ACCREDIA
ENTE ITALIANO DI ACCREDITAMENTO

Calibration Laboratories Department

Regulation for the Accreditation of Calibration Laboratories

REVISION
10

DATE
03-12-2025

TITLE **Regulation for the Accreditation of Calibration Laboratories**

REFERENCE **RG-13**

REVISION **10**

DATE **03-12-2025**

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

PREPARATION
Management System Head Officer

APPROVAL
Directive Council

AUTHORIZATION
Director General

APPLICATION DATE
01-01-2026

Contents

0. Foreword

ACCREDIA's purpose through the Calibration Laboratories Department is to favour the development of confidence in the conformity 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 Laboratories Department, accredits the Calibration Laboratories:

- operating in compliance with the requirements of 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 ISO/IEC 17025:2018 standard (for the performance of reference measurement procedures in laboratory medicine), together with the 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 attestations 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 Laboratories 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 Regulation takes into account the developments in the applicable normative references, the experience gained by the SIT and subsequently by ACCREDIA, and the guidance provided by ACCREDIA’s Institutional Bodies, aimed at improving the accreditation system.

With reference to the provisions set out in Ministerial Decree No. 93 of 21 April 2017, laboratories carrying out periodic verification activities on measuring instruments must be accredited in accordance with ISO/IEC 17025:2018 (as a Calibration Laboratory) or ISO/IEC 17020:2012 or ISO/IEC 17065:2012.

With reference to the provisions set out in Executive Decree No. 563 of 17 December 2024, laboratories carrying out metrological conformity assessment of technical equipment used for the inspection of motor vehicles and their trailers at testing centres must be accredited in accordance with ISO/IEC 17025:2018 (as a Calibration Laboratory) or ISO/IEC 17020:2012.

0.1. Introduction

The application of the requirements of the reference standard EN ISO/IEC 17025:2018 and of other applicable documents is intended to promote the establishment and maintenance of client confidence in the calibration activities of accredited laboratories, as well as in the impartiality and integrity of the associated technical and commercial operations.

Accreditation attests to the Laboratory's technical competence to perform the calibrations and other conformity assessments specified within the scope of accreditation, and to the implementation of a management system that generally complies with the principles of UNI EN ISO 9001.

Laboratories accredited by ACCREDIA DT are deemed competent to carry out calibration activities in support of other categories of accredited CABs.

In order to promote the effectiveness and credibility of the accreditation process, it is necessary to introduce a set of specific rules and application criteria which, without departing from the spirit and the letter of the standard, facilitate its full and substantive implementation by accredited Bodies, while at the same time providing unequivocal, objective and impartial references for the assessments carried out by the Accreditation Body in respect of them.

This objective can be achieved through the correct and effective implementation of this Regulation.

0.2. Scope and Field of Application

This regulation applies to Calibration Laboratories.

The purpose of this document is to describe the procedures to be followed by:

1. The Laboratory, for the purposes of:

- submitting an application for accreditation as a Calibration Laboratory in accordance with ISO/IEC 17025:2018, or in accordance with ISO/IEC 17025:2018 together with ISO 15195:2019;
- cooperating with the assessment carried out by ACCREDIA DT, and with all acts related thereto;
- implementing the corrective actions required following the results of the accreditation procedure, and all acts related thereto;
- entering into the accreditation agreement;
- cooperating in the surveillance activities and in the maintenance of accreditation;
- submitting applications for extension, variation and renewal of accreditation;
- implementing ACCREDIA DT requirements in case of suspension, reduction, renunciation and withdrawal of accreditation.

2. ACCREDIA DT, in carrying out 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.

The circulars issued by ACCREDIA DT, specific to the relevant metrological area or sector, and shared with the interested parties and included in document ACCREDIA LS-18, shall also be regarded as a source of contractual obligation in the relationship between ACCREDIA DT and Laboratories that are either accredited or applying for accreditation.

In accordance with the principle of speciality, a circular issued by ACCREDIA DT supplements the general provisions set out 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).

With regard to the provisions set out in points b), c) and d), it shall be the responsibility of ACCREDIA DT to inform the Calibration Laboratories by issuing the appropriate circulars.

ACCREDIA DT also considers the following as reference points, to be taken into account in the event of disputes:

- the FAQs issued by the Laboratory Committee of EA, and by the Technical Committee of ILAC and its respective working groups;
- the interpretations provided by the maintenance groups of 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 this regulation and any other relevant requirements.

This General Regulation 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 is specified that the timeframes set out in this Regulation may not be complied with during company closure periods, which are published on the website of ACCREDIA.

0.3. Normative References

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

This Regulation also makes reference, where and insofar as applicable, to Law 273/91 Establishment of the National Calibration System and to the following statutory standards and ACCREDIA regulations, in their latest version 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 logo and mark (RG-09);
- ACCREDIA Pricelist (TA-00);
- Contractual accreditation Agreement (CO);
- Application for Accreditation (DA-00);
- Accreditation Application for Calibration Laboratories (DA-05);
- Applicable ACCREDIA Technical Regulations (RT);
- ACCREDIA Circulars.

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

For each of the ACCREDIA documents referred to, the latest revision in force shall apply. ACCREDIA documents may be downloaded free of charge from the Documents section and/or from the Laboratories' reserved area of the website of ACCREDIA.

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 Reg. 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 Reg. 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, the term conformity assessment body (CAB) shall mean a Calibration Laboratory.

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

Note: the definition of Laboratory is present in 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.

Note 1 The term "calibrazione" should not be used to designate calibration (national note).

Note 2: 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.

Note 3: 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 4: 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 ISO/IEC 17025:2018.

Requirement, provision: 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 (NC): finding indicating the presence of a deviation/deficiency that:

- endangers the reliability of the results/performance/services produced by the CAB and/or
- affects the capacity 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 the repeated failure to resolve a previously formalized CAB Concern.

Concern: a finding caused by a partial implementation of a requirement (of a standard or referred to in the Accreditation Regulations/Circulars) but which does not or is not likely to directly or immediately affect 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 itself is based and the reference to the specific requirement that has been violated.

Note: An unclosed Concern of the subsequent periodic assessment can be reclassified as non-conformity.

Comment: finding raised by ACCREDIA DT towards the CAB not resulting from the identification of an objective failure to meet a requirement, but to prevent such a situation from occurring (as potentially feasible) and/or to provide guidance for the improvement of documents and/or operational modalities of the Laboratory.

Management of findings by the Laboratory: activity to be carried out by Laboratory against findings formalised by ACCREDIA DT.

Impartiality: presence of objectivity.

Note: Types of conflicts of interest are covered 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 standards ISO/IEC 17025:2018 and ISO 15195:2019.

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

Note 1: the scope of accreditation of the Laboratory, namely its metrological capabilities together with the sites where the related calibration activities are performed, is set out in the Accreditation Table (a document attached to the Accreditation Certificate)

Note 2: The Laboratory shall not issue Calibration Certificates reporting measurement results beyond the metrological capabilities indicated in the **Accreditation Table**.

Flexible scope of accreditation: scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body as confirmed by the accreditation body (ISO/IEC 17011:2017, § 3.7)

- For calibration laboratories, the scope of accreditation is understood to be expressed in such a way as to allow modifications to the methodology and other parameters that could influence the Calibration and Measurement Capability (CMC), provided that the measurand, measurement range and uncertainty values do not change and that they fall within the competence recognised for the Laboratory.

Report: a communication of external or internal origin that does not inherently constitute a complaint, but serves as a point of attention regarding potentially non-conforming situations, by accredited CABs and/or their clients and/or certified organisations.

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

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 perform assessments.

Note: 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 assessments;
- interviews;
- measurement audit (including drafting of the Comparison Report);
- experimental on-site assessment (including the drafting of the Comparison Report).

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

Remote assessments: assessments carried out remotely using electronic means.

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

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

Unannounced 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 (five) 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 scope of accreditation.

Extension of Accreditation: the addition of conformity assessment activities to the accreditation scope. (A variation of the table attached to the Accreditation Certificate that results in the introduction of at least one new sector).

Flexible scope extension: the extension of flexibility to the entire accreditation scope or to a part of it.

Modification of the Accreditation Scope: a change in the conformity assessment activities within the accreditation scope (variations to the table attached to the accreditation certificate that do not entail the addition of a new sector, e.g., change in the measurement range, change in the uncertainty, addition of a new instrument, change of a method, new site).

Reassessment: assessment carried out to renew the accreditation cycle.

Note: for the purposes of this Regulation, reassessment is referred to as renewal.

Reduction of accreditation: cancellation of a part of the scope of accreditation of a Laboratory (variation of the table attached to the accreditation certificate resulting in the complete removal of one or more sectors). This may be requested by the Laboratory or decided by the CSA DT as a sanctioning measure.

Suspension of accreditation: the implementation of temporary restrictions on all or part of a Laboratory's scope of accreditation. This may be requested by the Laboratory (self-suspension) or decided by the CSA DT as a sanctioning measure.

Withdrawal of accreditation: a sanctioning measure involving the withdrawal of a Laboratory's accreditation for the entire accreditation scope.

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

- measurand or reference material
- calibration or measurement method or procedure and type of instrument or material to be calibrated or measured
- measurement range
- measurement conditions (additional parameters relevant to the definition of capabilities)
- measurement uncertainty.

Note 1: Calibration and Measurement Capability is also referred to as "metrological capability"

Note 2: Within the context of the CIPM MRA and ILAC mutual recognition agreements, the measurement and calibration capability can be consulted:

- in the Laboratory's accreditation scope available on the websites of the signatories to the ILAC Mutual Recognition Agreement;
- n the BIPM KCDB (Key Comparison Data Base) under the framework of the CIPM MRA.

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, coordinating the activities of System Assessors and Technical Assessors/Experts.

Department Technical Secretariat: a function appointed by ACCREDIA DT to provide information to Laboratories seeking accreditation, to Calibration Laboratories/Centres already accredited and to their users, interfacing where necessary with the other functions of ACCREDIA DT.

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, 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 categories for which the Laboratory is accredited or has applied for accreditation.

Technical Expert: a qualified person appointed by ACCREDIA DT, who works under the responsibility of an Assessor within the assessment team, providing specific knowledge or expertise regarding the evaluation of particular technical aspects. The expert may interact directly with the CAB.

Assessment Report: a document that outlines the outcomes of a Laboratory's competence assessment, including the assessment of the management system, measurement result comparisons, operational and technical procedures verification and accreditation table.

Experimental Assessment Report (RC): document reporting the results of a measurement audit or of an on-site experimental assessment.

Technical Report (RT): document reporting the evaluation of participation in and results from an interlaboratory proficiency test (PT) or interlaboratory comparison (ILC).

It should be noted that, in cases where different definitions are provided for specific metrological terms, the definitions in the VIM shall take precedence.

0.5. Acronyms

- ACCREDIA DT: ACCREDIA Department of Calibration Laboratories;
- CSA DT: Sectoral Accreditation Committee for the Calibration Laboratories Department;
- CdA: Committee for Accreditation Activities;
- DDT: Directorate 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 request, in writing or verbally, to STD in order to obtain details regarding accreditation.

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

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

Operating Headquarters: ACCREDIA Calibration Laboratories Department, Strada delle Cacce, 91 – 10135 Torino.

If e-mail is used, it is required that all communications are addressed to the appropriate e-mail boxes indicated on the site 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 current ACCREDIA DT documents, which includes the documents useful for the purposes of accreditation, 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 § 2.1 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 interested Laboratory. These meetings, to which experts on the relevant quantities may be invited, do not imply any mutual commitment and must not assume the character of consultancy (even involuntary).

1.1.2. Preliminary Assessment

When necessary and at the request of the Laboratory interested in accreditation, a preliminary assessment may be organised for which a special technical and financial quotation expressed in man-days is issued, in accordance with the conditions set out in ACCREDIA's current pricelist. This assessment may result in the identification of deficiencies in the system or in the Laboratory competence, for which ACCREDIA DT guarantees formalisation, but does not provide for requests for corrections/corrective actions. In any case, the results of this assessment will not influence the outcome or duration of the assessments in any subsequent request for accreditation. Only one preliminary assessment may be conducted against a single Laboratory.

2. Accreditation Process

2.1. Submission and Assessment of the Accreditation Application

The Laboratory intending to initiate the accreditation process must complete the Accreditation Application (DA-00 and DA-05, which may be drawn up in Italian or in English), providing all the required information, and submit it, together with the relevant annexes, to STD of ACCREDIA DT at the dedicated email address 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 (e.g., notary power of attorney, executive determination, Board of Directors resolution).

The applicant Laboratory 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 include calibration activities among its stated objectives.

Should the Laboratory wish to specify, in the Accreditation Application, a designation to be shown on the Accreditation Certificate that is more specific than the legal identity (e.g. Department, Division, etc.), such designation must be included in the Chamber of Commerce Register as the identifier of the operational site or "trade name", or otherwise be explicitly stated in the CAB's statutory or organisational documents (to be attached to the accreditation application).

Accreditation may cover calibrations in one or more metrological sectors, carried out at one or more of the Laboratory's offices or at the site where the instrument or measurement standard is installed.

Any requests for accreditation in metrological sectors not covered by ACCREDIA DT (i.e., not listed in the Annex to DA-05 "Metrological Areas – LAT Sectors"), or in any case differing from existing ones, are reviewed by the Department Directorate in order to proceed with their inclusion in the Annex to DA-05 at the next available CSA DT meeting.

Within **30 (thirty) 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 to the Laboratory the acceptance thereof;
- if this assessment is negative: STD formalises to the Laboratory its non-acceptance and requests in writing the necessary integrations that the Laboratory must send **within 12 (twelve) months** from the date of the integration request.

Acceptance of the application may 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 shall inform it that the deadlines for starting the accreditation procedure have expired. In this case, the Laboratory wishing to restart the accreditation procedure 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 overseeing the accreditation process and the subsequent routine maintenance activities, the appointed FT shall handle all other types of procedures. As a rule, the appointed FT follows a Laboratory at least until the subsequent Renewal.

Where there is evidence of fraudulent behaviour, or where the Laboratory deliberately provides false information or conceals information, DDT shall proceed to reject the application and reserves the right not to offer further services to the Laboratory. Furthermore, where the Laboratory is already accredited by ACCREDIA under other schemes, the case shall be submitted to the relevant CSA for the appropriate assessments (e.g. suspension or withdrawal of accreditation). During the application review phase, ACCREDIA DT verifies whether the applicant CAB has previously been subject to withdrawal of accreditation and:

- where the withdrawal was decided due to fraudulent behaviour or the provision of false information, ACCREDIA DT shall reject the application;
- where the withdrawal was decided for other reasons, ACCREDIA DT verifies that at least **6 (six) months** have elapsed since the decision. Failing this, the decision on whether to accept or reject the application shall be submitted to CSA DT.

2.2. Quotation

Within **60 (sixty) calendar days** from the date of acceptance of the application, the appointed FT will prepare the technical and financial quotation 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.

In the technical and financial quotation, the Laboratory is notified of the names of the Assessors that ACCREDIA DT intends to appoint for the assessment and of any Experts.

Different Assessors may be assigned to different stages of the assessment process. In cases where highly specific technical aspects need to be analysed, Technical Experts (outside the lists of ACCREDIA DT Assessors) may be identified to assist the Assessors in the evaluations.

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 challenge Assessors (or request their replacement) in the event of a conflict of interest, which shall be notified to ACCREDIA DT, who will verify its substantiation on the basis of the prior declarations provided by the Assessor. Where the reasons put forward are deemed valid, the Assessor/Expert shall be replaced and the matter will be subject to assessment within the framework of the relationship between ACCREDIA DT and the Assessor/Expert. Assessors who are employees of ACCREDIA may not be challenged by the Laboratory concerned except for serious grounds of incompatibility, which must be expressly communicated directly to DDT.

Assessors may be replaced by other Assessors of equivalent qualification, subject to assessment by DDT 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.

Upon expiry of **5 (five) working days** from the dispatch of the quotation, in the absence of any communication, the Assessors and Experts shall be deemed accepted, without prejudice to the Laboratory's right to request their replacement even after the assignment has been made.

2.3. Accreditation Process

Upon receipt of the order/acceptance of the quotation from the Laboratory or the organisation to which the Laboratory belongs, the accreditation process is initiated, which consists of the following four steps:

- preliminary operations;
- document review;
- on-site/remote/blended assessments;
- decision-making process.

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

2.4. Appointment of Assessors

Upon receipt of the order/acceptance of the quotation from the Laboratory, the appointment of the members of the assessment team is formalised.

The appointed assessors, unless otherwise decided by DDT for justified technical or force majeure reasons, will also be appointed for subsequent surveillance assessments at the same Laboratory in the following **4 (four) years** (accreditation cycle).

It is emphasised that ACCREDIA DT 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 declaration of absence of conflicts of interest with regard to the Laboratory in question.

2.5. 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, including any records, the FT shares the complete documentation with all members of the assessment team, who will carry out its evaluation. The above-mentioned document review is conducted and notified to the Laboratory within **90 (ninety) calendar days** from receipt of the order/acceptance of the quotation.

If the results of participation in proficiency tests and/or inter-laboratory comparisons have not been attached to DA-05, ACCREDIA DT will await them for **12 (twelve) months**; however, the analysis of the remaining documentation may proceed. The specific evaluation of PTs and/or ILCs, when requested, is notified to the Laboratory within **30 (thirty) calendar days** of their receipt.

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

- if the outcomes are positive, or if there are minor deficiencies whose corrections can be assessed by the Assessor directly on-site, the subsequent accreditation phase is prepared;
- if the outcomes are not positive and modifications and/or additions to the documentation are required, the document review is repeated, for no more than two additional times. The Laboratory must update/modify the documentation within a maximum of **12 (twelve) months** from the first request for adjustment, and within **6 (six) months** from any subsequent request;
- If the negative outcomes relate to the evaluation of participation in and outcomes of proficiency tests and/or inter-laboratory comparisons, the Laboratory is required to formalise nonconformities by analysing the causes, assessing the scope of the issue, and proposing Corrections and Corrective Actions within a maximum of **12 (twelve) months**. ACCREDIA DT reserves the right to propose an adjustment to the quotation for the assessment of the effectiveness of such actions;
- If the outcomes of the evaluation of participation in and outcomes of proficiency tests and/or inter-laboratory comparisons are positive with comments, the Laboratory must:
    - In the case of acceptance of the comments, submit the revised documentation to FT, and the assessment will be carried out in the next phase;
    - In the case of non-acceptance, submit justifications to FT regarding the matter.
- If negative outcomes persist following the third assessment, he proposes to the DDT to terminate the accreditation process, applying the provisions set out in § “2.7.3 Closure of the Accreditation Process”;
- If the **12 (twelve) month** period from the last request for adjustment has elapsed without the Laboratory having complied, he proposes to the DDT to terminate the accreditation process, applying the provisions set out in § “2.7.3 Closure of the Accreditation Process”.

In the event that numerous and serious findings are identified by the assessors in the documentation, the Laboratory may request a meeting with ACCREDIA DT involving the System Assessor and/or the Technical Assessor, in the presence of a Technical Officer. Such meeting, to be held at ACCREDIA premises or remotely and with a duration not exceeding half a day, is aimed at analysing and clarifying the identified deficiencies

and shall not take on the nature of consultancy (including inadvertently). The activity shall be quoted and invoiced in accordance with the conditions set out in ACCREDIA's current pricelist.

2.6. Assessment

2.6.1. 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 internal calibration aspects (where applicable).

ACCREDIA DT may carry out on-site, remote and blended assessments, making use, where appropriate, of the Laboratory's Information Technology (IT) systems. In all cases, ACCREDIA DT shall perform an appropriate feasibility analysis in advance in order to determine whether an assessment can be carried out fully remotely or in blended mode.

For the purposes of this analysis, it may also be necessary to conduct a prior simulation of how the assessment will be carried out by the Laboratory, especially in cases where experimental activities are planned both at the Laboratory's own premises and externally, including at the Client's facilities.

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 relevant assessment report. The costs of follow-up activities are to be borne by the Laboratory if the Laboratory is responsible for the causes of the ineffective conduct of the remote assessment.

2.6.2. Assessment Plan

2.6.2.1. Preparation and Notification

FT agrees, with the Laboratory and the assessors involved, the date for the assessment, prepares and sends to the Laboratory the document "Notification and Assessment Plan" 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 verified, in particular, all metrological sectors must be assessed. With regard to the sampling of instruments falling within the scope of accreditation (as requested by the Laboratory in the Accreditation Application and reported in DA-05), ACCREDIA DT considers the risk associated with the relevant calibration activity, the sites, and the personnel.

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

In the case of an assessment:

- in presence or blended: at least **10 (ten) calendar days** prior to the date of the assessment, the Laboratory must send ACCREDIA DT the MD-19 form "Information regarding specific, real risks in the workplace and protection measures", filled in with information on the location of the assessment and any special risks existing in the workplace where the assessment will be carried out.

In the event that the MD-19 form is not received on time, ACCREDIA DT reserves the right to proceed with the assessment in any case: in this case, during the initial meeting (section 2.6.4.2), the Laboratory must hand over the duly completed document to the Assessment Team Manager. The ACCREDIA DT Assessors undertake to respect the security conditions received.

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

As a general rule, the Lead assessor is responsible for managing and coordinating the logistical aspects of the assessment for all members of the assessment team.

2.6.2.2. Acceptance of the Plan

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

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

If the Laboratory is still not available, the provisions of Section 2.7.3 "Closure of the Accreditation Process" shall apply".

2.6.3. Assessment Preparation

In specific cases, where the Laboratory has a large number of metrology sectors and/or is multi-site, FT, in agreement with DDT, evaluates whether the participation of the appointed FT on site during the assessment is necessary.

The costs related to any on-site participation of the FT are borne by ACCREDIA DT within a specifically allocated 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 ISO/IEC 17011 standard and with the applicable ACCREDIA DT documents;

- provide Assessors and/or the Laboratory with any clarifications concerning the requirements of ISO/IEC 17025, ISO 15195 and ACCREDIA documents.

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

Should DDT deem it necessary to involve Observers in the assessment (e.g. Assessors in training, EA peer assessors, etc.), the FT shall give prior notice to the Laboratory, providing, where necessary, a confidentiality undertaking signed by the Observers themselves. Should the Laboratory wish to raise any objections to the proposed Observers, such reservations shall be duly justified in writing and sent to ACCREDIA DT within **five (5) working days** of the notification; after this period has elapsed, after which the names shall be deemed accepted. The costs related to the participation of such Observers shall not be borne by the Laboratory.

Under no circumstances may any Observers (whether appointed by the Laboratory or by ACCREDIA DT) interfere with the conduct of the assessment. Should this occur, it shall be the responsibility of the Lead Assessor to request the immediate removal of the Observer.

The assessment, conducted by the appointed assessors in accordance with the ISO 19011 standard, includes the following phases:

- preliminary meeting between 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 DA-05, responsible for the Laboratory, the management system, and their collaborators;
- conduct of the assessment, with the support of Laboratory personnel;
- intermediate meetings between the assessors, if deemed necessary by the lead assessor;
- pre-final meeting, at which the assessors define the outcomes of the assessment;
- final meeting, with Laboratory staff and acknowledgement of any reservations.

The Laboratory shall make a dedicated room available to the assessment team, preferably equipped with an Internet connection, for the preliminary, interim and final internal meetings of the Assessors.

The Laboratory must also allow the Assessors access to the Laboratory premises and to the records (whether in paper or electronic form) for the purposes of carrying out the assessment.

2.6.4. Opening of the Assessment

2.6.4.1. Preliminary Meeting to the Opening of the Assessment

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

2.6.4.2. Initial Meeting with the Laboratory

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

a. introduce the assessment team with its tasks;
b. clarify the roles and responsibilities of possible ACCREDIA DT (EVA), assessors, FT, guides (i.e., those responsible for the Laboratory to accompany the Assessors), training assessors and observers, in compliance with ISO 19011;
c. explain the purposes of the assessment, which shall be carried out in compliance with the safety conditions;
d. present the assessment plan, clarify any points not fully understood and agree on any amendments thereto;
e. define the details of any calibrations to be carried out in the presence of the Assessor;
f. describe any division of the assessment team into sub-teams and to identify the assessment activities to be assigned to each sub-team, in order to optimise the duration of the assessment;
g. agree on the timing and modalities for the assessment of any off-site activities;
h. agree on any changes to the assessment plan;
i. explain the assessment procedure and the Laboratory's right to raise reservations;
j. recall the commitment of each member of the team to the confidentiality of information;
k. inform that confidential meetings of the Assessors may be necessary during the assessment;
l. request confirmation of the presence of the Laboratory's Management, or its Representative, at least at the final meeting, and to complete the list of participants in the assessment;
m. provide the Laboratory with the opportunity to request any further clarifications;
n. formalise the safety arrangements as required in the notification and assessment plan, verifying that the safety conditions previously communicated through document MD-19 are in place.

This meeting shall be planned both in the case of an in-presence assessment and in the case of a remote assessment.

2.6.5. Carrying out the Assessment

2.6.5.1. General

The assessment activities are carried out with the support of the ACCREDIA DT checklists, which include a set of indications aimed at verifying the compliance of the Laboratory with the requirements of the applicable standards and with the ACCREDIA DT requirements.

The checklist used by the System Assessor, available on the website www.accredia.it, is the same as that used by the Laboratory for the self-assessment attached to Application DA-05.

The investigations carried out by the assessors may be of two types:

- “horizontal” assessment, mainly focused on one or more clauses of the standard and on their implementation;
- “vertical” assessment, consisting of the evaluation of the implementation of the requirements of the standard within a specific area of activity.

It is recalled that the purpose of accreditation assessments is to verify the compliance of the Laboratory with the requirements of the applicable standards and of the EA, ILAC and ACCREDIA DT application documents, for the purpose of attesting the technical competence of the Laboratory to carry out the calibrations included in the scope of accreditation; mandatory requirements, for example relating to safety, privacy, administrative liability, etc., do not fall within the accreditation requirements and are not subject to assessment, unless expressly required by the applicable standard; the conduct to be adopted by ACCREDIA DT assessors in the event of potentially violated mandatory requirements is described in § 2.6.5.4; non-compliance with legal requirements is identified as a non-conformity only if relevant to the requirements of the management system, irrespective of the controls and sanctions imposed by the competent Authorities.

In carrying out assessments, ACCREDIA DT Assessors will have to abstain from requesting Laboratory copies of the documentation examined, 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 relevant FT. No Laboratory’s document may be retained by the Assessors on any grounds, except copies of Calibration certificates, sampled in archive and/or Certificates of calibrations performed during the audit that are to be attached to the checklist.

2.6.5.2. Tasks of the System Assessor

The assessment activities are carried out using the ACCREDIA DT checklist, which contains a list of items intended to verify the Laboratory’s compliance with the requirements of the applicable standards and with ACCREDIA DT requirements.

The checklist used by the System Assessor, available on the website www.accredia.it, is the same as that used by the Laboratory for the self-assessment attached to Application DA-05.

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

- “horizontal” assessment, primarily focused on one or more clauses of the standard and their implementation;
- “vertical” assessment, consisting of the verification of the implementation of the requirements of the standard within a specific area of activity.

It should be noted that the purpose of accreditation assessments is to verify the Laboratory’s compliance with the requirements of the applicable standards, the EA and ILAC application documents, and ACCREDIA DT documents, for the purpose of attesting the Laboratory’s technical competence to perform the calibrations covered by the scope of accreditation. Mandatory regulations — for example those relating to health and safety, data protection, administrative liability, etc. — do not fall within the requirements for accreditation and

are not subject to assessment, unless expressly required by the applicable standard. The conduct to be followed by ACCREDIA DT Assessors in the event of potentially breached mandatory requirements is set out in § 2.6.5.4.

When carrying out assessments, ACCREDIA DT Assessors shall refrain from requesting copies of the documentation examined from the Laboratory, except where this is necessary to provide objective evidence of nonconformities or in the event of reservations raised by the Laboratory. In such cases, the copies shall be attached to the checklist and sent to the relevant FT. No Laboratory documents may be retained by the Assessors on any grounds, with the exception of copies of calibration certificates sampled from the records and the certificates relating to calibrations performed during the audit, which shall be attached to the checklist.

2.6.5.3. Tasks of the Technical Assessor

The Technical Assessor must verify the Laboratory's technical competence in accordance with the requirements of the reference standard ISO/IEC 17025:2018, the standard ISO 15195 (where applicable), the EA and ILAC documents and/or other relevant reference standards, the specific requirements of ACCREDIA DT, and the applicable sector technical standards.

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

- if he/she is the Lead Assessor, he/she organises 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.

2.6.5.4. 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 leading to findings. The findings will then be reviewed by the assessment team and then classified as Non-Conformities, Concerns or Comments as per § 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 audits;
- any violations encountered by the Assessors on binding requirements falling within the scope of the audit must be reported as non-conformity.

2.6.5.5. 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 Laboratory Management.

In case of acceptance by the Management or by the appointed personnel of the Laboratory, the Assessors will carry out the planned meetings formalizing the findings so far emerged and reporting in the ACCREDIA DT checklist that the assessment was interrupted with the relevant motivations.

If, on the other hand, the Management or the staff appointed by the Laboratory expresses their willingness to continue the assessment, the assessors will report 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 assessment 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 pricelist (see §8 of the TA-00 document in force).

2.6.6. Final meeting and acknowledgement of reservations

During 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 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, 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 raised by the Laboratory; alternatively, the Laboratory may submit reservations by completing the relevant form within **3 (three) working days**; the acceptance or otherwise of the reservations submitted by the Laboratory is the responsibility of the DDT;
- request from the Laboratory evidence of acceptance of the report containing the findings and the summary feedback of the assessment, by signature or by equivalent means;
- issue a copy of the Report to the Laboratory, containing both the list of findings and the Summary Feedback, specifying that ACCREDIA DT reserves the right to confirm or not confirm its contents.

2.6.7. Actions Following the Assessment

2.6.7.1. Request of Findings Management Plan

Following the assessment, FT and/or DDT, carry out a review of the findings raised by the Assessors, reserving the right to modify and/or classify them differently, 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), an analysis of the extent and root cause, and the corrective actions related to the identified causes, including an indication of the implementation timeline; the closure evidence for this type of finding must be positively evaluated by ACCREDIA DT before the case is submitted to the CSA DT.
- For Concerns: the correction, an analysis of the extent and root cause, and, when determined by the Laboratory in relation to the identified causes, the corrective actions, including an indication of the implementation timeline. Evidence of corrections and/or corrective actions is assessed in documentary form prior to the next assessment. Depending on the nature and number of Concerns, ACCREDIA DT may require that, even for this type of finding, the closure evidence be positively evaluated before the application (for granting or extension) is submitted to the CSA DT.
- For Comments: the reasons for any non-acceptance of the comment. If, on the other hand, the Laboratory intends to act on the comment, for example by undertaking an improvement action, the resulting actions implemented will be verified by ACCREDIA DT at the first available assessment.

The Laboratory must communicate to FT **within 10 (ten) working days** from the sending of the request its plan for the management of the findings and the implementation timeframe. The timeframe for implementing corrections and corrective actions may not exceed **3 (three) months** from the date on which FT confirms the findings, except in justified cases 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 prescribed time limit, ACCREDIA DT proceeds with the request for closure of the accreditation process as described in § **Errore. L'origine riferimento non è stata trovata.** “Closure of the Accreditation Process”.

2.6.7.2. 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 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 documentary evidence is not suitable or the timing was not respected, ACCREDIA DT may perform the closure of the accreditation process as described in § 2.7.3. “Closure of the Accreditation Process”.

In the event that the Laboratory, for internal needs, intends to change the findings management plan approved by ACCREDIA DT, it must notify ACCREDIA DT who will proceed with the new assessment.

2.6.7.3. Assessment of Evidence

The assessment of the evidence shall be 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 proceed with the closure of the accreditation process as described in the following § **Errore. L'origine riferimento non è stata trovata.**. “Closure of the Accreditation Process”.

Finally, if the deadlines set out in the approved plan are not met, ACCREDIA DT may proceed with the closure of the accreditation process as described in § 2.7.3. “Closure of the Accreditation Process”.

In the case of a non-conformity or a significant number of Concerns, the DDT may authorise a supplementary assessment to verify the effective closure of the corresponding corrective actions/corrections.

The evidence required for non-conformities must be positively evaluated before the CSA DT meeting.

2.7. Decision-making Process

2.7.1. Assessment of Results

At the conclusion of the assessments described above and based on their final outcomes, the FT collects all documentation related to the case, in particular the results of the document review, technical reports, results from the assessment, experimental assessment reports, and prepares the assessment report along with its annexes.

It is possible that during the assessments:

- the Laboratory may request modifications or reductions of the scope of accreditation within the requested metrological area and/or sector, which must be formalised through the submission of DA-05;
- ACCREDIA DT imposes modifications or reductions to the scope as a result of the assessment outcomes (document reviews and/or PT and/or ILC results and/or assessments), which the FT formalises to the Laboratory through a registered letter.

The DDT performs conformity checks on the process implemented against the applicable requirements and decides whether the case can be submitted to the CSA DT for evaluation or if further additions and/or revisions are required.

2.7.2. CSA DT Resolution on Accreditation

The CSA DT evaluates the competence of the Laboratory and decides on the accreditation. In the event that accreditation is granted, the CSA DT also determines the frequency of scheduled surveillance assessments and of the subsequent renewal. If the Laboratory has recorded a significant number of findings, the CSA DT may decide to increase the number of surveillance assessments, providing justification for this.

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

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

The Laboratory is required to return the signed acceptance of the accreditation agreement within **30 (thirty) calendar days** of receipt; otherwise, the CSA DT may apply one of the sanctions provided for in § 7.1.2 “Suspension Decided by Accredia DT”.

If the Laboratory intends to request authorisation to use the ILAC-ACCREDIA Combined Mark, it must submit an example of its intended use and obtain written approval from ACCREDIA DT before using it, in accordance with the instructions provided by ACCREDIA at the time of accreditation notification.

The accreditation certificate may not be transferred 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 applicable general and sectoral regulatory provisions.

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

The accreditation and the relevant agreement are valid **for 4 (four) years.**

If the CSA DT decides not to grant the accreditation and considers necessary to have further assessments, DDT shall notify the Laboratory, within **5 (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 quotation.

If the CSA DT decides not to grant accreditation, the provisions of paragraph § **Errore. L'origine riferimento non è stata trovata.**. "Closure of the Accreditation Process" shall apply.

2.7.3. Closure of the Accreditation Process

If any of the conditions provided for in this Regulation for the closure of the accreditation process occur, ACCREDIA DT submits the case to the CSA DT for the adoption of the measure, providing reasons for the proposed closure. Within **15 (fifteen) working days** from the date of the CSA DT decision, the DDT notifies the Laboratory of the closure of the accreditation process by certified email (PEC).

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

In case the Laboratory wishes to initiate a new accreditation process, it will have to submit a new application (DA-00 and DA-05).

3. "Cross-frontier" Accreditation

If ACCREDIA DT receives applications concerning calibration activities from a Laboratory based abroad, the provisions of Regulation (EC) 765/2008 and subsequent amendments, the ACCREDIA procedure PG-12 "Management of "Cross Frontier" Accreditations," the relevant EA and ILAC documents, as well as documents issued by the European Commission, shall apply. Accreditation may be carried out in collaboration with another accreditation body recognised within the EA and ILAC frameworks. In this case, the document review and on-site assessment phases may also be performed using assessors appointed by the other accreditation body. A copy of the relevant documentation, in Italian or English, must be officially provided to ACCREDIA DT by the other accreditation body. All phases of the assessment, from the submission of the application to the decision-making process, are carried out in accordance with the Accreditation process (§ **Errore. L'origine riferimento non è stata trovata.**).

ACCREDIA DT will issue a non-conformity if it becomes aware that a CAB established in Italy does not comply with ACCREDIA Circular No. 3/2016, issued in relation to the application of Regulation (EC) 765/2008 and subsequent amendments, with specific reference to Article 7 (Cross-Frontier Accreditation). It is reminded that a CAB established in Italy is prohibited from requesting accreditation in a scheme/sector from another accreditation body, whether within Europe or outside Europe, if the same accreditation can be provided by ACCREDIA.

If the CAB is already covered by ACCREDIA accreditation in that scheme/metrological area/metrological sector, it may request additional accreditation, but only from a non-European accreditation body.

4. Surveillance and Maintenance of Accreditation

4.1. General

During the validity period of the accreditation, ACCREDIA DT is required to implement an assessment programme to assess the scope and sites of accredited Laboratories, in accordance with the requirements established by the standards and rules deriving from Regulation (EC) 765/2008 and subsequent amendments (ISO/IEC standards and EA/ILAC documents).

Accordingly, all accredited Laboratories must undergo surveillance activities, both through scheduled assessments and unscheduled assessments, to verify the continued compliance with the provisions of this Regulation, international standards and guides, and any other applicable normative references, using all assessment techniques provided for by ACCREDIA DT regulations (for example: unannounced assessments, mystery audit activities, etc.) at its/their own premises and at its clients' premises, where the accreditation covers activities carried out at the site of installation of the samples/measuring instruments. In the event of extraordinary circumstances preventing the assessments, ACCREDIA DT applies the provisions of IAF ID3 and any other applicable requirements issued internationally by EA/IAF/ISO.

4.2. Maintenance of Accreditation

The maintenance activity includes:

a. Support for the operation of the Laboratory, which includes:
   - updating the Laboratory's records and data;
   - distributing documentation related to the applicable requirements.

b. Notification and/or forwarding of documentation from ACCREDIA, EA, ILAC, or other sources relevant to the Laboratory's activities.

c. Review of any updates to the management system documentation (e.g., quality manual, procedures).

Note: Any documentation that the Laboratory deems appropriate or necessary to update must be submitted to ACCREDIA DT in advance for evaluation.

Changes to the management system that do not affect the Laboratory's compliance with the requirements may also be communicated after their implementation.

Document updates that require evaluation by Technical Assessors and/or Technical Experts do not fall within maintenance activities and are therefore subject to a specific quotation.

If the changes made to the documentation result in modifications to the Laboratory's metrological capabilities, the provisions for "Modification of the Scope of Accreditation" (§ 4.2.4) or "Extension" (§ 6) cases shall apply.

d. Review of calibration certificates issued in the case of initial accreditation or extension of accreditation to a new sector.
   In such cases, the Laboratory shall submit to the relevant FT the first 10 certificates issued, together with the related technical records, which will be examined during the first surveillance assessment.
e. Organisation of scheduled surveillance assessments approved by the CSA DT at the time of granting or renewal of accreditation (§ 4.2.1).
f. Organisation of extraordinary and supplementary surveillance assessments (§ 4.2.2.1, § 4.2.2.2).
g. Management of the procedures for adopting new editions of standardised methods or reference standards by the Laboratories. For the procedural workflow, see § 4.2.3.
h. Management of requests for changes to the scope of accreditation, including, by way of example: changes to the measurement range, changes to the uncertainty, addition of a new instrument, or modification of a method. For the procedural workflow, see § 4.2.4.
   Management of procedures relating to the maintenance of the flexible scope. For the procedural process, see § 4.2.5.

The costs of the activities listed above are generally included in the annual maintenance fee that the Laboratory is required to pay, except in cases where the issuance of a dedicated quotation is explicitly required in ACCREDIA pricelist.

The annual maintenance fee also covers all training activities provided by ACCREDIA DT for the benefit of the Laboratories.

4.2.1. Scheduled Surveillance Assessment

The schedule established by ACCREDIA DT for planning surveillance activities is as follows:

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

During the accreditation cycle, activities at all Laboratory sites must be assessed, including activities carried out at the Client's premises where these are covered by the scope. In exceptional cases, and where it is not possible to organise such activities externally, assessments may be conducted by recreating the same conditions in environments other than the Client's premises. Assessments may also be carried out remotely; however, it is excluded that all surveillance assessments within the accreditation cycle may be performed solely by this method.

In any case, remote assessment will not be conducted:

- where a stable internet connection cannot be guaranteed;
- where it is not possible to monitor the experimental calibration/verification activity remotely;
- where the Laboratory requests that the assessment be carried out on-site;

- where the level of digitalisation of the Laboratory, including its system and technical documentation, does not allow for an effective remote assessment.

ACCREDIA DT shall carry out an appropriate preliminary feasibility analysis in order to determine whether an assessment can be conducted entirely remotely.

For the purposes of this analysis, it may also be necessary to carry out a preliminary simulation of how the assessment will be conducted by the Laboratory, particularly in cases where experimental activities are planned both at its own premises and externally at the Client's premises.

For the purpose of determining the number of assessor days for surveillance assessments, ACCREDIA DT carries out periodic risk analyses, based on general guidelines defined in collaboration with the ACCREDIA Steering and Guarantee Committee, which has approved them. These analyses include factors such as: the outcomes of previous assessments; the results of internal corrective actions undertaken by the Laboratory in response to internal technical non-conformities and/or negative results from participation in PT/ILCs; any sanctioning measures; the traceability of measurements resulting from supplier qualifications directly performed by the Laboratory; the presence of substantiated complaints/reports; the existence of critical accreditations (ionising radiation); the number of certificates issued; etc...

Any adjustments to the surveillance programme may be applied by ACCREDIA DT on the basis of the Laboratory's experience and competence.

The purpose of the scheduled surveillance assessment is to assess the continued compliance with the provisions of this Regulation, international standards and guides, and any other applicable normative references, covering both system and technical aspects.

In general, within the validity period of the accreditation, each metrological sector must be assessed at least once, as must each aspect of the management system, with the exception of sectors relating to measurements involving ionising radiation (metrological area with critical sectors and periodic verifications), for which assessment is required at every surveillance assessment.

On the occasion of each scheduled surveillance assessment, the overall set of sampled metrological sectors and sites must in any case enable the assessment of a representative range of the Laboratory's accredited activities.

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

Particular attention is also given verifying the planning of participation in proficiency testing and/or interlaboratory comparisons, internal audits, reviews, complaints, calibration certificates issued, as well as to the maintenance and improvement of the management system, the compliance of technical activities, and the correct use of the ACCREDIA mark and/or reference to accreditation.

Where possible, the Technical Assessor, in accordance with the instructions provided by the FT at the time of Notification, has both the right and the duty to require that the activity be carried out by authorised personnel other than those assessed during the previous assessment.

The planning and execution of the surveillance assessment are carried out in a manner similar to that applied for the accreditation assessment.

During the preparation phase of the scheduled surveillance of a Laboratory accredited with a flexible scope, ACCREDIA DT applies the requirements set out in Technical Regulation RT-26, in its current revision.

Scheduled surveillance activities are detailed in a quotation specifically prepared by FT, approved by DDT, and sent by STD to the Laboratory at least **2 (two) months** before the expiry month determined by the CSA DT. If no response is received within **5 (five) days** of sending the quotation, it is considered fully accepted.

In the event of an interruption of the assessment (§ 2.6.5.5), ACCREDIA DT reserves the right to submit the case to the CSA DT for the adoption of any sanctions, as provided in § 7 “Suspension, Reduction, Withdrawal and Renunciation of Accreditation”

Following the assessment, FT and/or DDT reviews the findings raised by the Assessors, reserving the right to modify and/or reclassify them, after which FT officially sends the final version of the findings to the Laboratory, together with a request for the management plan to address them.

The Laboratory must submit to FT, within **10 (ten) working days** of the request, its plan for managing the findings and the associated implementation timeline. The implementation period for corrections and corrective actions must not exceed **3 (three) months** from the date of FT’s confirmation of the findings, except in justified cases approved by DDT, which may authorise extensions, in any case not exceeding **6 (six) months**. All evidence must be submitted simultaneously by the established deadline. The assessment of the plan is communicated by FT to the Laboratory within **15 (fifteen) working days** of receipt of the findings management plan.

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

If the second proposal of the findings management plan and/or the documentary evidence is not deemed adequate, DDT may directly submit the case to the CSA DT for the adoption of sanctioning measures, such as suspension, reduction, or withdrawal of accreditation, in accordance with the provisions set out in § **Errore. L'origine riferimento non è stata trovata.** “Suspension, Reduction, Withdrawal and Renunciation of Accreditation”.

4.2.2. Unscheduled Surveillance Assessment

4.2.2.1. Supplementary Surveillance Assessment

Supplementary surveillance assessments may be carried out in the following cases:

- The need to verify the restoration of compliance of activities following a self-suspension requested by the Laboratory or a suspension imposed by ACCREDIA DT as a sanctioning measure;
- Verification of the maintenance of accreditation conditions up to the date of cessation of the accredited activities, in the event of renunciation to accreditation by the Laboratory;

- Accreditation standard transition assessments, where these are not carried out in conjunction with scheduled surveillance assessments or renewal.
- Assessments decided by the CSA DT in order to evaluate the effectiveness of the corrective actions implemented by the Laboratory following findings issued by ACCREDIA.
- Assessments decided by the CSA DT, prior to expressing a decision on the granting of accreditation, in order to evaluate the effectiveness of the corrective actions implemented by the Laboratory following findings issued by ACCREDIA.

The supplementary surveillance activities are described in a quotation specifically prepared by FT, approved by DDT and forwarded by STD to the Laboratory. After **5 (five) days** from the date of dispatch of the quotation, it shall be deemed fully accepted.

In the event of a negative outcome (i.e. the persistence of deficiencies such as to prevent assurance of the Laboratory's reliability to carry out activities under accreditation) of the supplementary assessment, the CSA DT may apply the following measures:

- where the supplementary assessment was preparatory to the granting of accreditation, the provisions set out in § 2.7.3 "Closure of the Accreditation process" shall apply;
- where the assessment was triggered by numerous and serious non-conformities affecting the competence and reliability of the Laboratory, the CSA DT may decide to withdraw the accreditation, as set out in § 7.3.2 "Withdrawal Measure";
- where the assessment was decided for specific metrological sectors, the CSA DT may decide to grant maintenance/renewal of accreditation, excluding those sectors, as set out in § 7.2 "Reduction of Accreditation.

Where the Laboratory intends to initiate a new accreditation procedure or an extension of accreditation, it shall submit a new Application for Accreditation and make all payments in accordance with the ACCREDIA pricelist (TA-00).

4.2.2.2. Extraordinary Surveillance Assessment

An extraordinary assessment shall be imposed on the Laboratory by DDT, after consultation with FT, in the event of complaints from clients and/or users or of objectively substantiated reports received by ACCREDIA DT that call into question the conformity of the Laboratory's competence.

Extraordinary surveillance assessments include Unannounced Assessments (VSP).

Unannounced Assessments may be arranged:

- In exceptional situations that call into question compliance with the accreditation requirements and/or the competence of the CAB (Unannounced Assessments decided by DDT following objectively substantiated reports/complaints, delays in pending matters; Unannounced Assessments decided by

the CSA DT on the basis of the outcomes of assessments and/or proposals submitted by Management);

- In situations not falling within the above cases, as they have not shown evident critical issues, but where elements requiring attention arise from document reviews and on-site assessments (e.g. volumes of activity apparently inconsistent with the size or organisational structure of the Laboratory, aggressive or unclear commercial policies); in such cases, the Unannounced Assessment may be decided by DDT, submitting the case to the CSA DT, where deemed necessary.

The costs of Unannounced Assessments shall be charged to the Laboratory where the reasons for such assessments are found to be justified, non-conformities are identified, or a high number of Concerns is recorded. Otherwise, the costs shall be borne by ACCREDIA DT.

In the event of a negative outcome, further assessments may follow (e.g. document review of evidence, supplementary assessments), and, where necessary, the case may be submitted to the CSA DT for the adoption of any sanctioning measures.

In the event of a positive outcome, the results of the Unannounced Assessment may be taken into account for the planning of subsequent scheduled surveillance assessments (for example, with a reduction in the requirements to be assessed and, consequently, in the duration of the assessment).

4.2.2.3. Decision-making process for the maintenance of accreditation following surveillance

Following the outcomes of surveillance assessments, the following shall apply:

- in the absence of non-conformities:

FT confirms the maintenance of accreditation, subject to a positive evaluation of the findings management plan by the assessment team.

- in the presence of one or more non-conformities:

DDT assesses whether to confirm the maintenance of accreditation or to submit the case to the CSA DT with a proposal to carry out a supplementary assessment aimed at verifying the effectiveness of the corrective actions implemented.

- in the event of a particularly critical non-conformity situation (number and severity of the non-conformities identified, absence of recovery actions, or actions that are inadequate or not timely):

FT, after consultation with DDT, submits the case to the CSA DT for the adoption of sanctioning measures such as suspension, reduction or withdrawal of accreditation, in accordance with § 7.

4.2.3. Regulatory Alignment

4.2.3.1. Submission of the application

The Laboratory is required to submit to ACCREDIA DT the Accreditation Application DA-05, duly completed and accompanied by all relevant attachments.

Within **30 (thirty) calendar days** from receipt of the application, RST shall assess the completeness and correctness of the application in terms of field completion and the presence of the required attachments, and STD shall inform the Laboratory of the outcome using the procedures established for accreditation cases (§ **Errore. L'origine riferimento non è stata trovata.**).

The acceptance of the application shall not be invoiced to the Laboratory.

4.2.3.2. Conduct of Assessments

Where, following verification by ACCREDIA DT, the regulatory update does not impact the technical competence of the Laboratory, DDT may prepare a non-chargeable case. In such a case, ACCREDIA DT shall publish the amended table within **10 (ten) working days**.

Where, instead, the regulatory update affects the technical competence of the Laboratory and requires assessment by Technical Assessors and/or Technical Experts, the activities shall be subject to a specific quotation and carried out in accordance with the procedures described below.

Assessments may be conducted:

- exclusively by means of document review, including, where applicable, the evaluation of participation in PT/ILC; or
- by means of document review combined with an on-site assessment.

Upon receipt of the documentation by FT, the Technical Assessors and/or Technical Experts shall carry out the assessment, the outcome of which shall be communicated to the Laboratory within **60 (sixty) calendar days** from receipt of the order or acceptance of the quotation.

In the event of a negative outcome, the Laboratory shall propose the required corrective actions within **30 (thirty) working days**.

If the evaluation of the corrective actions also results in a negative outcome, the case shall be submitted to the CSA DT with a proposal to suspend the accreditation, in accordance with § 7.

In the event of a positive outcome of the document review, and where an on-site assessment is required, FT shall be responsible for organising the assessment, which shall follow the procedures established for other types of cases.

4.2.3.3. Decision-making process for Regulatory Alignment

Where the assessment has been conducted exclusively through document review and the outcome is positive, the case shall be submitted to the CSA DT with a proposal to maintain the accreditation and implement the regulatory alignment (table attached to the certificate).

In the event of a second negative outcome of the document review, the case shall be submitted to the CSA DT with a proposal to suspend the accreditation, in accordance with § 7.1.2.

Where, in addition to the document review, an on-site assessment has also been carried out and the outcome is positive (evidence assessed positively), the case shall be submitted to the CSA DT with a proposal to maintain the accreditation and implement the regulatory alignment.

In the presence of non-conformities or a high number of Concerns not effectively resolved, the case shall be submitted to the CSA DT with a proposal to:

- carry out a supplementary assessment, or
- adopt a sanctioning measure, as provided in § 7.

4.2.4. Modification of the Scope of Accreditation

4.2.4.1. Submission of the Application

The Laboratory is required to submit to ACCREDIA DT the Accreditation Application DA-05, duly completed and accompanied by all relevant annexes.

Within **30 (thirty) calendar days** from receipt of the application, RST shall assess its completeness and correctness in terms of field completion and the presence of the required annexes, and STD shall inform the Laboratory of the outcome using the procedures established for accreditation cases (§ **Errore. L'origine riferimento non è stata trovata.**).

The acceptance of the application shall not be invoiced to the Laboratory.

4.2.4.2. Carrying out the Assessments

Assessments may be conducted:

- exclusively by means of document review, including, where applicable, the evaluation of participation in PT/ILC; or
- by means of document review combined with an on-site assessment.

Assessments shall follow, in terms of timing and methods, the process established for accreditation procedures (§ 2.3).

Procedures that are positively assessed may enter into force only upon completion of the process, i.e. after the CSA DT has issued a favourable resolution approving the amendment to the scope of accreditation.

4.2.4.3. Decision-making process for change to the scope of accreditation

If the assessment has been conducted exclusively through a document review, including evaluation of participation in proficiency testing and/or interlaboratory comparisons where required, and the outcome is positive, the application will be submitted to the CSA DT with a proposal to maintain the accreditation and to amend the scope of accreditation (table attached to the certificate).

If, in addition to the document review, an on-site assessment has also been carried out, and the outcome is positive (with evidence submitted in response to the findings evaluated positively), the application will be submitted to the CSA DT with a proposal to maintain the accreditation and to amend the scope of accreditation.

4.2.5. Maintenance of the Flexible Scope

4.2.5.1. Submission of the Application

The Laboratory is required to submit to ACCREDIA DT the Accreditation Application DA-05, duly completed and accompanied by all relevant attachments, 2 (two) months prior to the scheduled surveillance assessment.

Within **30 (thirty) calendar days** of receipt of the application, the RST shall assess its completeness and correctness in terms of the completion of the relevant fields and the presence of the required annexes, and the STD shall inform the Laboratory of the outcome in accordance with the procedures laid down for accreditation applications (§ 2.1).

Acceptance of the application does not entail any financial charge for the Laboratory.

4.2.5.2. Conduct of the Assessments

The assessments are carried out by means of a document review and an assessment and follow the procedural arrangements laid down for Renewal (§ 5.1), with the exception of the evaluation of participation in proficiency testing and/or interlaboratory comparisons.

4.2.5.3. Decision-making process for the maintenance of the flexible scope

In the event of a positive outcome of the assessments (with evidence submitted in response to the non-conformities evaluated positively), the application shall be submitted to the CSA DT with a proposal to maintain the flexible scope.

5. Renewal of Accreditation

5.1. Procedure for the Renewal of Accreditation

The accreditation renewal procedure is carried out in the same manner as the accreditation process described in § 2 and subsequent sections, except as specified in the following paragraphs.

5.1.1. Submission of Application

Where the Laboratory intends to renew its accreditation, it shall, at least **8 (eight) months** prior to the expiry of the accreditation, submit to the STD the Renewal Application (DA-00 and DA-05), accompanied by the documentation required therein, including the results of participation in PT/ILC, where applicable).

At the time of submitting the application, it is allowed:

- that the Laboratory formally requests changes to the scope of accreditation, for example in terms of extending the measurement range and/or improving the accreditation uncertainty, or adding a new instrument. Such changes do not constitute an extension of the scope, and the related case is managed according to the procedures set out in this paragraph, provided that the procedures leading to these changes are positively assessed during the document review or the assessment. In the event of a negative assessment, the proposed changes will not be included in the Renewal application submitted to the CSA DT; for such changes, the Laboratory must therefore submit a subsequent application for a change to the scope of accreditation.
- that the Laboratory may submit the renewal application without enclosing the results of participation in PT/ILC for the metrological sectors in which it has obtained an extension of accreditation in the **2 (two) years** preceding the expiry date of the accreditation, provided that the corresponding PT/ILC have already been carried out and positively evaluated by ACCREDIA DT.

Within **30 (thirty) calendar days**, RST performs an assessment of the completeness and correctness in terms of field completion and the presence of the required attachments:

- if such evaluation is positive, the STD shall formalise its acceptance and inform the relevant FT, who shall prepare the technical and financial quotation for the renewal activities. Where the Laboratory has requested the performance of a measurement audit and has not enclosed the Calibration Certificate, the STD shall formalise its acceptance subject to reservation and request the necessary supplementation at least **4 (four) months** prior to the expiry of the accreditation.
- if such evaluation is negative, the STD shall formalise the non-acceptance and request in writing the necessary documentary supplements. Acceptance of the application and the subsequent preparation of the corresponding technical and financial quotation may take place only after a positive assessment of the requested supplements.

If the renewal application, complete with all attachments, or any requested additions, is submitted late such that its acceptance results in **ACCREDIA DT commencing assessments later than 4 (four) months before the Certificate's expiry date, ACCREDIA DT does not guarantee the continuity of the accreditation**. Consequently, upon expiry of the accreditation, the Laboratory will be removed from the list of accredited

laboratories and will not be authorised to carry out activities under accreditation until its reinstatement, i.e., until completion of the assessments and the favourable resolution of the CSA DT.

In the event of accreditation lapse, the CSA DT will be informed.

If the Laboratory has not submitted the Renewal application at least **2 (two) months** before the expiry of the Certificate, ACCREDIA DT reserves the right to organise an assessment in order to verify the proper operation of the Laboratory up to the expiry of the accreditation and the effectiveness of any corrective actions implemented by the Laboratory in response to any findings issued during the last Surveillance assessment.

5.1.2. Quotation

At the time of acceptance of the application, the relevant FT of the Laboratory prepares the technical and financial quotation for the Renewal of accreditation activities, in accordance with the procedures set out in § 2.2.

In the event that the Laboratory has obtained one or more extensions in the calendar year preceding the Certificate's expiry date, it is not necessary to repeat the assessment for the metrological sectors covered by these extensions. Such assessments will, however, be carried out during the first surveillance activity following the renewal.

Among the reasons for rejecting the Assessors/Experts proposed in the quotation, in addition to those already indicated in Section 2.2, the Laboratory may invoke the unethical conduct of an Assessor. This reason must be demonstrated to ACCREDIA DT with objective evidence, and in any case only after the Laboratory has raised substantiated reservations regarding the performance of the Assessor/Expert.

5.1.3. Document Review

The document review (similarly to what occurs during the initial accreditation phase (§ 2.5)) includes the evaluation of the results of proficiency tests and/or interlaboratory comparisons in which the Laboratory has participated during the accreditation cycle.

Submission of participation in proficiency tests and/or interlaboratory comparisons that have already been used in applications approved during the accreditation cycle is not permitted and therefore gives rise to non-conformities during the document review.

The outcome of the document review (carried out by the appointed Assessors) is notified by the 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: the FT prepares the next stage of the Accreditation Renewal procedure;
- is negative: the Laboratory must correct/complete the documentation and submit it to **the FT within 30 (thirty) working days, and always prior to the assessment**. The submitted documentation will be evaluated by the Assessors during the assessment.

If the negative outcome (presence of non-conformities) relates to the evaluation of participation in proficiency tests and/or interlaboratory comparisons, the Laboratory must analyse the causes of the non-conformity, assess its extent, and propose corrections and corrective actions **prior to the assessment**. For the assessment of the effectiveness of such actions, ACCREDIA DT reserves the right to propose any additional items to the quotation.

Procedures that are positively assessed may enter into force only once the application process is completed, i.e., after the CSA DT has issued a favourable resolution for the Renewal of accreditation.

5.1.4. Preparation and Notification of the Plan

In the case of multi-site Laboratories, it is possible, during the Renewal process, not to carry out assessments at all sites where the Laboratory operates, provided that they have been assessed within the previous **2 (two) years**.

ACCREDIA DT may conduct on-site, remote, or blended assessments, making use, if necessary, of the Laboratory's Information Technology (IT) systems. In any case, ACCREDIA DT will carry out an appropriate preliminary feasibility analysis in order to determine whether it is possible to conduct the assessment entirely remotely or in a blended mode.

For the purposes of this analysis, it may also be necessary to carry out a preliminary simulation of how the assessment will be conducted by the Laboratory, particularly in cases where experimental activities are planned both at the Laboratory's own sites, externally and the Client's sites.

If the activities conducted remotely prove unsatisfactory at the end of their execution (e.g., due to connection problems, difficulties in sharing documents and/or obtaining evidence, or difficulties in observing experimental activities), follow-up activities must be carried out. These follow-up activities will be agreed with the Laboratory by the assessment team and recorded in the corresponding assessment report. The costs of the follow-up activities will be borne by the Laboratory if it is responsible for the causes that led to the ineffective conduct of the remote assessment.

In the case of Laboratories accredited for calibrations at the client's premises, it is possible not to carry out the assessment at the instrument/sample installation site, provided that it has been performed within the preceding **2 (two) years**. In exceptional cases, where it is not possible to organise such an activity, it is permitted to conduct the assessments by recreating the conditions in environments other than the client's premises.

Renewal assessments, similarly to surveillance assessments, also aim to verify the implementation and effectiveness of corrective actions/corrections related to findings identified in previous assessments, as well as internal calibrations (where applicable).

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

.

5.1.5. Acceptance of the Plan

If the Laboratory fails to be available despite the FT having implemented all measures set out in § 2.6.2.2, DDT shall proceed with the adoption of the sanctioning measures referred to in § 7.

5.1.6. Assessment

Assessment activities are carried out in accordance with the provisions of § 2.6.

If the Laboratory fails to make itself available to undergo the assessment before the expiry of its current accreditation, ACCREDIA DT will nevertheless continue the Accreditation Renewal procedure; however, the current accreditation will lapse at the expiry date. In this case, the Laboratory will be removed from the list of accredited Laboratories and will not be authorised to carry out accredited activities until the accreditation is restored, i.e., until the completion of the assessments and the favourable resolution of the CSA DT.

The validity of the current accreditation may instead be extended by the CSA DT beyond the expiry date, provided that the scheduled assessment activities are initiated before the accreditation expiry date.

5.1.7. Interruption of the Assessment

In the event of an interruption of the assessment (see § 2.6.5.5) ACCREDIA DT may impose the sanctioning measures referred to in § **Errore. L'origine riferimento non è stata trovata.**.

5.1.8. Assessment of the Findings Management Plan and Evidence

With reference to the provisions of § 2.6.7.2 and 2.6.7.3, if the second proposal of the findings management plan and/or the evidence provided are found to be inadequate (negative assessment by the assessment team), ACCREDIA DT will request the CSA DT to adopt the sanctions referred to in § **Errore. L'origine riferimento non è stata trovata.**.

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 evaluated and the full implementation of corrective actions takes place, possibly even at a later date, provided that it is within a maximum of **3 (three) months** from the first request of the findings management plan.

5.1.9. Assessment of 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 § 4.2.2.1) and/or the adoption of a sanction measure as per § **Errore. L'origine riferimento non è stata trovata.**.

5.1.10. 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 event of a negative outcome thereof, the procedure set out below shall apply:

- if the supplementary assessment was required due to numerous serious non-conformities which affect the competence of the Laboratory: the CSA DT may decide to withdraw accreditation, as stated in § **Errore. L'origine riferimento non è stata trovata.**;
- if the supplementary assessment has been decided on for specific metrological sectors: the CSA DT may decide to grant the renewal of accreditation, excluding these sectors, as set out in § 7.2.2.

If the Laboratory wishes to initiate a subsequent accreditation extension procedure, it must submit a new Application for Accreditation and make all payments as per the ACCREDIA pricelist (TA-00).

5.1.11. CSA DT Resolution on Renewal

The operations are carried out in a manner similar to that provided for the accreditation process, as set out in § 2.7.2, except as specified below.

The CSA DT also decides the frequency of the scheduled surveillances for the new accreditation cycle, taking into account the risks associated with the Laboratory and the performance of the previous cycle.

In the event of a negative decision by the CSA DT, either a reduction or a withdrawal of the accreditation will be applied, in accordance with the provisions of § 7.2.2. or § **Errore. L'origine riferimento non è stata trovata.**, respectively.

For justified reasons, the validity of the accreditation may be extended by the CSA DT beyond the expiry date. This process may be repeated, provided that the limit of **5 (five) years** from the accreditation decision or the last Renewal is not exceeded.

6. Extension of Accreditation

6.1. Procedure for the Extension of Accreditation

During the validity period of the accreditation, the Laboratory may request ACCREDIA DT to extend its scope of accreditation in order to add additional metrological sectors.

Any requests for extension for metrological sectors not covered by ACCREDIA DT (not listed in the Annex to DA-05 “Correspondence of Quantities – LAT Sectors”), or differing from existing ones, are submitted to DDT

in order to carry out a review of the resources and subsequently include them in the Annex to DA-05 at the next available CSA DT meeting.

The accreditation extension procedure is carried out in the same manner as the accreditation process provided in § 2 and following, except as specified in the paragraphs below.

6.1.1. Submission of Application

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

Within **30 (thirty) calendar days** from the receipt of the application, RST performs the assessment of 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 its acceptance and informs the relevant FT which prepares the relative technical and financial quotation for the extension activities;
- if said assessment is negative, STD formalises to the Laboratory its non-acceptance and requests in writing the necessary integrations that the Laboratory must send within **2 (two) months** from the date of the integration request.

The acceptance of the application can take place only after the positive assessment of the integrations sent to Laboratory within the deadline.

If STD has not received the required documentation within this period, the provisions of § 2.7.3 shall apply, and in this case, a Laboratory wishing to restart the accreditation extension procedure must submit a new formal extension request.

Upon acceptance of the application, STD informs the ACCREDIA administration, which prepares the invoicing for the acceptance of the application in accordance with TA-00.

The only exception for which ACCREDIA DT accepts the accreditation extension application with reservation is the absence of results from participation in proficiency tests and/or interlaboratory comparisons, where applicable, provided that evidence of registration is available.

However, the document review will not be considered complete until the Laboratory submits the missing results.

6.1.2. CSA Resolution on Extension

The operations are carried out in a manner similar to that provided for the accreditation process, as set out in § 2.7.2 “CSA DT Resolution on Accreditation”. In the event of a favourable decision by the CSA DT, ACCREDIA DT updates the annex to the accreditation certificate based on the approved extension of accreditation.

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

6.2. Extension of Accreditation to the Flexible Scope

With reference to the provisions of the current revision of Technical Regulation RT-26 concerning accreditation with a flexible scope, during the validity period of the accreditation, the Laboratory may request ACCREDIA DT to extend its accreditation to the flexible scope, provided that the Laboratory has held accreditation for the fixed scope in the same sectors subject to the requested flexibility for at least **2 (two) years**.

7. Suspension, Reduction, Withdrawal and Renunciation of Accreditation

ACCREDIA DT may impose sanctioning measures, including suspension (partial or total), reduction, or withdrawal of accreditation, in cases of particular severity, whether from a managerial, technical, or ethical standpoint, following scheduled surveillance, supplementary, extraordinary, or Renewal assessments, or other checks and investigations (e.g., reports and complaints).

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

Resolutions of the CSA DT concerning suspension, withdrawal, or reduction are communicated to the affected Laboratory via certified email (PEC) and subsequently published on the ACCREDIA website.

The Laboratory is required to inform the affected clients and, where appropriate, other interested parties of the sanctioning measure imposed.

7.1. Suspension

The suspension of accreditation may concern the entire scope of accreditation (total suspension) or only 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 implies, for the Laboratory, the prohibition to issue calibration certificates under ACCREDIA accreditation, for the activities subject to suspension. The total suspension implies, for the Laboratory, the prohibition to declare itself accredited and to issue calibration certificates under ACCREDIA accreditation.

Moreover, in 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.

The suspension does not change the frequency of surveillance assessments. However, if the suspension of the accreditation is total, in the period of validity of the suspension, the assessments are not carried out, except for those aimed at verifying the overcoming of the causes of the suspension itself. In any case, all the surveillance assessments required for the accreditation cycle must be carried out.

If the suspension extends beyond **6 (six) months**, ACCREDIA DT will proceed with the reduction of accreditation for the affected sectors, or, in the case of a total suspension, ACCREDIA DT will initiate the procedure for the withdrawal of accreditation.

The suspension does not affect the Laboratory's contractual obligations towards ACCREDIA.

7.1.1. Suspension Requested by the Laboratory (Self-Suspension)

The Laboratory may request ACCREDIA DT to suspend, partially or totally, its accreditation at any time.

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

- exceptional temporary unavailability of significant equipment for calibration (excluding unavailability of instrumentation due to scheduled calibration);
- temporary unavailability of the Laboratory's premises (e.g., in the event of failure to control environmental conditions);
- relocation of the Laboratory premises where calibrations are performed;
- non-conformities/deficiencies that could call into question the validity of the calibration/verification results (e.g., negative evaluations of participation in interlaboratory comparisons, etc.);
- temporary unavailability or deterioration of resources (e.g., personnel, premises, equipment, etc.).

The Laboratory shall submit a written request for self-suspension to the relevant FT, using the MD-08-04-DT form provided by ACCREDIA DT, specifying the reasons and including the activity resumption plan, indicating the anticipated duration of the suspension.

FT submits the request for self-suspension submitted by the Laboratory to DDT for assessment. DDT may amend and/or supplement the conditions proposed for the restoration of compliance, ordering in any case the necessary enquiries to verify full compliance, at the end of the self-suspension period.

FT draws up the technical and financial quotation for the assessments necessary for the restoration of the self-suspended activities and STD sends the quotation to the Laboratory.

The Laboratory is informed by the FT, via written communication, of the assessment activities planned for the restoration of compliance and of the maximum period allowed, which shall not exceed **6 (six) months**, and in any case, the end date of the self-suspension shall not be later than the expiry date of the accreditation certificate.

The Laboratory is required to promptly inform its clients and the competent authorities, providing details of the date and duration of the suspension, and to submit the relevant communication to ACCREDIA DT.

Assessments and decisions regarding the resumption of activities following self-suspension are carried out in accordance with the procedures described in § 7.1.3 "Assessments on the Cancellation of the Suspension".

If the restoration of conformity does not take place within these deadlines, ACCREDIA DT proposes to the CSA DT:

- in the case of partial self-suspension: the reduction of accreditation (§ **Errore. L'origine riferimento non è stata trovata.**) for the part of the scope and/or of the sites affected by the self-suspension;
- in the case of total suspension: withdrawal of accreditation (§ **Errore. L'origine riferimento non è stata trovata.**).

The CSA DT shall be informed of the self-suspension of accreditation and the resulting actions.

7.1.2. Suspension Decided by Accredia DT

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

a. failure to comply with the requirements of the accreditation standards / the requirements of this General Regulation, the specific Regulations for each accreditation standard, and the Accreditation Agreement;
b. failure to return the signed Acceptance of the Accreditation Agreement;
c. the Laboratory's unavailability to undergo the scheduled surveillance assessment within the deadlines indicated by ACCREDIA DT;
d. negative outcome of the assessments (failure to resolve serious non-conformities such as to compromise the reliability of the Laboratory in carrying out activities under accreditation);
e. unavailability of the Laboratory to undergo unscheduled assessment;
f. contractual insolvency (§ 7.1.2.1);
g. failure to send the findings management plan or its amendment, if requested by ACCREDIA DT, within the specified deadlines;
h. failure to resolve findings in accordance with the procedures of ACCREDIA DT;
i. failure to implement corrections/corrective actions in the case of improperly issued Calibration Certificates;
j. ineffective handling of unsatisfactory results in participation in PT/ILC;
k. failure to manage complaints/reports received from ACCREDIA;
l. failure to promptly notify ACCREDIA DT of the loss of key personnel identified by the Laboratory;
m. exceptional temporary unavailability of significant equipment for calibration (excluding unavailability of instrumentation due to scheduled calibration);
n. temporary unavailability of Laboratory premises (e.g., in case of failure to control environmental conditions);
o. relocation of the Laboratory's premises;
p. change of legal entity (e.g., change of company name, transfer of ownership).

If the FT detects the occurrence of any of the above conditions (with the exception of case f)) it shall inform DDT, which in turn shall inform 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, shall transmit to ACCREDIA DT in writing its possible counterarguments 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 suspension, assesses the respective reasons and the correctness of the procedures followed and decides on the measure and its possible duration.

FT draws up the technical and financial quotation for the assessments necessary to reinstate 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 may, in any case, be extended until the decision to resume by the CSA DT (which takes place in accordance with the provisions of § 7.1.3).

If the Laboratory is not available to carry out the assessments within the prescribed time limits and/or if the assessments carried out by ACCREDIA DT have not ascertained that the causes underlying the measure have been effectively overcome, the case is submitted to the CSA DT for further sanctioning measures. In particular:

- in the case of a partial suspension, this may be converted, by decision of the CSA DT, into a reduction (§ 7.2) for the part of the scope and/or the sites affected by the suspension;
- in the case of a total suspension, this may be converted into a withdrawal (§ 7.3.2), also by decision of the CSA DT.

The Laboratory, informed of the possible withdrawal measure, transmits to ACCREDIA DT in writing its possible counter-arguments 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 CSA DT by DDT.

The Laboratory is obliged to promptly inform its clients and, where applicable, the competent Authorities, providing details regarding the effective date of the sanctioning measure, and to forward the corresponding communication to ACCREDIA DT.

The CSA DT may, however, decide to extend the suspension period, provided that the total duration does not exceed **12 (twelve) months** and remains within the validity of the accreditation certificate, if the Laboratory has provided evidence of its commitment to address the issues that prevented the suspension from being lifted within the originally scheduled timeframe.

7.1.2.1. Suspension for Contractual Insolvency

Total suspension of accreditation may be ordered ex officio by the ACCREDIA General Management in the event that payment of the fees due to ACCREDIA DT is delayed by more than **60 (sixty) days** with respect to the date foreseen by the contractual conditions (payment date indicated on the invoice), despite the reminder sent by ACCREDIA DT at the end of the **45th (forty-fifth) day** of delay. This is without prejudice to any payment deferral agreements, which must be authorised by 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 other hand, the Laboratory persists in its non-compliance after **6 (six) months** have elapsed from the communication of the suspension measure, the case shall be submitted by DDT to the CSA DT for the adoption of the withdrawal measure in the manner set out in § 7.3 “Withdrawal of Accreditation”.

7.1.3. Assessments on the Cancellation of the Suspension

When the Laboratory considers that the reasons leading to the suspension or self-suspension have been resolved:

- accepts the technical and financial quotation;
- formally notifies the relevant FT of its availability to resume activities;
- submits documentation demonstrating the full restoration of compliance.

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

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

Upon completion of the compliance verification, FT shall prepare the corresponding report and submit it to the DDT. In the event of:

- positive outcome of the assessments:
  - 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 the DDT and subsequently communicated to the CSA DT.
- negative outcome of the assessments: the report is submitted to the CSA DT for the adoption of further sanctioning measures. In particular:
  - in the case of a partial suspension: this may be converted, by decision of the CSA DT, into a reduction for the part of the scope and/or the sites affected by the suspension;
  - in the case of a total suspension: this may be converted into a withdrawal, also by decision of the CSA DT.

7.2. Reduction of Accreditation

During the validity period of the accreditation, the Laboratory may request ACCREDIA DT to modify its accreditation scope in order to reduce the number of metrological sectors.

The reduction may also be decided by ACCREDIA DT (§ 7.2.2).

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

7.2.1. Reduction Requested by the Laboratory

For the purposes of requesting a reduction of accreditation, the Laboratory must submit to the STD the Reduction Application (DA-05), accompanied by the documentation required therein, in particular an assessment of the effects on other accredited sectors. For the evaluation of the application under the responsibility of the RST, the provisions set out in § 6 "Extension of Accreditation" shall apply.

Upon acceptance of the request, the FT examines the reduction request and, with the possible support of Technical Assessors and/or Experts, verifies any potential effects on other accredited fields. If necessary, the FT prepares additional assessments at the Laboratory's expense (with issuance of a quotation), through, for example, document review, supplementary assessments, or measurement comparisons. In cases where the Laboratory has issued Certificates in the period between the last assessment and the reduction request, ACCREDIA DT reserves the right to carry out the necessary assessment activities.

7.2.2. Reduction Decided by ACCREDIA DT

Accreditation reduction may be applied by ACCREDIA DT in the following cases:

a. negative outcome of the assessments (failure to resolve serious non-conformities such as to compromise the reliability of the Laboratory in carrying out activities under accreditation);
b. failure to address findings in accordance with ACCREDIA DT procedures;
c. ineffective handling of unsatisfactory results from participation in PT/ILC;
d. unavailability of key personnel identified by the Laboratory;
e. unavailability of equipment essential for calibration;
f. unavailability of the Laboratory's premises.

If the FT detects the occurrence of any of the above conditions, after having heard the opinion of Technical Assessors/Experts where appropriate, 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, shall send ACCREDIA DT in writing its counter-arguments, if any, 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 reduction, assesses the respective reasons and the correctness of the procedures followed and decides on the measure.

7.3. Withdrawal of Accreditation

7.3.1. Grounds for Withdrawal

The reasons why ACCREDIA DT may decide to withdraw the accreditation of the Laboratory are related to the persistent and serious failure to meet accreditation requirements or accreditation rules.

Reasons that may lead to the withdrawal of accreditation include:

a. failure to resolve the causes that led to a suspension measure;
b. a total suspension or self-suspension of accreditation lasting more than **6 (six) months**;
c. failure to comply with the Accreditation Agreement;
d. objective situations that would have prevented the conclusion of the Accreditation Agreement;
e. failure to pay the amounts due, if the Laboratory persists in its non-compliance **6 (six) months** after notification of the suspension measure (§ 7.1.2);
f. negative outcome of the supplementary assessment;
g. unfavourable decision on the accreditation renewal by the CSA DT;
h. evidence showing that the assumptions of the Laboratory's competence, impartiality, and integrity have not been met;
i. unlawful, intentional, or seriously unethical behaviour by the Laboratory in terms of professional ethics;
j. evidence of fraudulent behaviour, or that the Laboratory deliberately provides false information or conceals information;
k. use of the accreditation by the Laboratory that causes serious harm or disrepute to ACCREDIA and/or to the accreditation and certification system;
l. the Laboratory's bankruptcy;
m. the cessation of operations of the Organisation in which the Laboratory operates, whatever the reason;
n. confirmed fraudulent situations reported by the competent Authorities in the areas covered by the accreditation.

Withdrawal of an accreditation may also be carried out at the sole discretion of ACCREDIA for geopolitical reasons, in application of regulations concerning international resolutions (e.g., sanctions).

In the case of withdrawal due to fraudulent behaviour or false information, the Laboratory will no longer be allowed to submit an accreditation application.

The accreditation withdrawal procedure entails, with immediate effect:

- removal of the Laboratory from the list of Accredited Centres published on the ACCREDIA DT website;
- loss of the right to refer to itself as an Accredited Calibration Laboratory/Calibration Centre;
- suspension of the issuance of Calibration Certificates;
- loss of the right to use the ACCREDIA mark.

7.3.2. Withdrawal Measure

If the FT identifies the occurrence of any of the conditions listed in § 7.3.2 above, it informs the DDT, who in turn notifies the Laboratory in writing, where applicable, of the potential withdrawal measure.

Once informed of the potential withdrawal measure and its reasons, the Laboratory must submit any written counterarguments to ACCREDIA DT within **10 (ten) working days** from the notification. The FT prepares its report on the matter, including the observations received from the Laboratory, for submission of the case to the CSA DT by the DDT. The CSA DT discusses the withdrawal, evaluates the respective reasons and the correctness of the procedures followed, and decides on the measure.

Following the CSA DT's decision, the withdrawal notification, signed by the President of ACCREDIA, is sent to the Laboratory within **5 (five) working days** by certified email (PEC). The notification must include at least the following points:

- the statement of withdrawal of accreditation;
- the reasons for the measure;
- the date of entry into force of the measure;
- the statement that the Laboratory is no longer included in the List of ACCREDIA 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 clients involved and, where appropriate, the interested parties of the measure.

The table attached to the Laboratory's Accreditation Certificate remains published on ACCREDIA's website, indicating the withdrawal measure and its effective date.

The withdrawal of accreditation does not terminate the contractual obligations towards ACCREDIA, which reserves the right to initiate enforcement and cost-recovery procedures, including interest, in accordance with the law.

7.4. 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 pricelist, non-acceptance of changes in the regulations governing the accreditation activity, etc.).

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

In the event that the Laboratory renounces accreditation, indicating a future date for its termination, the following conditions shall apply:

- until the indicated termination date, the Laboratory may continue to operate under the accreditation regime;

- ACCREDIA DT may decide whether, in addition to the routine assessments already scheduled during that period, any additional one should be carried out;
- ACCREDIA DT may ask for any additional guarantees to be certain that the activities, up to the actual interruption of accreditation, are being carried out correctly (e.g., closure of any open findings, etc…).

The DDT acknowledges the Laboratory's decision and proceeds to inform the CSA DT.

The renunciation of accreditation does not release the Laboratory from its contractual obligations towards ACCREDIA DT, which reserves the right to apply enforcement and cost recovery procedures, including interest, in accordance with the applicable laws.

8. Complaints/Reports, Reservations and Appeals

8.1. Complaints and Reports

ACCREDIA DT may receive complaints/reports:

- on the work of ACCREDIA DT;
- on the work of accredited Calibration Laboratories;
- on the activities of third parties that are connected with the activity of accredited Laboratories or those undergoing accreditation.

Complaints and reports must be submitted via the designated form available on the website.

Within **30 (thirty) working days** of receiving the complaint/report, GRS shall acknowledge and process it in accordance with the applicable procedures, in order to assess the validity of the issues that gave rise to it. These procedures ensure that the examination and management of the complaint/report are carried out by a person independent of the subject of the complaint/report.

Complaints or reports submitted anonymously will not be accepted, in order to prevent submissions made for speculative purposes or to disrupt 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 employees, through the Reporting 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 to Laboratories accredited by ACCREDIA DT but in any case, relating to accreditation.

All complaints/reports must be closed (except for exceptions related to legal disputes) within **12 (twelve) months** of their receipt by ACCREDIA DT.

8.2. Reservations

With reference to the findings issued by the ACCREDIA DT Assessors, any reservations must be presented by the Laboratory **within 3 (three) working days** of the assessment. The submission of a reservation does not exempt the Laboratory from managing the findings not subject to a reservation according to § **Errore. L'origine riferimento non è stata trovata.** "Request of Findings Management Plan".

The acceptance or rejection of the reservations submitted is entrusted to DDT. However, where the reservations are of a technical nature requiring specific sectoral metrological knowledge and expertise, or where DDT has participated in the evaluation, 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 appointed Technical Assessor/Expert shall, within **10 (ten) working days**, provide DDT and FT with a detailed report specifying the documents that were evaluated, a technical response to each individual objection raised by the Laboratory, and a clear statement of the outcome. The costs of these assessment activities shall be entirely borne by ACCREDIA DT.

Upon receipt of such 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.

The response to a reservation must in any case be provided to the Laboratory **within 30 (thirty) working days** from receipt of the reservation.

8.3. Appeals

If the accredited Laboratory, or one in the process of being accredited, intends to request ACCREDIA DT to reconsider the measures taken against it, it may lodge an appeal, in the manner described in ACCREDIA document RG-06, which also includes any cases of ineligibility of the appeal.

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

9. Additional Provisions

For all matters not expressly provided for in this Regulation, the provisions set out in Article 4 of the "Accreditation Agreement between ACCREDIA and Conformity Assessment Bodies (CABs)" (CO) shall apply.

9.1. Registry Variations

The Organisation must notify STD, using the designated forms (DA-00, DA-05 and applicable annexes), of any changes to its registry details concerning 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 the accreditation. The Laboratory is also obliged to promptly inform ACCREDIA DT of administrative and judicial measures relating to internal and external personnel of the Laboratory, 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.

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

In the event of significant changes affecting the management system and/or the technical competence of the Laboratory, the FT shall inform DDT, which may determine the measures referred to in § 5.1.2 and/or order an unscheduled assessment (with the issue of the relevant quotation).

9.1.1. Change of Company name

9.1.1.1. Without Change of Legal Entity (without change of VAT number)

This category includes changes that do not entail a change in the legal entity, i.e., without a change in the VAT/tax code (e.g., 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 certificate annex. The changes introduced do not change the expiry date of the accreditation certificate.

An exception is made for cases of bankruptcy, for which the accreditation withdrawal measure is activated according to the provisions of § **Errore. L'origine riferimento non è stata trovata.**.

9.1.1.2. With Change of Legal Entity (with change of VAT number)

A change in the company name of the Laboratory with a change in the VAT number results in a change in the legal entity that holds the accreditation, therefore the accreditation must be transferred to a new legal entity.

9.1.2. Change of Location and/or Contact Details

This type of change includes, for example, changes in the address of the registered office and/or other locations, whether due to changes in street names 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 data in its database and on the ACCREDIA website and revises, if necessary, the accreditation

certificate and/or the annex to the certificate. The changes introduced do not change the expiry date of the accreditation certificate.

The change due to relocation (moving) of the address of the premises where the Laboratory 's activities are performed (including calibration/verification operations) entails self-suspension as described in section 7.1.1 of this document.

9.1.3. Change in the Organisational Structure of the Laboratory

The Laboratory shall notify any substantial change to its organisation compared to what was declared in the Accreditation Application, for example: Technical Management/personnel authorised to sign Calibration certificates, and the designated contact person for ACCREDIA DT.

9.2. 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 notify the STD, using the appropriate form (DA-00, DA-05 and applicable annexes), of 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 (§ 7.1.2), until the subsequent decision of the CSA DT on the transfer of ownership of the accreditation;
- issues a financial quotation for assessments as provided for in § 2.2 of the ACCREDIA Pricelist (TA-00).

The FT assesses the maintenance of the conditions for accreditation, which can be verified by the following elements from the documentation sent by the Laboratory:

- Chamber of Commerce certificate or equivalent document proving the legal identity of the Laboratory;
- copy of the notarial deed from which the transfer of resources pertaining to the activities subject to accreditation to the different legal entity (e.g., premises, personnel, equipment) is also evidenced
- organisational structures;
- human resources (in terms of numbers and skills);
- any other applicable conditions.

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

Following the assessments carried out, 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 DT, ACCREDIA DT will send the new accreditation agreement and subsequently update the accreditation certificate, its annex (accreditation table) and the website. However, the changes introduced do not change the expiry date of the accreditation.

In the event of a negative assessment, ACCREDIA DT will communicate the failure to transfer the Laboratory's accreditation and will initiate the accreditation withdrawal procedure (according to § 7.3. “Withdrawal of Accreditation”), except in cases where accreditation can be confirmed to the previously accredited party.

9.3. Transfer of Accreditation between Accreditation Bodies

A Laboratory intending to request from ACCREDIA DT the transfer of accreditation from another Accreditation Body that is a signatory to the EA MLA – ILAC MRA agreements shall submit an Accreditation Application in accordance with the provisions set out in § 2.1 “Submission and Assessment of the Accreditation Application”, including all the documentation required therein, together with the latest assessment report issued by the transferring Accreditation Body and a valid accreditation certificate.

The accreditation transfer process shall be carried out in the same manner as the accreditation process (§ 2.3), except for the assessments, for which a sampling of the categories of accredited sectors shall be conducted, taking into account their criticality.

Where the Laboratory intends to request from ACCREDIA DT the transfer of accreditation from another Accreditation Body that is not a signatory to the EA MLA agreements, the full provisions of accreditation shall apply.

The transfer of accreditation is approved by the CSA DT in accordance with the procedures set out in § 2.7.2, with a favourable decision by the CSA DT. Upon transfer, the Laboratory ceases to use the original accreditation and commences accreditation with ACCREDIA.

9.4. Cyberattacks Suffered by the Laboratory

The Laboratory shall promptly notify ACCREDIA of any hacking or cyberattacks, detailing the impact on system records/documents and the corrective actions the CAB intends to implement to ensure that all potentially affected users are informed, without causing disrepute or undermining the reputation of the accreditation. ACCREDIA reserves the right to carry out extraordinary assessments.

10. Obligations to be borne by ACCREDIA

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

10.1. Variations of Accreditation Conditions

In the event of a revision of ACCREDIA documents, the Laboratory is granted a transitional period of **3 (three) months**, unless otherwise indicated in the notice of change, to adapt its operational procedures to the new requirements. The start date of the transitional period shall be the date of publication of the notice on the ACCREDIA website.

The Laboratory may, within the transitional period granted by ACCREDIA, choose not to comply and thus withdraw from accreditation. In such a case, the provisions set out in § 7.4 “Renunciation of Accreditation” shall apply.

10.2. Modifications to the Pricelist

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

In the event of a change in the 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 the service performed. Therefore, should the rates change, the Laboratory will be promptly informed (via e-mail or PEC) of the changes, bearing in mind that the updated Pricelist will be published on the ACCREDIA website.

The Laboratory has the right to renounce accreditation within **6 (six) months** from the date of receipt of the notification of tariff changes. In this case, the provisions of § **Errore. L'origine riferimento non è stata trovata.** “Renunciation of Accreditation” shall apply.

During the notice period, a Laboratory that exercises the right to renounce accreditation shall be charged the fees in effect prior to the change, solely for the activities carried out up to the moment of renunciation.

ACCREDIA
Via Guglielmo Saliceto, 7/9 – 00161 Rome
T +39 06 8440991 / F +39 06 8841199
info@accredia.it

Certification and Inspection Department
Via Tonale, 26 -– 20125 Milan
T +39 02 2100961 / F +39 02 21009637
milano@accredia.it

Testing Laboratories Department
Via Guglielmo Saliceto, 7/9 – 00161 Rome
T +39 06 8440991 / F +39 06 8841199
info@accredia.it

Calibration Laboratories Department
Strada delle Cacce, 91 – 10135 Turin
T +39 011 328461 / F +39 011 3284630
segreteriadt@accredia.it