possible, if necessary, during the assessment, in order to enable evaluation by the team.

The applicant PTP shall be a legal entity, natural person or legal person accepting the obligations and rights deriving from the performance of activities and in possession of a VAT number, possessing the personnel, infrastructure, equipment, systems and support services necessary for managing and carrying out interlaboratory PTs under accreditation.

A legal public person is also a juridical entity (e.g. region, province, public entity, public economic entity, institutional public entity such as I.N.P.S., I.N.A.I.L., universities etc.).

For foreign PTPs, where applicable, the definition of legal entity applied in the relevant country is valid in accordance with the local legislation.

Natural persons cannot present an application for accreditation except for persons with a VAT number (see CERTIF 2012-04 REV4 and subsequent revisions).

If the applicant PTP is a trust company, or, among its partners, there is a trust company, in order to accept the application, ACCREIA-DL shall perform all the necessary controls, requesting declarations from the applicant PTP. It is necessary to communicate all the names of the members of the trust company to be able to assess any potential conflicts of interest.

The PTP shall attach to the application the Chamber of Commerce profile or, if not applicable, another document attesting its legal identity (e.g., in the case of the Public Administration, the founding act). Such document shall state the PTP's activities as a provider of interlaboratory proficiency tests (or wording with this specific meaning), except for internal PTPs within producer companies which do not conduct test or exam activities with third parties. It shall also contain all the operative locations specified in the application for accreditation except for temporary sites, regarding which, refer to Regulation RG-02-01.

If the PTP intends to specify on the accreditation application a name to be reported on the accreditation certificate that is shorter than the legal identity (e.g. Department, Division, etc.), this wording must be present in the Chamber of Commerce registration as identification of the operational head office or "Sign" or in any case be specified in the CAB's corporate documents (to be attached to the accreditation application).

If ACCREDIA-DL receives an application regarding test/exam activities undertaken by PTPs in foreign locations, Regulation (CE) 765/2008 is applicable, as well as the procedure PG-12 "Policy for the application of Cross Frontier accreditations" and also the relevant EA and ILAC documents.

Within 30 calendar days of receipt of the application, ACCREDIA-DL evaluates its completeness and the correctness of completion of the fields, and the presence of the required attachments, and verifies, in collaboration with the DDL, that ACCREDIA-DL possesses the competences and resources sufficient to perform the requested accreditation (the review of the application).

The absence of one or more required documents or incomplete completion of the application means that the start process cannot go ahead. In such cases ACCREDIA-DL requests (in written form) the missing documents or information, waiting a maximum of 12 months. If this is not done in time, ACCREDIA-DL informs the PTP that the time limit for starting the process has expired, and that the file will be closed. If the PTP wishes to restart the application process, it shall present a new one and pay in accordance with the ACCREDIA pricelist (TA-00).

If there is evidence of fraudulent behaviour or from the checks carried out on the application it emerges that the PTP provides false information or hides information, ACCREDIA-DL will reject the application and reserves the right not to offer other services to the PTP. Furthermore, in the event that the CAB is already accredited by ACCREDIA for other schemes, the file will be submitted to the relevant CSA for the appropriate assessments (e.g. suspension or withdrawal of accreditation).

During the review of the application, ACCREDIA-DL verifies whether the applicant CAB has, in the past, been subject to withdrawal of accreditation and:

- if the withdrawal was decided because of fraudulent behaviour/false information, ACCREDIA-DL will reject the application;
- if the withdrawal was approved for other reasons (see §7.3), ACCREDIA verifies that at least 6 months have passed since the decision. Otherwise it will reject the application, unless otherwise decided by the CSA DL.

ACCREDIA-DL, after checking that the application is fully complete and that payment has been made in accordance with the pricelist, communicates as follows to the PTP:

- a) the serial code number of the file and the reference, to which both ACCREDIA-DL and the PTP shall refer in their correspondence, also after the granting of accreditation;
- b) the name of the Technical Officer to whom the PTP shall refer in its relations with ACCREDIA-DL.

3.2 PRELIMINARY ACTIVITIES

3.2.1 Identification of assessors and communication of their names to the PTP

An assessment team is assigned for every accreditation procedure.

An assessment team includes one system assessor (engaged for coordination) and one or more technical assessors/technical experts, depending on the type of proficiency test for accreditation.

The DDL, with the assistance of the Technical Officer chooses and contacts the system and technical assessors for the assessment of the PTP bearing in mind their tasks and the competences needed regarding the availability in the preliminary phase. The selection of assessors takes place in such a way that their competences cover the techniques and statistics of each interlaboratory PT scheme for accreditation of the PTP.

The selection of all the system and technical assessors is the responsibility of the Director of Department.

The Technical Officer communicates the names of all the members of the team to the PTP.

A PTP which intends to present reservations regarding the assessors, shall do so in writing to ACCREDIA-DL **within 3 working days** of receipt of the communication, and if there is no response in this period the assessment team is to be considered accepted.

ACCREDIA-DL does not disclose the CVs of its assessors, who are qualified on the basis of the ACCREDIA procedures and are approved by the CdA upon proposal of the Director of Department.

PTPs may object to assessors (or ask for their replacement after the engagement) for the following reasons:

- conflict of interests (to be communicated to ACCREDIA-DL, which verifies in accordance with declarations made by the assessor). If the reasons presented are considered valid, the matter is evaluated between ACCREDIA and the assessor in question;
- unprofessional behavior (to be proved to ACCREDIA by means of objective evidence of behavior on-site and only after the PTP has expressed reservations concerning the performance of the assessor. Such reservations are evaluated by the Department Director and by the officer responsible for the monitoring of assessors).

The ACCREDIA assessors cannot be objected to by the PTP if not for grave reasons of incompatibility which shall be described directly to the Director of Department.

3.2.2 Engagement of the assessors

Following acceptance of the team by the PTP the tasks in question are formalized by ACCREDIA-DL.

Unless otherwise decided by the DDT for justifiable technical or other reasons, the assessors are tasked also for the performance of the subsequent surveillance visits at the same PTP for the next 4 years (the period of the accreditation cycle).

The assessors of ACCREDIA-DL shall sign the ACCREDIA Code of Ethics and Conduct. They shall respect the requirements of impartiality, independence, confidentiality and absence of conflicts of interest with regard to the PTP.

Excluding the assessment activities, the assessors can communicate with the PTP only for the purpose of the logistical aspects of the assessment (overnight stays, station/airport transfers etc.). Any other communication concerning the assessment for accreditation purposes must be made through the ACCREDIA-DL technical officer.

3.3 DOCUMENT REVIEW

3.3.1 Drawing up of the report of the document review (RED)

The Technical Officer sends the documentation received from the PTP to the system and technical assessors, together with the confirmation of the engagement, for the performance of the examination of the conformity of the documents with the applicable requirements.

During the examination of the conformity of the documents of the PTP, the assessment team evaluates the conformity of the system as documented to the requirements of the normative documents, as well as the contractual ones with ACCREDIA-DL as set out in this Regulation and other applicable technical regulations.

The ACCREDIA assessors shall examine thoroughly the PTP's documentation, taking into consideration any indications from the Technical Officer and exchanges of opinion in order to decide as to whether it is satisfactory with regard to form and to content and also if the conditions exist to carry out an assessment visit.

The assessors can ask ACCREDIA-DL for any additional documents to complete the document review, for the subsequent proposal regarding the sampling of tests and for the preparation of the assessment visit (e.g. testing standards, other documents of the PTP etc.)

The outcome of the document review, together with any request for additional information, is communicated to the PTP within four months of the opening of the file.

If the outcome of the document review is negative and the documents of the PTP present significant failures regarding the management system or technical factors, ACCREDIA-DL sends to the PTP a request for revision of the documents on the basis of the findings reported. The PTP shall provide the reviewed documentation.

Within 8 months of receipt of the first request for additional information, the documentation shall be in conformity with the accreditation standard and with ACCREDIA's requirements, sufficient – in the opinion of the DDL – for the process of accreditation to continue in accordance with the procedures defined in the points below.

If this is not the case the accreditation procedure is closed as set out in § 4.4.

If the outcome of the document review is positive and the documents conform with the applicable requirements, ACCREDIA-DL sends to the PTP any findings regarding the documents presented and proceeds to organize the on-site assessment.

If, despite the positive outcome of the document review, the PTP is not available to undergo the first visit **within 12 months** of the date of receipt of the first request for additional information by ACCREDIA-DL, the accreditation procedure is closed in accordance with § 4.4 below.

The duration of the assessment visit, in terms of team man-days, is determined taking into account the specificities of the PTP (e.g.: structure, organization, locations and activities to be assessed), the results of the document review and, for assessment coming under the competence of technical assessors, the time necessary to perform the assessment of the proficiency testing schemes and the activities to be assessed (see § 3.4 below).

3.3.2 Preliminary technical meeting

In the presence of numerous and major findings reported by the assessors in the PTP's documentation and if it is considered necessary for the continuation of the accreditation process, ACCREDIA-DL may propose to the PTP a meeting with the system and/or technical assessor with the presence of the FT.

The meeting is held at ACCREDIA's office (or in remote mode) and lasts not more than half a day, for the analysis and clarification of the findings, and it shall not have the characteristics of a consultancy (also unintended). The activity is estimated and invoiced in accordance with ACCREDIA's current pricelist.

3.4 SAMPLING OF SCHEMES

Following receipt of the engagement and at least one month before the proposed date of the assessment, the technical assessors propose to ACCREDIA the sampling of tests for assessment during the assessment visit.

The sampling plan is prepared on a 4-year basis in order to ensure coverage of all types of schemes during the accreditation cycle. For the choice of activities to check, ACCREDIA-DL considers the risk involved, the sites and the staff within the field of application of the accreditation.

The schemes to check during each visit are sampled according to the annual planning of the PTP (checking out also its website) and in accordance with the following criteria:

- ensure assessment of all types of schemes during the cycle;
- ensure assessment of outsourced critical activities (with a significant effect on the quality of the scheme) where necessary;
- ensure assessment of all types accredited circuit (UNI CEI EN ISO IEC 17043 – Annex A), during the cycle;
- ensure assessment of all techniques and equipment for preparation and testing/calibration of proficiency testing objects during the accreditation cycle;
- ensure assessment of staff competences;
- ensure assessment of the PTP's site where accredited activities take place;
- ensure assessment of adequacy of the statistical model used and correct implementation of the statistical techniques declared to be in use;
- assess the PRP's performance regarding measurement uncertainties.
- in the case of accreditation with a flexible scope, ensure the verification of the records and validations of the methods for which there have been changes compared to the previous assessment visit.

See also the criteria reported in the document ILAC G18 "*Guideline for describing Scopes of Accreditation*".

If the PTP has an internal testing/calibration lab which carries out some activities for the interlaboratory PTs (e.g. tests for the preparation of materials, homogeneity and stability evaluation tests, the determination of assigned values), the technical assessor shall assess the conformity of testing activities against the requirements of UNI CEI EN ISO/IEC 17025. The accreditation of the testing/calibration laboratory according to UNI CEI EN ISO/IEC 17025 for specific tests/calibrations is sufficient to demonstrate compliance; otherwise, these activities will be sampled and verified by ACCREDIA during the assessment visits.

The four-year sampling plan prepared by the FTs according to the above indications is approved by the Department Direction and may be modified following a request for extension or reduction of the scope of accreditation, or owing to complaints or remarks or the need to assess the effectiveness of CAs implemented by the PTP.

A number of schemes shall be sampled in all cases, sufficient to ensure the compliance on the part of the PTP with all the requirements of the reference standard and to determine its technical competence, with a minimum of two schemes per assessment, where possible.

The sampled schemes are not usually communicated in advance to the organization except in cases where failed communication could compromise the possibility of performing the assessments. Below are some examples of cases where advance communication is required:

- the assessments foreseen are not in line with the PTP's planning, and therefore ACCREDIA-DL may ask the PTP to prepare and have available simulated activities;
- the assessment requires access to locations and organizations which are not under the direct authority of the accredited PTP which has the responsibilities for logistics and access.

The sampling of schemes may also be modified during the assessment in accordance with § 3.6.4.3 below.

3.5 PLANNING AND ORGANIZATION OF THE ASSESSMENT

3.5.1 General

The on-site assessment can be performed in person, i.e. with the entire team physically at the PTP's premises, in mixed mode (partly in presence and partly remotely) or completely remotely. In general, the first accreditation assessment must not be carried out completely remotely, except in cases where the Department Director may authorize this with suitable reasons.

ACCREDIA-DL will carry out a preliminary feasibility analysis, in order to determine the possibility of carrying out an assessment remotely or in mixed mode.

3.5.2 Times and logistics of the visit

As a general rule, coordination is the lead assessor's task, taking care of the management/coordination of the logistics of the visit for all members of the assessment team.

The date of the assessment is agreed by the FT with the PTP and with the assessors.

In the case of a mixed mode or in presence assessment, at least **10 calendar days** before the date of the visit, the PTP shall send to ACCREDIA-DL the module MD-19 "Information regarding the specific risks in the workplace and protection measures", completed with the information regarding the location of the assessment and any related risks. During the initial meeting it is the task of the ACCREDIA-DL team leader to request confirmation that safety conditions are adequate by means of MD-19, during the planning phase of the assessment.

If ACCREDIA-DL does not receive the form MD-19 within the set timeframe, it retains the right to perform the assessment as planned. In such cases, during the opening meeting, the PTP shall give the module MD-19, duly completed, to the assessment team leader.

The ACCREDIA-DL assessors shall respect the safety/security instructions they receive.

If it transpires, during the initial meeting or during the performance of the assessment, that the necessary safety/security conditions are not in place, the assessment may be annulled or interrupted with costs to be met by the CAB and in accordance with § 7 of the ACCREDIA pricelist, TA-00.

3.5.3 Preparation and communication of the plan

ACCREDIA-DL, having agreed the date of the on-site assessment with the PTP and with the assessors, draws up the plan and communicates it to the PTP.

The plan contains as follows:

- a) the timeframe for the performance of the assessment;
- b) the cost of the assessment;
- c) the dates of the visit and an indication of whether it will be conducted remotely or in mixed mode;
- d) the names of the appointed assessors;
- e) the PTP personnel who must be available during the visit;
- f) any requests to provide materials or make other preparations for activities for the performance of the tests planned by ACCREDIA-DL.

3.5.4 Acceptance of the plan

Having received the assessment plan, the PTP shall notify the Department in writing of its acceptance or of any objections by returning the module sent by the Department jointly with the visit plan **within 3 working days** of receipt, after which the plan is considered to be accepted.

3.5.5 Reservations regarding the assessment plan

If the PTP wishes to raise reservations regarding the visit plan, it shall promptly inform the Department in writing. Such objections shall be accompanied by reasons and will be dealt with by the Department Director.

If the PTP accepts or resolves its reservations, ACCREDIA continues with the accreditation process. In all cases, if the PTP fails to make itself available for the assessment **within 6 months from the sending of the plan**, the accreditation procedure is closed as described in § 4.4 below.

3.6 ASSESSMENT

3.6.1 General

As a rule, each accreditation and/or renewal assessment is attended by an ACCREDIA-DL management representative.

The presence of observers is admitted during the assessment, upon request of the PTP, which must inform ACCREDIA-DL in advance.

In cases where the Department Director considers necessary the attendance of a department observer or trainee assessor, this shall be communicated to the PTP in writing, providing also the declaration of confidentiality by the observer. If the PTP wishes to present reservations concerning the observers in question, it shall do so in writing, with motivation, **within 3 working days**, after which the presence of the persons in question is considered to be accepted.

The observers shall not interfere in any way in the performance of the visit. Should this occur, the coordinating assessor shall provide for the instant exclusion of the observer.

The tasks of the representative of the Department (if present) are as follows:

- to cooperate with the assessors to ensure an assessment performance in conformity with the standard UNI CEI EN ISO/IEC 17011 and with the applicable ACCREDIA documents;
- to provide the assessors and/or PTP with clarifications regarding the requirements of UNI CEI EN ISO/IEC 17043 and the applicable ACCREDIA documents;
- to raise, where necessary any Nonconformities regarding the work of the assessors with respect to fulfilment of the ACCREDIA regulations and documents concerning behavior and operative modalities.

The assessment at the PTP's premises, performed by the appointed assessors in accordance with UNI EN ISO 19011, will take place as follows:

- preliminary meeting among assessors to define and agree the last details for the performance of the assessment;
- opening meeting with the presence of the personnel as indicated in the application for accreditation with the PTP's officer and the quality management officer and their collaborators;
- performance of the assessment with the support of the PTP's personnel;
- intermediate meetings held by the assessors, if considered necessary by the lead assessor;
- meeting preliminary to the closing meeting among the assessors to discuss and define the results of the assessment;
- closing meeting with the PTP's personnel and taking note of any reservations.

The PTP shall make a room available for the exclusive use of the assessment team, preferably with internet connection for all the assessors' meetings.

The PTP shall allow the assessors (and any experts and observers) access to the PTP's work areas and to the documents for their assessment activities and shall cooperate fully with them. If sampling is performed off-site of external structures of the PTP, the PTP shall organize the logistics, agreeing the dates, when necessary, with the clients and obtaining authorization for the presence of ACCREDIA-DL assessors.

3.6.2 Preliminary meeting at the start of the assessment visit and preparation of the assessment program

The assessment team holds a meeting before the opening meeting with the PTP, and including, if present, an ACCREDIA-DL management representative who shall draw the assessors' attention to the general criteria for performance of the visit.

The lead assessor, assisted by the other assessors, prepares and makes available the time plan to show the PTP at the opening meeting, taking account of:

- the availability of staff and the means to fulfill a full review of the QMS;
- the need, if necessary, to verify corrective actions concerning the findings raised in the document review or in preceding assessments;
- the number, the sequence and the sites for the performance of activities;
- the need to verify the veracity of any complaints or comments deriving from the market.

3.6.3 Opening meeting with the PTP

During the initial meeting between the ACCREDIA-DL team and the PTP, the lead assessor introduces the assessors as well as the management representative (when present), describing the role of each, explaining the aims of the visit and performing all the required steps provided for in the checklist in relation to each specific phase of the assessment.

As stated in § 3.5.2, during the initial meeting the representative of ACCREDIA-DL's assessment team asks the PTP to confirm the adequacy of the safety conditions by means of MD-19, in the planning phase of the assessment.

3.6.4 Performance of the assessment

3.6.4.1 General

The objective of the assessment for accreditation is to verify the conformity of the PTP to the requirements of the reference standards, of the applicable EA, ILAC and ACCREDIA documents, in order to attest the technical competence of the PTP to carry out the tests contained in the scope of accreditation. Mandatory standards such as security and privacy (except in cases as defined in a reference standard), administrative responsibilities etc., are not part of the requirements for accreditation and are not assessed. The behavior to be respected by the ACCREDIA assessors with respect to potentially breached mandatory requirements, is defined in § 3.6.4.4.

All the assessment activities are performed using the ACCREDIA-DL checklists which include a list of questions designed to assess the conformity of the PTP with the provisions of the reference standard and the ACCREDIA-DL requirements.

The PTP can see on www.accredia.it, the checklists used by assessors for the conduct of the assessment. These may be added to in both the general and the technical part by the assessors also during the assessment.

The management system assessment covers all the requirements in order to assess the continuous and correct application of the MS by the PTP.

In performing the assessments, the ACCREDIA-DL assessors shall not request the PTP for copies of the documents examined, except when necessary to provide objective evidence of nonconformities or in the event of objections by the PTP. In such cases the copies shall be attached to the checklist and sent to ACCREDIA-DL. No document of the PTP may be retained by the assessors for any reason other than copies of the sampled and archived proficiency test reports and statistical analyses to be attached to the checklist.

3.6.4.2 Assessments performed by the system assessor

The system assessor shall verify the conformity of the PTP's management system with the requirements of the reference standard (UNI CEI EN ISO/IEC 17043) and with the requirements of ACCREDIA-DL by reporting the evidences examined in the appropriate section of the checklist in line with the indications given in the checklist.

3.6.4.3 Assessments performed by the technical assessor

The technical assessor shall assess the performance of the sampled schemes regarding all technical aspects related to them, by completing the specific checklist.

The PTP shall operate in compliance with the modalities declared as corresponding to those of normal operations.

In general, regarding the sampled proficiency testing schemes, the PTP prepares and performs activities/tests for the benefit of the client and of participants.

Provided this is compatible with the timeframe, with the reference standards and the needs of the performance of the assessment, the technical assessor may request to assess the conduct of activities/tests/calibrations carried out for exclusive use of ACCREDIA-DL.

Concerning this, ACCREDIA-DL may carry out, when necessary, one or more tests/activities/calibrations in partially and/or totally simulated form for reasons of time or for operative or economic reasons and provided that this does not compromise the possibility of performing a thorough assessment.

If it is not possible to perform one or more than one tests/activities/calibrations relating to the sampled schemes for any particular reason, (e.g. a breakdown in equipment) the technical assessor shall carry out those activities/tests (as a part of the accredited proficiency tests) which s/he thinks are more in keeping with the criteria on the basis of which the sampling of the schemes was performed.

If any nonconformities are raised with respect to tests/activities/calibrations such as to result in a negative judgment, the assessor shall verify if the nonconformity is systematic for the group of schemes in question, by performing, if possible, the assessment of one or more than one additional activities/tests.

3.6.4.4 Formulation of the findings

During the performance of the assessment every failure to fulfill the requirements for accreditation raised by the assessors shall be recorded in writing as a finding in the checklists. At the end of every important phase the assessor shall present a summary of the outcome of the assessments of the person who has been interviewed, communicating verbally the failures which caused the findings. The assessor shall specify that the findings will be reviewed subsequently by the assessment team under the lead assessor for confirmation and grading as an NC, Concern or Comment in accordance with §1.3 of this Regulation.

Below is a description of the behavior required of ACCREDIA assessors with respect to potentially breached mandatory requirements:

- any breaches or violations of the mandatory requirements found by the assessors which do not come within the scope of the assessment shall not be included in the assessment report;
- any breaches or violations of the mandatory requirements found by the assessors related to the scope of the assessment shall be posted as Comments in order to encourage the CAB to keep such matters under control for subsequent assessments;
- any breaches or violations of the mandatory requirements found by the assessors coming within the scope of the assessment shall be recorded as NCs.

3.6.4.5 Interruption of the assessment

When in the course of the assessment a serious failure on the part of the PTP arises with respect to the accreditation standards or the ACCREDIA-DL documents, the lead assessor, in agreement with other assessors and the Department Director, may propose to the PTP manager to interrupt the assessment.

If this is accepted, the assessors hold meetings to formalize the findings until the moment when the interruption takes place, and to record the interruption in the summary report of the assessment together with the relative motivations.

If the PTP requests that the assessment shall continue, the assessors shall record the request in the summary report of the assessment and their activities shall duly continue.

The lead assessor is responsible for the detailed description of both situations in the summary report of the assessment.

If the assessment is interrupted and, in agreement with the PTP, the conditions do not exist to continue, the activities performed shall be invoiced in accordance with the pricelist (§ 7 "Special cases" of the document TA-00).

If the assessment is interrupted, ACCREDA-DL shall submit the file to the CSA DL with the proposal of closure of the PTP's accreditation procedure as specified in § 4.4 below.

3.6.4.6 Closing meeting and acknowledgement of objections and reservations

The closing meeting will be attended by the ACCREDIA-DL team, the PTP manager, his/her closest collaborators, and the PTP's management system officer.

In the closing meeting, the lead assessor, assisted by the technical assessor for the parts within his/her competence, presents as follows to the PTP manager:

- a) a summary of the actions performed;
- b) the opinion of the PTP formulated by the assessment team;
- c) the findings issued, explaining the content and specifying that the part related to the plan for the management of findings proposed by the PTP, shall be completed only after request by ACCREDIA-DL.

The PTP manager shall sign for acknowledgment (or validate through the appropriate online application, if available³), the opinion and findings, formulated by the assessment team. A copy of the results of the visit is delivered or, in the case of an online application, made available to the manager of the PTP, by the lead assessor.

Any reservations regarding the findings may be presented directly by the PTP during the closing meeting, to the lead assessor using the appropriate module. Alternatively, any reservations may be sent to ACCREDIA **within 3 working days** of the conclusion of the assessment (see § 8.2).

NOTE: In the case of activities involving a number of sites, the three-day period starts from the day of the closing meeting held at the last site to be assessed.

The acceptance or non-acceptance of the reservations formulated by the PTP is forwarded to the Department Director.

4 DECISION-TAKING PROCESS AND GRANTING OF ACCREDITATION

4.1 ACTIONS RESULTING FROM THE ASSESSMENT

4.1.1 Plan for management of the findings and relative evaluation

Following the assessment, ACCREDIA-DL, after carrying out a review of the findings raised by the assessors and retaining the right to modify them or re-classify them, formally sends the definitive version to the PTP, with the relative request of the plan for the management of the findings.

The PTP **shall send to ACCREDIA-DL, within 15 working days** from the date of sending the request, its own plan for the management of findings and the implementation times.

The corrections to the NCs and Concerns shall be undertaken as soon as possible. Implementation times of CAs shall not exceed 3 months from the planning date except in cases which are justified and approved by the DDL, who can authorize delays of not more than 6 months.

³ For recording the results of the assessment and post-assessment activities, ACCREDIA DL has implemented an online application (called 3A), accessible to the assessment team, the Laboratory and ACCREDIA, according to specific credentials and qualifications. Currently the application is available only for the UNI CEI EN ISO/IEC 17025 scheme for testing laboratories, while it is being developed for the other accreditation schemes. The operation of the application is described in the appropriate instructions available on the ACCREDIA website.

ACCREDIA-DL, having checked the opinions of the assessors, and deciding that the plan communicated by the PTP (in terms of contents and/or implementation/closure times) is not acceptable, can ask, **within 15 working days** from the evaluation of the plan, for a new proposal.

ACCREDIA-DL has the option to ask for objective evidence of the closure of the findings, within the times indicated by the PTP.

If the second proposal of the plan for the management of the findings (the objective documental evidence) is not suitable, ACCREDIA-DL can **close the accreditation procedure** as defined in § 4.4 below.

The plan for the management of the findings shall be approved by ACCREDIA before the meeting of the CSA DL.

If the PTP, for internal reasons, wants to modify the plan for the management of the findings approved by ACCREDIA-DL, it shall communicate as such promptly to ACCREDIA-DL for approval of the new modified plan.

4.2 EVALUATION OF THE OUTCOME OF THE ASSESSMENT

On the basis of the results of the assessment ACCREDIA-DL prepares and makes available, in accordance with the procedures and using the modules in force, the assessment report of the PTP which, after approval of the management, is submitted to the CSA DL.

The CSA DL may decide as follows:

- to grant accreditation;
- to grant accreditation depending upon a positive assessment of objective evidence;
- to grant accreditation which is limited with respect to the application for accreditation;
- to perform a supplementary assessment.

4.2.1 Supplementary assessment

The supplementary assessment can be decided by the CSA DL if there are findings graded as NCs or a significant number of Concerns.

The objective of the supplementary assessment is to verify the closure of the findings to emerge during the previous assessment, to verify on-site that the corrections and/or CAs have been correctly implemented as communicated by the PTP.

The supplementary assessment takes place using the same modalities as those given in § 3.6, with the same modules.

ACCREDIA-DL informs the PTP of the need to perform a supplementary assessment by registered mail or certified email **within 15 days** of the decision of the CSA DL.

The PTP shall be available for the performance of the supplementary assessment **within one month from the final date of completion of the plan for the management of findings**, accepted by ACCREDIA-DL. Otherwise the accreditation procedure is closed as defined in § 4.4 below.

In cases of a positive outcome of the supplementary assessment, the accreditation procedure continues, otherwise, after decision by the CSA DL, it is closed as defined in § 4.4 below.

4.3 GRANTING OF ACCREDITATION

4.3.1 Decision and notification of accreditation

The decision to grant accreditation is the sole responsibility of the CSA DL, which decides independently by means of an in-depth study of the documents concerning the assessments.

Following the decision to grant accreditation, the PTP is included in the database accredited bodies, published on ACCREDIA's website.

The granting of accreditation is formalized in the form of an agreement (CO) between ACCREDIA-DL and the PTP, with the issuance of the certificate of accreditation and corresponding attachment describing the scope of accreditation (the list of accredited schemes).

Accreditation has a validity of four years starting from the date of the decision.

ACCREDIA-DL notifies the PTP of accreditation by sending:

- a communication containing:
 - the time period and duration for the next surveillance assessment;
 - the quotation regarding the next surveillance assessment;
 - the availability on the ACCREDIA website of the accreditation certificate and related attachments;
- the accreditation agreement containing all the requirements concerning the issuance and use of accreditation;
- any requests for information and/or objective evidence of closure of the plan for the management of findings.

The PTP shall return acceptance of the accreditation agreement, signed, within 30 days of receipt. If this is not done, the CSA DL may impose a sanction as defined in § 7 below.

The accreditation certificate, provided with a QRcode, together with the attachments, contains all the information relating to the accreditation of the PTP and cannot be transferred to third parties.

Acceptance of the agreement and inclusion on the list of accredited bodies commits the PTP to maintain its organizational structure and proceedings in conformity with the requirements of this Regulation, with all other applicable ACCREDIA documents and with the applicable general and sector standards and normative references.

Regarding use of references to accreditation and especially use of the ACCREDIA mark and/or reference to accreditation, the PTP shall conform with the requirements of this Regulation and the regulation for use of the ACCREDIA mark RG-09.

If the PTP intends to request authorization to use the ILAC MRA Combined mark, it must send an example of use of the combined mark and obtain written approval from ACCREDIA-DL, before using it, according to the instructions provided by ACCREDIA during the notification of accreditation.

4.4 CLOSURE OF THE ACCREDITATION PROCEDURE

For PTPs which are not yet accredited the closure of the accreditation procedure in all cases as set out in this Regulation is provided for, and, in particular, in cases where:

- the PTP, within 8 months of receipt of the first request for additional information, does not comply with this request as required by the reference standard and by the ACCREDIA-DL documents;
- the PTP is not available, despite a positive outcome of the document review, to undergo the initial assessment within 12 months of the date of receipt of the first request for additional information by ACCREDIA-DL, and is also not available to undergo the initial assessment within 6 months after the first sending of the assessment plan;
- the PTP has not sent an adequate plan for the management of findings respecting the timeframe given by ACCREDIA-DL, and the requested documental evidences are not suitable;
- the supplementary assessment of the PTP has not had a positive outcome;
- the assessment has been interrupted;
- the PTP has requested interruption of its ongoing accreditation procedure.

The above situations are presented to the CSA DL with the proposal to close the accreditation procedure.

After the decision of the CSA DL, within 15 days, ACCREDIA-DL communicates by registered post or certified electronic mail the closure of the accreditation procedure to the PTP.

In addition to the cases as defined in this Regulation, ACCREDIA-DL may interrupt the accreditation process and therefore close the procedure in cases of failed payment with regard to the document review and/or the performance of the assessment.

If the PTP intends to start a new accreditation procedure it shall present a new application for accreditation and it shall make all the payments in accordance with the ACCREDIA pricelist (TA-00).

5 SURVEILLANCE AND RENEWAL OF ACCREDITATION

5.1 SURVEILLANCE

During the accreditation cycle ACCREDIA-DL shall implement a program of assessments to evaluate by sampling the scope of accreditation and locations of the PTP in conformity with the

requirements of the standards and of those deriving from Regulation CE 765/2008 (ISO/IEC standards and EA/ILAC documents).

All accredited PTPs shall undergo surveillance activities both through programmed and non-programmed assessments in order to ascertain continued respect for this Regulation, the standards and international guidances and all other applicable normative references. To achieve this, all the assessment techniques provided for by the ACCREDIA Regulations can be used (for example: unannounced visits, mystery audit activities, Market Surveillance Visit, etc.) at the CAB and at clients' premises. Some assessment activities may be carried out by ACCREDIA also in remote mode.

In the case of extraordinary events that prevent the assessment from being carried out ACCREDIA-DL applies the applicable provisions issued internationally by EA/ILAC/IAF/ISO (e.g. IAF ID3, IAF ID12).

Regarding such assessments, all the PTP's locations shall be accessible for the ACCREDIA-DL assessment team.

Surveillance visits can also be carried out remotely. Except for situations attributable to the provisions of the document IAF ID3 (or other international provisions issued by ILAC or EA), the performance of the surveillances will be applicable under the following conditions:

- in the surveillance cycle at least one of the assessments must be carried out in presence or in mixed mode;
- in cases where the assessment carried out remotely proves unsatisfactory at the end of its performance, follow-up assessments must be carried out, with costs met by the CAB if it has agreed responsibilities which are included in the specific activities report (e.g. connection problems, lack of collaboration in providing evidence, etc.);
- the CAB has in any case the possibility of requesting ACCREDIA to replace the remote assessment, even if it is in a position to do it, with one in presence.

The possibility of carrying out the assessment completely remotely (or also in mixed mode) is subject to a risk assessment on the PTP and a feasibility check by ACCREDIA.

For example, it is not possible to conduct a remote assessment:

- where it is not possible to guarantee a stable internet connection;
- where the degree of computerization of the PTP, including its system and technical documentation, does not allow for adequate remote assessment;
- where it is not possible to follow the sampled activities remotely (e.g. performance of tests/calibration);
- where the PTP requests the conduct of the assessment activities in presence.

For the purposes of analyzing the feasibility of the remote visit, it may be necessary to carry out a simulation of how the assessment will be carried out by the PTP, especially in cases where experimental activities are planned both at its own premises, both externally and at those of the client.

5.1.1 Programmed surveillance assessment

The first programmed surveillance visit takes place **6 months** after the date of granting first accreditation. The subsequent visits take place **every 12 months** unless otherwise decided by the CSA due to the results of a previous surveillance or a renewal visit. The interval between the two assessments shall not be more than two years.

An allowance period of **more or less one month** is permitted for the performance of programmed surveillances with respect to the period communicated by ACCREDFIA-DL. Any deferment beyond this timeframe must be authorized in writing by the DDL and shall not be more than 6 months later than the originally programmed visit.

The surveillance procedure is opened by ACCREDIA-DL sufficiently in advance of the date of the assessment, and the PTP is requested to check its list of accredited schemes, also asking, if necessary, for an update (see § 5.1.3). The PTP has the option, during this phase, of requesting extension to its scope of accreditation (extension together with surveillance. See § 6.1.3).

The planning and the performance of the surveillance assessment are carried out with similar modalities to those used for the accreditation assessment, other than in cases as described below:

- the date of the assessment is agreed with the PTP by the lead assessor;
- a management representative may be present during the surveillances if considered necessary by the DDL, with the tasks as defined in § 3.6.1;
- during the phase of preparation of the surveillance of a PTP with flexible scope accreditation, the ACCREDIA-DL assessors shall always verify the detailed list managed by the PTP, to analyze the elements included in the flexible scope and to update, if necessary, the test sampling;
- during the surveillance visit, the implementation and effectiveness of the corrections and/or CAs opened during the previous visit are verified;
- if the surveillance visit results in the issuance of numerous and/or major NCs, ACCREDIA-DL may impose the sanction of partial or total suspension of accreditation in accordance with § 7;
- if the assessment is interrupted (see § 3.6.4.5) ACCREDIA-DL shall submit the case to the CSA DL for the possible imposition of sanctions in accordance with § 7.

On the basis of the results of the surveillance, the CSA decides regarding the maintenance of accreditation and plans the timeframe for the next surveillance. If the surveillance results are positive the CSA DL decides for the maintenance of accreditation, and if they are negative sanctions can be imposed (see § 7); the CSA DL can decide to perform an assessment which is supplementary to the scope in order to verify the closure of findings raised during the previous visit and the full implementation of corrections and/or CAs communicated by the PTP.

The supplementary assessment is organized using the modalities as for the supplementary assessment for initial accreditation (see § 4.2.1).

If the supplementary assessment has a positive outcome or if the PTP is not available for the performance of the supplementary assessment the procedure for maintenance goes ahead.

If the result of the supplementary assessment is negative or if the PTP is not available for the supplementary assessment **within one month of the deadline of completion of the plan for the management of findings** accepted by ACCREDIA-DL:

- if the findings raised in the assessment have not been effectively closed in the supplementary assessment, compromising the competence of the PTP, its accreditation is withdrawn, in accordance with § 7.3;
- if the findings raised in the assessment have not been effectively closed in the supplementary assessment regarding only one sector or specific tests, the CSA can decide for the maintenance of accreditation with a reduction of the scope of accreditation for that sector/scheme/activity.

In order to determine the audit days for the surveillance, ACCREDIA-DL conducts periodical risk analyses, on the basis of general indications defined in collaboration with the Steering and Guarantee Committee which has approved them and which include the following factors: the outcomes of previous assessments, (presence of Nonconformities, negative judgment of the sampled activities), any sanction measures, the management of complaints/feedbacks, criticalities of the management system and of the findings management plan, improper references to accreditation, presence of flexible accreditation, multi-site CAB, accreditation in the mandatory field, etc. The outcome of the assessment is communicated to the PTP with the notification of the granting/maintenance/extension/renewal.

5.1.2 Non-programmed surveillance assessments

Non-programmed assessments may be performed in the following cases:

- of significant changes to the PTP, which occurred after accreditation (e.g. transfer of offices, change of key persons, organizational changes, etc.);
- the need for on-site assessment of the resumption of activities after suspension or self-suspension (see §7.1.3);
- assessment of the maintenance of the accreditation conditions up to the date of renunciation (see §7.4);
- checks for changes in accreditation or regulatory updates, where the documentary examination referred to in §5.1.3 below is not sufficient;
- assessments of transition of the accreditation standard, if not conducted at the same time as scheduled surveillance or renewal;
- where the CSA decides additional assessment activities (including any unannounced audits), for example to verify the completion and effectiveness of the corrections and corrective actions to the findings issued by ACCREDIA.

The costs of these checks are met by the PTP, regardless of the outcome, in accordance with the pricelist.

Extraordinary non-programmed assessments may be performed if there are reasons to doubt that the accredited PTP is maintaining conformity to the standard UNI CEI EN ISO/IEC 17043 or, where applicable, to the standard UNI CEI EN ISO/IEC 17025 or UNI EN ISO 15189 and to the ACCREDIA regulations (e.g. following a complaint or feedback written and with objective motivation or situations of inadequacy of which ACCREDIA obtains knowledge. Advance notice of **7 working days** shall be given, within which time period the PTP may promptly exercise its right to object to any members of the ACCREDIA-DL assessment team. The costs of non-programmed visits are met by the PTP if the reasons for the assessment are well founded, if there are any NCs or numerous Concerns such as to result in a negative outcome of the assessment. In other cases, the costs are met by ACCREDIA-DL.

Other control methods may be adopted by ACCREDIA-DL to verify the operation of the PTP (e.g. checks directly on companies that operate in outsourcing for a PTP (where applicable); unannounced assessments at the PTP offices; mystery shopping or mystery audit; request for news from ACCREDIA to organizations or consulting firms, or other control methods). In cases where these activities are configured as additional activities or as a result of a NC issued or additional activities required by the CSA, the costs will always be met by the PTP regardless of the outcome. If, on the other hand, they derive from reports or complaints or from inadequate situations of which ACCREDIA has obtained knowledge, the costs are met by the PTP in cases where the reasons for the visits themselves are well-founded, The PTP shall also meet the costs if Nonconformities or a high number of Concerns are raised, resulting in a negative outcome of the visit. In other cases the costs are met ACCREDIA-DL.

In the case of unannounced assessments (VSP), the organization of the audit is carried out by ACCREDIA with the assessment team, without prior communication to the PTP. Once arrived at the PTP, the team will ask to be able to interface with a responsible/person in charge to whom it will explain the purpose of the assessment and to whom it will deliver:

- a communication from the of ACCREDIA-DL management, containing the reasons underlying this assessment;
- the assessment plan where the PTP will be able to record any objections/non-acceptances regarding the plan itself or the names of the ACCREDIA audit team.

The outcome of non-programmed assessments is submitted to the CSA DL for a decision with regard to the maintenance of accreditation, as is the case for programmed surveillances.

5.1.3 Changes to the scope of accreditation

The PTP can, at any time, ask ACCREDIA-DL to modify the PT schemes already under accreditation concerning:

- the denomination of objects, materials or products for testing;
- the denomination of measurands, quantities, measured properties;
- the number of accredited schemes.

If the PTP wishes to vary the scope accreditation it sends a written communication of such to ACCREDIA, using the module for the application for accreditation.

Upon receipt of the module and after positive verification of the request for modification ACCREDIA-DL revises the laboratory's accredited test list, except in cases where the need for an on-site audit does not emerge from the document review. In this case it is managed as a non-programmed surveillance (§5.1.2).

In cases of a negative evaluation or if, during normal work activities, ACCREDIA-DL finds errors in the PTP's accredited test lists, it shall inform the PTP, requesting revision of the list of schemes and/or the integration of documents. If the PTP does not resolve findings **within one month** of receipt of the communication or within the timeframe indicated by ACCREDIA-DL, ACCREDIA could impose sanctions for the proficiency tests in question (see § 7).

The modification involves the re-issuing of the accredited proficiency test schemes at no extra cost for the PTP and without requiring the performance of a document review on the PTP.

5.2 RENEWAL OF ACCREDITATION

If the PTP intends to renew its accreditation, it shall send to the ACCREDIA-DL Dept. of Testing Labs the application for accreditation with all applicable parts duly filled in and complete with the required attachments, **at least 8 months** before the expiry of the existing 4-year accreditation in order to organize the renewal assessment 3 to 4 months before, as a minimum, in advance of the certificate expiry date. Otherwise ACCREDIA cannot ensure continuity of accreditation beyond the certificate expiry date.

On receipt of the application for renewal of accreditation, ACCREDIA-DL will start the procedure with the same modalities as those used for the first accreditation, except in cases as set out in the paragraphs below.

5.2.1 Failure of receipt of the application for renewal and performance of the assessment in the established timeframe

If the application for renewal, with all the required attachments, is not received within the fixed timeframe and/or if the PTP is not available for the performance of the renewal visit before the expiry of accreditation, ACCREDIA-DL shall activate the renewal procedure, however the accreditation will lapse at the expiry date. After the decision issued by the CSA DL regarding renewal, a new accreditation number will be assigned to the PTP.

If the application for renewal, with the necessary documents, arrives in time to perform the assessment before the expiry of the existing accreditation, the validity of the accreditation can be prolonged by the CSA DL. The prolongation process, with adequate justification, can be repeated as long as the limit of 5 years of validity of the certification certificate has not been exceeded.

5.2.2 Appointment of assessors

Usually different assessors are used by ACCREDIA-DL for the assessment of a PTP from those used in the previous accreditation cycles.

5.2.3 Performance of the assessment

The implementation and effectiveness of the corrections and/or CAs from the previous assessment shall be verified.

5.2.4 Request for the plan for the management of findings

If, owing to lack of documental evidence, the second proposal of the plan for the management of findings is not suitable, ACCREDIA-DL will evaluate the imposition of suspension of the the accreditation as defined in § 7.1.

5.2.5 Evaluation of the results of the assessment

If there are NCs and/or numerous Concerns, the CSA DL may decide that it is necessary to carry out a supplementary assessment and/or the imposition of sanctions as defined in § 7 of this Regulation.

5.2.6 Supplementary assessment

If a PTP is not available to undergo a supplementary assessment **within one month from the final date of completion of plan for the management of findings** sent to ACCREDIA-DL, or if the supplementary assessment has a negative outcome, the CSA DL applies the following provisions:

- if the findings which were raised in the assessment were not closed effectively in the supplementary assessment and impact negatively on the competence of the PTP, the CSA DL decides regarding the withdrawal of accreditation and the closure of the renewal procedure, as described in § 7.3;
- if the findings which were raised in the assessment were not closed effectively in the supplementary assessment regarding only sector-specific and/or single interlaboratory PTs, the CSA DL can decide to grant renewal of accreditation excluding those sectors and/or proficiency tests.

5.2.7 Interruption of the assessment

If the assessment is interrupted (see § 3.6.4.5) ACCREDIA-DL shall present the file to the CSA DL for the imposition of the withdrawal of accreditation of the PTP as defined in § 7.3.

5.2.8 Decision-taking process and the granting of renewal of accreditation

Operations take place in a similar way as for the process of accreditation (see § 4) except for cases as described below.

In cases of a negative decision by the CSA DL the process continues, either with the reduction or withdrawal of accreditation, applying the requirements of § 7.2 or § 7.3 of this Regulation.

6 EXTENSION OF ACCREDITATION

An accredited PTP may, during the period of validity of the accreditation, request ACCREDIA-DL to extend the accreditation to other interlaboratory PT schemes.

6.1 PROCEDURE FOR THE EXTENSION OF ACCREDITATION

To extend accreditation a PTP shall present to ACCREDIA-DL the following documents:

- The application for accreditation giving the new data concerning the tests for which extension is requested (e.g. list of schemes for extension, parameters, matrices, calibration, typology etc.) and the relative attachments;
- the new internal test/calibration methods of distribution together with the relative declarations of validation, when applicable (only if the PTP has an internal lab which is not accredited for the specific tests/calibrations);
- the procedures describing the general criteria for the management of data and the evaluation of the performance of the labs, if revised for the new schemes undergoing extension;
- the latest PT report interlaboratory PT issued for schemes undergoing extension;
- if automatic extension is requested (§ 6.1.1), the documentation describing the scheme design, the evaluation of the homogeneity and stability of the items of the test and the statistical approach used for the evaluation of data;
- in cases of extension of locations: the application for accreditation and the attachments for the accreditation of multisite laboratories (see RG-02-01);
- in cases of extension of accreditation with the flexible scope: the application for accreditation and the attachments as required by Reg. RT-26.

On receipt of the application for extension, ACCREDIA-DL decides if the accreditation of the tests for which extension is sought can be granted to the PTP:

- without a specific assessment visit (postponing the checks to the next surveillance visit), see § 6.1.1;
- following the satisfactory outcome of a specific assessment (see § 6.1.2 or 6.1.3).

The document review of the application for extension is performed using the same modalities as for accreditation (see § 3.3). In particular, if the result of the document review is negative, the PTP shall send to ACCREDIA-DL the revised document **within 8 months** of receipt of the first request for additional information; if this is not done the extension procedure is closed.

6.1.1 Automatic extension

Automatic extension may be granted in cases where the tests for which extension is sought are similar to those already accredited (e.g. same preparation, handling, management of samples etc.).

The PTP seeking automatic extension shall specify in the application, the criterion of similarity considered (e.g. aspects in common with already accredited schemes).

If ACCREDIA-DL acknowledges that the tests for which extension is sought are similar to those already accredited, the DDL, after consulting the competent technical assessor, proposes to the rapporteur member of the Sector Accreditation Committee an automatic extension for the PT schemes requested by the PTP, postponing the relative control to the time of the performance of the initial surveillance visit.

If the Sector Accreditation Committee member rapporteur approves the request, ACCREDIA-DL notifies the PTP of the approval of extension of accreditation, attaching to the communication the revised list of accredited PTs. If the extension file is assigned to an expert of the DL CSA, the results of the assessment of the CAB will be discussed in the first due meeting of the CSA DL, for the extension decision.

6.1.2 Ad hoc extension

When the conditions as set out in § 6.1.1 do not occur, the PT schemes regarding the extension shall be verified in the course of a specific assessment at the PTP.

The organization of the ad hoc extension assessment and the decision-taking process are the same as those for surveillance. The DDL decides the composition of the assessment team.

6.1.3 Extension combines with the surveillance assessments

If the PTP intends to combine the scheme extension and first surveillance visit, it shall present a request for extension at least 3 months before the expiry of the surveillance.

In such cases the extension procedure is activated together with the surveillance procedure.

6.1.4 Decision-taking process and the granting of extension of accreditation

The activities take place using the same modalities as those for the process of accreditation (see § 4) except in cases as defined below.

Following the granting of extension of accreditation, ACCREDIA-DL updates the list of accredited schemes to include the new scope of accreditation.

The extension of accreditation does not prolong the validity of the accreditation. The existing accreditation agreement does not have to be signed once again.

7 SUSPENSION, REDUCTION AND WITHDRAWAL OF ACCREDITATION

ACCREDIA-DL may impose sanctions of suspension (partial or total), reduction or withdrawal of accreditation, in critical cases, either technical or professional, following surveillance, supplementary, extraordinary or renewal assessments or other controls (e.g. resulting from feedbacks).

In conformity with the statutory and regulatory documents and regulations, the sanctions and their duration are decided by the CSA DL.

The decisions of the CSA DL relating to suspension/withdrawal/reduction are communicated to the PTP concerned, within **5 working days** from the date of the decision, by registered mail, or by certified email and subsequently published on the website.

The PTP shall inform its clients involved with regard to the imposition of a sanction.

7.1 SUSPENSION

Suspension of the accreditation may regard all the accredited testing schemes (total suspension) or some of them (partial suspension) and, in the case of multisite PTPs, it may involve one or more accredited locations.

In the case of accreditation with flexible scope (see RT-26), suspension may regard:

- the accredited schemes with flexible scope (schemes which are indicated in a generic way): in such cases the suspension includes the scheme in the flexible scope (generic) and all other related schemes. The PTP shall eliminate from its list all the related schemes regarding the suspended scheme with flexible scope. This situation constitutes the only case in which a flexible scheme does not have at least one associated scheme;
- one or more related schemes: in such cases the PTP shall eliminate from its list all the schemes related to the object of the suspension, maintaining only those not involved by the suspension. Due to the fact that every scheme with flexible accreditation must have at least one associated scheme, if the suspension regards all the related schemes the PTP shall also suspend the generic scheme in the flexible scope.

Suspension may be imposed by ACCREDIA-DL or requested by the PTP.

Partial suspension involves, for the PTP, termination of the right to issue test reports under ACCREDIA accreditation for the suspended schemes. Total suspension involves, for the PTP, termination of the right to declare accreditation and to issue interlaboratory PT reports under ACCREDIA accreditation.

During the period of suspension, the PTP shall conform with the requirements of the regulation regarding use of ACCREDIA's mark (RG-09).

Suspension is published on ACCREDIA's website by means of an asterisk (*) next to each suspended test.

Suspension does not alter the scheduling of the surveillances. However, if the suspension of accreditation is total, during the period when it is in force no assessments are conducted except for those for verifying the removal of the causes of the suspension. In all cases all the surveillance assessments programmed for the accreditation cycle shall be performed.

If suspension is continued for **over 6 months**, ACCREDIA-DL shall reduce the accreditation for the PTs in question or, if the accreditation has been suspended for all PTs, ACCREDIA starts the process for the withdrawal of accreditation.

Suspension does not involve the termination of contractual obligations concerning ACCREDIA.

7.1.1 Suspension decided by ACCREDIA-DL

Partial or total suspension of accreditation may be decided by the CSA DL if there are numerous and/or grave findings raised during the assessment or document review. In cases of particular urgency and criticality, suspension of one or more schemes may be decided by the DDL after consultation with the competent rapporteur. Such measure shall be communicated to the CSA DL at the first due meeting.

Reasons for which the CSA DL may decide to impose partial or total suspension include:

- a) non-observance of the requirements of the accreditation standards, the requirements of this General Regulation, of the specific regulations for the accreditation standard and the accreditation agreement;
- b) failure to return the acceptance of the accreditation agreement;
- c) unavailability of the PTP for the performance of the supplementary assessment in the timeframe set by ACCREDIA-DL;
- d) unavailability of the PTP for the performance of the supplementary assessment communicated by ACCREDIA-DL within one month of the date of completion of the plan for the management of findings accepted by ACCREDIA-DL;
- e) negative outcome of an assessment;
- f) failure to send the plan for the management of findings within the timeframe set unless with motivated justification;
- g) failure to resolve the findings in accordance with ACCREDIA-DL's procedures;
- h) failure to update the list of accredited tests following remarks made by ACCREDIA DL (see § 5.1.3);
- i) failure to send objective evidence regarding the implementation of corrections/CAs considered acceptable within the timeframe agreed with ACCREDIA-DL;
- j) failure to implement corrections/CAs in cases of reports of tests/reports which have been unduly issued;
- k) failure or ineffective management complaints/feedbacks received by ACCREDIA;
- l) improper use of the ACCREDIA mark or reference to accreditation;
- m) significant modifications made subsequent to an assessment and/or failure to communicate them to ACCREDIA-DL;
- n) change of location of the PTP (see § 9.1);
- o) failure to promptly notify ACCREDIA DL of the loss of the key figures identified by the PTP;
- p) change of legal identity (change of name, transfer of ownership of accreditation);
- q) contractual insolvency.

In cases of contractual insolvency (case "q"), the total suspension of accreditation is applied automatically by ACCREDIA's General Director without submission to the CSA DL in cases where payment owed to ACCREDIA is **more than 60 days** late with respect to the date set by the contract (payment date in the invoice), despite a reminder from ACCREDIA at the end of the **45th day** of delay. Exception is made if payment is deferred following authorization by the ACCREDIA General Director.

7.1.2 Suspension requested by the PTP (self-suspension)

The PTP may ask ACCREDIA-DL for the application of partial or total suspension of accreditation at any time. In particular, it shall suspend the accreditation of one or more tests and communicate this to ACCREDIA in cases of:

- nonconformity or failures which could cast doubt on the validity of the results of accredited tests (e.g. negative evaluation of participation at inter-laboratory circuits etc.);
- temporary unavailability or deterioration of resources for accredited tests (e.g. personnel, rooms, equipment etc.);
- significant changes (which impact on the competence of the CAB and/or on the information reported on the accreditation certificate) that have occurred with respect to what was previously communicated with the application for accreditation (e.g. change in key figures, etc.);
- changes in the legal entity (e.g. change of corporate name, transfer of ownership);
- relocation of site.

The request for self-suspension shall be sent to ACCREDIA-DL (using the appropriate module available in ACCREDIA's website) specifying the reasons and the plan for restoration of accreditation. The reasons and duration regarding the request are evaluated by the DDL who may modify and/or add to the conditions and timelines for the restoration of conformity, performing the necessary verifications to ensure full return to conformity at the end of the period of self-suspension.

The request for self-suspension of accreditation shall be communicated at the first due CSA DL meeting.

7.1.3 Annulment of suspension

If the PTP believes that it has eliminated the causes of the suspension it can ask ACCREDIA-DL to examine the possibility of annulling the suspension, attaching the documents as evidence that the causes of suspension have been eliminated.

After receiving the request for annulment, on the basis of the reasons for suspension, ACCREDIA-DL performs the assessment of resolving of the causes of the suspension by means of one or more of the following actions:

- a review of the PTP's documents;
- an on-site assessment.

Following verification of the return to conformity of the PTP's system, the positive outcome is presented to the first due meeting of the CSA DL which decides with regard to the annulment of suspension.

In cases of self-suspension and it is not necessary to perform an on-site assessment the annulment of suspension is approved by the DDL who informs the first due meeting of the CSA DL to this effect.

The annulment of suspension is communicated in writing to the PTP and the list of accredited PTPs on ACCREDIA's website is updated accordingly.

If the verification performed by ACCREDIA-DL did not ascertain the effective resolution of the causes of the sanction or if the duration of the suspension is over 6 months, the case is submitted to the CSA DL for the imposition of a sanction of reduction of accreditation in cases of partial suspension and withdrawal of accreditation in cases of total suspension.

7.2 REDUCTION OF ACCREDITATION

Reduction of a PTP's accreditation means the elimination of a part of its scope of accreditation, and it can therefore affect one or more accredited schemes and/or accredited sites. Consequently a revision is performed of the list of accredited schemes and, in cases of a reduction of locations, of the certificate of accreditation.

Following the reduction of accreditation, the PTP shall immediately cease to make any reference to accreditation for the schemes in question and it shall not issue PT reports with the ACCREDIA mark and/or reference to accreditation.

The reduction of accreditation may be required by ACCREDIA-DL, following a decision taken by the CSA DL, or following request by the PTP.

7.2.1 Reduction decided by ACCREDIA-DL

The CSA DL, on the basis of the outcome of assessments or after the 6 months of partial suspension of accreditation, may exclude from the scope of accreditation one or more PT schemes.

If the PTP chooses to seek accreditation again for the excluded schemes, it may, after successfully eliminating the cause of the reduction of accreditation, present the application for extension of accreditation in accordance with § 6.

7.2.2 Reduction requested by the PTP (self-reduction)

The PTP may, at any moment, request the reduction of accreditation for one or more interlaboratory PT schemes.

The request for a reduction of tests shall be sent to ACCREDIA-DL using the application for accreditation module.

The assessments conducted by ACCREDIA-DL particularly with regard to their possible impact on accredited schemes and the modalities of revision of the list of accredited schemes are the same as those used for modifying the scope of accreditation as set out in § 5.1.3 of this Regulation.

7.3 WITHDRAWAL OF ACCREDITATION

The motivations for which ACCREDIA-DL may decide to withdraw the PTP's accreditation are related to failure to fulfill, persistently and gravely, the rules or requirements for accreditation.

The motivations leading to withdrawal include as follows:

- a) failure to resolve the causes of the problems which led to the suspension;
- b) exceeding 6 months of total suspension of accreditation;
- c) failure to respect the accreditation agreement;
- d) objective situations which would have impeded the signing of the accreditation agreement;
- e) failure to pay sums owed when the PTP continues to fail to meet its payment requirements over 6 months after the imposition of the sanction of suspension as per § 7.1.1;
- f) negative outcome of a supplementary surveillance assessment;
- g) interruption of the accreditation renewal assessment;
- h) negative decision regarding the accreditation renewal assessment on the part of the CSA DL;
- i) expiry of accreditation if the PTP has not begun, in due time, the procedure for renewal and/or successfully undergone the assessment;
- j) evidence that the obligations of competence, impartiality and good working practices of the PTP have not been verified;
- k) illicit, damaging or improper professional behavior by the PTP;
- l) evidence of fraudulent activities or that the PTP intentionally provides false information or that it conceals information;
- m) use of accreditation by the PTP such as to gravely damage and discredit ACCREDIA and/or the accreditation/certification system;
- n) financial failure of the PTP;
- o) cessation of activities of the body in which the PTP operates, for whatever reason;
- p) renunciation on the part of the PTP (see § 7.4);
- q) situations that make it impossible to conduct an on-site assessment at the laboratory within a period of two years from the previous visit.

It is also possible to withdraw an accreditation, at the sole discretion of ACCREDIA, for geopolitical reasons, in the application of the regulations concerning international decisions (e.g. sanctions).

The President of ACCREDIA informs the PTP of the decision by the CSA DL by means of registered post or certified email and published on ACCREDIA's website.

Withdrawal of accreditation involves the following actions with immediate effect:

- a) removal of the PTP from the database of accredited bodies on ACCREDIA's website;
- b) loss of the right to declare itself an accredited testing/medical PTP;
- c) loss of the right to use the ACCREDIA mark and/or reference to accreditation.

The QRcode on the accreditation certificate makes the withdrawal of the accreditation and its effective date traceable, also after removal from the database of accredited laboratories on the ACCREDIA website.

The PTP shall not use any copies or reproductions of certificate of accreditation and it shall conform with the regulation regarding use of the ACCREDIA mark.

Withdrawal of accreditation does not nullify the PTP's contractual obligations towards ACCREDIA which reserves the right of enforced recovery of expenses, plus interest, in keeping with the applicable laws.

In cases of withdrawal of accreditation the PTP cannot present a new application before 6 months after the date of the withdrawal decision of the CSA DL, unless otherwise decided by the CSA DL.

In cases of withdrawal of accreditation owing to fraudulent activities or false information, the PTP cannot present any further application for accreditation.

7.4 RENUNCIATION OF ACCREDITATION

An accredited PTP may renounce accreditation at any time and for any reason (e.g. non-acceptance of changes to the pricelist or of modifications to the rules governing accreditation activities etc.).

The PTP intending to renounce accreditation shall send written notification, returning its accreditation certificate and it shall comply with the requirements of the accreditation agreement.

The following conditions are applicable if the PTP intends to renounce accreditation for a period subsequent to the communication:

- the PTP may operate under accreditation until the moment of the withdrawal decided by the CSA DL;
- ACCREDIA-DL may decide to perform, in addition to the normal assessments of the period in question, other ones (e.g. assessment for the maintenance of accreditation until expiry);
- ACCREDIA-DL may ask for further assurances to be certain that the activities, until the withdrawal of accreditation, are properly conducted (e.g. closure of any findings still open, the performance of unannounced assessments etc.).

Withdrawal resulting from renunciation of accreditation requested by the PTP is deliberated by the CSA DL unless the renunciation is presented at the same time as the expiry of the certificate. In such cases the DDL acknowledges the decision by the PTP and informs the CSA DL.

The decision regarding withdrawal is published on the ACCREDIA website and the PTP is removed from the database of accredited bodies.

The renunciation of accreditation does not nullify the contractual obligations towards ACCREDIA, which reserves the right of forced recovery the sums due, with interest, in accordance with the applicable laws.

8 COMPLAINTS, FEEDBACKS, RESERVATIONS AND APPEALS

8.1 COMPLAINTS AND REMARKS

ACCREDIA-DL may receive complaints/remarks regarding:

- ACCREDIA's own operations;
- the operations of other accredited PTPs,
- the activities of third parties related to the management of interlaboratory PT schemes on the part of accredited or applicant organizations.

Within **30 calendar days** from receipt of the complaint/feedback, ACCREDIA-DL shall, after evaluating the causes and validity of the complaint/feedback, decide whether to accept or to reject it. These procedures ensure that the examination and management of the case are carried out by personnel who are independent of the subject of the complaint/feedback.

Complaints/feedbacks which are sent anonymously will not be accepted so as to avoid the possibility of speculative actions which are disruptive of competition.

With regard to the behavior of the ACCREDIA-DL assessors (internal and external), any complaints/feedbacks must be presented within **10 working days** of the performance of the assessment.

PTPs may signal to the Surveillance Body any behavior in conflict with the Code of Ethics and Conduct on the part of ACCREDIA-DL staff using the appropriate section in ACCREDIA'S website.

Using the same criteria and modalities, ACCREDIA-DL deals with improper activities related to third parties which are not attributable to ACCREDIA-DL and/or to PTPs accredited by ACCREDIA, but which, nevertheless, are related to accreditation.

8.2 RESERVATIONS

With reference to the findings raised by the ACCREDIA-DL assessors, any reservations must be presented **within 3 working days** of the conclusion of the assessment.

The presentation of a reservation does not exempt the PTP from the management of the findings not subject to the reservation.

ACCREDIA-DL sends to the PTP which presented the reservation, the outcome of the evaluation undertaken, indicating acceptance or non-acceptance and specifying the motivations.

Acceptance or non-acceptance of reservations formulated by the PTP is submitted to the DDL.

8.3 APPEALS

If an accredited or applicant PTP wishes to ask ACCREDIA-DL to reconsider sanctions imposed on it (see § 7), it can lodge an appeal using the modalities set out in ACCREDIA document RG-06, which also includes any cases of inadmissibility.

The management of appeals is the responsibility of the Appeals Commission and it does not require any involvement on the part of the CSA DL which is nevertheless informed regarding their presentation and result. During the appeal process all decisions concerning the accreditation files of the PTP (renewal, transition, extension etc.) are taken by the Appeals Commission, acting in place of the CSA DL.

ACCREDIA-DL undertakes, where required, to report any appeals received from accredited/applicant CABs operating in certain areas to the competent authorities (e.g. Ministries) and to provide a response concerning management of the appeal.

9 OBLIGATIONS OF THE PTP

Regarding matters not covered by this Regulation, article 4 of the contractual accreditation agreement is applicable.

The following obligations apply:

- the PTP commits to pay the annual maintenance fees for accreditation as defined in the pricelist;
- the PTP commits to maintain conformity with the requirements of accreditation and shall constantly maintain behavior based on correctness, transparency and collaboration with ACCREDIA. It shall inform ACCREDIA if it is no longer in a position to be able to meet the accreditation requirements;
- the PTP shall permit the performance of assessments by ACCREDIA-DL at its location/s and other places where testing activities take place;
- the PTP shall formally communicate to ACCREDIA-DL any operative or corporate changes, properly documented, which affect its activities (see § 9.1 and § 9.2);
- the PTP shall possess a procedure identifying the responsibilities and operative modalities followed for the inclusion of every new element within its flexible scope (where applicable), in accordance with RT-26. The PTP shall demonstrate that it possesses and applies a process of design of its flexible scope with regard to the introduction of new tests within the flexible part of the scope of accreditation;
- the PTP shall respect all the applicable safety requirements in accordance with the relevant normative requirements and shall give to ACCREDIA-DL, during the programming phase of on-site activities, detailed information concerning the safety and emergency measures by sending the module MD-19 as indicated in § 3.5.2;
- the PTP shall promptly inform ACCREDIA-DL regarding all pending legal actions regarding activities covered by accreditation. The PTP shall also promptly inform ACCREDIA-DL regarding any administrative or legal proceedings related to its internal and/or external staff regarding activities covered by accreditation. The PTP shall not send to ACCREDIA-DL any legal data, in accordance with the privacy laws and regulations;
- the PTP shall collaborate with regard to the analysis and resolution of complaints communicated to it by ACCREDIA-DL concerning its accreditation.

9.1 GENERAL CORPORATE VARIATIONS

The PTP shall notify ACCREDIA, using the appropriate forms (MD-09-29-DL and relevant annexes), with regard to any changes made with respect to what was previously communicated with the application for accreditation (e.g. change of key figures in the organization, change of corporate name, change of location, etc.). In the event of significant changes (which impact on the PTP's competence and/or on the information reported on the accreditation certificate) the PTP must immediately self-suspend and notify ACCREDIA.

Following receipt of the documents sent by the PTP, ACCREDIA-DL shall verify that the changes do not involve nonconformities with respect to the requirements of independence and impartiality requirements or impact the management system or the technical competence of the PTP.

In cases of major changes which impact the management system and/or the technical competences of the PTP, the DDL may establish rules and/or arrange for the performance of a non-programmed assessment, or, if necessary, bring forward the date of the programmed assessment (see § 5.1).

9.1.1 CHANGE OF CORPORATE NAME

In the case of changes in the corporate name (with or without a change in the legal entity), the CAB is required to notify ACCREDIA **within 7 days of signing the deed**, using the appropriate modules and the related annexes.

Upon receipt of the documentation, ACCREDIA proceeds as indicated in the following paragraphs.

9.1.1.1 *Without change to the legal identity (without modification of the VAT number)*

This includes changes which do not involve variations of the legal identity, i.e. of the VAT or fiscal code number (e.g. change of name of the PTP, liquidation, failure etc.).

Following a positive evaluation of the PTP's documents ACCREDIA-DL updates the accreditation certificate and the list of accredited interlaboratory PTs, except in cases of failure, for which the withdrawal of accreditation is applied. Any variations introduced do not change the expiry date of the accreditation certificate.

9.1.1.2 *With change to the legal identity (with modification of the VAT number)*

Change of name of a PTP and of the VAT number involves a variation to the legal entity which possesses the accreditation, and therefore it is necessary to transfer the accreditation to a new legal entity.

For the transfer of ownership of accreditation to a different legal entity see § 9.2.

9.1.2 Change of location and/or contact details

This type of variation includes, for example, changes of address of the registered office and/or operative locations, street/place name, due to relocation or other changes to contact details.

Following a positive evaluation of the PTP's documents ACCREDIA-DL updates the PTP's data in its database and on the ACCREDIA website and ACCREDIA-DL revises, where necessary, the accreditation certificate and the list of accredited interlaboratory PTs.

Change of address of an operative location due to relocation involves an effective variation to the location where accredited activities are performed. This may be performed as a document review or an on-site assessment (non-programmed or with a surveillance/renewal assessment) and it is established by the DDL taking into consideration the results of previous assessments, any criticalities, relocation times, typology of accredited tests and the schedule for surveillance visits. This activity is invoiced in accordance with the ACCREDIA pricelist in force.

9.1.3 Changes to the PTP's organizational set-up

The PTP shall communicate all substantial variations to its organization with respect to the information provided in the application for accreditation, such as management tasks and/or management system, personnel authorized to sign/authorize reports and PT reports, the staff member responsible for communication with ACCREDIA-DL and any replacements.

9.2 TRANSFER OF OWNERSHIP OF ACCREDITATION

The accreditation ownership may be transferred to a new legal identity in accordance with the conditions and modalities described below.

Transfer of ownership of accreditation may take place due to corporate changes such as the ceding of an organization or branch of an organization, merger, or other legal operation which involves changes to the fiscal code and/or VAT number, following evaluation by ACCREDIA-DL regarding the maintenance of conditions of accreditation, verifiable by means of the following documentation:

- Chamber of Commerce profile or equivalent document attesting the PTP's legal identity;
- copy of the legal deed setting out the transfer of resources pertinent to the activities for accreditation to another legal entity (e.g. premises, personnel, equipment);
- organizational set-up;
- human resources (in terms of quantities and competences);
- all other applicable conditions.

The request to change the ownership of accreditation may be accepted in the absence of pending legal actions towards the initial owner of accreditation, unless the receiving entity does not take on jointly the responsibility related to the situation.

The assessment shall be based on the document review sent by the PTP, unless the complexity of the changes makes an on-site assessment necessary.

The activity shall be invoiced in accordance with the ACCREDIA pricelist in force.

The granting of the transfer of the ownership of accreditation is the exclusive decision of the CSA DL which examines the outcomes of the assessments performed and may also request others.

The CSA DL grants the transfer of the ownership of accreditation from the date of the decision of the CSA DL unless the start is fixed for a later date.

During the period of absence of accreditation, if there is one, i.e. if the variation has been completed before the communication to ACCREDIA-DL and/or of the relative decision, no activities under accreditation whatsoever shall be undertaken by neither of the two legal entities until accreditation is obtained by the new legal entity.

Therefore, following communication sent by the PTP, the ACCREDIA-DL communicates the need, if necessary, to suspend accreditation until the decision of the CSA DL regarding the transfer of ownership of accreditation.

If the outcome of the evaluation by the CSA DL is positive, ACCREDIA-DL shall arrange to send the new accreditation agreement and to update the certificate and the list of accredited PT schemes. Such changes do not alter the expiry date of the accreditation.

If the outcome is negative, ACCREDIA-DL shall communicate the failed transfer of accreditation of the PTP's accreditation and shall start the procedure for the withdrawal of accreditation, except in cases where the accreditation can be confirmed under the original ownership as before.

9.3 TRANSFER OF ACCREDITATION BETWEEN ACCREDITATION BODIES

A PTP intending to request ACCREDIA-DL for transfer of accreditation to another AB signatory to the IAF MLA-ILAC MRA agreements shall present an application for accreditation in accordance with the modalities set out in § 3 together with all the necessary documentation and the latest assessment report of the previous AB and the active certificate of accreditation.

The process of transfer of accreditation involves using the same modalities as for the process of accreditation. However during the phase of the granting of accreditation, the CSA can decide to perform a first surveillance assessment 12 months from the granting of accreditation.

If the PTP intends to ask ACCREDIA-DL for the transfer of accreditation from an AB which is not signatory to the EA MLA agreements, all the requirements for accreditation shall be applicable.

With the transfer, the PTP ceases to use the accreditation and it starts accreditation with ACCREDIA.

10 OBLIGATIONS OF ACCREDIA

Regarding matters not specifically covered by this Regulation, article 3 of the contractual accreditation agreement (CO-00) is applicable.

10.1 CHANGES TO THE CONDITIONS OF ACCREDITATION

If the ACCREDIA documents are revised and there is no indication otherwise in the informative communication of the revision, there is a 3-month transition period for the PTP to adapt its operative modalities to the new requirements, as applicable.

The PTP can decide within the 3 month period or within the transition period allowed by ACCREDIA, not to fulfill such requirements and, therefore, to annul its accreditation. In these cases, it shall inform ACCREDIA-DL in writing in accordance with the modalities defined in the accreditation agreement.

The starting date of the transition period is the date of publication of the information on the ACCREDIA website.

10.2 CHANGES TO THE PRICELIST

The costs of accreditation activities are established by the ACCREDIA Directive Council and are stated in the ACCREDIA pricelist.

In cases of changes to the pricelist, even if the quotation has been accepted by the PTP, the services are still invoiced at the time of the activity in question. If prices are changed, immediately after approval from the Inter-ministerial Surveillance Commission, the PTP is informed accordingly (by email or certified email) and the updated pricelist is published on ACCREDIA's website.

The PTP can renounce accreditation within 6 months of receipt of this communication, during which period the PTP which chooses renunciation is charged in accordance with the costs preceding the changes introduced only for the activities undertaken until the time of renunciation.