TITLE **REGULATION FOR THE ACCREDITATION OF TESTING LABORATORIES AND MEDICAL LABORATORIES**

REFERENCE **RG-02**

REVISION **08**

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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

APPLICATION DATE

01-02-2023

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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 assessing and attesting the conformity of testing and medical laboratories 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:

- testing laboratories operating in conformity with the requirements and with the standard UNI CEI EN ISO/IEC 17025 and with the applicable ACCREDIA, EA and ILAC documents;
- medical laboratories operating in conformity with the requirements of the standard UNI CEI EN ISO/IEC 15189 and the applicable ACCREDIA, EA and ILAC documents,

ensuring that the laboratories possess and maintain fulfillment of the organizational, procedural, technical and professional requirements such as to foster, among all interested parties and, in particular, consumers, a high level of trust in their activities 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, the ACCREDIA-DL has defined rules and criteria for the application of the normative references, formalized by means of the present 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 reference standards UNI CEI EN ISO/IEC 17025 or UNI EN ISO 15189 and other applicable documents is intended to benefit the creation and maintenance of the trust of clients in the testing activities of accredited laboratories and the impartiality and integrity of their associated technical and commercial operations.

Accreditation attests the technical competence of a laboratory to carry out the tests/exams set out in the scope of accreditation and the implementation at the laboratory of a quality management system in line with the principles of UNI EN ISO 9001.

Laboratories with ACCREDIA-DL accreditation are considered competent to undertake testing activities also in support of the 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 of accredited bodies 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:

- testing laboratories;
- medical laboratories;

hereafter referred to collectively as "laboratories".

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

The specific procedural requirements and modalities for the accreditation of multisite testing and medical laboratories 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 laboratory'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 laboratory and the relative data in the ACCREDIA database of accredited laboratories;
- the laboratory shall conform with the requirements of this Regulation and maintain conformity throughout the cycle of accreditation which is fixed at 4 years.

The specific circulars/provisions that are issued by ACCREDIA, including the clarifications and details illustrated in the presentations of the annual congresses, must also be considered as a contractual obligation in the relationship between ACCREDIA and the accredited and applicant bodies, pending the implementation by means of specific 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 the standardization bodies;
b) any applicable provisions deriving from resolutions adopted by the general assemblies of EA and ILAC (see the document EA-INF/17);
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 the laboratories regarding the issuance of provisions by means of circulars/notifications.

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

- the FAQ issued by the EA Laboratories Committee, by the ILAC Technical Committee and by the 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 performed by sampling – that the laboratory possesses the competence required (in terms of organization, procedures and documents, human and instrument resources) for the performance of its test/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 laboratory is competent, impartial and consistent, concerning its rules in carrying out conformity assessment activities.

It is the responsibility of the laboratory 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 Guarantee Committee is also involved in the process in a consulting capacity.

1.2 NORMATIVE REFERENCES

The normative references for the application of the present Regulation are given in the ACCREDIA-DL document LS-04 *"Standards and reference documents for the accreditation of testing laboratories, medical laboratories and interlaboratory proficiency testing providers",* including all the applicable ISO, ILAC and EA documents cited in the revision in force. It is the responsibility of the laboratory to verify and use these documents in the versions in force.

It follows that – within the ambit of a determined accreditation scheme – the use of the present 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 Committee of Control and Guarantee (RG-05);
- Regulation for the proceedings of the Commission of Appeals (RG-06);
- Regulation for the use of ACCREDIA Mark (RG-09);
- Accreditation pricelist (TA-00);
- Contractual accreditation agreement (CO-00);
- Application for Accreditation (DA-00);
- Application for accreditation for Testing Laboratories (DA-02);
- Application for accreditation for Medical Laboratories (DA-08);
- Application for Accreditation for CABs and Testing Laboratories for notification purposes according to Reg. (EU) 305/2011 (DA-13);
- ACCREDIA Technical Regulations, as applicable;
- Applicable technical Documents (DT);
- EA, ILAC and other documentation applicable to testing laboratories and medical laboratories;
- Mandatory normative documents and regulations, as applicable;
- Informative/technical circulars.
- Operative instructions of the on-line applications for the testing laboratories, for the presentation of the application (DA-online) and for the management of the assessment and post-assessment activities (application 3A).

Each of the above documents is applicable in the current revision. ACCREDIA documents are freely downloadable from the documents area and/or the reserved area for laboratories in the ACCREDIA 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, point 10 and subsequent additions/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/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, paragraph 13 and subsequent additions/amendments. For the purpose of the present Regulation a CAB is intended as a testing or medical laboratory.

Laboratory: a legally recognized entity or a part of one (e.g. department, location area etc.) with unequivocal identification. In this document, unless otherwise indicated, the term "laboratory" means a laboratory which carries out **tests/samplings** (testing laboratory) and also a laboratory which performs **examinations** (medical laboratory).

Testing laboratory: a laboratory which carries out chemical, microbiological, mechanical, electronic, physical tests etc. or sampling related to a successive test (see RT-08).

Medical laboratory: a laboratory for exams carried out on materials derived from the human body with the aim of providing information concerning the diagnosis, prevention and treatment of illnesses and the evaluation of the health of people, and which can provide a service of consultancy covering all aspects of the laboratory's research including the interpretation of results and suggestions regarding further examinations.

NOTE: These examinations include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms.

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

NOTE: in the case of testing and medical laboratories the scope of accreditation consists of the list of tests/exams requiring the attestation of the laboratory's technical competence. The list, which is attached to the certificate of accreditation, describes the testing materials/matrices/products, the quantities to determine (e.g. measurands) and the testing methods and procedures of examination used by the laboratory.

Fixed scope of accreditation or fixed field of application of accreditation: description of the scope of accreditation giving full details of the activity (test/sampling/exam) in terms of testing materials/matrices/products, quantities/parameters to determine, the testing methods and procedures of examination used and the category of the test.

Flexible scope of accreditation or flexible field of application of accreditation: more general description of the scope of accreditation, regarding the testing materials/matrices/test products/exam or the parameters, quantities to determine, accepting the possibility, on the part of the CAB, on the basis of competences possessed and previously assessed, with a positive result, for accreditation, to modify the field of application of the testing methods developed by the accredited laboratory, to use new revisions of the accredited methods (if the testing technique is the same as the previous revision) or to add new methods based on the same techniques as those already accredited.

Testing: determining one or more characteristics of an object of conformity assessment in accordance with a procedure. A test is defined by the testing materials/matrices/products, the quantities/parameters, the testing methods used and the category. For the purpose of this document, unless otherwise indicated, the term "test" is taken to mean also "sampling related to a subsequent test" (see RT-08).

Examination: the set of operations performed by a medical laboratory with the aim of determining the value or characteristics of a property. An exam is defined by the materials/matrices, quantities/parameters, exam procedures and the category.

NOTE 1: in certain fields (e.g. microbiology) the exam is the total activity of a number of tests, observations and measurements.

NOTE 2: the exams of laboratories which determine the value of a property are known as quantitative exams. Those which determine the characteristics of a property are known as qualitative exams.

NOTE 3: the laboratory exams may also be described as tests.

In the present document, unless otherwise indicated, the term "test" is used with the same meaning as "examination" (or "exam").

Site: facility where the laboratory activities are carried out. A site can be a permanent, temporary or mobile facility of the Laboratory or a site outside the permanent facilities of the Laboratory. The sites where laboratory activities are carried out are reported on the accreditation certificate and in the relative attachments.

Test categories: modalities for the classification of tests/exams, relating to the place of performance and the management modalities.

- **Category 0**: tests carried out at the laboratory, either tests or medical tests;
- **Category 1**: tests carried out at a temporary location of a testing laboratory, equipped in a fixed place and operating for a period of time which is limited and defined in advance;
- **Category II**: tests carried out using a mobile site of testing of a testing laboratory equipped to perform certain specific tests;
- **Category III**: tests carried out by laboratory personnel at locations situated externally from the main premises of the testing laboratory;
- **POC**: exams carried out by medical laboratories near to or at the location of a patient with the result of leading to a possible change in the treatment given to the patient (Point Of-Care Testing – POCT);
- **Category IV**: accredited tests with flexible scopes performed both by testing laboratories and medical laboratories.

Test method: the specific technical procedure for conducting a test.

Test report: the modalities used for the presentation of the results for testing laboratories in accordance with the standard ISO/IEC 17025.

Report: the modalities used for the presentation of the results for medical laboratories in accordance with the standard UNI EN ISO 15189.

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 (see 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 conducted in remote or mixed mode, according to the rules and limits of applicability defined by ACCREDIA-DL.

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

Remote assessments: remote assessments performed by ACCREDIA-DL assessors not physically present at the Laboratory site. This is an assessment of a physical or virtual site of a CAB 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 CAB/organization conducts its activities or provides a service, using an online environment that allows 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 laboratory at its head office or, if applicable, at a branch location.

Assessment plan: description of the activities and dispositions regarding an assessment.

Cycle of accreditation: period of validity of the accreditation- An accreditation cycle has a duration of 4 years and, in the event of any postponements[1] (in cases foreseen by this Regulation), 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.

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

[1] In the cases provided by this Regulation.

Extension: enlargement of the scope of accreditation for:

a) the inclusion new test typologies;
b) the inclusion of additional tests for accredited matrices and parameters using different test methods from those used for accreditation;
c) the substitution of accredited test methods with other ones (where they are not the result of updates as provided for in point a) of the definition of the variation);
d) the addition of tests in different categories from those already accredited;
e) the addition of new locations where tests are performed;
f) the introduction of tests with flexible scope accreditation.

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

a) the updating of the test method by the standardization body (or possible replacement), by the competent authority or the laboratory in cases of the revision of the internal method;
b) the reduction of the number of accredited tests (renunciation of the accreditation of one or more tests);
c) use of accredited test methods for testing further products or for measuring new properties provided for by the method;
d) variation to the range of measurement for accredited test methods (both internal and standardized);
e) the updating of legal identity (organization or name of organization).
f) the reduction of the number of accredited locations (renunciation of accreditation of one or more locations);
g) the addition of tests deriving from calculations using accredited tests.

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

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

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

Renunciation of accreditation: a request presented by the laboratory 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 assessment formalized by ACCREDIA 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) derives 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 with respect to 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 of the root causes and the CAs related to the related identified causes, with indication of the timeline for implementation. Evidence of closure for this type of finding shall be evaluated with a positive outcome by ACCREDIA-DL before the decision by the CSA DL (Sector Accreditation Committee Department of Testing Laboratories) regarding the granting or extension of accreditation.

For maintenance and renewal the CSA DL 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 laboratory 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 evidence 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 issue or extension by the CSA DL.

For Comments: the management of a Comment can be conducted with the opening of an improvement action or it may not be implemented. For Comments it is not mandatory (but recommended) to formulate a plan for the management in the ACCREDIA modules, as the implementation or the reasons for non-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 and procedures and activities performed by ACCREDIA for the issuance, extension and maintenance of accreditation in conformity with the standards (e.g. ISO/IEC 17025 or 15189).

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 tasked 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 tasked by ACCREDIA-DL, either individually or as an audit group member, to assess the conformity of the QMS of a laboratory with the applicable reference standard and with ACCREDIA-DL's regulations.

Technical assessor: a person qualified and tasked 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 evaluated. 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 issue (first issue or revision) of any ACCREDIA prescriptive document and the date of entry into force of such documents.

1.4 ACRONYMS

- **ACCREDIA-DL**: Department of Testing Laboratories
- **CSA**: Sector Accreditation Committee
- **CdA**: Committee of Accreditation Activities
- **DDL**: Director of the Dept. of Testing Laboratories
- **FT**: Technical officer
- **SGQ (QMS)**: Quality Management System
- **CAB**: Conformity Assessment Body[2]
- **LAB**: Testing Laboratory
- **MED**: Medical Laboratory

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

2 REQUIREMENTS AND INFORMATION FOR ACCREDITATION

2.1 INFORMATION PHASE

Any laboratory 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 addresses are:

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

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

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

When necessary, it is possible to organize a preliminary meeting at ACCREDIA-DL's offices, or remotely, with a maximum duration of half a day in order to clarify the process of accreditation to the applicant and to the laboratory. 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 CAB requests a preliminary meeting, this shall be specified in the quotation, invoiced in man-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 laboratories.

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 laboratory. A preliminary assessment cannot be an initial assessment.

2.2 COST QUOTATION

In order to receive an estimate for the cost of accreditation, the laboratory shall send by email the application for accreditation (DA-00, DA-02 or DA-08 or DA 13) with the list of tests/exams which it wishes to obtain accreditation using the modules indicated in the application for accreditation[3] to the following email address info@accredia.it.

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

[3] For the testing laboratories, the list of tests to be accredited shall be completed by the online applications (DA-online), available in the appropriate section on the ACCREDIA's website. For the medical and testing laboratories for CPR notification the online application is being implemented.

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 laboratory prepares the application for accreditation and sends it to ACCREDIA.

The application shall contain the documents DA-00 and DA-02/DA-08, fully completed with the necessary attachments.

The application for accreditation of a laboratory shall be presented to ACCREDIA-DL by means of the forms available in ACCREDIA's website, DA-00 and DA-02/DA-08, 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 laboratory 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 Laboratory, the name of the person who ensures the contact and the email address of the laboratory for official communications with ACCREDIA. For reasons of confidentiality and information property, it is recommended to indicate laboratory references (e.g. email addresses on the laboratory 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 laboratory uses different languages, it must provide for the translation of the relevant documentation. For internal laboratory 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 visit, in order to allow evaluation by the team.

The applicant laboratory shall be a legal entity, i.e. a **juridical 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 tests/exams under accreditation.

A juridical 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 laboratories 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 laboratory 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 CAB. It is necessary to communicate all the names of the members of the trust company so as to be able to assess any potential conflicts of interest.

The laboratory 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 laboratory's activities, except for internal laboratories at production 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, with the exception of temporary locations for which reference should be made to Regulation RG-02-01.

If the laboratory 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 laboratories 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 correctness in terms of filling in the fields and the presence of the required attachments, and verifies, in collaboration with the DDL, that ACCREDIA-DL has the competences and resources sufficient to carry out the required 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 ACCREDIA-DL informs the laboratory that the time limit for starting the process has expired, and that the file will be closed. If the laboratory 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 Laboratory provides false information or hides information, ACCREDIA-DL will reject the application and reserves the right not to offer other services to the Laboratory. 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 approved for 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 complete and that payment has been made in accordance with the pricelist, communicates as follows to the laboratory:

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

An assessment team is assigned for every accreditation procedure.

An assessment team includes one system assessor engaged by the lead assessor, and one or more technical assessors/technical experts, depending on the type of 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 laboratory 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 entire scope of accreditation of the laboratory.

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 laboratory.

A laboratory which intends to present reservations regarding the assessors, it shall do so in writing **within 3 working days**, 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.

Laboratories may object to assessors (or ask for their replacement after the assignment) 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 deemed 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 laboratory 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 laboratory if not for grave reasons of incompatibility which shall be explained directly to the Director of Department.

3.2.2 Engagement of the assessors

Following acceptance of the team by the laboratory the tasks in question are formalized.

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 laboratory for the next 4 years (the duration period of the accreditation cycle).

The ACCREDIA-DL assessors 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 laboratory.

Excluding the assessment activities, the assessors can communicate with the Laboratory 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 Preparation of the report of the document review (RED)

The Technical Officer sends the documentation transmitted by the laboratory 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 laboratory, 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 laboratory's relevant 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 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 laboratory etc.)

The result of the document review, together with any request for additional information, is carried out and the laboratory is notified within four months of the opening of the file.

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

If this is not done, 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 laboratory any findings regarding the documents presented and proceeds to organize the on-site assessment.

If, despite the positive outcome of the document review, the laboratory 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 Laboratory (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 sampling tests (see § 3.4 below).

3.3.2 Preliminary technical meeting

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

The meeting is held at ACCREDIA's office or remotely 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 will be budgeted and invoiced according to the conditions set out in the current ACCREDIA pricelist.

3.4 SAMPLING OF TESTS

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 verification during the assessment.

This sampling plan is prepared on a four-year basis, in order to ensure at least the coverage of all test matrices and techniques during the accreditation cycle. For the choice of activities to assess, ACCREDIA-DL considers the risk related to the activity, the locations and personnel coming within the field of application of the accreditation.

The tests are sampled in accordance with the following criteria:

a) the tests for which the laboratory seeks accreditation are divided into homogeneous groups, for example: the test methodology, equipment used, the typology of scope of accreditation (fixed/flexible), the matrix / product which is the object of the test, the

location of the test, the frequency of controls, the health considerations, where applicable;

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

c) using appropriate checklists, at least one test shall be vertically assessed on all the applicable requirements, while the others shall be conducted assessing one or more of the following requirements:
   - personnel qualification, including results of PTs (scope: verification of the competence of an adequate number of technicians);
   - calibration of equipment, including measurement traceability;
   - measurement uncertainty and repeatability (always duplicate tests, where applicable);
   - sampling of archived test reports, verification of the records for evidence of the traceability from the sampling of the approval of the results;
   - results of PTs or the results of other quality guarantee activities (always);
   - other requirements: limit of determination (LOD), limit of qualification (LOQ), recovery etc. and conformity with mandatory requirements;
   - records regarding the validation of test methods and/or the assessment of laboratories in the application of standardized methods;
   - in the case of accreditation of tests with flexible scope it is necessary to assess the records and validations of the methods to which modifications have been made with respect to the previous visit.

d) in some cases it is necessary to assess conformity to specific requirements (e.g. WADA, FCC, EPA, CPR).

See also the requirements contained in ILAC G18:2010 "Guideline for describing Scopes of Accreditation".

The 4-year sampling plan, prepared and made available by the technical assessors in line with the above indications, is approved by the Director of Department and it can be modified following a request for extension or reduction of the scope of accreditation or a complaint or comment, negative assessment test results or the need to verify the effectiveness of corrective actions implemented by the laboratory.

Generally, the sampled tests are not communicated beforehand to the laboratory, except in cases where failure to communicate could compromise the possibility of performing the tests; some cases that need notification in advance are listed below:

- need for preparation before the assessment;
- necessity of particular environmental conditions such as long conditioning of the specimen;
- performance on samples which may not be ordinarily available in the laboratory.

The sampling of the tests 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 carried out in presence, i.e. with the physically complete team at the Laboratory'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 cases.

In all cases, ACCREDIA-DL performs 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

Generally, coordination is the assessor's task, taking care of the management/coordination of the logistics of the assessment for all members of the assessment team.

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

In cases of an in presence or mixed mode assessment at least **10 calendar days** before the date of the assessment, the laboratory must send to ACCREDIA-DL the form 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 laboratory shall give the form 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 laboratory and with the assessors, draws up the plan and communicates it to the laboratory.

The plan contains as follows:

a) the necessary timeframe for the performance of the assessment;
b) the cost of the assessment;
c) the dates of the assessment and indication of the mode: remote or mixed;
d) the names of the appointed assessors;
e) the laboratory 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 visit plan, the laboratory shall notify the Department in writing of its acceptance or of any objections by returning the form 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 Laboratory 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 laboratory accepts or resolves its reservations, ACCREDIA continues with the accreditation process. In all cases, if the laboratory fails to make itself available for the assessment visit **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

Generally, each accreditation or renewal assessment is attended by an ACCREDIA-DL management representative.

The presence of observers is admitted during the assessment, upon request of the laboratory, which shall 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 laboratory in writing, providing also the declaration of confidentiality by the observer. If the laboratory 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.

Under no circumstances may any observers interfere in the conduct of the assessment. Should this occur, it will be the responsibility of the lead assessor to request the immediate 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 laboratory with clarifications regarding the requirements of UNI CEI EN ISO/IEC 17025, UNI ISO 15189 and the applicable ACCREDIA documents;

- to raise, where necessary, any nonconformities regarding the work of the assessors with respect to compliance with the ACCREDIA regulations and documents concerning behavior and operative modalities.

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

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

The laboratory shall allow the assessors (and any experts and observers) access to the laboratory's work areas and to the documents for their assessment activities and shall cooperate fully with them. If sampling is performed off-site the laboratory 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 team holds a meeting before the opening meeting with the laboratory, 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, with the aid of the other assessors, prepares and makes available the time plan to show the laboratory at the opening meeting, taking account of:

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

3.6.3 Opening meeting with the laboratory

During the opening meeting between the ACCREDIA-DL team and the laboratory, 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 check-list in relation to the specific phase of the assessment.

As stated in § 3.5.2 above, during the opening meeting ACCREDIA-DL's lead assessor asks the laboratory to confirm the adequacy of the safety conditions by means of MD-19, during the planning of the assessment.

3.6.4 Performance of the assessment

3.6.4.1 General

The assessment visit for accreditation is aimed at verifying the conformance of the laboratory to the requirements of the reference standards, of the applicable EA, ILAC and ACCREDIA documents, in order to attest the technical competence of the laboratory to carry out the tests contained in the scope of accreditation. Mandatory standards (except in cases as defined in a reference standard such as ISO 15189), 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 with the aid of the ACCREDIA-DL checklists which include a list of questions designed to assess the conformity of the laboratory with the provisions of the reference standard and the ACCREDIA-DL requirements.

The Laboratory can see on www.accredia.it, the checklists used by assessors for 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 laboratory.

In performing the assessments, the ACCREDIA assessors shall not request the laboratory for copies of the documents examined, except when necessary to provide objective evidence of nonconformities or in the event of objections by the laboratory. In such cases the copies shall be attached to the checklist and sent to the ACCREDIA-DL. No Laboratory document may be retained by the assessors for any reason other than copies of the sampled test/exam reports of tests carried out during the audit to be added to the checklist, making anonymous, for those sampled in archive, the data of the laboratory's clients.

3.6.4.2 Assessments performed by the system assessor

The system assessor shall verify the conformity of the laboratory's management system with the requirements of the reference standard (UNI CEI EN ISO/IEC 17025 or ISO 15189) and with those of ACCREDIA-DL by filling in the corresponding sections of the checklist in accordance with the instructions given in the appropriate section of the checklist itself.

3.6.4.3 Assessments performed by the technical assessor

The technical assessor shall assess the performance of the sampled tests and all technical aspects related to them, by filling in the specific checklist.

The laboratory shall perform the sampling tests in compliance with the methods declared and in conditions as similar as possible to those of normal operations.

Usually it is necessary for the laboratory to arrange and carry out the tests for the exclusive use of ACCREDIA-DL but, where possible, the technical assessor can verify the performance of tests done on behalf of the laboratory's clients, as long as they are compatible with the timeframe, the normative references and the needs of the assessment.

When really necessary, due to time, operative or cost reasons, and provided it does not jeopardize the chance of performing a thorough and comprehensive assessment of the laboratory's technical capability, ACCREDIA-DL may decide that it is necessary to conduct one or more tests in partial and/or completely simulated way.

ACCREDIA-DL reserves the right, if necessary, to use specimen samples.

When foreseen in the sampling plan or by the sampled method, the laboratory shall do the tests in duplicate, verifying that the difference between the results is compatible with the repeatability limits established by the testing method or calculated by the laboratory itself. Instead of a double performance of the test during the visit, the assessors may (if this does not impact negatively the effectiveness of the assessment) ask the laboratory to repeat the test on a sample already tested (for example, on behalf of a client).

The assessors shall nevertheless always compare the results obtained by the two tests performed.

If the performance of a test is characterized by successive phases with long time intervals (e.g. due to conditioning of the specimen, the occurrence of chemical reactions or the growth of cellular/microbic cultures), the technical assessor shall, in order to reduce the dead times during the assessment, request the performance of a series of repetitions of the same test on different samples at correct starting intervals, in order to verify the most important phases over a limited period of time and/or go ahead with other necessary activities and ensure that the laboratory is ready to perform the required tests.

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

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

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 laboratory arises with respect to the standards or the ACCREDIA-DL documents, the lead assessor, in agreement with other assessors and the Department Director, may propose to the laboratory 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 laboratory requests to continue the assessment, the assessors shall record such 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 laboratory, 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 laboratory'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 laboratory manager, his/her closest collaborators, and the staff responsible for the management system.

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

a) summary of the actions performed;
b) the opinion of the laboratory 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 laboratory, shall be completed only after request by ACCREDIA-DL.

The Laboratory's manager shall sign for acknowledgment (or validate through the appropriate online application, if available[4]), the opinion and the findings made by the assessment team. A copy of the results of the assessment is delivered or, in the case of an online application, made available to the Laboratory's manager, by the lead assessor.

Any reservations regarding the findings may be presented directly by the laboratory during the closing meeting, to the assessor with coordination responsibilities. 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 multisite laboratories, the three-day period starts from the day of the closing meeting held at the last site to be assessed.

Acceptance or rejection of the reservations on the part of the laboratory is the responsibility of 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 laboratory, with the relative request of the plan for the management of the findings.

The laboratory **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 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.

ACCREDIA-DL, having checked the opinions of the assessors, and deciding that the plan communicated by the laboratory (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 laboratory.

[4] 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.

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.

In cases of accreditation the plan for the management of the findings shall be approved by ACCREDIA-DL before the meeting of the CSA DL.

If the laboratory, 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 laboratory 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 laboratory.

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

ACCREDIA-DL informs the laboratory 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 laboratory 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, 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 laboratory entered in the database of accredited laboratories and published on ACCREDIA-DL's website.

The granting of accreditation is formalized by means of an agreement (CO) between ACCREDIA-DL and the laboratory, with the issuance of the certificate of accreditation and corresponding attachment describing the scope of accreditation (the list of accredited tests).

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

ACCREDIA-DL notifies the laboratory of accreditation by sending:

- a communication containing:
  - the time period and duration for the next surveillance assessment;
  - the cost estimate regarding the next surveillance assessment;
  - 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 laboratory 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 Laboratory and cannot be transferred to third parties.

Acceptance of the agreement and inclusion on the list of accredited laboratories commits the laboratory 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 laboratory shall conform with the requirements of this Regulation and the regulation for use of the ACCREDIA mark RG-09.

If the laboratory intends to request authorization for use of the combined ILAC MRA mark, it must send an example of use of the combined mark and obtain the written approval of ACCREDIA-DL before using it, in line with ACCREDIA's instructions during the notification of accreditation phase.

Upon granting accreditation, for the regulated areas (e.g. for the CPR construction products sector for notification purposes according to Reg. (EU) 305/2011), ACCREDIA-DL shall send, where applicable, a descriptive communication of the decisions to the competent authorities (e.g. Ministries), for the appropriate decisions.

4.4 CLOSURE OF THE ACCREDITATION PROCEDURE

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

- the laboratory, 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 laboratory is not available, despite a positive outcome of the document review, to undergo the first 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 first assessment within 6 months after the first sending of the assessment plan;
- the laboratory has not sent an adequate plan for the management of findings respecting the timeframe given by ACCREDIA-DL; the requested documental evidences are not suitable.
- the supplementary assessment has not had a positive outcome;
- the assessment has been interrupted;
- the laboratory 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 laboratory.

In addition to the cases as defined in the present 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 laboratory 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 ACREDIA 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 laboratory in conformity with the requirements of the standards and of those deriving from Regulation EC 765/2008 (ISO/IEC standards and EA/ILAC documents).

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

In 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 laboratory's locations shall be accessible for the ACCREDIA-DL assessment team.

Surveillance visits can also be carried out remotely. Except for situations as provided for according to IAF ID 3 document, the execution of these assessments 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 an assessment in presence.

The possibility of carrying out the assessment completely remotely (or also in mixed mode) is subject to a risk assessment on the laboratory 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 Laboratory, 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/sampling);
- where the Laboratory 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 Laboratory, 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: the laboratory is requested to check its list of accredited tests, also asking, if necessary, for an update (see § 5.1.3). The laboratory has the option, during this phase, of requesting extension to its scope of accreditation (extension jointly with surveillance. See § 6.1.3).

The planning and the performance of the surveillance visit 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 laboratory by the lead assessor;
- a management representative may be present during the surveillances if deemed necessary by the DDL, with the tasks as defined in § 3.6.1;
- during the phase of preparation of the surveillance of a laboratory with flexible scope accreditation, the ACCREDIA-DL assessors shall always verify the detailed list managed by the laboratory, 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 results of the surveillance are numerous and/or major NCs are raised, ACCREDIA-DL may impose the sanction of partial or total suspension of accreditation in accordance with § 7 below;
- 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 CAs communicated by the laboratory.

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 the procedure for maintenance goes ahead.

If the result of the supplementary assessment is negative or if the laboratory is not available for the supplementary assessment **within one month of the date 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 laboratory, its accreditation is withdrawn, in accordance with § 6.3;

- 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 or test/s.

In order to determine the man-days of surveillance assessment activities, ACCREDIA-DL conducts periodic risk analyzes, based on general indications defined in collaboration with the ACCREDIA Steering and Guarantee Committee which approved them and which include factors such as: the outcomes of the previous assessments (presence of Nonconformities, negative judgment of the sampled activities), any sanctions imposed, 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 CABs, mandatory area accreditation, etc. The outcome of the assessment is communicated to the laboratory with the notification of granting/maintenance/extension/renewal.

5.1.2 Non-programmed surveillance assessments

Non-programmed surveillance visits can be performed in cases:

- of significant changes to the CAB, which occurred after accreditation (e.g. transfer of offices, change of key figures, 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;
- of assessments of transition of the accreditation standard, if not conducted at the same time as scheduled surveillance or renewal;
- in which the CSA resolves 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 CAB, 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 laboratory is maintaining conformity 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 motivation or situations of inadequacy of which ACCREDIA obtains knowledge. Advance notice of **7 working days** shall be given, within which time period the CAB 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 laboratory 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 Laboratories (e.g. checks directly on companies that operate in outsourcing for a Laboratory (where applicable); unannounced assessments at the Laboratory 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 Laboratory 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 Laboratory in cases where the reasons for the visits themselves are well-founded, the laboratory 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 Laboratory. Once arrived at the Laboratory, 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 Laboratory 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 decisions with regard to the maintenance of accreditation, as is the case for programmed surveillances.

5.1.3 Changes to the field of accreditation

An accredited laboratory may, at any time, request ACCREDIA-DL to change the accredited tests concerning:

- materials, products and matrices;
- measurands/measured properties;
- norms/test methods;
- field of measurement and/or test;
- update of the normative references.

If the laboratory wishes to modify the field of accreditation it shall make its request in written form, to ACCREDIA-DL by using the module for the application for accreditation.

If the changes regard the use of accredited testing methods, in order to test further products or for the measurement of new properties as specified for the field of application of the method, the laboratory shall attach to the application a summary of the data of performance verification for the new parameters/matrices requested and the quality assurance tests (e.g. results of inter-laboratory circuits, tests conducted on reference materials) where applicable.

If the change concerns the updating of the reference legislation, the laboratory must attach to the application a summary (gap analysis) of the new requirements required by the updated versions of the legislation, and of the measures adopted to comply with them (for example new skills, equipment, materials, etc.).

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 laboratory's accredited test lists, it shall inform the laboratory, requesting revision of the list and/or the integration of documents. If the laboratory does not resolve the findings **within one month** of receipt of the communication or within the timeframe indicated by ACCREDIA-DL, ACCREDIA could impose sanctions for the tests in question (see § 7).

The modification involves the re-issue of the accredited test list without requiring the performance of a document review.

5.2 RENEWAL OF ACCREDITATION

If the laboratory intends to renew its accreditation, it shall send to the ACCREDIA-DL Dept. of Testing Laboratories the application for accreditation with all applicable parts duly filled in and complete with the attachments requested, **at least 8 months** before the expiry of the existing 4-year accreditation in order to organize the renewal assessment 3 to 4 months, as a minimum, in advance of 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 laboratory 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, e new accreditation number will be assigned to the laboratory.

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 ACCREDA-DL for the assessment of a laboratory 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 use of the accreditation as defined in § 7.1.

5.2.5 Evaluation of the results of the assessment

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

5.2.6 Supplementary assessment

If a laboratory is not available to undergo a supplementary assessment **within one month from the final date of completion of CAs** indicated in the plan 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 laboratory, the CSA DL decides regarding the withdrawal of accreditation and the closure of the re-newal 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 tests, the CSA DL can decide to grant renewal of accreditation excluding those sectors and/or tests.

5.2.7 Interruption of the assessment

If the assessment is interrupted (see § 3.6.4.5) ACCREDIA shall present the file to the CSA DL for the imposition of the withdrawal of accreditation of the laboratory 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 Laboratory may, during the period of validity of the accreditation, request ACCREDIA-DL to extend the accredited test program to new tests and/or sites.

6.1 PROCEDURE FOR THE EXTENSION OF ACCREDITATION

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

- the application for accreditation[5] giving the new data concerning the tests for which extension is requested (e.g. list of extended tests, of equipment, calibrations etc.) and relative annexes;
- the new test methods, in controlled distribution, together with the relative declarations of validation (when applicable);
- in cases of requests for automatic extension (§ 6.1): a summary of the performance verification data of the methods presented in extension and the quality assurance tests (e.g. results of inter-laboratory circuits, tests performed on reference materials) where applicable;
- 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 laboratory:

- without conducting a specific assessment (postponing the checks to the next surveillance assessment), see § 6.1.1;
- following the positive outcome of a specific assessment, § 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 laboratory 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. tests to be performed in conformity with new standards requiring test methods similar to the already accredited ones).

The laboratory seeking automatic extension shall specify in the application, the criterion of similarity considered.

If ACCREDIA-DL acknowledges that the tests for which extension is sought are similar to those already accredited and evaluates with positive outcome the performance data and quality assurance sent by the laboratory, the DDL, after consulting the competent technical assessor, proposes to the rapporteur member of the Sector Accreditation Committee an automatic extension for the tests requested by the laboratory, postponing the relative control to the time of the performance of the first surveillance visit.

[5] For the testing laboratories, shall be used the online applications (DA-online), instead for the medical and testing laboratories for CPR notification, shall be used the appropriate module DA-08/DA-13 and related attachments.

If the Sector Accreditation Committee rapporteur approves the request, ACCREDIA-DL notifies the laboratory of the approval of extension of accreditation, attaching to the communication the revised list of accredited tests. If the extension file is assigned to an Expert of the DL CSA, the results of the CAB evaluation 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 tests pertaining to the extension shall be verified in the course of a specific assessment at the laboratory.

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 Joint extension and surveillance assessments

If the laboratory intends to combine the extension and first surveillance visits, 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 tests 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 laboratory concerned, within **5 working days** from the date of the decision, by registered mail, or by certified email and subsequently published on the website.

Furthermore, in some areas (e.g. CPR Reg. 305/2011), ACCREDIA-DL informs, where required, the competent Authorities (e.g. Ministries) about the measures adopted against accredited CABs.

The Laboratory is required to inform the clients involved of the sanction measure imposed on it.

7.1 SUSPENSION

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

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

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

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

Partial suspension involves, for the laboratory, termination of the right to issue test reports under ACCREDIA accreditation for the suspended tests. Total suspension involves, for the laboratory, termination of the right to declare accreditation and to issue test reports under ACCREDIA accreditation.

Furthermore, during the period of suspension, the laboratory 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 tests in question or, if the accreditation has been suspended for all tests, 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 major findings raised during the assessment or document review. In cases of particular urgency and criticality, suspension of one or more tests 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 laboratory for the performance of the supplementary assessment in the timeframe set by ACCREDIA-DL;
d) unavailability of the laboratory 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 the 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 considerations 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/other reports which have been unduly issued;
k) failure or ineffective management of complaints/feedbacks received by ACCREDIA;
l) improper use of the ACCREDIA mark or references 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 laboratory (see § 9.1);
o) failure to promptly notify ACCREDIA DL of the loss of the key figures identified by the Laboratory;
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 laboratory (self-suspension)

The laboratory 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 times 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 laboratory 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 or resolution of the causes of the suspension by means of one or more of the following actions:

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

Following verification of the return to conformity of the laboratory's system, the positive outcome is presented during 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 laboratory and the list of laboratories on ACCREDIA's website is updated accordingly.

If the verification performed by ACCREDIA-DL did not confirm 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 accreditation means the elimination of a part of the scope of accreditation, and it can therefore affect one or more accredited tests and/or accredited sites. Consequently a revision is performed of the list of accredited tests and, in cases of a reduction of locations, of the certificate of accreditation.

Following the reduction of accreditation, the laboratory shall immediately cease to make any reference to accreditation for the tests in question and it shall not issue test or other 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 laboratory.

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 tests and/or one or more locations.

If the laboratory chooses to seek accreditation again for the excluded tests/locations, 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 laboratory (self-reduction)

The laboratory may, at any moment, request the reduction of accreditation for one or more tests and/or one or more locations.

The request for a reduction of tests shall be sent to ACCREDIA-DL using the module for the application for accreditation; the request for a reduction of accreditation for one or more locations shall be communicated in writing to the laboratory's legal representative.

The assessments conducted by ACCREDIA-DL particularly with regard to their possible impact on accredited tests and the modalities of revision of the list of accredited tests 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 laboratory'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 laboratory 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) the expiry of accreditation, in cases where the laboratory has not started, 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 laboratory have not been verified;

k) illicit, damaging or improper professional behavior by the laboratory;

l) evidence of fraudulent activities or that the laboratory intentionally provides false information or that it conceals information;

m) use of accreditation by the laboratory such as to gravely damage and discredit ACCRDEIA and/or the accreditation/certification system;

n) financial failure of the laboratory;

o) cessation of activities of the entity in which the laboratory operates, for whatever reason;

p) renunciation on the part of the laboratory (see § 7.4);

q) situations that make it impossible to conduct an on-site assessment visit to 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 laboratory of the decision by the CSA DL by means of registered mail or certified email and published on ACCREDIA's website.

Withdrawal of accreditation involves the following actions with immediate effect:

- removal of the laboratory from the database of accredited laboratories on ACCREDIA's website;
- loss of the right to declare itself an accredited testing/medical laboratory;
- 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 CAB shall not use any copies or reproductions of the accreditation certificate and it shall conform with the regulations regarding use of the ACCREDIA mark.

Withdrawal of accreditation does not nullify the laboratory'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 laboratory 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 laboratory cannot present any further application for accreditation.

7.4 RENUNCIATION OF ACCREDITATION

An accredited laboratory 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.).

A laboratory 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 laboratory intends to renounce accreditation for a period subsequent to the communication:

- the laboratory 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. maintenance of accreditation assessment 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 laboratory 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 laboratory and informs the CSA DL.

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

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 FEEDBACKS

ACCREDIA-DL may receive complaints/remarks regarding:

- ACCREDIA's operations;
- the operations of other accredited laboratories,

- the activities of third parties related to the testing activities of accredited or applicant laboratories.

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 people who are independent of the subject of the complaint/feedback.

Complaints/feedbacks which are sent anonymously will not be accepted in order 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 shall be presented **within 10 working days** of the performance of the assessment.

Laboratories may signal, confidentially, 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 laboratories accredited by ACCREDIA, but which, nevertheless, are related to accreditation.

8.2 RESERVATIONS

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

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

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

Acceptance or non-acceptance is handled by the DDL.

8.3 APPEALS

If an accredited or applicant laboratory 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, including also any cases of inadmissibility.

The handling of appeals is the responsibility of the Commission of Appeals 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 laboratory (renewal, transition, extension etc.) are taken by the Commission of Appeals, 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 CAB

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

The following obligations apply:

- the laboratory shall pay the annual maintenance fees for accreditation as defined in the pricelist;
- the laboratory shall 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 laboratory shall permit the performance of assessments by ACCREDIA-DL at its location/s and places where inspection activities take place;
- the laboratory shall formally communicate to ACCREDIA-DL any operative or corporate changes, properly documented, which affect its activities (see § 9.1 and § 9.2);
- the laboratory shall possess a procedure identifying the responsibilities and operative modalities followed for the inclusion of every new element within its flexible scope, in accordance with RT-26. The laboratory 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 laboratory 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 required by § 3.5.2;
- the laboratory shall promptly inform ACCREDIA-DL regarding all pending legal actions regarding activities covered by accreditation. The laboratory 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 laboratory shall not send to ACCREDIA-DL any legal data, in accordance with the privacy laws and regulations;
- the laboratory 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 Laboratory 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 Laboratory's competence and/or on the information reported on the accreditation certificate) the Laboratory must immediately self-suspend and notify ACCREDIA.

Following receipt of the documents sent by the laboratory, ACCREDIA-DL will verify that the changes do not prejudice the conformity to the independence and impartiality requirements or impact the management system or the technical competence of the laboratory.

In cases of major changes which impact the management system and/or the technical competences of the laboratory, 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 laboratory, liquidation, failure etc.).

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

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 laboratory's organizational structure

The laboratory shall communicate all substantial variations to its organization with respect to the information provided in the application for accreditation, such as laboratory management tasks, the quality management system personnel, personnel authorized to sign/authorize reports and tests/reports, the staff member responsible for contact with ACREDIA-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 or accreditation, verifiable by means of the following documentation:

- Chamber of Commerce profile or equivalent document attesting the laboratory'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 the 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 laboratory, 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 not 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 before the relative decision, no activities under accreditation whatsoever shall be undertaken (e.g. the issuance of reports or test reports) by neither of the two legal entities until accreditation is obtained by the new legal entity.

Following communication sent by the laboratory, 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 tests. 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 laboratory'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 laboratory intending to ask 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 § 2 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 laboratory 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 CAB ceases to use the accreditation and it starts accreditation with ACCREDIA.

10 OBLIGATIONS OF ACCREDIA

Regarding matters not specifically covered by the present Regulation, article 3 of the contractual accreditation agreement 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 laboratory to adapt its operative modalities to the new requirements, as applicable.

The laboratory can decide within 3 months or within the transition period set by ACCREDIA, not to fulfill such requirements and, therefore, to annul its accreditation. If so, 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 pricelist for accreditation activities is established by the ACCREDIA Directive Council and stated in the ACCREDIA pricelist.

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

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