TITLE **REGULATION FOR THE ACCREDITATION OF CALIBRATION LABORATORIES**

REFERENCE **RG-13**

REVISION **09**

DATE **05-10-2022**

PREPARATION

THE DIRECTOR OF CALIBRATION LABORATORIES DEPARTMENT

APPROVAL

THE DIRECTIVE COUNCIL

AUTHORIZATION

THE GENERAL DIRECTOR

APPLICATION DATE

01-02-2023

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0. FOREWORD

ACCREDIA's purpose through the Calibration Laboratory Department is to favour the development of confidence in the compliance assessment system - called to assess and attest conformity of Calibration Laboratories to the requirements set by national and international applicable technical standards - and to ensure the effectiveness and uniformity of the approach by the System Operators, thereby promoting the growth of the competitiveness of the national production system and the improvement of the well-being of citizens.

For this purpose, ACCREDIA, through the Calibration Laboratory Department, accredits the Calibration Laboratories:

- operating in compliance with the requirements of UNI CEI EN ISO/IEC 17025:2018 standard, with ACCREDIA, EA, ILAC documentation and in accordance with articles 3 and 4 of Law 273/1991;
- operating in compliance with the UNI CEI EN ISO/IEC 17025:2018 standard (for the performance of reference measurement procedures in laboratory medicine), together with the UNI EN ISO 15195 standard, the ACCREDIA, EA, ILAC documents and the provisions of Articles 3 and 4 of Law 273/1991;

ascertaining that they possess and maintain over time the required organisational, procedural, technical and professional requirements, in such a way as to generate, in all social and economic parties concerned - and, in particular, in end users and consumers - a high degree of confidence in the work of these Entities and in the value of the certificates of conformity issued by them.

In line with the purposes set out above and in accordance with the guidelines issued by its statutory Bodies - in order to better ensure the effectiveness of the accreditation process - ACCREDIA Calibration Laboratory Department (DT) has developed appropriate rules and appropriate criteria for applying the general requirements of the regulatory references applicable, formalized through the issuance of this Regulation (as well as through other documentation to be used in conjunction with the Regulation itself).

This document shall consider the evolution of the applicable regulatory references, the experience gained from SIT and then ACCREDIA and the statements expressed by the ACCREDIA Institutional Bodies, aimed at improving the accreditation system.

0.1. INTRODUCTION

The application of the requirements of the UNI CEI EN ISO/IEC 17025:2018 reference standard and other applicable documents has the purpose of favouring the creation and maintenance of customer confidence in the calibration activities of the accredited Calibration Laboratories, as well as the impartiality and integrity of the technical and commercial operations associated with them.

The accreditation attests the technical competence of the laboratory to carry out the calibrations and other conformity assessments indicated in the scope of accreditation, and the implementation of a quality management system generally in accordance with the principles of UNI EN ISO 9001.

Laboratories accredited by ACCREDIA DT are deemed competent to carry out calibration and also supporting the activity of accredited testing laboratories, certification bodies, inspection, verification and validation bodies.

In order to promote the efficiency and credibility of the accreditation process, it is necessary to introduce a set of specific rules and criteria that, without exceeding the spirit and the wording of the standard, favour its full and substantial application by the accredited subjects, being at the same time, unequivocal, objective and impartial references for the assessments conducted by the Accreditation Body towards the same.

This purpose can be achieved through the correct and effective application of this Regulation.

0.2. SCOPE AND FIELD OF APPLICATION

This regulation applies to Calibration Laboratories

The purpose of this document is to set out the modalities that shall be complied with:

1. By the Laboratory to:

    - submit an application for accreditation as a Calibration Laboratory in accordance with UNI CEI EN ISO/IEC 17025:2018 or in accordance with UNI CEI EN ISO/IEC 17025:2018 and in conjunction with UNI EN ISO 15195:2019;
    - collaborate on ACCREDIA DT's assessment and all related acts;
    - implement the required corrective actions following the results of the accreditation process and all related acts;
    - stipulate the accreditation agreement;
    - collaborate on the subsequent activity of monitoring and maintaining accreditation;
    - submit applications for extension, variation and renewal of accreditation;
    - implement ACCREDIA DT requirements in case of suspension, reduction, renunciation and withdrawal of accreditation.

2. By ACCREDIA DT, when performing the following operations:

    - Accreditation;
    - Surveillance and maintenance of accreditation;
    - Variations in the scope of accreditation;
    - Renewal of accreditation;
    - Extension of accreditation;
    - Suspension of accreditation;
    - Reduction of accreditation;
    - Withdrawal of accreditation;
    - Renunciation of accreditation.

Also, to be considered as a source of contractual obligation in the relationship between ACCREDIA DT and the accredited and accrediting laboratories are the technical circulars issued by ACCREDIA DT, specific to the metrological area/metrological sector, which will be shared with the interested parties and included in the ACCREDIA document LS-18.

Based on the principle of speciality, a technical circular issued by ACCREDIA DT supplements the general provisions in the applicable regulations.

ACCREDIA DT considers as mandatory:

a) mandatory documents issued by EA/ILAC;

b) any applicable provisions arising from the resolutions adopted by the General Assemblies of the Bodies referred to in the preceding paragraph (see document EA-INF/17 in the current revision);

c) any provisions issued by the Public Authority;

d) any applicable provisions issued by ACCREDIA's Institutional Bodies (e.g., CD, CIG, CSA, etc.).

As far as the provisions under b), c) and d) are concerned, it will be the task of ACCREDIA DT to inform the Calibration Laboratories about the issue of appropriate circulars.

ACCREDIA DT also considers points of reference, to be evaluated in the event of disputes:

- the FAQs issued by EA's Laboratory Committee and ILAC's Technical Committee and related working groups;
- the interpretations provided by the maintenance group of the ISO CASCO.

ACCREDIA DT does not assume any a priori obligation regarding the positive outcome of the assessments conducted and, therefore, regarding the granting/maintenance/extension/renewal of accreditation.

ACCREDIA DT is responsible for verifying - within the limits of typical sampling assessments - that the Laboratory has the required competences (in terms of organisation, procedures and working/operational documents, human and instrumental resources) to carry out its activities according to these regulations and any other relevant requirements.

These General Regulations and the specific Regulations per accreditation standard are subject to specific approval by the ACCREDIA Directive Council (Art. 14 of the ACCREDIA Statute), subject to the favourable opinion of the Accreditation Activity Committee and are issued under the authority of the ACCREDIA President. The Steering and Guarantee Committee is also involved in the process for consultation.

General note: it should be noted that the timeframes in this Regulation may not be adhered to during company closure periods that are published on the ACCREDIA website.

0.3. NORMATIVE REFERENCES

The normative references to be considered for the application of this Regulation are given in the ACCREDIA document LS-09 "*List of reference standards and documents for the accreditation of Calibration Laboratories and RMPs*", in the current revision, including all applicable ISO, ILAC, and EA documents.

This Regulation also refers, where and as applicable, to Law 273/91 Establishment of the national calibration system and to the following ACCREDIA Statutory Rules and Regulations, in the latest revision in force:

- ACCREDIA Statute (ST-00);

- General Regulation enforcing Statutory Provisions (ST-01);
- Regulation for the procedures of the Accreditation Committee (RG-04);
- Regulation for the Functioning of the Sector Accreditation Committees of the Department of Calibration (RG-04-DT);
- Regulation for the procedures of the Steering and Guarantee Committee (RG-05);
- Regulation of the Appeals Commission (RG-06);
- Regulation for the use of the ACCREDIA Mark (RG-09);
- Accreditation Price-list (TA-00);
- Accreditation contractual agreement (CO);
- Application for Accreditation (DA-00);
- Accreditation Application for Calibration Laboratories (DA-05);
- Applicable ACCREDIA Technical Regulations (RT);
- Technical Circulars

and EA, ILAC documents and other documents applicable to Calibration Laboratories.

For each of the ACCREDIA documents quoted above, the latest revision is valid and can be downloaded freely from the Institutional and Operative Documents area and/or the Calibration Laboratory Department area.

0.4. TERMS AND DEFINITIONS

Accreditation: attestation by a national accreditation body certifying that a conformity assessment body meets the requirements set by harmonized standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific Conformity assessment activity (EC No 765/2008 Chapter 1, Article 2, paragraph 10 and subsequent amendments).

Note: Accreditation consists of a statement of the adequacy (adequacy audit and therefore not compliance or conformity audit) of the organisation and the procedures adopted by the conformity assessment body in providing a competent, consistent and impartial service, as evidenced by full compliance with the relevant standards/regulations.

Accreditation certificate: a statement issued by the accreditation body, based on a decision, certifying the compliance of a conformity assessment body with the requirements of a specific accreditation standard**.**

National Accreditation Body: the sole body in a Member State that performs accreditation with authority derived from the State (EC No 765/2008 Chapter 1, Article 2, paragraph 11 and subsequent amendments).

Conformity Assessment Body: body carrying out conformity assessment activities, including calibration, testing, certification and inspection (EC Reg. No. 765/2008 Chapter 1, Art. 2, Para. 13 and subsequent amendments)

Note: For the purposes of this Regulation, conformity assessment body (or CAB) means the Calibration Laboratory.

Calibration Laboratory: Conformity assessment body performing calibration activities in accordance with UNI CEI EN ISO/IEC 17025:2018, also in conjunction with UNI EN ISO 15195:2019 for the performance of reference measurement procedures in the field of laboratory medicine.

Note: the definition of Laboratory is present in UNI CEI EN ISO/IEC 17025:2018 but only the part referring to calibration activities is adopted in this document.

Calibration Centre: Accredited Calibration Laboratory (Law 273/91 Establishment of the National Calibration System).

Site: facility where Laboratory activities, including calibration operations, are performed. A site may be a permanent, temporary or mobile facility of the Laboratory or a site outside the Laboratory's permanent facilities or a customer's facility

Note: the sites where calibration operations are performed are listed in the annex to the Accreditation Certificate.

Calibration: operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

NATIONAL NOTE: The term "calibrazione" should not be used to designate calibration.

NOTE 1: a calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. It may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

NOTA 2: calibration should not be confused with the adjustment of a measuring system, which in some sectors is often wrongly called 'self-calibration', nor with the verification of the calibration status.

NOTE 3: Often, the first step alone in the above definition is perceived as being calibration.

Internal calibration: calibration the results of which significantly influence the CMC (*Calibration and Measurement Capabilities*) of the Calibration Laboratory but which does not fall within its scope of accreditation (and as such cannot be offered as an accredited calibration service) and which is carried out using personnel and equipment of the Calibration Laboratory (or under its direct control), applying technical procedures positively evaluated by ACCREDIA DT.

Certificate of calibration: document issued by the Laboratory for the presentation of the results of a calibration in accordance with UNI CEI EN ISO/IEC 17025:2018**.**

Requirement, prescription: a provision that defines the needs to be fulfilled and is expressed by the auxiliary "shall". The requirements of a normative document must be observed in order to comply with the document**.**

Finding: an assessment result formalized by ACCREDIA DT and classified as Non-Conformity, Concern or Comment.

Non conformity: finding indicating the presence of a deviation/lack that:

- endangers the reliability of the results/performances/services produced by the CAB and/or;
- affects the ability of the Management System to retain the established quality level of conformity assessments or indicates a failure in the functioning of the Management System and/or;
- threatens the credibility of the accreditation process or the integrity/honesty of ACCREDIA and/or;
- reveals a failure to respect the applicable mandatory requirements of the scope of accreditation;
- derives from a repeated failure to resolve a previously formalized CAB concern.

ACCREDIA DT will also proceed to issue an NC, if it becomes aware that the CAB located in Italy does not comply with ACCREDIA circular no. 3/2016 issued in relation to the application of EU Regulation 765/2008 and subsequent amendments, with specific reference to art.7 (Cross-border Accreditation). Please note that it is forbidden for a CAB located in Italy to request accreditation in a scheme/sector from another Accreditation Body, whether located in Europe or outside Europe, if the same accreditation can be provided by ACCREDIA.

If, on the other hand, the CAB is already covered by ACCREDIA accreditation, in that scheme/metrological area/metrological sector, it is possible for it to apply for further accreditation, but only to a non-European accreditation body.

In addition, the detection of non-compliance with legal requirements is only highlighted as non-conformity if it is relevant to the requirements of the management system, irrespective of controls and sanctions by the relevant Authorities.

NOTE 1: The Non-conformity is formulated by ACCREDIA DT Assessors through a clear identification of the finding and must indicate the evidence on which the finding is based and the reference to the specific requirement that has been violated.

NOTE 2: Non-conformity may give rise to the adoption of one of the sanctioning measures described in §5 "SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION".

Concern: finding caused by a partial implementation of a requirement (normative or referred to Accreditation Regulations/Technical circulars) but which does not affect or is likely to affect directly or immediately the quality of the Laboratory performance and results.

NOTE 1: The Concern is formulated by ACCREDIA DT Assessors, through a clear identification of the finding and must indicate the evidence on which the finding is based and the reference to the specific requirement that has been violated.

NOTE 2: A Concern not closed at the next periodic assessment may be reclassified as a non-Conformity.

Comment: the finding raised by ACCREDIA DT against the CAB is classified as a comment when it is not consequent to the finding of an objective situation of non-fulfilment of a requirement, but is aimed at preventing such a situation from occurring (insofar as it is potentially realisable) and/or at providing indications for the improvement of the Laboratory's documents and/or operating methods.

Management of findings by the Laboratory: activities to be carried out by the Laboratory in response to findings formalised by ACCREDIA DT.

All findings formalised by ACCREDIA DT as Non-conformities/Concerns, according to the above-mentioned criteria, must be appropriately reviewed by the Laboratory, which must transmit to ACCREDIA DT **within 10 (ten) working days** from receipt of the letter of confirmation of findings, an appropriate findings management plan including:

- **For Non-Conformities:** Correction (where applicable), Root Cause Analysis, and Corrective Actions related to the identified causes, indicating the timing of implementation. Closing evidence for this type of findings should be evaluated positively by ACCREDIA DT prior to the approval (grant or extension of accreditation) of the CSA. For the maintenance and renewal, the CSA may issue a positive resolution, subject to sufficient information showing a satisfactory implementation of the findings. An assessment may be required to ensure that Corrective Actions are implemented effectively.
- **For Concerns:** Correction, Root Cause Analysis, and, when established by the Laboratory in relation to the identified causes, Corrective Actions, indicating the timing of implementation. The evidence of Correction and/or Corrective Actions is evaluated in document form before the next assessment. Depending on the nature and the number of Concerns, ACCREDIA DT may establish that for this type of finding the evidence of closure must also be evaluated positively before the CSA decision (grant or extension).
- **For Comments:** this type of finding may be handled with the opening of an Improvement Action or it may not be acknowledged. In the first case, the degree of acknowledgement is verified by ACCREDIA DT during the first useful assessment, while in the second case the reasons for non-acceptance must be communicated by the Laboratory.

If a Laboratory fails to transmit to ACCREDIA DT the findings management plan or the required documentary evidence, within the terms applicable to the various cases, ACCREDIA DT Management may submit the case to the CSA DT, for the adoption of sanction measures (section 5 SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION)

The findings formalised by the assessment team at the end of the assessment may be subject to reclassification by the Technical Officer/Director of ACCREDIA DT following review.

Impartiality: presence of objectivity.

Note: The types of conflicts of interest are dealt with in the Technical Regulation RT-25.

Accreditation scheme: set of rules, defined procedures and activities performed by ACCREDIA relating to the accreditation of conformity assessment bodies, to which the same requirements apply**.**

Note: For the purposes of this Regulation, the requirements are those set out in UNI CEI EN ISO/IEC 17025:2018 and EN ISO 15195:2019.

Scope of accreditation: Specific conformity assessment activities for which accreditation is sought or has been granted.

Note: scope of accreditation also means the field of application of accreditation (ref. UNI CEI EN ISO/IEC 17011:2018 section 3.6).

Assessment: Process undertaken by ACCREDIA DT to determine the competence of a Laboratory, on the basis of one or more standards and/or other normative documents, and for a defined accreditation scope.

Assessment plan: description of the activities and organisation of an assessment.

Assessment programme: A set of assessments consistent with a specific accreditation scheme that ACCREDIA DT performs towards a Laboratory during the accreditation cycle.

Assessment techniques: methods used by ACCREDIA DT to carry out assessments**.**

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

- - on-site assessment;
- - remote assessment;
- - document review (including drafting of Technical Reports);
- - examination of records;
- - unannounced visits;
- - interviews;
- - measurement audit (including drafting of the Comparison Report);
- - experimental on-site assessment (including drafting of the Comparison Report).

On-site assessments: assessments carried out in presence at the Laboratory's premises.

Remote assessments: assessments carried out remotely from a physical or virtual CAB site, using electronic means.

Mixed assessments: assessments conducted partly in presence and partly remotely.

Note: For the purposes of this regulation, unless otherwise specified, the term " visit" is used to refer to an assessment that indistinctly may be on-site, remote or mixed.

Unscheduled assessments: assessments carried out by ACCREDIA DT at one or more laboratory sites, without prior notification of the assessment plan**.**

Accreditation cycle: validity period of accreditation.

Note: The accreditation cycle begins on the date of the decision to grant initial accreditation or renewal of accreditation and shall not exceed 5 years.

Accreditation decision: decision for granting, maintaining, extending, reducing, suspending or withdrawing accreditation.

Granting of accreditation: granting of accreditation for a specific accreditation scope**.**

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

Extension of accreditation: addition of conformity assessment activities to the scope of accreditation**.**

Reassessment: assessment performed to renew the accreditation cycle

Note For the purposes of this regulation, the reassessment is indicated as a renewal.

Reduction of accreditation: cancellation of part of a Laboratory's scope of accreditation.

Suspension of accreditation: implementation of temporary restrictions on all or part of a Laboratory's scope of accreditation.

Withdrawal of accreditation: cancellation of a Laboratory's accreditation for the entire scope of accreditation.

Calibration and Measurement Capability*:* measurement and calibration capability of the Laboratory as available to Customers under normal conditions, expressed in terms of***:***

- measurand or reference material
- method or procedure of measurement or calibration and type of instrument or material to be calibrated or measured
- measuring range
- measurement conditions (additional parameters important for capability definition)
- measurement uncertainty

Note: calibration and measurement capability is also referred to as 'metrological capability".

Note: In the context of the CIPM MRA and ILAC mutual recognition agreements, the measurement and calibration capability can be consulted:

- in the scope of accreditation of the Laboratory available on the sites of the signatory of the ILAC mutual recognition agreement ILAC;
- in the BIPM KCDB (Key Comparison Data Base) under the mutual recognition agreement CIPM MRA.

Accreditation Table: a document attached to the Accreditation Certificate that contains the Laboratory's scope of accreditation, i.e., its metrological capabilities together with the sites where the relevant calibration operations are performed.

Note: The Laboratory may not issue Calibration Certificates showing measurement results outside the metrological capabilities indicated in the Accreditation Table.

Metrological area: area of measurement and calibration activities of a Laboratory characterised by specific metrological competences of the Laboratory itself.

Note: examples of metrological areas are physical quantities (such as temperature, pressure, volume) or specific areas of measurement (such as optical measurements, acoustic measurements, periodic verification.

Metrology sector: Identifies, for a specific metrology area, metrology chains, measuring ranges and parameters, types of instruments that have common calibration procedures and methods.

Technical Officer: Person appointed by ACCREDIA DT to manage the assessment phases for accreditation purposes, coordinating the activities of System Assessors and Technical Assessors/Experts.

Department Technical Secretariat: Function appointed by ACCREDIA DT to provide information to laboratories applying for accreditation, to already accredited Calibration Laboratories/Centres and their users, interfacing where necessary with other ACCREDIA DT functions.

Application Review Function: Function entrusted by ACCREDIA DT to review applications for accreditation/renewal/extension/reduction/renunciation/transfer of ownership submitted by Laboratories.

System Assessor: Person qualified by ACCREDIA and appointed by ACCREDIA DT, either alone or as part of an assessment team, to assess the conformity of a Laboratory's management system.

Technical Assessor: Person qualified by ACCREDIA and appointed by ACCREDIA DT to assess the technical competence of a Laboratory with reference to the metrological fields for which the Laboratory is accredited or has applied for accreditation.

Technical Expert: A person qualified and appointed by ACCREDIA DT, working under the responsibility of an Assessor, to provide specific knowledge or experience regarding the assessment of particular areas of measurement.

Assessment Report: Document reporting the results of the assessment of the competence of a Calibration Laboratory, including the evaluation of the management system, the results of measurement comparisons, the verification of the application of operational and technical procedures, and the accreditation table.

Experimental Assessment Report: A document containing the results of the measurement audit or on-site experimental assessment.

Technical Report: Document reporting the evaluation of participation and results in an interlaboratory proficiency test (PT)/interlaboratory comparison (ILC).

It should be noted that in cases where different definitions are given for specific metrological terms, the VIM definitions have preference.

0.5. ACRONYMS

- ACCREDIA DT: ACCREDIA Department of Calibration Laboratories;
- CSA DT: Sector Accreditation Committee for the Calibration Laboratory Department;
- CdA: Committee for Accreditation Activities;
- DDT: Direction of Department of Calibration Laboratories;
- ATM: Assessors' monitoring;
- FT: Technical Officer;
- STD: Department Technical Secretariat;
- CAB: Conformity assessment Body;
- CMC: Calibration and Measurement Capability
- RST: Technical Review of Applications;
- GRS: Complaints and Reports Management.

1. CRITERIA AND INFORMATION FOR ACCREDITATION

1.1. INFORMATIVE PHASE

Any Laboratory may submit a written, verbal or computerised request to STD in order to know the details of accreditation.

Unless otherwise indicated, the references for ordinary correspondence are as follows:

Legal Headquarters: ACCREDIA, Via Guglielmo Saliceto, 7/9 - 00161 Rome;

Operating Headquarters: ACCREDIA Dipartimento Laboratori di Taratura, Strada delle Cacce, 91 - 10135 Torino.

If e-mail is used, it is requested that all communications be addressed to the appropriate e-mail boxes indicated on the website www.accredia.it.

Upon receipt of the request STD provides the requesting Laboratory with the address of the website www.accredia.it from which it is possible to download the list of ACCREDIA DT documents in force, which includes the documentation useful for accreditation purposes, as well as any other necessary information.

In any case, the feasibility analysis of the accreditation process cannot commence until ACCREDIA DT receives the application for accreditation, completed in all applicable parts in accordance with the requirements of section 1.2 below, 'Submission and assessment of the application for accreditation' and complete with all the annexes required therein in the appropriate form.

1.1.1. PRELIMINARY MEETING

When necessary, and at the request of the Laboratory interested in accreditation, a preliminary meeting may be organised at the ACCREDIA DT premises (or via remote connection) with a time commitment not exceeding half a day, to clarify the accreditation process to the Laboratory concerned. These meetings, to which the experts of the quantities involved may be invited, do not imply any mutual commitment and must not assume the character of consultancy (even involuntary).

1.1.2. PRELIMINARY VISIT

When necessary and at the request of the Laboratory interested in accreditation, a preliminary visit may be arranged for which a special technical-economic estimate is issued, expressed in man-days, in accordance with the conditions set out in ACCREDIA's current price-list. This visit may result in the identification of deficiencies in the system or in the Laboratory's competence, for which ACCREDIA DT guarantees formalisation, but does not provide for requests for corrections/corrective actions. In any case, the results of this visit will not influence the outcome

and duration of any subsequent request for accreditation. Only one preliminary visit may be conducted against a single Laboratory.

1.2. SUBMISSION AND ASSESSMENT OF THE APPLICATION FOR ACCREDITATION

The organisation wishing to start the accreditation procedure must fill in the accreditation application (DA-00 and DA-05, which may be written in Italian or in English), with all the required data and send it, together with the relevant attachments, to the STD of ACCREDIA DT to the appropriate mailbox segreteriadt@accredia.it.

The application must be signed by the Legal Representative of the applicant Organisation or by a duly authorised delegate. In the case of a delegation, for the purposes of the validity of the signature, ACCREDIA DT reserves the right to request the organisation to provide the document attesting to the delegate's powers of legitimisation in the field (e.g., notary power of attorney, managerial determination, Board of Directors resolution).

The applicant organisation must be a *legal entity*, i.e., **a legal entity**, natural person or legal person that assumes the obligations and rights arising from the operation of the business and possesses a VAT number. A legal entity is also a public legal person (e.g.: Region, Province and Municipality, Public Economic Bodies, Public Institutional Bodies such as I.N.P.S., I.N.A.I.L., Universities, etc.). For foreign organisations, the definitions of *legal* entity applied in the various countries, according to local legislation, apply. Natural persons are not eligible to apply for accreditation, with the exception of individuals with a VAT number (see also CERTIF 2012-04 REV4 and subsequent revisions)

The statute, or other equivalent document, of the applicant organisation must expressly provide for calibration activities as the object of its activities.

Accreditation may cover calibrations in one or more metrological fields, performed at one or more of the organisation's sites.

Any requests for accreditation for metrological areas not covered by ACCREDIA DT (not present in the Annex to DA-05 "Metrological Areas - LAT Sectors"), or in any case differing from the existing ones, are reviewed by the Department Direction in order to proceed with their inclusion in the Annex to DA-05 at the first suitable meeting of CSA DT.

If ACCREDIA DT receives applications concerning calibration activities carried out by the Laboratory in a foreign country, the provisions of Regulation (EC) 765/2008 and subsequent amendments, of ACCREDIA procedure PG-12 "Management of "Cross Frontier" accreditations", of the relevant EA and ILAC documents and of the documents issued by the European Commission apply. Accreditation may be performed in cooperation with another accreditation Body recognised within EA and ILAC. In this case, the document review and on-site assessment phases may also be carried out using assessors appointed by the other Accreditation Body. A copy of the relative documentation, in Italian or English, must be officially provided to ACCREDIA DT by the other Accreditation Body.

Within 30 calendar days of receipt of the application, RST assesses its completeness and correctness in terms of filling in the fields and the presence of the required annexes, and verifies, in cooperation with DDT and ATM, that ACCREDIA DT has sufficient expertise and resources to carry out the requested accreditation:

- if this assessment is positive: STD formalises its acceptance to the Laboratory;
- if this assessment is negative: STD formalises to the Laboratory the non-acceptance of the assessment and requests in writing the necessary integrations that the Laboratory must send within **12 months from the date of the request for integration.**

Acceptance of the application can only take place following the positive assessment of the integrations sent by the Laboratory within the deadline.

If the Laboratory has not sent the necessary documentation by this deadline, SDT will inform it that the deadline for starting the accreditation process has expired. In this case, the Laboratory wishing to restart the accreditation process must submit a new formal request for accreditation.

The only exceptions allowed, for which ACCREDIA DT accepts the accreditation file with reservation, are:

- the lack of the results of participation in proficiency testing and/or interlaboratory comparisons, where applicable, provided that evidence of registration is present;
- the lack of Certificates to be used for measurement audits as long as information on the reference instrument/materials and calibration service provider is present.

Upon acceptance of the application

- SDT informs the administration of ACCREDIA which prepares the invoicing of the acceptance of the application as per TA-00;
- DDT appoints the FT who will follow the process.

In addition to following the accreditation and then the ordinary maintenance operations, the appointed FT will follow up any extensions or changes in the scope of accreditation. The appointed FT normally follows a Laboratory at least until the next renewal.

If there is evidence of fraudulent behaviour, or if the Laboratory deliberately provides false information or conceals information, DDT will reject the application and reserve the right not to offer further services to the Laboratory.

If the Laboratory has had its accreditation withdrawn in the past for fraudulent behaviour/false information, DDT will proceed to reject the application for accreditation.

1.3. QUOTATION

D **60 (sixty) calendar days** from the date of acceptance of the application, the appointed FT will prepare the technical and economic estimate for the accreditation activities.

Quotations will be formulated according to the rates applied by ACCREDIA DT, contained in document TA-00, published on the ACCREDIA website.

The following are notified to the Laboratory in the technical and economic quotation: the names of the Assessors that ACCREDIA DT intends to appoint for the assessment and of any Experts.

Several Assessors may be appointed for different phases of the assessment process. In the event that very specific technical aspects are to be analysed, Technical Experts may be identified (outside the ACCREDIA DT Assessors' lists) to assist the Assessors in the assessments.

ACCREDIA DT does not provide the curricula vitae of its Assessors and Technical Experts. However, upon request, it can provide information about the existing collaborations of its Assessors and Technical Experts with potentially competing laboratories.

Laboratories may reject Assessors/Experts (or request that they be replaced) in the event of a conflict of interest, to be communicated to ACCREDIA DT, which will verify the consistency on the basis of prior declarations provided by the Assessor. If the reasons given are considered valid, the Assessor/Expert is replaced and the matter will be subject to evaluation within the framework of the relationship between ACCREDIA DT and the Assessor/Expert. Assessors employed by ACCREDIA DT cannot be recused by the Laboratory concerned except for serious reasons of incompatibility, which must be made explicitly clear to DDT.

Assessors may be replaced by other assessors with the same qualification, subject to DDT's assessment of the validity of the grounds for the submitted objection. An assessor who has been recused may be reappointed by ACCREDIA DT only after ascertaining that the conditions for recusal have been overcome.

After **5 (five) working days** from the submission of the quotation, in the absence of any communication, the Assessors and Experts shall be deemed accepted.

1.4. ACCREDITATION PROCESS

Upon receipt of the Laboratory's, or belonging to the Laboratory, order/acceptance of the quotation, the accreditation process is initiated, consisting of the following four steps:

- preliminary operations;
- review of documentation;
- on-site/remote/mixed assessments (visits);
- decision-making process.

Assessments must include all metrological sectors, and all sites. If the laboratory performs internal calibrations, these will be subject to documentary evaluation and assessed during the visit

1.5. PRELIMINARY OPERATIONS

Once the Laboratory has received the order/acceptance of the quotation, the appointment of the assessment team members is formalised.

Unless otherwise decided by DDT for justified technical or force majeure reasons, the appointed assessors will also be entrusted with subsequent surveillance assessments of the same Laboratory in the following four years (accreditation cycle).

It is to be noted that ACCREDIA DT's Assessors and/or Experts, being obliged to sign an agreement with ACCREDIA DT, are obliged to comply with the requirements of impartiality, independence, confidentiality and absence of conflicts of interest towards the Laboratory.

1.6. DOCUMENT REVIEW

During the review of the documentation of the Laboratory, the assessment team must assess the compliance of the system as documented, with the requirements of the regulatory documents and the contractual requirements foreseen by ACCREDIA DT, contained in this Regulation and other technical applicable Regulations/Documents. If the Laboratory performs internal calibrations, the relevant procedures will be evaluated.

As regards the participation in proficiency tests and/or interlaboratory comparisons, the Technical Assessors evaluate this documentation in terms both of the validity of the comparison with the Metrological Capacity required by the Laboratory in DA-05 and of the effectiveness of corrective actions implemented (where applicable).

Upon receipt of the documentation, complete with any registrations, the Assessors shall examine it. The above-mentioned document review is carried out and notified to the Laboratory **within 90 (ninety) calendar days** of receiving the order/acceptance of the quotation.

In case the results of the participation in proficiency testing and/or interlaboratory comparisons have not been attached to the DA-05, ACCREDIA DT waits for the same for **12 (twelve) months** (case admitted under 1.2 SUBMISSION AND ASSESSMENT OF THE APPLICATION FOR ACCREDITATION section 1.2 "Quotation"), however the analysis of the remaining documentation can be started. The specific evaluation of PTs and/or ILCs, when conferred, is notified to the Laboratory within **30 (thirty) calendar days** from its receipt.

Following the results of the document review, FT proceeds as follows:

- if the results are positive, it prepares the next accreditation phase;
- if the results are not positive and documentary changes are necessary, it arranges for the documental assessment to be repeated, no more than two more times. The Laboratory must implement corrective actions/corrections within a maximum period of **12 (twelve) months** from the first adjustment request and **6 months** from the 2 subsequent ones;
- if the negative results refer to the assessment of participation and results in proficiency testing and/or interlaboratory comparisons, he/she will require the Laboratory to analyse the causes and propose Corrections and Corrective Actions. For the evaluation of the effectiveness of these Actions ACCREDIA DT reserves the right to propose, if necessary, an integration to the quotation;
- if the negative results of the third assessment persist, he/she proposes to DDT to discontinue the accreditation process by applying the provisions of section 1.8.3 CLOSURE OF THE ACCREDITATION PROCESS
- once **12 (twelve) months** have elapsed since the last adjustment request without the Laboratory having done so, it proposes to DDT to terminate the accreditation process, applying the provisions of section 1.8.3 CLOSURE OF THE ACCREDITATION PROCESS

In the presence of positive outcomes with comments the Laboratory shall:

- in case of acknowledgement transmit the revised documentation to FT and the assessment will be carried out in the next step;
- in case of non-acceptance must transmit justifications to FT.

If from the review of the documentation presented - as well as of any direct contact with the requesting Laboratory - is clear that the Laboratory does not have sufficient competence and impartiality, ACCREDIA DT will interrupt the accreditation process, applying the established provisions at section 3.2.1 CLOSURE OF THE ACCREDITATION PROCESS

1.7. ASSESSMENT

1.7.1. GENERAL

The scope of the assessment is to verify the implementation of the management system and the verification of technical aspects of the laboratory such as personnel competence, instrumentation and environmental requirements, including aspects related to internal calibrations (where applicable).

ACCREDIA DT can carry out in-presence, remote and mixed assessments, possibly using the Laboratory's Information Technology (IT) systems. In any case, ACCREDIA DT will carry out an appropriate preliminary feasibility analysis in order to determine the possibility of carrying out a fully remote or mixed assessment activity.

For the purposes of this analysis, it may also be necessary to carry out a prior simulation of how the assessment will be performed by the Laboratory, especially in cases where experimental activities are planned both at the Laboratory's own premises and at those of the Customer.

In the event that the activity carried out remotely proves unsatisfactory at the end of its implementation (e.g., due to connection problems, difficulties in sharing documents and/or retrieving evidence, difficulties in observing experimental activities) follow-up activities must be carried out, shared with the Laboratory by the assessment team and recorded in the relative assessment report. The costs of the follow-up activities are borne by the Laboratory if it is responsible for the causes of the ineffective remote assessment.

1.7.2. ASSESSMENT PLAN

1.7.2.1. PREPARATION AND NOTIFICATION

FT agrees, with the Laboratory and the Assessors involved, the date for the visit, prepares and sends the document "Notification and Assessment Plan" to the Laboratory, with the scope of formalising the composition of the team, the objectives, the field, the criteria and the significant elements of the assessment.

The assessment plan must be articulated in such a way that all aspects of the Laboratory activity involved in the accreditation process are adequately evaluated, in particular all metrological sectors must be assessed. Concerning the sampling of the instruments falling within the scope of accreditation (as requested by the Laboratory when applying for accreditation and reported in DA-05) ACCREDIA DT considers the risk associated with the related calibration activity, sites and personnel.

In the event that the request for accreditation concerns activity carried out in several locations, each of the sites must be evaluated.

In the case of an assessment:

- in presence or mixed: at least **10 (ten) calendar days before** the date of the assessment, the Laboratory shall send ACCREDIA DT the MD-19 form "Information regarding specific, real risks in the workplace and protection measures", filled in with information on the place where the audit is to be performed and on any special risks existing in the workplace where the audit will be performed.

In the event of non-receipt of the MD-19 form on time, ACCREDIA DT reserves the right to proceed with the assessment in any case: in this case, during the initial meeting (section 1.7.4.2), the Laboratory must deliver the duly completed document to the Assessment Group Manager. ACCREDIA DT assessors undertake to respect the safety conditions received.

- remote: ACCREDIA DT assessors undertake to respect confidentiality commitments regarding the information and/or documents shared by the Laboratory during the assessment, as recalled in the assessment plan.

1.7.2.2. ACCEPTANCE OF THE PLAN

The assessment can only take place after the Laboratory has received acceptance of the plan described in the document 'Notification and Assessment Plan'. This acceptance must be received within **3 (three) working days** of receipt.

In the event that FT, after repeated attempts, is unable to agree with the Laboratory on the dates of the assessment, he/she will nevertheless send, at least **10 (ten) working days** in advance of the date agreed with the assessment team, the assessment plan. This may be repeated a maximum of two more times.

If the Laboratory is still not available, the provisions of Section 1.8.3 'CLOSURE OF THE ACCREDITATION PROCESS' apply.

1.7.3. PREPARATION OF ASSESSMENT

In special cases (e.g., in cases of unscheduled accreditation, renewal and surveillance, for those laboratories with a large number of metrological sectors and/or for multi-location laboratories) FT in agreement with DDT assesses, on the basis of the results of previous assessments, whether the participation of the appointed FT is necessary.

The costs related to the possible participation of the FT in presence are borne by ACCREDIA DT within the framework of a specially prepared annual expenditure budget.

When present, the tasks assigned to the FT are as follows

- collaborate with the Assessors in order to ensure that the assessment of the Laboratory takes place in compliance with the UNI CEI EN ISO/IEC 17011 standard and the applicable ACCREDIA DT documents;
- provide Assessors and/or the Laboratory with any clarifications concerning the requirements of UNI CEI EN ISO/IEC 17025, UNI EN ISO 15195 and ACCREDIA documents.

During the assessment, the presence of observers is also permitted, at the request of the Laboratory, which must give ACCREDIA DT prior notice of it, also providing the commitment to confidentiality of the observers themselves.

If DDT needs Observers to participate in the assessment (e.g., Assessors in training, EA peer assessors, ...), the FT will give prior notice to the Laboratory providing, if necessary, a commitment to confidentiality of the Observers themselves. If, however, the Laboratory wishes to place reservations on the names of the Observers, it must justify them in writing to ACCREDIA DT within **5 (five) working days**, after which the names will be considered accepted. The costs relating to the participation of such Observers shall be borne by ACCREDIA DT.

Under no circumstances may any Observers (whether from the Laboratory or ACCREDIA DT) interfere with the performance of the assessment. Should this occur, it will be the responsibility of the Lead Assessor to request/provide for the immediate removal of the Observer.

The assessment carried out by the appointed assessors in the terms envisaged in the UNI EN ISO 19011 standard includes the following phases:

- preliminary meeting of the assessors in order to define and agree on the final operational details for carrying out the assessment;
- initial meeting with the presence of the personnel indicated in the DA 05 with responsibility for the Laboratory, the management system and their staff;
- carrying out of the assessment, with support from the Laboratory staff;
- holding of intermediate meetings of the assessors, if deemed necessary by lead assessor;
- pre-final meeting, at which the assessors define the findings of the assessment;
- final meeting, with the Laboratory staff and acknowledgement of any reservations.

The Laboratory must make available a reserved room to the assessment team, preferably with computer and internet connection, for the preliminary, intermediate and final internal meetings of the Assessors.

The Laboratory must also allow Assessors the access to the Laboratory premises and archives (whether paper or electronic) for the purpose of carrying out the assessment.

1.7.4. OPENING OF THE ASSESSMENT

1.7.4.1. PRELIMINARY MEETING TO OPEN THE ASSESSMENT

Prior to the initial meeting with the Laboratory, a meeting of the assessment team is held to discuss how to evaluate and distribute the tasks.

1.7.4.2. INITIAL MEETING WITH THE LABORATORY

During the initial meeting between the assessment team and the representatives of the Laboratory agreed in "Notification and Assessment Plan", the Lead Assessor has to:

a) introduce the assessment team with its tasks;

b) clarify the roles and responsibilities of any ACCREDIA DT (EVA) assessors, FTs, guides (i.e., persons assigned by the Laboratory to accompany Assessors), Assessors-in-Training and observers, according to ISO 19011;

c) explain the purposes of the Assessment, which shall be carried out in compliance with the safety conditions;

d) outline the assessment plan, clarify any points not included, and agree any changes to it;

e) define the details of any calibration to be carried out in the presence of the Assessor;

f) explain any subdivisions of the team into subgroups and identify the verification steps to be assigned to the subgroups in order to optimize the timing of the assessment;

g) agree on the timing and modalities for assessment of any off-site calibrations;

h) agree on possible changes to the assessment plan;

i) illustrate the assessment process and the possibility of the Laboratory to make reservations;

j) remind the commitment of each member of the group to the confidentiality of the information;

k) make it known that confidential meetings of assessors may be necessary in the course of the assessment;

l) ask for confirmation of the presence of the Laboratory Management or its representative at least at the final meeting and complete and sign the list of persons taking part in the assessment;

m) offer the Laboratory the opportunity to ask for further clarification;

n) formalize the security requirements as required in the Notification and Assessment Plan document, verifying the existence of the safety conditions previously communicated through the MD-19 document.

This meeting is to be foreseen both in the case of an assessment in presence and in a remote one.

1.7.5. CARRYING OUT THE ASSESSMENT

1.7.5.1. GENERAL

Assessment activities are carried out using the ACCREDIA DT checklist, which includes a list of indications aimed at verifying the compliance of the Laboratory with the provisions of the standards and ACCREDIA DT requirements.

The checklist used by the System Assessor, which can be found on the website www.accredia.it, is the same as the one used by the Laboratory for the self-assessment attached to Application DA-05.

The enquiries carried out by the assessors are of two types:

- "horizontal" assessment, mainly focused on one or more points of the standard and their implementation;
- "vertical" assessment, consisting in assessing the implementation of standard requirements in an area of activity.

It is reminded that the purpose of assessments for accreditation is to verify the compliance of the Laboratory with the requirements of reference standards, EA, ILAC, ACCREDIA DT implementing documents for the attestation of technical competence of the Laboratory for the execution of the calibrations indicated in the scope of accreditation. Binding standards, such as

safety, privacy, administrative responsibility, etc. do not fall within the requirements for accreditation and are not subject to verification, unless expressly stated in the reference standard. The behaviour that ACCREDIA DT Assessors have to keep against potentially violated binding requirements is reported in paragraph 1.7.5.4.

In carrying out assessments, ACCREDIA DT Assessors will have to abstain from requesting the Laboratory copies of the examined documentation, unless it is necessary to demonstrate the objective evidence of non-conformity or any Laboratory reservations. In this case the copies must be enclosed to the checklist and sent to the reference FT. No Laboratory's document may be retained by the Assessors in any way, except copies of Calibration Certificates sampled in archive and the Certificates of the calibrations performed during the audit, that are to be attached to the checklist.

1.7.5.2. TASKS OF THE SYSTEM ASSESSORS

The System Assessor must verify the compliance of the Laboratory Management System with the requirements of the UNI CEI EN ISO/IEC 17025:2018 standard, EA, ILAC and/or other reference standards and ACCREDIA DT requirements.

Assessment of the management system will be extended to all applicable requirements in accreditation and renewal assessments.

In addition, the System Assessor performs the following tasks:

- organizes and coordinates tasks during assessment, if he is the Lead Assessor;
- assesses the managing competence of the key personnel individuated by the Laboratory discussing aspects related to the management procedures;
- replaces and/or cooperates with the Technical Assessor in the assessment of those general technical requirements such as those relating to environmental conditions, production process, equipment and samples management and staff.
- assess the compliance of the use of references to accreditation and, in particular, the use of the ACCREDIA accreditation mark, with respect to the provisions of this Regulation and of the Regulations for the use of the mark ACCREDIA RG-09.

1.7.5.3. TASKS OF THE TECHNICAL ASSESSOR

The Technical Assessor must verify the technical competence of the Laboratory in compliance with the requirements of the UNI CEI EN ISO/IEC 17025:2018 standard, UNI EN ISO 15195 (where applicable), EA, ILAC and/or other reference standards, specific ACCREDIA DT requirements and sectorial technical standards.

In particular, the Technical Assessor carries out the following tasks:

- if he/she is the Lead Assessor, he/she organizes and coordinates activities during Assessment;
- assesses the state of metrology chains and their compliance with applicable requirements;
- assesses the status and adequacy of all measuring and auxiliary equipment including the characteristics of the environments where the calibration activities are carried out and their conditioning systems;

- assesses the technical competence of personnel, also through measurements carried out in his presence;
- collaborates with the System Assessor.

1.7.5.4. FORMULATION OF FINDINGS

At the end of each significant phase of the Assessment, the Assessor will briefly present the outcome of the assessment to the interviewee by verbally communicating any deficiencies found that give rise to findings. The findings will then be reviewed by the assessment team and then classified as Non-Conformity, Concerns or Comments as per section 0.4 "Terms and Definitions" of this Regulation.

The following is the behaviour that the Assessors must keep against potentially violated binding requirements:

- any violations found by the Assessors on binding requirements not covered by the audit are not to be included in the assessment report;
- any violations encountered by the Assessors on binding requirements linked to the purpose of the audit should be reported as comments to prompt the affected Laboratory to monitor these aspects during subsequent assessments;
- any violations encountered by the Assessors on binding requirements for audit purposes must be reported as NC.

1.7.5.5. INTERRUPTION OF THE ASSESSMENT

If during the assessment, serious Laboratory deficiencies from the requirements of the standard or ACCREDIA DT documents arise, the Lead Assessor, after speaking to FT and/or DDT, may propose the interruption of the assessment to the Direction of the Laboratory.

In case of acceptance by the Direction or the appointed staff of the Laboratory, the Assessors will carry out the scheduled formalizing the findings so far emerged and registering in the ACCREDIA DT checklist that the assessment was interrupted with the relevant motivations.

If, on the other hand, the Direction or the appointed staff of the Laboratory express its willingness to continue the assessment, the assessors will record that declaration on the ACCREDIA DT checklist and continue the activities planned.

The Lead Assessor is responsible for describing in detail both situations in the assessment report.

If the activity is interrupted, by agreeing with the Laboratory that the conditions for coordinated work are not met, the activity will be invoiced according to the terms of the current price-list (section 7 "Special cases" of the TA-00 document in force).

1.7.6. FINAL MEETING AND ACKNOWLEDGEMENT OF RESERVATIONS

At the final meeting between the assessment team and the Laboratory representatives, the Lead Assessor shall:

- present a summary of the activities carried out;

- submit the opinion on the Laboratory formulated by the assessment team;
- remind that the assessment outcomes are the result of sampling, and therefore other criticalities, in addition to those found, may be present and be identified in subsequent assessments of both ACCREDIA DT and internal audits;
- present any findings detected, illustrating their content and motivation by seeking the understanding and sharing of the findings by the Laboratory, specifying that the corrective action part proposed by the Laboratory must be completed only after the request for Corrective actions by ACCREDIA DT;
- collect any reservations submitted by the Laboratory; alternatively, the Laboratory may make reservations by completing its form (DT-Mod-007) within **3 (three) working days**; the acceptance of the reservations made by the Laboratory is subject to the DDT;
- request evidence of acceptance from the Laboratory of the report containing the findings and summary report of the assessment by signature or equivalently;
- issue the Laboratory with a copy of the report containing both the list of findings and the summary report, specifying that ACCREDIA DT reserves the right to confirm or not its contents.

1.7.7. ACTIONS FOLLOWING THE ASSESSMENT

1.7.7.1. REQUEST OF FINDINGS MANAGEMENT PLAN

Following the assessment, FT and/or DDT perform a review of the findings made by the Assessors, reserving the right to modify and/or classify them differently, and FT officially transmits the final version of the findings to the Laboratory, with the corresponding request for the management plan including:

- For **Non-Conformities**: the correction (where applicable), a root cause analysis and corrective actions related to the identified causes, with an indication of the timeframe for implementation;
- For **Concerns**: the correction, a root cause analysis and, when determined by the Laboratory in relation to the identified causes, corrective actions, with an indication of the timeframe for implementation;
- For **Comments**: the reasons for any non-acceptance of the comment. If, on the other hand, the Laboratory intends to acknowledge the comment, the consequent actions implemented will be verified by ACCREDIA DT during the first suitable assessment.

The Laboratory must communicate to FT **within 10 (ten) working days** from the sending of the request its management plan of the findings and the implementation timeframe. The implementation time **for corrections and corrective actions** cannot exceed **3 (three) months** from the date of confirmation of findings by FT, except in justified cases and approved by DDT, which may authorise exceptions, however not exceeding **6 (six) months**. All evidence must be submitted at the same time by the established date.

If the Laboratory does not transmit the findings management plan to ACCREDIA DT within the deadline, ACCREDIA DT proceeds with the request for closure of the accreditation process as described in paragraph 1.8.3 CLOSURE OF THE ACCREDITATION PROCESS below.

1.7.7.2. ASSESSMENT OF THE FINDINGS MANAGEMENT PLAN

The assessment of the findings management plan is communicated by FT to the Laboratory within **15 (fifteen) working days** from its receipt.

If the assessment team's evaluation of the findings management plan is not positive, FT requests a new proposal from the Laboratory, which must be received within **10 (ten) working days**.

Should the second proposal of the findings management plan and/or the documentary evidence prove to be inadequate or should the timeframe not be met, ACCREDIA DT may proceed with **the closure of the accreditation** process as described in paragraph 1.8.3 CLOSURE OF THE ACCREDITATION PROCESS below.

In the event that the Laboratory, due to internal necessity, wishes to modify the findings management plan approved by ACCREDIA DT, it must notify ACCREDIA DT, which will proceed with a new assessment.

1.7.7.3. ASSESSMENT OF EVIDENCE

The assessment of the evidence is communicated by FT to the Laboratory, **within 15 (fifteen) working days** from their receipt.

If the assessment of the evidence by the Assessment Team is not positive, FT requests updates/integrations from the Laboratory, which must be received **within 10 (ten) working days**. The assessment of updates/integrations is communicated by FT to the Laboratory, **within 15 (fifteen) working days** from their receipt.

If the second assessment is negative, ACCREDIA DT may **close the accreditation process** as described in Section 1.8.3 "CLOSURE OF THE ACCREDITATION PROCESS" below.

Finally, if the deadlines indicated in the approved plan are not met, ACCREDIA DT may proceed with **the closure of the accreditation process** as described in Section 1.8.3 "CLOSURE OF THE ACCREDITATION PROCESS" below.

In the case of non-Conformity or a significant number of Concerns, a supplementary assessment may be carried out to verify the closure with effectiveness of the corresponding corrective/corrective actions. In this case, upon authorisation by DDT in the case of accreditation or following a resolution of the CSA DT in other cases, the provisions of section 2.1.3.1 SUPPLEMENTARY SURVEILLANCE ASSESSMENT shall apply.

Evidence required for **non-Conformities** must be assessed positively before the CSA DT meeting.

1.8. DECISION-MAKING PROCESS

1.8.1. ASSESSMENT OF RESULTS

Upon completion of the above assessments and their final outcome, FT collects all the documentation relating to the file, in particular the results of the document review, the technical reports, the assessment findings, the experimental assessment reports, and prepares:

- the accreditation table;
- the assessment report.

It is possible that during the assessments

- the Laboratory requests reductions of the scope of accreditation within the requested metrological area and/or metrological sector that have to be formalised by sending the DA-05;

- ACCREDIA DT imposes reductions of the scope following the outcomes of the assessments (documental assessments and/or PT and/or ILC outcomes and/or on-site assessments) that FT formalises to the Laboratory by means of a registered letter.

DDT performs conformity assessments on the implemented process against the applicable requirements and decides whether the file can be submitted for evaluation by the CSA DT or whether it needs further additions and/or revisions.

1.8.2. CSA DT RESOLUTION ON ACCREDITATION

The CSA DT evaluates the competence of the Laboratory and decides on accreditation. In the case of granting of accreditation, CSA DT also decides on the timing of the programmed surveillance. In the event that the Laboratory has registered a significant number of non-conformities, the CSA DT may decide to increase the surveillances, motivating this need.

SDT, **within 5 (five) working days** of the resolution, submits the results to the Laboratory, including: Assessment Report, Experimental Reports and/or Technical Reports, attachment to the Accreditation Certificate (Accreditation Table).

The name of the accredited Laboratory is published on the ACCREDIA DT website. The granting of accreditation is formalized through a special agreement signed between ACCREDIA DT and the Body. Accreditation begins on the date of CSA resolution, but performs its legal effects by the Laboratory signing the agreement with ACCREDIA (CO-00).

The Laboratory is required to return the signed Accreditation Agreement within **30 (thirty) calendar days of transmission**. Otherwise, the CSA may apply one of the sanctions provided for in paragraph 6 below p 5.1 SUSPENSION.

If the Laboratory intends to request authorization to use the Combined Mark, it must send an example of use of the aforementioned Combined Mark and obtain written approval from ACCREDIA DT, before using it, according to the instructions provided by ACCREDIA during the accreditation notification phase.

The accreditation certificate cannot be given to third parties.

Acceptance of the Agreement and registration on the list of accredited Laboratories commit the Laboratory to maintain its organizational structure and its functioning in compliance with the requirements established in this Regulation, in all other applicable ACCREDIA documents, in the standards and in the general and sectoral normative references '

With regards to the use of references to accreditation and, in particular, the use of the ACCREDIA accreditation mark and/or the reference to accreditation, the Laboratory is required to comply with the provisions of this Regulation and the Regulations for the use of the ACCREDIA mark RG-09.

The accreditation and the relevant agreement are valid for **four years**.

If the CSA DT decides not to release the accreditation and considers necessary to have further assessments, DDT shall notify the Laboratory, within five days of the date of the resolution, the reasons for it and any conditions for continuing the process. In case the Laboratory decides to continue, ACCREDIA DT prepares a new assessment activity programme and issues the relevant estimate.

If the CSA DT decides not to grant accreditation, the provisions of paragraph 1.8.3 CLOSURE OF THE ACCREDITATION PROCESS apply.

1.8.3. CLOSURE OF THE ACCREDITATION PROCESS

In the event that one of the conditions set forth in this Regulation to close the accreditation process appears, ACCREDIA DT submits the file to CSA DT for the adoption of the sanction, giving reasons for the closure proposal. Within **15 (fifteen) days** of the date of the CSA DT's decision, DDT will notify the Laboratory of the termination of the accreditation process by registered letter with return receipt or certified electronic mail (PEC).

ACCREDIA's administration prepares the issue of the related invoice for the services already given.

In the event that the Laboratory wants to start a new accreditation process, it will have to submit a new application for accreditation (DA-00 e DA-05).

2. SURVEILLANCE AND MAINTENANCE OF ACCREDITATION

2.1. SURVEILLANCE

2.1.1. GENERAL

During the period of validity of the accreditation, ACCREDIA DT is obliged to implement a verification programme to assess the scope and sites of the accredited laboratories in accordance with the requirements of the standards and rules deriving from EC Regulation 765/2008 and subsequent amendments (ISO/IEC Standards and EA/ILAC documents).

Therefore, all accredited laboratories must undergo surveillance activities both by means of scheduled and unscheduled assessments, in order to ascertain continuous compliance with the requirements of these Rules, international standards and guides and any other applicable

regulatory reference, using all the assessment techniques envisaged by the ACCREDIA DT Regulations (for example: unscheduled visits, mystery audits, etc.) at their own site(s) and at their customers' sites. In the event of extraordinary events that prevent assessments from taking place, ACCREDIA DT applies the requirements of the IAF ID3 documents and any other applicable requirements issued at international level by EA/IAF/ISO.

Surveillance assessment activities are described in an individual quotation prepared by FT, approved by DDT and forwarded by STD.

2.1.2. SCHEDULED SURVEILLANCE ASSESSMENT

The time frame established by ACCREDIA DT for scheduling surveillance is as follows:

- first surveillance: **within 12 (twelve) months** from the decision of the CSA DT of accreditation or renewal of accreditation;
- second surveillance: **within 18 (eighteen) months** after the assessment.

In the accreditation cycle, activities at all laboratory sites, including those at the customer's premises, must be assessed. In exceptional cases and if it is not possible to organise this activity externally, it is permissible to carry out the assessments by recreating the same conditions in environments other than the customer's premises. Assessments may also be performed remotely, excluding that all surveillance assessments of the accreditation cycle may be performed in this single mode.

In any case, no remote assessment activity will be performed:

- where a stable Internet connection cannot be guaranteed;
- where it is not possible to follow the experimental calibration activity remotely;
- where the Laboratory requires the assessment activity to be carried out in presence;
- where the degree of computerisation of the laboratory, including that of its system and technical documentation, does not allow effective remote assessment.

ACCREDIA DT will carry out an appropriate preliminary feasibility analysis in order to determine whether or not a fully remote or mixed-mode assessment activity can be carried out.

For the purposes of this analysis, it may also be necessary to carry out a prior simulation of how the assessment will be performed by the Laboratory, especially in cases where experimental activities are envisaged both at the Laboratory's own premises and at those of the Customer.

In order to determine the surveillance assessment man days, ACCREDIA DT conducts periodic risk analyses, 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 previous assessments, outcomes of internal corrective actions taken by the Laboratory against internal technical NCs and/or negative outcomes of participation in PT/ILCs, possible sanctioning measures, particularly low uncertainties, traceability of measures deriving from supplier qualifications directly from the Laboratory, the presence of well-founded complaints/reports, the presence of critical accreditations, the number of certificates issued, etc.

Any lightening of the surveillance programme can be applied by ACCREDIA DT depending on the experience and capacity of the Laboratory.

The purpose of scheduled surveillance assessment is to assess the continued compliance with the requirements of this Regulation, international standards and guides and any other applicable regulatory reference, both for system and technical aspects.

In general, within the period of validity of the accreditation, each metrology sector must be assessed at least once, as well as any aspect of the management system, with the exception of the ionizing radiation measures (metrological area with critical sectors), for which the assessment is expected for each surveillance.

Furthermore, in the course of each scheduled surveillance, the set of metrological sectors and sampled locations must nevertheless allow the assessment of a representative set of activities accredited to the Laboratory.

Specifically, during a surveillance assessment, the implementation and effectiveness of corrective actions initiated following the previous assessment is always verified.

Particular attention must then be paid to the verification of the results of participation in proficiency testing and/or interlaboratory comparisons, internal audits, reviews, complaints, calibration certificates issued, the maintenance and improvement of the management system, the conformity of the technical activity and the correct use of the ACCREDIA mark and/or reference to accreditation.

Whenever possible the Technical Assessor, according to the FT's indications in the Notification, has the right and the duty to request that the calibration be carried out by licensed operators other than those verified during the previous assessment.

The planning and implementation of the surveillance assessment is carried out in a similar way to the accreditation assessment.

In the preparation phase of the scheduled surveillance of the accredited laboratory with flexible scope, ACCREDIA DT applies the requirements of Technical Regulation RT-26 in the current revision.

Scheduled surveillance activities are described in an estimate specifically prepared by FT, approved by DDT and forwarded by STD to the Laboratory at least **2 (two) months** in advance of the deadline month decided by the CSA DT.

In the event of interruption of the assessment (see section.2.4.5 "Interruption of the on-site assessment") ACCREDIA DT reserves the right to submit the file to the CSA DT for the adoption of any sanction measures, as per section 6 "Suspension, reduction, withdrawal and renunciation of accreditation".

Following the assessment, FT and/or DDT carry out a review of the findings made by the Assessors, reserving the right to modify and/or classify them differently, and FT officially transmits the final version of the findings to the Laboratory, with the corresponding management plan request.

The Laboratory must communicate to FT **within 10 (ten) working days** from the sending of the request its findings management plan and implementation timeframe. The implementation time **for corrections and corrective actions** cannot exceed **3 (three) months** from the date of confirmation

of findings by FT, except in justified cases and approved by DDT, which may authorise exceptions, however not exceeding **6 (six) months**. All evidence must be submitted at the same time by the established date. The plan assessment is communicated by FT to the Laboratory **within 15 (fifteen) working days** from receipt of the findings management plan.

If the assessment of the findings management plan by the Assessment Team is not positive, FT shall request a new proposal from the Laboratory which must be received **within 10 (ten) working days**.

If the second proposal of the findings management plan and/or the documentary evidence is not suitable, DDT may proceed to submit the case directly to the CSA DT for the adoption of sanctioning measures such as suspension, reduction or withdrawal of accreditation, applying the provisions of § 5 SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION.

2.1.3. NON-SCHEDULED SURVEILLANCE ON-SITE ASSESSMENT

2.1.3.1. SUPPLEMENTARY SURVEILLANCE ASSESSMENT

The Laboratory is required to communicate to the competent FT any changes that have occurred in relation to what has previously been communicated with the Accreditation Application (e.g., change of key figures in the organization, change of company name, change of location).

On the basis of these communications and/or following the identification of unsuitable situations by ACCREDIA DT, during scheduled assessments or from indications of the CSA DT, the above-mentioned surveillance activities may be intensified, subsequent to the granting of accreditation/extension/renewal by carrying out supplementary unscheduled surveillance.

In the event of major changes, the provisions of § 5.1 SUSPENSION shall apply.

The Laboratory is informed promptly and must accept the technical quotation **within 10 (ten) working days**; within this time period, the Laboratory may, where appropriate, exercise the right to recuse the members of the Assessment Group on the basis of the provisions of paragraph 1.3 QUOTATION.

If the quotation is not accepted:

- In cases of accreditation, the provisions of paragraph 1.8.3 CLOSURE OF THE ACCREDITATION PROCESS shall apply;
- In the case of maintenance of the accreditation, the provisions of paragraph 5.1 SUSPENSION shall apply.

In the event of a negative outcome of the supplementary assessment, the CSA may apply the following measures:

- In the case of accreditation as set out in section 1.8.3 CLOSURE OF THE ACCREDITATION PROCESS;
- if the assessment has been caused by numerous and serious non-Conformities that compromise the competence of the Laboratory, it may decide to withdraw accreditation, as set out in 5.3 WITHDRAWAL OF ACCREDITATION;
- if the assessment has been decided for specific metrological sectors, it may decide to grant the maintenance/renewal of accreditation, excluding those sectors, as set out in section 5.2 REDUCTION OF ACCREDITATION.

If the Laboratory wishes to start a new accreditation process or extension of accreditation, it must submit a new Application for Accreditation and make all payments according to the ACCREDIA Price-list (TA-00).

2.1.3.2. EXTRAORDINARY SURVEILLANCE ASSESSMENT

An extraordinary assessment is imposed on the Laboratory by FT, after consulting DDT, in case of customer and/or user complaints or objectively motivated reports received by ACCREDIA DT questioning the compliance of the Laboratory's competence.

The Laboratory is promptly informed about this and must accept the technical quotation within **10 (ten) working days**; within this timeframe the Laboratory may, if necessary, promptly exercise the right to reject the members of the assessment team, on the basis of what is set out in section 1.3 QUOTATION if this estimate is not accepted, what is set out in section 5.1 SUSPENSION applies.

Unscheduled assessments of an extraordinary nature may also be those without prior notice ordered by the CSA DT to verify the effectiveness of corrective actions to the findings issued by ACCREDIA DT, for which the CSA DT, when deliberating, has expressed doubts or the need for monitoring or ordered by the Management following the receipt of reports from the market/competent authorities or for feedback from mystery audit activities that cast doubt on the reliability of the Laboratory's calibration activities or following risk analysis.

The costs of these assessments are only charged to the Laboratory in the event that non-conformities are identified or a large number of concerns are found. Otherwise, the costs are borne by ACCREDIA DT.

In the case of unscheduled assessments, the Assessment Team, upon arrival at the laboratory premises, will ask to be allowed to interface with a Laboratory Manager or Contact Person to whom it will explain the purpose of the assessment and to whom it will deliver:

- a communication from the Management of ACCREDIA DT, containing the reasons for this assessment;
- the Assessment Plan where the Laboratory may record any objections/non-acceptances to the plan itself or to the names of the ACCREDIA Assessment Team.

2.2. MAINTENANCE

The maintenance activity involves:

a) assistance for the operation of the Laboratory (archive and Laboratory data update, diffusion of documentation on applicable requirements);

b) the reporting and/or forwarding of ACCREDIA, EA, ILAC or other relevant documentation for the Laboratory activity;

c) review of any updated management system documentation (e.g., quality manual, procedures);

Documentation that the Laboratory may deem convenient or necessary to update must be sent in advance for assessment to ACCREDIA DT. Changes to the management system that do not affect the

Laboratory's fulfilment of the requirements may also be communicated immediately after their application.

Any updates to the documentation that require assessment also by Technical Assessors and/or Technical Experts do not fall under maintenance activities and are therefore subject to a specific quotation.

In the event that the changes made to the documentation result in changes to the Laboratory's metrological capabilities, including cases of improvement or worsening of uncertainties, the requirements of section 4 EXTENSION OF ACCREDITATION and section 5.2 REDUCTION OF ACCREDITATION respectively shall apply.

d) the control of Calibration Certificates issued in the case of initial accreditation and extension of accreditation to a new sector;

In that case, the Laboratory must send the first 10 Certificates issued and the relevant technical records to the reference FT, which will be examined during the first surveillance visit.

e) the examination of the update of the documentation following the Laboratory's implementation of updates of standardised methods due to reissue of the reference standards. The update must be formalised by the Laboratory by sending the Application for Accreditation DA-05 duly filled in and complete with the relevant annexes.

   In the event that, following verification by ACCREDIA DT, the regulatory update has no impact on the technical competence of the Laboratory, DDT may prepare a non-burdensome dossier for the Laboratory. In this case ACCREDIA DT shall publish the modified table within **10 (ten) working days**.

   In the event that, following an assessment by ACCREDIA DT, the regulatory update has an impact on the technical competence of the Laboratory that also requires assessment by Technical Assessors and/or Technical Experts, the assessments will be the subject of a specific quotation and the assessments will be carried out according to the following section 2.2.1 ASSESSMENTS FOR REGULATORY ALIGNMENT

The costs of the above activities are normally included in the annual maintenance fee that the Laboratory is required to pay, except in cases where a specific budget is explicitly provided for.

The annual maintenance fee also includes all the training activities provided by ACCREDIA DT for the laboratories.

2.2.1. ASSESSMENTS FOR REGULATORY ALIGNMENT

Upon receipt of the documentation by the FT, the Technical Assessors and/or Technical Experts will examine the same, the outcome of which will be notified to the Laboratory within **60 (sixty) calendar days** from receipt of the order/acceptance of the quotation. If the results are not positive the Laboratory will have to propose corrections within **30 (thirty) working days.**

2.2.2. MAINTENANCE DECISION-MAKING PROCESS

Following the outcomes of the surveillance and maintenance assessments (ACCREDIA DT Assessors' reports), as well as the subsequent assessments conducted by FT on the findings

management plans submitted by the Laboratories and approved by the assessment teams, the following steps are taken:

- in the case of no Non-Conformities: FT confirms the maintenance of accreditation, and waits for the completion of the treatments and corrective actions for the findings classified as Concerns;
- in the case of one or more Non-Conformities, DDT decides whether to confirm the maintenance of accreditation or to submit the case to the CSA DT with a proposal for a supplementary assessment in order to verify the effectiveness of the closure of the findings;
- if a particularly critical nonconformity situation is found, in terms of the number and severity of Non Conformities detected, of absent, incomplete, untimely or doubtful recovery actions, FT, having heard DDT, submits the case to the CSA DT for the adoption of sanction measures such as suspension, reduction or withdrawal of accreditation, applying the provisions set out in section 5 SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION.
- in the case of a laboratory accredited for flexible scope, FT submits the file to CSA DT.

2.2.2.1. DECISION-MAKING PROCESS FOR REGULATORY ALIGNMENT

Following the results of the assessments referred to in Section 2.2.1 ASSESSMENTS FOR REGULATORY ALIGNMENT, the effectiveness of the corrections will be evaluated:

- on a documentary basis, if no assessment is scheduled. If the results are positive, the file is submitted to the CSA DT with a proposal to maintain accreditation with modification of the table. If the negative results persist after the second assessment, the maintenance file is submitted to the CSA DT with a proposal to suspend accreditation, applying what is established in section 5 SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION**;**
- during the assessment. If the results are positive, the file is submitted to the CSA DT with a proposal to maintain accreditation with modification of the table. In the presence of findings classified as non-conformities and/or numerous concerns that have not been effectively resolved, the maintenance file is submitted to the CSA DT with a proposal to carry out an additional assessment as described in section 2.1.3 NON-SCHEDULED SURVEILLANCE ON-SITE ASSESSMENT and/or the adoption of a sanction measure as referred to in paragraph 5 SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION.

3. RENEWAL OF ACCREDITAION

3.1. PROCEDURE FOR RENEWAL OF ACCREDITATION

The accreditation renewal procedure is carried out in the same way as for accreditation as set out in paragraphs 1 CRITERIA AND INFORMATION FOR ACCREDITATION and following, with the exception of the paragraphs below.

3.1.1. SUBMISSION OF THE APPLICATION

If the Laboratory wishes to renew its accreditation, at least **8 (eight) months** prior to the expiry of the accreditation, it must send the Application for Renewal (DA-00 and DA-05) to STD, accompanied by the documentation requested therein, including the results of participation in PT/ILC, where applicable).

Upon submission of the application the following is allowed:

- that the Laboratory formally requests variations to the scope of accreditation in terms of extension of the measurement range and/or improvement of the accreditation uncertainty. Such variations are not considered as extensions and the file will be treated as follows on the understanding that the procedures determining such variations are positively evaluated, both during the document review and during the assessment. In the event of a negative assessment, the relative variations will not be included in the Renewal dossier submitted to CSA DT: for such variations the Laboratory must therefore submit a subsequent application for extension of accreditation.

- that the Laboratory does not present PT/ILC participation results for metrological sectors for which it has obtained extensions in the previous 2 (two) years.

Within 30 (thirty) calendar days, RST performs the assessment of completeness and correctness in terms of filling in the fields and the presence of the required annexes:

- if the assessment is positive, STD formalises acceptance thereof and informs the reference FT which prepares the technical and economic quotation for the renewal activities; if the Laboratory has requested a measurement audit and has not attached the Calibration Certificate, STD formalises acceptance with reservations and with a request for integration at least 4 (four) months before the accreditation expires.

- if such assessment is negative, STD shall formalise the non-acceptance of the same and request, in writing, the necessary documental integrations. The acceptance of the application and the subsequent preparation of the relative technical-economic quotation may take place only after the positive assessment of the requested integrations

If the late submission of the renewal application, complete with all the annexes, or of the additions requested to the same, results in the acceptance of the application in such a time that ACCREDIA DT begins its assessments beyond the deadline of **4 (four) months** before the expiry of the Certificate, **ACCREDIA DT does not guarantee the continuity of the accreditation itself.**

3.1.2. QUOTATION

Upon acceptance of the application, the Laboratory's reference FT prepares the technical-economic quotation for the accreditation renewal activities, according to the modalities described in paragraph1.3 QUOTATION.

If the Laboratory has obtained extensions in the past calendar year, it is permissible not to carry out assessments for the metrological sectors covered by those extensions, but these will be carried out at the first surveillance.

Among the reasons for recusal of the Assessors/Experts proposed in the quotation, in addition to what is already indicated in 1.3 QUOTATION, the Laboratory may invoke the deontologically incorrect behaviour of the Assessor, such motivation must be demonstrated to ACCREDIA DT with relative objective evidence and in any case only after the Laboratory has expressed reservations about the work of such Assessor/Expert.

3.1.3. DOCUMENT REVIEW

The document review (similarly to what is performed during initial accreditation, section 1.6 DOCUMENT REVIEW includes assessments of the results of Proficiency Testing and/or Interlaboratory Comparisons in which the Laboratory participated during the accreditation cycle.

The outcome of the document review (carried out by the appointed Assessors) is notified by FT to the Laboratory within **60 (sixty) calendar days** from receipt of the order/acceptance of the quotation.

If the outcome of the document review

- is positive: FT will prepare the next step of the accreditation renewal procedure;
- is negative: the Laboratory shall propose suitable corrections **and implement them and transmit them to FT within 30 (thirty) working days**. The effectiveness of the corrections will be evaluated by the Assessors during the assessment.

If the negative result refers to the assessment of PT and/or ILC participation, the Laboratory must analyse the causes and propose corrections and corrective actions. For the assessment of the effectiveness of these actions, ACCREDIA DT reserves the right to propose any additions to the quotation.

3.1.4. PREPARATION AND NOTIFICATION OF THE PLAN

In the case of multi-site laboratories, it is possible, in the renewal process, not to carry out on-site assessments at all locations where it operates, provided that they have been subject to an assessment in the previous two years.

ACCREDIA DT may carry out in-presence, remote and mixed assessments, possibly using the Laboratory's Information Technology (IT) systems. In any case, ACCREDIA DT will carry out an appropriate preliminary feasibility analysis in order to determine the possibility of carrying out a fully remote or mixed assessment activity.

For the purposes of this analysis, it may also be necessary to carry out a prior simulation of how the assessment will be performed by the Laboratory, especially in cases where experimental activities are scheduled both at own premises and at those of the Customer.

In the event that the activity carried out remotely proves unsatisfactory at the end of its implementation (e.g., due to connection problems, difficulties in sharing documents and/or retrieving evidence, difficulties in observing experimental activities) follow-up activities must be carried out, shared with the Laboratory by the assessment team and recorded in the relative assessment report. The costs of the follow-up activities are borne by the Laboratory if it is responsible for the causes of the ineffective remote assessment.

In the case of accredited Laboratories for calibrations at the Customer's premises, it is possible not to carry out the assessment at a location where the instrument/sample is installed, provided that it has been carried out within the previous two years. In exceptional cases, where it is not possible to organise such an activity, it is permissible to carry out assessments by recreating conditions in environments other than the customer's premises.

Renewal assessments, similarly to surveillance assessments, also have the scope of verifying the implementation and effectiveness of corrective actions/corrections related to the findings of previous assessments (e.g., document review, assessments) and internal calibrations (where applicable).

Particular attention must then be paid to how the Laboratory has managed the implementation of the programme of participation in proficiency testing and/or interlaboratory comparisons and the review of their results, internal audits, reviews, complaints, calibration certificates issued, the maintenance and improvement of the management system, the conformity of the technical activity and the correct use of the ACCREDIA mark and/or references to accreditation.

3.1.5. ACCEPTANCE OF THE PLAN

If the Laboratory should fail to make itself available despite the FT's implementation of all the provisions of paragraph 1.7.2.2 ACCREDIA DT will proceed with the adoption of the sanction measures referred to in paragraph 5 SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION.

3.1.6. ASSESSMENT

Assessing activities are carried out according to section 1.7 ASSESSMENT.

If the Laboratory is not available to carry out the assessment before the expiry date of the existing accreditation, ACCREDIA DT will in any case continue the accreditation renewal procedure; however, the existing accreditation will lapse upon expiry and, following the renewal resolution by the CSA DT, the Laboratory will be assigned a new accreditation number.

On the other hand, the validity of the existing accreditation may be extended by the CSA DT beyond the expiry date provided that the scheduled assessment activities are carried out before the accreditation expiry date.

3.1.7. INTERRUPTION OF ASSESSMENT

In the event of an interruption of the inspection (see section 2.4.4.5) ACCREDIA DT may proceed with the adoption of the sanctioning measures set out in para. 5 SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION.

3.1.8. ASSESSMENT OF FINDINGS MANAGEMENT PLAN AND EVIDENCE

With reference to the provisions of sections 1.7.7.2 and 1.7.7.3, if the second proposal of the findings management plan and/or the evidence is not suitable (negative assessment by the assessment team), ACCREDIA DT proceeds with the request to the CSA DT for the adoption of the sanction measures referred to in section 5 SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION.

In the presence of findings classified as non-Conformities, the submission of the file to the CSA DT is allowed provided that the findings management plan submitted by the Laboratory is positively assessed and the full implementation of the corrective actions takes place, possibly even at a later date, provided that it is no later than **3 (three) months** from the first request of the findings management plan.

3.1.9. EVALUATION OF ASSESSMENT RESULTS

In the event of findings classified as non-Conformity and/or numerous Concerns, the CSA DT may decide on the need to carry out a supplementary assessment (see section 3.1.10) and/or the adoption of a sanction measure as set out in section 5 SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION.

3.1.10. SUPPLEMENTARY ASSESSMENT

If the Laboratory is not available to carry out the supplementary assessment within one month from the last date of completion of the corrective actions indicated in the findings management plan positively assessed by ACCREDIA DT, or in the case of a negative outcome of the same, the following procedure will be followed:

- if the supplementary assessment was caused by numerous serious non-Conformities impairing the competence of the Laboratory: the CSA DT may decide to revoke the accreditation, as set out in section 5.3 WITHDRAWAL OF ACCREDITATION
- if the supplementary assessment has been decided for specific metrological sectors: the CSA DT may decide to grant the renewal of the accreditation, excluding these sectors, as set out in section 5.2 REDUCTION OF ACCREDITATION

If the laboratory wishes to start a subsequent accreditation extension procedure, it must submit a new Application for Accreditation and make all payments according to the ACCREDIA price-list (TA-00).

3.1.11. CSA DT RESOLUTION ON RENEWAL

The operations are carried out in the same way as for the accreditation process, referred to in section **Errore. L'origine riferimento non è stata trovata.** CSA DT RESOLUTION ON ACCREDITATION with the exception of the following.

The CSA DT also decides on the frequency of scheduled surveillance assessments for the new accreditation cycle, taking into account the risks related to the laboratory and the performance of the previous cycle.

In the event of a negative decision by the CSA DT, accreditation shall be reduced or withdrawn in accordance with Section 5.2 REDUCTION OF ACCREDITATION or Section 5.3 WITHDRAWAL OF ACCREDITATION respectively.

For justified reasons, the validity of the accreditation may be extended by the CSA DT beyond the expiry date. This may be repeated, provided that the limit of five years from the accreditation resolution or the resolution of the last renewal is not exceeded.

4. EXTENSION OF ACCREDITATION

4.1. PROCEDURE FOR THE EXTENSION OF ACCREDITATION

During the period of validity of the accreditation, the Laboratory may request ACCREDIA DT to extend its scope of accreditation in order to:

- Add other metrological sectors;

Any extension requests for metrological sectors not covered by ACCREDIA DT (i.e., not present in the Annex to DA-05 "Correspondence Quantities - LAT Sectors"), or in any case differing from the existing ones, are submitted by RST to DDT in order to carry out the review of the resources and then proceed with their inclusion in the Annex to DA-05 at the first suitable meeting of CSA DT.

- add new sites (remember the definition of 'site' in section 0.4);
- extend measurement ranges and/or improve measurement uncertainties.
- extend any other element of metrological capabilities.

The procedure for the extension of accreditation is carried out in the same way as for the accreditation referred to in section **Errore. L'origine riferimento non è stata trovata.** SUBMISSION AND ASSESSMENT OF THE APPLICATION FOR ACCREDITATION et seq. with the exception of the following paragraphs.

4.1.1. SUBMISSION OF THE APPLICATION

In order to apply for an extension of accreditation, the Laboratory must send the Application for Extension (DA-05) to STD together with the documents required therein.

Within **30 (thirty) calendar days** from the receipt of the application, RST performs the assessment of its completeness and correctness in terms of filling in the fields and the presence of the required annexes, and verifies, in cooperation with DDT and ATM, that ACCREDIA DT has sufficient expertise and resources to carry out the assessment of the requested extension:

- if such assessment is positive, STD formalizes the acceptance of the same and informs the reference FT that will prepare the relative technical-economic quotation for the extension activities
- if such assessment is negative, STD formalises to the Laboratory the non-acceptance of the same and requests in writing the necessary integrations that the Laboratory will have to send within 2 months from the date of the integration request

Acceptance of the application can only take place following the positive assessment of the integrations sent by the Laboratory within the deadline.

If STD has not received the necessary documentation by this deadline, the provisions of Section 1.8.3 CLOSURE OF THE ACCREDITATION PROCESS apply and, in this case, the Laboratory wishing to restart the accreditation extension procedure must submit a new formal request for extension.
Upon acceptance of the application, SDT informs the administration of ACCREDIA, which prepares the invoicing of the acceptance of the application as per TA-00.

The only permissible exception for which ACCREDIA DT conditionally accepts the extension of accreditation is the absence of results of participation in proficiency testing and/or

interlaboratory comparisons, where applicable, provided that the evidence of registration is present.

However, the examination of the documentation will not be completed until the Laboratory transmits the missing results.

4.1.2. CSA RESOLUTION ON EXTENSION

The operations are carried out in the same way as for the accreditation process, referred to in Section **Errore. L'origine riferimento non è stata trovata.** CSA DT RESOLUTION ON ACCREDITATION. In the event of a positive resolution by the CSA DT, ACCREDIA DT updates the annex to the accreditation certificate accordingly on the basis of the approved extension of accreditation.

The extension of accreditation does not extend the validity of the existing accreditation.

4.2. EXTENSION OF ACCREDITATION TO A FLEXIBLE SCOPE

With reference to what is stated in the Technical Regulation RT-26 in current revision regarding accreditation with **flexible scope**, during the period of validity of the accreditation the Laboratory can ask ACCREDIA DT to extend the accreditation to the flexible scope as long as the Laboratory itself has held accreditation for the fixed scope for at least **2 (two) years** on the same sectors subject to the flexibility requested.

5. SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION

ACCREDIA DT may impose sanctioning measures of suspension (partial or total), reduction or withdrawal of accreditation, in the event of particularly serious situations, both from a technical and ethical point of view, following surveillance, supplementary, extraordinary or renewal assessments or other checks and investigations (e.g., from reports and complaints).

In accordance with the statutory and regulatory provisions, these sanction measures and their duration are adopted by resolution of the CSA DT.

The deliberations of the CSA DT concerning suspension/withdrawal/reduction are communicated to the Laboratory concerned by registered letter with return receipt or by PEC and subsequently published on the ACCREDIA website.

The Laboratory is required to inform the customers involved, and, where appropriate, the interested parties of the sanctioning measure against it.

5.1. SUSPENSION

The suspension of accreditation may affect the scope of accreditation (total suspension) or part of it (partial suspension) and, in the case of multi-site laboratories, may affect one or more of the accredited sites.

The suspension can be ordered by ACCREDIA DT or requested by the Laboratory.

The partial suspension involves, for the Laboratory, the prohibition of issuing calibration certificates under ACCREDIA accreditation, for the activities subject to suspension. The total suspension entails the prohibition for the Laboratory to declare itself accredited and to issue calibration certificates under ACCREDIA accreditation.

Furthermore, during the period of validity of the suspension, the Laboratory must comply with the provisions of the Regulation concerning the use of the ACCREDIA mark (RG-09).

The suspension provision is published on the ACCREDIA website.

Suspension does not change the frequency of surveillance assessments. However, if the suspension of accreditation is total, no assessments are carried out during the period of suspension, except for those aimed at verifying that the causes of the suspension have been overcome. In any case, all surveillance assessments scheduled for the accreditation cycle must be carried out.

Suspension does not entail the forfeiture of contractual obligations towards ACCREDIA.

5.1.1. SUSPENSION REQUIRED BY THE LABORATORY (SELF-SUSPENSION)

The Laboratory may apply to ACCREDIA DT for partial or total suspension of its scope of accreditation at any time.

Reasons for requesting self-suspension may be (non-exhaustive list):

- exceptional temporary unavailability of significant calibration equipment (excluding unavailability of instrumentation for scheduled calibration);
- temporary unavailability of the Laboratory premises (e.g., in the event of failure to control environmental conditions);
- relocation of the Laboratory premises where calibrations are carried out;
- changes in the legal entity (e.g., change of company name, transfer of ownership).

In particular, self-suspension must always be requested by the Laboratory if the conditions for carrying out calibrations foreseen in its scope of accreditation are no longer met, for example in the case of non-conformities/shortcomings that could cast doubt on the validity of the results of the calibrations themselves (e.g. negative assessments of participation in interlaboratory circuits, etc.) or in the case of temporary unavailability or deterioration of resources (e.g. personnel, premises, equipment, etc.).

The Laboratory transmits to the reference FT the written request for self-suspension (using form MD-08-04-DT prepared for this scope by ACCREDIA DT) specifying the reasons, and reporting the activity resumption plan containing also the presumed duration of the suspension and attaching DA-00 and/or DA-05 if necessary.

FT shall submit the Laboratory's request for self-suspension to DDT for assessment. DDT can modify and/or integrate the conditions proposed for the restoration of conformity, ordering in any case the necessary assessments to verify full conformity, at the end of the self-suspension period.

FT draws up the technical and economic quotation for the assessments necessary to restore the self-suspended activities and STD sends the estimate to the Laboratory.

The Laboratory shall be informed by FT by means of written communication of the assessment activities planned to restore conformity and of the maximum period granted, which may not exceed **12 (twelve) months** and in any case the end date of self-suspension may not be later than the end date of validity of the accreditation certificate.

Resumption of self-suspension is carried out in the manner described in Section 5.1.3 ASSESSMENTS REGARDING THE CANCELLATION OF SUSPENSION.

If compliance is not restored within these deadlines, ACCREDIA DT proposes to the CSA DT

- in the case of partial self-suspension: the reduction of accreditation (5.2 REDUCTION OF ACCREDITATION) for the part of the scope and/or sites affected by the self-suspension;
- in the case of total suspension: the withdrawal of accreditation as per 5.3 WITHDRAWAL OF ACCREDITATION.

The CSA DT is informed of the self-suspension of accreditation and consequent actions.

5.1.2. SUSPENSION DECIDED BY ACCREDIA DT

Suspension (total or partial) of accreditation may be ordered by ACCREDIA DT in the event of:

a) violation of the accreditation standards requirements/this General Regulation requirements, the Specific Regulations per accreditation standard (RT) and the Accreditation Agreement;

b) failure to return acceptance of the Accreditation Agreement;

c) unavailability of the Laboratory to undergo scheduled surveillance assessment within the terms indicated by ACCREDIA DT;

d) negative outcome of the assessments;

e) unavailability of the Laboratory to undergo unscheduled assessment

f) contractual insolvency (see paragraph 5.1.2.1);

g) failure to send the findings management plan or its amendment, if requested by ACCREDIA DT, within the indicated deadlines;

h) failure to resolve findings in accordance with ACCREDIA DT procedures;

i) failure to implement corrections/corrective actions in the case of improperly issued Calibration Certificates (a corrective action could for example also lead to a decision by the Laboratory to withdraw a Calibration Certificate improperly issued, because outside the accreditation of ACCREDIA DT, or because it does not comply with the accreditation standards)

j) ineffective handling of unsatisfactory results of participation in PT/ILC;

k) failure to handle complaints;

l) failure to promptly notify ACCREDIA DT of the loss of key figures identified by the Laboratory;

m) exceptional temporary lack of significant calibration equipment (excluding unavailability of instrumentation for scheduled calibration);

n) temporary unavailability of the Laboratory's premises (e.g., in the event of failure to control environmental conditions);

o) relocation of the Laboratory;

p) changes in the legal entity (e.g., change of company name, transfer of ownership).

If the FT detects the occurrence of any of the above conditions (except for case f)) it informs DDT, who in turn informs the Laboratory in writing of the possible suspension measure if the detected non-conformity situation persists.

The Laboratory, informed of the possible suspension measure and its reasons, transmits to ACCREDIA DT in writing its possible counter-deductions within **10 (ten) working days** from the communication. The FT prepares its report on the matter and the concerns received from the Laboratory for submission of the case to the CSA DT by DDT. The CSA DT discusses the suspension, assesses the respective reasons and the correctness of the procedures followed and decides on the measure and its duration, if any.

FT draws up the technical and economic quotation the assessments necessary to restore the activities subject to suspension and STD sends the quotation to the Laboratory.

Suspension measures have a maximum duration of **6 (six) months**, it being understood that the duration of the suspension measure is in any case to be possibly extended up to the resolution of resumption by the CSA DT (which takes place in accordance with Section 5.1.3).

If the Laboratory has not made itself available to carry out the assessments within the foreseen deadlines and/or if the assessments carried out by ACCREDIA DT have not ascertained that the causes of the measure have been effectively overcome, the case is submitted to the CSA DT for the adoption of further sanctioning measures. In particular:

- in the event of partial suspension, this may be changed to a reduction (section 5.2 REDUCTION OF ACCREDITATION) for the part of the scope and/or sites affected by the suspension, by decision of the CSA DT;
- in the case of a full suspension, this may be changed to a withdrawal (SECTION 5.3 WITHDRAWAL OF ACCREDITATION) again by decision of the CSA DT.

The Laboratory, informed of the possible withdrawal measure, transmits to ACCREDIA DT in writing its possible counter-deductions within **10 (ten) working days** from the communication. The FT prepares its report on the matter and the comments received from the Laboratory for submission of the case to CSA DT by DDT.

The CSA DT may, however, decide to extend the expiry of the suspension period, in any case no longer than **12 (twelve) months** in total and within the limits of the validity of the accreditation certificate, if the Laboratory has provided evidence of its commitment to overcome the reasons that prevented the suspension from being lifted within the prescribed timeframe.

5.1.2.1. SUSPENSION FOR CONTRACTUAL INSOLVENCY

Total suspension of accreditation may be ordered ex officio by ACCREDIA's General Management in the event that the payment of fees due to ACCREDIA is delayed by more than **60 (sixty) days** with respect to the date foreseen by the contractual conditions (payment date indicated in the invoice), despite the reminder sent by ACCREDIA at the end of the **45th day** of delay. This

is without prejudice to any deferred payment agreements, which must be authorised by the ACCREDIA General Management.

The cancellation of such suspension measure may be ordered ex officio by the ACCREDIA General Management once the contractual conditions have been restored. If, on the contrary, the Laboratory persists in its non-compliance after 6 (six) months from the communication of the suspension measure, the case is submitted by DDT to the CSA DT for the adoption of the withdrawal measure with the modalities described in paragraph.5.3 WITHDRAWAL OF ACCREDITATION.

5.1.3. ASSESSMENTS REGARDING THE CANCELLATION OF SUSPENSION

When the Laboratory considers that the reasons for suspension or self-suspension have been overcome:

- accepts the technical and economic quotation
- formally informs the relevant FT of its readiness to resume the activity;
- transmits the documentation proving the full restoration of conformity.

Depending on the reason for the suspension or self-suspension, FT verifies the restoration of compliance by means of one or more of the following actions (as provided for in the quotation):

- assessment of documentation (including, where necessary, the results of participation in PT/ILC)
- assessment (including, where necessary, measurement audit activities and/or experimental on-site assessments).

Upon completion of the conformity restoration assessment activities, FT prepares the relevant report and sends it to DDT. In the case of:

- positive outcome of assessment:
  - suspension decided by ACCREDIA DT: the report is submitted to the CSA DT which decides to cancel the suspension;
  - self-suspension: the resumption of activities is authorised by DDT and subsequently communicated to the CSA DT.
- negative outcome of the assessments: the report is submitted to the CSA DT for further sanctioning measures. In particular:
  - in the case of a partial suspension: this may be transformed, by resolution of the CSA DT, into a reduction for the part of the scope and/or sites affected by the suspension;
  - in the case of total suspension: this may be transformed into withdrawal, again by resolution of the CSA DT.

5.2. REDUCTION OF ACCREDITATION

During the period of validity of the accreditation, the Laboratory may request ACCREDIA DT to change its scope of accreditation in order to:

- reduce the number of metrological sectors;
- reduce accredited sites;
- reduce measurement fields and/or worsen measurement uncertainties;
- in the case of accreditation with flexible scope, partially or completely eliminating flexibility

The reduction can also be ordered by ACCREDIA DT (section. **Error. Reference source was not found**. 2 REDUCTION OF ACCREDITATION). However, the reduction is always only relative to a part of the scope of accreditation

Proposals for accreditation reduction, following any assessment by ACCREDIA DT, are always submitted to the CSA DT for subsequent deliberation. The reduction measure is published on the ACCREDIA website.

5.2.1. REDUCTION REQUESTED BY THE LABORATORY

In order to apply for a reduction of accreditation, the Laboratory must send the Application for Reduction (DA-05) to STD together with the documentation requested therein. For the assessment of the competence of RST, the provisions of Section.4.1 PROCEDURE FOR THE EXTENSION OF ACCREDITATION apply.

Upon acceptance of the application, FT examines the reduction request and, with the possible support of Technical Assessors and/or Technical Experts, checks for possible effects on other accredited fields. If such effects are detected, FT asks the Laboratory to implement appropriate corrective actions in advance. If necessary, FT arranges for additional assessments to be carried out by the Laboratory (with the issue of a quotation), through, for example, document review, additional assessments or measurement comparisons.

5.2.2. REDUCTION DECIDED BY ACCREDIA DT

The reduction of accreditation may be ordered by ACCREDIA DT in the event of

a) negative outcome of assessments;
b) failure to resolve findings in accordance with ACCREDIA DT's procedures;
c) ineffective handling of unsatisfactory results of participation in PT/ILC;
d) unavailability of key figures identified by the Laboratory;
e) unavailability of significant calibration equipment;
f) unavailability of Laboratory premises.

If the FT detects the occurrence of any of the above conditions, after consulting Technical Assessors/Experts, if necessary, it informs DDT, who in turn informs the Laboratory in writing of the possible reduction measure.

The Laboratory, informed of the possible reduction measure and its reasons, transmits to ACCREDIA DT in writing its possible counter-deductions within **10 (ten) working days** from the communication. The FT prepares its report on the matter and the comments received from the Laboratory for submission of the case to the CSA DT by DDT. The CSA DT discusses the reduction,

assesses the respective reasons and the correctness of the procedures followed, and decides on the measure.

5.3. WITHDRAWAL OF ACCREDITATION

5.3.1. GROUNDS FOR WITHDRAWAL

The reasons why ACCREDIA DT may decide to withdraw the accreditation of the Laboratory are related to the persistence and seriousness of the failure in compliance with accreditation requirements or accreditation rules.

Some reasons, that can lead to the withdrawal of the accreditation, follow:

a) failure to resolve the causes that led to a suspension measure;

b) a total self-suspension of accreditation for a period exceeding one year;

c) a total suspension of accreditation lasting more than six months;

d) non-compliance with the Accreditation Agreement;

e) objective situations that would have prevented the signing of the Accreditation Agreement;

f) the non-payment of the sums due, if the Laboratory persists in its non-compliance after six months from the communication of the suspension measure referred to in paragraph 5.1.2.1;

g) negative outcome of the supplementary assessment;

h) non-positive decision to renew accreditation by the CSA DT;

i) the expiry of the accreditation, if the Laboratory has not submitted an application for renewal of accreditation by the accreditation expiry date;

j) evidence that the Laboratory's assumption of competence, impartiality and fairness is not verified;

k) illegal or malicious conduct or serious misconduct in terms of professional ethics by the Laboratory;

l) evidence of fraudulent behaviour, or the Laboratory deliberately providing false information or concealing information;

m) use of accreditation by the Laboratory such as to bring serious harm and discredit to ACCREDIA and/or the accreditation and certification system

n) bankruptcy of the Laboratory;

o) the cessation of operations of the Organisation in which the Laboratory operates, for whatever reason.

There is also the possibility to proceed with the withdrawal of an accreditation at the sole discretion of ACCREDIA for geopolitical reasons.

In the case of withdrawal for fraudulent behaviour/false information, the Laboratory may no longer apply for accreditation, applying international standard resolutions (e.g. sanctions).

The accreditation withdrawal procedure entails, with immediate effect:

- the elimination of the Laboratory from the list of Accredited Centres published on the ACCREDIA DT website
- the loss of the right to call itself an Accredited Calibration Laboratory;
- the suspension of the issue of Calibration Certificates;
- the loss of the right to use the ACCREDIA mark.

5.3.2. WITHDRAWAL MEASURE

If the FT detects the occurrence of any of the conditions set out in paragraph 5.3.1 above, it informs DDT, which in turn notifies (where applicable) the Laboratory in writing of the possible withdrawal measure.

The Laboratory, informed of the possible withdrawal measure and its reasons, transmits to ACCREDIA DT in writing its possible counter-deductions within **10 (ten) working days** from the communication. The FT prepares its report on the matter and the comments received from the Laboratory for submission of the case to the CSA DT by DDT. The CSA DT discusses the withdrawal, assesses the respective reasons and the correctness of the procedures followed, and decides on the measure.

Following the resolution of the CSA DT, the withdrawal communication is signed by the President of ACCREDIA and sent within **5 (five) working days** to the Laboratory by registered letter with Return Receipt (A.R.) or certified electronic mail (PEC). This communication shall contain at least the following points:

- the declaration of withdrawal of accreditation;
- the reasons for the measure;
- the date of entry into force of the measure;
- the declaration that the Laboratory is no longer part of the ACCREDIA List of Accredited Calibration Laboratories
- the prohibition to continue issuing ACCREDIA calibration certificates;
- the prohibition of any further use of the ACCREDIA mark and reference to accreditation;
- the obligation for the Laboratory to inform the customers involved and, where appropriate, the parties affected by the measure.

The Laboratory's accreditation table shall remain published on the ACCREDIA website, indicating the withdrawal measure and its effective date.

Withdrawal of accreditation does not result in the forfeiture of contractual obligations towards ACCREDIA, which reserves the right to initiate the procedures for compulsory collection and recovery of expenses, plus interest, in the forms provided by law.

5.4. RENUNCIATION OF ACCREDITATION

An accredited Laboratory may renounce to accreditation at any time and for any reason (e.g., non-acceptance of changes in the price-list, non-acceptance of changes in the regulations governing the accreditation activity, etc.).

Renunciation must be communicated by the Laboratory to ACCREDIA DT, by registered letter with return receipt or certified electronic mail (PEC), stating the reasons for renunciation and the date from which the Laboratory intends to discontinue its accredited activities.

In the event that the laboratory renounces by indicating a future date of termination of accreditation, the following conditions apply:

- until the indicated date of interruption, the Laboratory may continue to operate under accreditation;
- ACCREDIA DT may decide whether, in addition to the normal audits already scheduled for that period, it should carry out other assessments;
- ACCREDIA DT may ask for any additional guarantees to be certain that the activities, until the actual interruption of accreditation, are carried out correctly (e.g., the closure of any open findings, etc.).

In this case, DDT acknowledges the Laboratory's decision and informs the CSA DT.

Renunciation of accreditation does not entail the forfeiture of contractual obligations towards ACCREDIA, which reserves the right to apply the procedures for compulsory collection and recovery of expenses, plus interest, in the forms provided for by the laws in force.

6. COMPLAINTS/COMMENTS, RESERVATIONS AND APPEALS

6.1. COMPLAINTS AND COMMENTS

ACCREDIA DT may receive complaints/comments:

- regarding ACCREDIA DT performance;
- regarding the performance of other accredited Calibration Laboratories;
- regarding third party activities related to the activities of accredited or accrediting Laboratories.

Within **30 (thirty) working days** of receipt of the complaint/comment, GRS will take charge of them in accordance with the procedures in force, in order to assess the justification of the causes that gave rise to it. These procedures ensure that the examination of the complaint/comment and its handling are carried out by a person who is independent of the subject of the complaint/comment.

Complaints/comment forwarded anonymously will not be accepted, in order to avoid speculative reports of disruption of competition.

Laboratories have the opportunity to confidentially report to the Supervisory Board any conduct contrary to the Code of Ethics and Conduct by ACCREDIA DT staff, through the Submission of Complaints section on the ACCREDIA website.

With the same criteria and procedures as for complaints, ACCREDIA DT also handles reports of improper or incorrect activities/behaviour relating to third parties, i.e., not attributable to ACCREDIA DT and/or laboratories accredited by ACCREDIA DT but, in any case, relating to accreditation.

All complaints/comments must be closed (except in the case of legal disputes) within **12 (twelve) months** of receipt by ACCREDIA DT.

6.2. RESERVATIONS

With reference to the findings issued by ACCREDIA DT Assessors, any reservations shall be presented by the Laboratory within **3 (three) working days** from the assessment. Submission of a reservation does not exempt the Laboratory from managing the findings not subject to reservation as foreseen in section 1.7.7.1 REQUEST OF FINDINGS MANAGEMENT PLAN.

The acceptance or non-acceptance of the reservations made is delegated to DDT. However, if the reservations submitted are of a technical nature for which specific sectoral metrological competence and knowledge is required or DDT has taken part in the assessment, the FT may agree with DDT to entrust the assessment of the reservation to a Technical Assessor/Expert (whose name will be communicated to the Laboratory).

The Technical Assessor/Expert in charge, **within the term of 10 (ten) working days**, shall provide DDT and FT with a detailed report specifying the documents that have been subject to assessment, the technical detail of the response to each single objection made by the Laboratory and a clear formulation of the outcome. The costs of these assessment activities are entirely borne by ACCREDIA DT.

Upon receipt of this report, the FT in agreement with DDT will review its contents and notify the Laboratory of the outcome of the assessment carried out, in terms of acceptance or rejection of the reservation, with the relevant reasons.

A reply to a reservation must in any event be provided to RMP **within 30 (thirty) working days** of receipt of the reservation.

6.3. APPEALS

If the Laboratory, accredited or with ongoing accreditation, intends to request ACCREDIA DT to reconsider the sanctions taken towards it, it may appeal in the manner described in the ACCREDIA RG-06 document, which also includes possible cases of ineligibility of the appeal.

The handling of the appeal is the responsibility of the Appeals Commission and does not require any involvement by the CSA DT, which is however informed of the submission and outcome of the appeal. While an appeal is pending, decisions concerning the Laboratory's accreditation practices (e.g., renewals or extensions) are taken by the Appeals Commission, which acts in place of the CSA DT.

7. OBLIGATIONS TO BE BORNE BY THE LABORATORY

For everything that is not expressly provided for in this Regulation, the contents of article 4 of "Accreditation contractual agreement between ACCREDIA and Bodies providing conformity assessment services (CABs)(CO).

7.1. REGISTRY VARIATIONS

The organisation must notify the STD, using the appropriate forms (DA-00, DA-05 and applicable annexes), of any changes in the organisation's details that relate to the aspects described in the following paragraphs.

The Laboratory is also required to promptly inform ACCREDIA DT of all pending legal proceedings concerning the activities covered by accreditation. The Laboratory is also obliged to promptly inform ACCREDIA DT of administrative and judicial measures concerning its internal and external personnel, again in relation to the activities covered by accreditation. The Laboratory must not transmit judicial data to ACCREDIA DT, as required by current privacy regulations.

On receipt of the documentation sent by the Laboratory, the reference FT verifies that the variations made do not lead to non-conformity with the applicable requirements of impartiality and independence, as well as the impact of the variation on the Laboratory's management system and technical competence.

In the event of major changes affecting the management system and/or the laboratory's technical competence, FT will inform DDT, which may establish the measures set out in section 5.1.2 and/or order an unscheduled assessment (with the issue of a corresponding quotation).

7.1.1. CHANGE OF COMPANY NAME

7.1.1.1. WITHOUT CHANGE OF LEGAL ENTITY (WITHOUT CHANGE OF VAT NUMBER)

This category includes modifications that do not involve a change in the legal entity, i.e., without changing the VAT number/Tax Code (change of name of the Laboratory, liquidation, etc.).

Following the positive assessment of the documentation submitted by the Laboratory, ACCREDIA DT, updates the Laboratory's data in its database and on the ACCREDIA website and updates the accreditation certificate and/or the annex to the certificate. The variations introduced do not change the expiry date of the accreditation certificate.

An exception to this is bankruptcy, for which the measure to withdraw accreditation is activated in accordance with the provisions of section 5.3 WITHDRAWAL OF ACCREDITATION

7.1.1.2. WITH CHANGE OF LEGAL ENTITY (WITH CHANGE OF VAT NUMBER)

The change of the Laboratory company name with a change in the VAT number leads to a change in the legal entity that holds the accreditation, therefore there is the need to transfer the accreditation to a new legal entity.

For the transfer of ownership of accreditation to a different legal entity, see the contents of 7.2 TRANSFER OF ACCREDITATION OWNERSHIP.

7.1.2. CHANGES OF LOCATIONS AND/OR CONTACT NUMBERS

This type of change includes, for example, changes in the address of the registered office and/or other locations either due to a toponymy change or relocation and changes in contact details (e.g., telephone, email).

Following the positive assessment of the documentation submitted by the Laboratory, ACCREDIA DT, updates the Laboratory's data in its database and on the ACCREDIA website and revises, if necessary, the accreditation certificate and/or the annex to the certificate. The variations introduced do not change the expiry date of the accreditation certificate.

The change due to relocation (moving) of the address of the sites where the Laboratory's activities are carried out (including calibration operations) entails self-suspension as described on section 5.1.1 of this document.

7.1.3. CHANGE OF THE ORGANIZATIONAL STRUCTURE OF THE LABORATORY

The Laboratory is required to communicate any substantial variation of the organization with respect to what was communicated with the application for accreditation, for example: Technical Direction/Personnel authorized to sign the Certificates of Calibration, person who ensures contacts with ACCREDIA DT.

7.2. TRANSFER OF ACCREDITATION OWNERSHIP

Ownership of the accreditation may be transferred to a different legal entity, e.g., as a result of the transfer of a company or business unit, merger by incorporation or any other legal transaction involving a change of tax code and/or VAT number.

The Organisation must communicate to STD, using the appropriate forms (DA-00, DA-05 and applicable annexes), the request for transfer of ownership, indicating the reasons and the date of the actual change of legal entity. Following this communication, ACCREDIA DT:

- activates the suspension measure (section 5.1.2), until the subsequent decision of the CSA DT on the transfer of ownership of the accreditation;
- issues an economic quotation for assessments as foreseen in section 3.3.2 of the ACCREDIA Price-List (TA-00).

The FT assesses the maintenance of the conditions for accreditation, verifiable through the following elements that can be deduced from the documentation sent by the Laboratory:

- Chamber of Commerce company registration or equivalent document attesting the legal identity of the Laboratory;
- a copy of the notary deed from which it is possible to deduce the transfer of the resources relevant to the activities subject to accreditation to the different legal entity (e.g., premises, personnel, equipment)
- organizational structures;
- human resources (in quantitative and competence terms);

- any other applicable condition.

If necessary, in relation to the complexity of the case, the FT may also prepare an assessment (with the issue of a supplementary estimate).

Following the assessments performed, the FT prepares its report for submission of the case to the CSA DT by DDT.

In the event of a positive assessment by the CSA, ACCREDIA DT will send the new accreditation agreement and subsequently update the accreditation certificate, its annex (accreditation table) and the website. The changes introduced do not, however, change the expiry date of the accreditation.

In the event of a negative assessment, ACCREDIA DT will communicate the non-transfer of the Laboratory's accreditation and will initiate the procedure to withdraw the accreditation itself, (as established in section 5.3 WITHDRAWAL OF ACCREDITATION, except in cases where accreditation can be confirmed in the hands of the previously entitled party.

7.3. TRANSFER OF ACCREDITATION BETWEEN ACCREDITATION BODIES

The Laboratory, which intends to apply to ACCREDIA DT for the transfer of accreditation from another Accreditation Body, signatory of the EA MLA - ILAC MRA agreements, is required to submit an application for accreditation in accordance with the procedures set out in paragraph 1.2, accompanied by all the documentation required therein, as well as the last assessment report of the transferring Accreditation Body and the valid Accreditation Certificate.

The accreditation transfer process is carried out in the same way as the accreditation process (section 1.4), except for the assessments, for which a sampling of the accredited sectors is carried out, taking into account their criticality.

In the event that the Laboratory intends to apply to ACCREDIA DT for the transfer of accreditation, from another accreditation body which is not a signatory to the EA MLA agreements, the accreditation requirements will apply in their entirety.

The transfer of accreditation shall be resolved by the CSA DT in the terms indicated in Section 1.8.2. With the positive resolution of the CSA DT about the transfer, the Laboratory ceases to use the original accreditation and begins accreditation with ACCREDIA.

8. OBLIGATIONS TO BE BORNE BY ACCREDIA

For all matters not expressly provided for in this Regulation, the provisions of Article 3 of "Accreditation contractual agreement between ACCREDIA and Bodies providing conformity assessment services (CABs)" (CO).

8.1. VARIATIONS OF ACCREDITATION CONDITIONS

In the event of revision of ACCREDIA documents, the Laboratory has a transitional period of **3 (three) months**, unless otherwise indicated in the change notice, to adapt its operating methods to the new requirements. The starting date of the transition period is the date of publication of the notice on the ACCREDIA website.

It is the Laboratory's right to decide, within the transitional period granted by ACCREDIA, not to comply and therefore to withdraw from accreditation. In this case, the provisions of Section 5.4 WITHDRAWAL OF ACCREDITATION shall apply.

8.2. MODIFICATIONS TO THE PRICE-LIST

The tariffs for accreditation activities are set by the ACCREDIA Directive Council (and approved by the Interministerial Supervisory Commission) and are listed in the ACCREDIA Price-List (TA-00).

In the event of a variation in rates, even if there is an estimate accepted by the Laboratory, the services will be invoiced at the rates in force at the time of performance. Therefore, in the event that the prices change, the Laboratory will be promptly informed (by mail or PEC) of the variations, bearing in mind that the updated Price-List will be published on the ACCREDIA website.

The Laboratory has the right to renounce its accreditation **within 6 (six) months** from the date of receipt of the communication about the tariff changes. In this case, the provisions of section 5.4 'Renunciation of accreditation' shall apply.”.

During the period of notice, the Laboratory availing itself of the option to renounce will be charged the rates prior to the change, for only those activities carried out up to the moment of renunciation.