ACCREDIA
ENTE ITALIANO DI ACCREDITAMENTO

Calibration Laboratories Department

Regulation for the Accreditation of Reference Material Producers

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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.*

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Management System Head Officer

APPROVAL
Directive Council

AUTHORIZATION
Director General

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0. Foreword

ACCREDIA's purpose through the Calibration Laboratories Department is to favour the development of confidence in the compliance assessment system - called to assess and attest conformity of Reference Materials Producers 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:

- Reference Material Producers, including certified reference materials, operating in compliance with the requirements of ISO 17034:2017 standard, ACCREDIA, EA, ILAC documentation and, where applicable, in accordance with Articles 3 and 4 of Law 273/1991

ensuring that they possess and maintain in time the organizational, procedural, technical and professional requirements in such a way as to create a high degree of trust in all relevant social and economic parties - and in particular end users and consumers - in the work of such Subjects and in the value of the assessment 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 document takes into account the evolution of the applicable regulatory references, the experience gained from ACCREDIA and the statements expressed by the ACCREDIA Institutional Bodies, aimed at improving the accreditation system.

0.1. Introduction

The application of the requirements of the ISO 17034:2017 standard and other applicable documents aims to promote the creation and maintenance of customer confidence in the activities of the accredited Reference Material Producers, as well as the impartiality and integrity of the technical and commercial operations associated with them.

Accreditation in accordance with ISO 17034:2017, which replaces ISO Guide 34, attests the competence of accredited Producers to produce the reference materials or types of reference materials specified in the scope of accreditation, as well as the implementation of a management system that generally complies with the principles of the ISO 9001 standard.

Where the reference material producer works in the medical field, ISO 15189 standard may be used as a regulatory reference as an alternative to ISO/IEC 17025:2018 standard. The ISO 15195 standard provides

specific requirements for reference laboratories in the field of laboratory medicine and can be used by the Reference Material Producers for calibration activities in conjunction with ISO/IEC 17025:2018, as a Level 4 Document (see ILAC R6 "*Structure of the ILAC Mutual Recognition Arrangement and Procedure for Expansion of the Scope of the ILAC Arrangement*").

Producers accredited by ACCREDIA DT operate within the framework of national regulations and are considered competent to produce materials supporting the activities of other types of accredited CABs.

In order to promote the effectiveness and credibility of the accreditation process, it is necessary to introduce a series of specific application rules and criteria that, without transcending the spirit and the letter of the standard, favour its full and substantial application by the accredited subjects, while constituting unambiguous, objective and impartial references for the assessments carried out by the Accreditation Body against them.

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

0.2. Scope and Field of Application

This Regulation applies to Reference Material Producers (RMP below) and covers the production of all reference materials (hereinafter RM), including certified reference materials (hereinafter CRM).

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

a. by the Reference Material Producer, to:

- submit an application for accreditation as a Reference Material Producer according to ISO 17034;
- collaborate on ACCREDIA DT's assessment and all related activities;
- implement the required corrective actions following the results of the accreditation procedure and all related acts;
- stipulate the accreditation agreement;
- to collaborate in the activities of surveillance and maintenance of accreditation;
- to submit requests for the extension, variation and renewal of accreditation;
- implement ACCREDIA DT requirements in case of suspension, reduction, renunciation and withdrawal of accreditation.

b. by ACCREDIA DT, when performing the following operations:

- accreditation;
- surveillance and maintenance of accreditation;
- variations in the scope of accreditation;
- renewal of accreditation;
- extension of accreditation;
- suspension of accreditation;
- reduction of accreditation;
- withdrawal of accreditation;
- renunciation of accreditation.

The circulars issued by ACCREDIA DT shall also be considered a source of contractual obligations in the relationship between ACCREDIA DT and the accredited and applicant reference material producers; such circulars shall be shared with the interested parties and shall be included in the document ACCREDIA LS-18.

On the basis of the principle of speciality, a circular issued by ACCREDIA DT supplements the general provisions set out in the applicable Regulations.

ACCREDIA DT considers 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 public authorities;
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 Reference Material Producers by issuing specific 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 EA Laboratory Committee and by the ILAC Technical Committee and by their respective working groups;
- the interpretations provided by the ISO CASCO maintenance groups.

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 typically sampling assessments - that the RMP has the required competences (in terms of organisation, procedures and working/operating documents, human and instrumental resources) to perform the activities in accordance with this Regulation and any other relevant requirements.

This General Regulation and other specific Regulations for Accreditation Standard are subject to specific approval by ACCREDIA's Directive Council (Article 14 of the ACCREDIA Statute), following the favourable opinion of the Committee for Accreditation Activity and are issued under the authority of the President of ACCREDIA. 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 periods of corporate closure, which are published on ACCREDIA's website.

0.3. Normative References

The regulatory references to be considered for the application of this Regulation are contained in the ACCREDIA LS-09 "Standards and Reference Documents for the Accreditation of Calibration Laboratories and Reference Material Producers", in the current revision, including all applicable ISO, ILAC, and EA documents.

This Regulation also refers, where and to the extent applicable, to the statutory rules and regulations of ACCREDIA, in the latest revision in force:

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

and to the EA, ILAC, and other documents applicable to Reference Material Producers.

For each of the ACCREDIA documents cited, the latest applicable revision shall apply. ACCREDIA documents can be freely downloaded from the Documents section and/or from the restricted area for producers on the website.

0.4. Terms and Definitions

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

Note: Accreditation consists of a statement of adequacy (adequacy audit and therefore not compliance or conformity audit) of the organisation and of 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 national accreditation body, based on a decision, certifying the conformity of a conformity assessment body with the requirements of a specific accreditation standard**.**

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

Conformity Assessment Body: a body that performs conformity assessment activities, including calibration, testing, certification, and inspections (EC No. 765/2008 Chapter 1, Article 2, paragraph 13). For the purposes of this Regulation CAB is a Reference Material Producer.

Note: For the purposes of this Regulation, a Conformity Assessment Body (CAB) is understood to mean a Reference Material Producer.

Reference Material Producer (RMP): body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials that they produce (ISO 17034 §3.1).

In this document it is also called only "Producer" or "RMP" (ISO 17034 standard).

Production (of Reference Materials - RM): all necessary activities and tasks leading to the release and maintenance of an RM (ISO Guide 30 §2.3.7).

Note: Activities include, e.g., planning, production control, material handling and storage, material processing/treatment, assessment of homogeneity and stability, characterization, assignment of property values and their uncertainties, authorization and issue of RM certificates or other statements (ISO Guide 30).

Body: the legal entity responsible for the Reference Material Producer**.**

Subcontractor: body (organization or company, public or private) that undertakes aspects of processing, handling, homogeneity and stability assessment, characterization, storage or distribution of reference materials on behalf of the Reference Material Producer on a contractual basis whether onerous or not.

Note 1: Key tasks/aspects of the production process of reference materials cannot be subcontracted. The following may not be subcontracted to third parties: production project planning, assigning and deciding on property values and associated uncertainties, authorizing of property values and issuing certificates or other necessary statements**.**

Note 2: The concept "subcontractor" is equivalent to the concept "collaborator".

Note 3: Experts, who could be asked for recommendations, but who are not involved in decision making or the execution of any aspect mentioned in the definition above, are not considered subcontractors (ISO Guide 30).

Reference Material - RM: material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Note 1: RM is a generic term.

Note 2: Properties can be quantitative or qualitative, e.g., identity of substances or species.

Note 3: Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

Note 4: ISO/IEC Guide 99: 2007 (UNI CEI 70099: 2008, §5.13) has an analogous definition, but restricts the term "measurement" to apply to quantitative values. However, note 3 of the definition in ISO/IEC Guide 99:2007 specifically includes qualitative properties, called "nominal properties".

Certified Reference Material - CRM: reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty and a statement of metrological traceability.

Nota 1: The concept of value includes qualitative attributes such as identity or sequences. Uncertainty for such attributes may be expressed as probability.

Nota 2: Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO 33405.

Nota 3: The ISO 33401 gives guidance on the contents of certificates.

Nota 4: ISO/IEC Guide 99 (UNI CEI 70099:2008, §5.14) has an analogous definition (ISO 17034, §3.2).

Characterization (of a reference material): determination of the property value or attributes of a reference material, as part of the production process (ISO Guide 30).

Reference material document: document containing all the information that is essential for using any reference material.

Note: The reference material document covers both the product information sheet and reference material certificate.

Reference material certificate: document containing the essential information for the use of a CRM, confirming that the necessary procedures have been carried out to ensure the validity and metrological traceability of the stated property values.

Product Information Sheet: document containing all the information necessary for the use of a reference material, excluding CRMs.

Site: Structure in which the activities of the RMP are carried out. A site may be a permanent or temporary structure of the RMP, or a location outside the permanent structures of the RMP.

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 formalised by ACCREDIA DT and classified as Non-conformity, Concern and 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 CAB 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 and/or;
- 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 RMP 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.

Nota 2: 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 RMP.

No formal, immediate response to the findings formulated as comments is required.

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

Impartiality: presence of objectivity.

Note: Types of conflicts of interest are covered in the Technical Regulation RT-34.

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 standard ISO 17034.

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

Note: the scope of accreditation of the RMP, i.e., a concise description of the activities together with the sites where they are performed, is set out in the Accreditation Table (a document attached to the Accreditation Certificate) in terms of the type of reference material (CRM, RM, or both) using the following fields:

- Metrological area;
- Identification of the material in terms of, for example, matrix and analyte, artefact, etc.;
- Property/properties;
- Assigned value range;
- Approach for assigning values to the property;
- Uncertainty (if CRM);
- Method (used for the determination of uncertainty and to ensure metrological traceability if CRM);
- Site.

Reference Material Sector: identifies a set of reference materials whose production is carried out using common methods (including stability and homogeneity assessment) with matrices of the same type.

Note: The description of the sectors may be determined using the guidance on categories and subcategories provided in ISO/TR 10989:2009 "*Reference materials — Guidance on, and keywords used for, RM categorization*".

Report: a report is understood as a communication, whether originating externally or internally, that does not inherently constitute a complaint but serves as a point of attention regarding potentially non-compliant situations by accredited CABs, and/or their clients, and/or certified organisations.

Assessment: a process undertaken by ACCREDIA DT to determine the competence of an RMP, 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 an RMP 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 RMP's premises.

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).

Modification of the Accreditation Scope: a change to the conformity assessment activities within the accreditation scope (variations to the table attached to the Accreditation Certificate that do not involve the addition of a new sector, e.g., addition or reduction of one or more analytes, addition or reduction of one or more materials in another matrix, addition or reduction of one or more properties, change in the value range of a property, change in uncertainty, 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 an RMP (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 RMP or decided by the CSA DT as a sanctioning measure.

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

Withdrawal of accreditation: a sanctioning measure involving the withdrawal of an RMP's **accreditation** for the entire scope of the scheme**.**

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 RMPs seeking accreditation, to RMPs 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 submitted by RMPs.

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

Technical Assessor: Person qualified by ACCREDIA and appointed by ACCREDIA DT to assess the technical competence of an RMP with reference to the categories for which RMP 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 RMP's competence assessment, including the assessment of the management system, measurement result comparisons, operational and technical procedures verification and accreditation table.

Where in the above-mentioned documents, different definitions of specific metrological terms for reference materials are given, preferences should be given to the definitions in ISO Guide 30.

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;
- RMP: Reference Material Producer;
- RM: Reference Material;
- CRM: Certified Reference Material;
- RST: Technical Review of Applications;
- GRS: Complaints and Reports Management.

1. Criteria and Information for Accreditation

1.1. Informative phase

Any RMP can send a written, verbal or computerized request to STD in order to know the details of accreditation.

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

Legal Headquarters: ACCREDIA, Via Guglielmo Saliceto, 7/9 - 00161 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 RMP 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 RMP 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 RMP. These meetings, to which experts in the

production and use of reference materials 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 RMP 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 RMP 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 and duration of any subsequent request for accreditation. Only one preliminary assessment may be conducted against a single RMP.

2. Accreditation Process

2.1. Submission and Assessment of the Application of the Accreditation

The organisation wishing to initiate the accreditation procedure must fill in the accreditation application (DA-00 and DA-09, which may be written in Italian or in English), with all the required data and send it, with the relevant attachments, to the STD of ACCREDIA DT at the appropriate mailbox segreteriadt@accredia.it.

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

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

The statute, or other equivalent document, of the requesting Organisation must explicitly provide, among its activities, that of Reference Material Producer.

Should the RMP 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 the production of different reference materials, in different matrices and of different types, carried out at the Organisation's site(s).

Any requests for accreditation for a reference material sector not included in the Annex to DA-09 *Metrological areas – RMP sectors*, or which otherwise differ from those currently listed, shall be reviewed by DDT in order to proceed with their inclusion in the Annex to DA-09 at the first available meeting of CSA DT.

It is emphasised that the RMP is an organisation that must be responsible for at least the following activities: project planning and management, assignment and decision-making regarding property values and associated uncertainties, authorisation of property values and the issuing of documents associated with reference materials. Therefore, the legal entity shall be accredited, or a well-defined part of it, responsible for all activities related to the production of RM.

In light of the above, an application from a company providing exclusively services, such as the assignment of a reference value to a candidate RM, cannot be accepted, as it does not meet the requirements of an RMP.

Accreditation as a Calibration/Testing/Medical Laboratory does not guarantee its compliance with ISO/IEC 17034 standard because the production of reference materials includes activities that are not considered in the scope of accreditation of a Laboratory. However, ACCREDIA DT as evidence of technical competence for the applicable requirements of ISO/IEC 17034 standard accepts accreditation as Calibration/Testing/Medical Laboratory.

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 RMP the acceptance thereof;
- if this assessment is negative: STD formalises to the RMP the non-acceptance of the same and requests in writing the necessary integrations that the RMP 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 RMP within the deadline.

If the RMP 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 RMP wishing to restart the accreditation procedure must submit a new formal request for accreditation.

Upon acceptance of the application:

- SDT informs the administration of ACCREDIA which will prepare 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 an RMP at least until the subsequent Renewal.

Where there is evidence of fraudulent behaviour, or where the RMP 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 RMP. Furthermore, where the RMP 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.

If the RMP performs activities already covered by accreditation (in particular as a Calibration, or Testing, or Medical Laboratory), ACCREDIA DT considers such attestation sufficient to demonstrate the fulfilment of part of the applicable requirements and takes this into account when preparing the quotation and organising the assessments.

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

The assessment team includes a System Assessor (Assessor usually in charge of coordination), one or more Technical Assessors depending on the type of Category/Sector of the reference materials and any Experts (in the event that very specific technical and/or statistical aspects are to be analysed).

The Assessors are chosen from among those included in the List of Assessors, qualified on the basis of ACCREDIA procedures and approved by the CdA upon proposal of DDT.

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.

RMPs 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 RMP concerned except for serious grounds of incompatibility, which must be expressly communicated directly to DDT.

Assessors may be replaced by other Assessors with the same 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 RMP's right to request their replacement at a later stage.

2.3. Accreditation Process

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

a. preliminary operations;
b. review of documentation;
c. on-site/remote/blended assessments;
d. decision-making process.

Assessments must include all stages of the production process for each category of reference material and all sites.

If the RMP subcontracts certain activities, these will be subject to documentary assessment. If the subcontracted activities are considered critical by ACCREDIA DT (e.g., the characterisation of a CRM) and the qualification is carried out through a second-party audit, ACCREDIA DT will attend such an audit in order to evaluate the procedures by which the RMP qualifies the subcontractor.

If the RMP performs internal calibrations, these will also 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 RMP, 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 RMP in the following **4 (four) years** (accreditation cycle).

It is emphasised that the Assessors and/or Technical Experts of ACCREDIA DT, 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 RMP in question and its subcontractors, if any.

2.5. Document Review

During the review of the documentation of the RMP, 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 RMP performs internal calibrations, the relevant procedures will be evaluated.

The technical assessors evaluate the approach adopted by the RMP to define the need for participation in proficiency testing and/or interlaboratory comparisons, as well as the related frequency. They also analyse the adequacy of the risk analysis underlying these decisions. For these aspects, the RMP shall refer to Regulations RT-39 and RT-34.

Accreditation covers all batches of RM that are part of the required accreditation scope, produced after obtaining the accreditation. However, as accreditation may include existing batches, the evaluation of the documentation also extends to the production of these, when the RMP so requests.

Upon receipt of the documentation, including any relevant records, FT shares the documentation in its entirety with all members of the assessment team, who shall carry out its evaluation. The above-mentioned document review is performed and notified to the RMP within **90 (ninety) calendar days** from receipt of the order/acceptance of the quotation.

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

- if the outcomes are positive, or where there are only minor deficiencies whose corrective actions can be assessed by the assessor directly on site, the process proceeds to the subsequent accreditation phase;
- if the outcomes are not positive and documentary amendments and/or additions are required, the document review shall be repeated, for no more than two further times. The RMP shall supplement/modify the documentation within a maximum period of **12 (twelve) months** from the first request for adjustment and **6 (six) months** from the subsequent request;
- if negative outcomes persist following the third assessment, FT proposes to DDT that the accreditation process be discontinued, in accordance with the provisions set out in § 2.7.3;
- if a period of **12 (twelve) months** elapses from the last request for adjustment without the RMP having taken the necessary action, FT proposes to DDT that the accreditation process be discontinued, in accordance with the provisions set out in § 2.7.3.

In the event that numerous and serious findings are identified by the assessors during the document review, the RMP 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 RMP 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 RMP'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.

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 RMP, especially in cases where experimental activities are planned.

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 RMP by the assessment team and recorded in the relevant assessment report. The costs of follow-up activities are to be borne by the RMP if the RMP 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 RMP and the assessors involved, the date for the assessment, prepares and sends to the RMP 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 RMP activity involved in the accreditation process are adequately verified.

If the RMP subcontracts activities deemed critical by ACCREDIA DT and the qualification is carried out through a second-party audit, ACCREDIA DT reserves the right to include an Assessor in the plan in order to attend such audit and evaluate how the RMP qualifies the subcontractor on site.

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 RMP 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 RMP 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 RMP 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 RMP. Such acceptance must be received within **3 (three) working days** of receipt of the same.

In the event that FT, after repeated attempts, is unable to agree with the RMP 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 RMP 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, FT, in agreement with DDT, assesses 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 RMP takes place in compliance with the ISO/IEC 17011 standard and with the applicable ACCREDIA DT documents;
- provide Assessors and/or the RMP with any clarifications concerning the requirements of ISO/IEC 17034 standards and ACCREDIA documents.

During the assessment, the presence of observers is also permitted, at the request of the RMP, 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 RMP, providing, where necessary, a confidentiality undertaking signed by the Observers themselves. Should the RMP wish to raise any objections to the proposed Observers, such objections shall be duly justified in writing and sent to ACCREDIA DT within **five (5) working days** of the notification; after this period has elapsed, the Observers shall be deemed to have been accepted. The costs related to the participation of such Observers shall be borne by ACCREDIA DT.

Under no circumstances may any Observers (whether appointed by the RMP 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 Management, Technical Management, Personnel responsible for the Management System, and their staff;
- conduct of the assessment, with the support of RMP 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 RMP staff and acknowledgement of any reservations.

The RMP 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 RMP must also allow the Assessors access to its premises and files (whether paper or electronic) and, if necessary, to those of its subcontractors, in order to perform the assessment. If the subcontractor is to be present at the audit, the RMP must organise the logistics in advance, agreeing dates and obtaining authorisation for the Assessors' presence.

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 RMP, a meeting of the assessment team is held to discuss assessment modalities and distribute tasks.

2.6.4.2. Initial Meeting with the RMP

During the initial meeting between the assessment team and the representatives of the RMP 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 RMP to accompany the Assessors), training assessors and observers;
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 any process for the production of reference material, or parts thereof, to be carried out in the presence of the Assessor;
f. define the details of any calibrations to be performed in the presence of the Assessor;
g. 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;
h. agree on the timing and modalities for the assessment of any off-site activities;
i. agree on any changes to the assessment plan;
j. explain the assessment procedure and the RMP's right to raise reservations;
k. recall the commitment of each member of the team to the confidentiality of information;
l. inform that confidential meetings of the Assessors may be necessary during the assessment;
m. request confirmation of the presence of the RMP's Management, or its Representative, at least at the final meeting, and to complete the list of participants in the assessment;
n. provide the RMP with the opportunity to request any further clarifications;
o. 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.
p. 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 RMP 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 RMP for the self-assessment attached to Application DA-09.

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 Reference Material Producer 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 RMP to carry out the production of RMs 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.

The assessment of the management system shall be extended to all applicable requirements during accreditation and renewal assessments. During surveillance and renewal, the implementation and effectiveness of the corrective actions opened as a result of the previous assessment are always verified.

The extension of the assessment to the RMP must also cover the second-part audit to the subcontractor in the applicable cases.

The RMP may use the results of participation in proficiency testing or interlaboratory comparisons (PT/ILC) to demonstrate the reliability of the testing/calibration activities performed; where such activities have an impact on metrological traceability and the measurement uncertainty of the value assigned to the property, participation in such activities is assessed in accordance with Technical Regulation RT-39.

In carrying out assessments, ACCREDIA DT Assessors will have to abstain from requesting RMP copies of the documentation examined, unless it is necessary to demonstrate the objective evidence of non-conformity or any RMP reservations. In this case, the copies must be enclosed to the checklist and sent to the relevant FT. No Producer's document may be retained by the Assessors in any way, except copies of documents

associated to a reference material, sampled in archive and/or Certificates or other documents relating to the measures taken during the audit that are to be attached to the checklist.

2.6.5.2. Tasks of the System Assessor

The System Assessor must verify the compliance of the RMP management system with the requirements of ISO 17034:2017, ISO/IEC 17025:2018 standards, where applicable, the EA, ILAC and/or other reference standards and to the ACCREDIA DT provisions.

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

In addition, the System Assessor performs the following tasks:

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

2.6.5.3. Tasks of the Technical Assessor

The Technical Assessor must verify the technical competence of the RMP in compliance to the requirements of the ISO 17034:2017 standard, of ISO/IEC 17025:2018 standard, where applicable, and the other standards recalled by it, of EA, ILAC and/or other reference standards, ACCREDIA DT specific requirements and technical provisions related to the category of reference material.

The key tasks that the Technical Assessor must evaluate are the following:

- robustness of statistical techniques related to the sampling method and to the samples for the assignment of property values in relation to homogeneity and stability of materials;
- content of the documents associated with a reference material with particular attention to the intended use of the material itself;
- aspects related to the handling and storage of reference materials with particular attention to the compliance of the RMP with the safety and transportation legal requirements. It should be noted that the Technical Assessor must assess the application by the RMP of the requirement, but that assessment of compliance with legal aspects does not fall within the requirements for accreditation;
- assessment of conformity to the applicable requirements of ISO/IEC 17025:2018 standard where the RMP directly performs non accredited testing/calibration tasks;

- application of metrology traceability policy and assignment of property value and its uncertainty, where applicable, by using different approaches in relation to the type of material properties: quantitative or qualitative. Such assessment is always carried out, regardless of whether the measurement task is performed at its premises or subcontracted, since the RMP has full responsibility to ensure the eligibility of the assigned value to the reference material and the contents of the documents associated with it;
- Where participation in proficiency testing and/or interlaboratory comparisons is required (see RT 34), the Technical Assessors evaluate the relevant documentation both in terms of the validity of the comparison with respect to the type and sector of the material produced and the effectiveness of any corrective actions implemented where the outcome of the comparison was not satisfactory.

If the property of the material is quantitative, the policy of metrological traceability is always applied to measurements that have a direct and/or indirect impact on the assigned value (an example of indirect impact is environmental conditions). With regard to the estimation of uncertainty, reference is made to ISO 33405. The assessment of the estimation of the uncertainty of the assigned value is carried out in accordance with ILAC P14 where the assignment is performed by calibration.

If the property of the material is qualitative, metrological traceability must be assessed on a case-by-case basis, taking into account the methods (as agreed by the scientific community) and the information used for the identification of the property and the traceability of its origin.

The Technical Assessor also:

- if Lead Assessor, organizes and coordinates tasks during the Assessment;
- assesses the state and adequacy of all measuring and auxiliary equipment including the characteristics of the environments where RM production, RM characterization and/or calibration activities are carried out and of the systems for their conditioning;
- assesses the technical competence of the staff of the RMP by evaluating how they implement the technical procedures by observing experimental activity;
- 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 RMP to monitor these aspects during subsequent audits;
- any violations encountered by the Assessors on binding requirements for audit purposes must be reported as non-Conformity.

2.6.5.5. Interruption of the Assessment

If during the assessment, serious RMP 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 RMP Management.

In case of acceptance by the RMP, 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 RMP 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 Management or the staff appointed by the RMP that the conditions for coordinated work are not met, the activity will be invoiced according to the terms of the current pricelist (see 7 "Specific cases" 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 RMP representatives, the lead assessor shall:

- present a summary of the activities carried out;
- submit the opinion on the RMP 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 RMP, specifying that the corrective action part proposed by the RMP must be completed only after the request for Corrective actions by ACCREDIA DT;
- collect any reservations raised by the RMP; alternatively, the RMP may submit reservations by completing the relevant form within **3 (three) working days**; the acceptance or otherwise of the reservations submitted by the RMP is the responsibility of the DDT;
- request from the RMP evidence of acceptance of the report containing the findings and the summary feedback of the assessment;

- issue a copy of the Report to the RMP, containing both the list of findings and the Summary Feedback, specifying that ACCREDIA DT reserve the right to confirm or not the 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 RMP, 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 RMP 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 CSA decision (granting or extending accreditation).
- For Comments: the reasons for any non-acceptance of the comment. If, on the other hand, the RMP 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 RMP 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 RMP 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 § 2.7.3.

2.6.7.2. Assessment of the Findings Management Plan

The assessment of the findings management plan is communicated by FT to the RMP 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 RMP 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.

In the event that the RMP, for internal needs, intends to change the RMP 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 RMP, 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 RMP, which must be received within **10 (ten) working days**. The assessment of updates/integrations is communicated by FT to the RMP, 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 § 2.7.3.

Finally, if the deadlines set out in the approved plan are not met, ACCREDIA DT may proceed with the closure of the accreditation procedure as described in § 2.7.3.

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 above assessments and based on their final outcomes, FT collects all documentation related to the case, in particular the results of the document review, the findings of the assessment, and prepares the assessment report and its annexes.

It is possible that during the assessments:

- the RMP 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-09;
- ACCREDIA DT may impose modifications or reductions of the scope as a result of the assessment outcomes, which FT formalises to the RMP via 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 RMP and decides on the accreditation. In the event that accreditation is granted, the CSA DT also determines the frequency of scheduled surveillance assessments. If the RMP has recorded a significant number of findings, the CSA DT may decide to increase the number of surveillance assessments.

Within **five (5) working days** of the decision, STD sends the results to the RMP, including the assessment report and its annexes.

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

The RMP 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.

The accreditation certificate cannot be given to third parties.

Acceptance of the Agreement and registration on the list of accredited RMPs commit the RMP 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 and/or the reference to accreditation, the RMP is required to comply with the provisions of this Regulation and of the Regulations for the use of the ACCREDIA mark RG-09.

If the RMP 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 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 RMP, within **5 (five) days** of the date of the resolution, the reasons for it and any conditions for continuing the process. In case the RMP 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 § 2.7.3. 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 procedure 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 RMP of the closure of the accreditation procedure by certified email (PEC).

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

In case the RMP wishes to initiate a new accreditation process, it will have to submit a new application (DA-00 and DA-09).

3. "Cross-frontier" Accreditation

If ACCREDIA DT receives applications concerning reference material production activities from an RMP 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 procedures indicated for accreditation (§ 2).

ACCREDIA DT will issue an NC 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 RMPs, 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 RMPs 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 their premises. 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 activities include:

a. Support for the operation of the RMP, which includes:
   - updating the RMP'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 RMP's activities.

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

Note: Any documentation that the RMP 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 RMP'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 RMP's scope of accreditation, the provisions for "Modification of the Scope of Accreditation" (§ 4.2.4) or "Extension" (§ 6) shall apply.

d. Control of the documents accompanying Reference Materials issued in the case of initial accreditation or the extension of accreditation to a new sector. In such cases, the RMP must submit to the relevant FT the first 10 Reference Material Certificates and the first 10 Information Sheets issued, together with the related technical records, which will be reviewed 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 RMP. For the procedural process, see (§ 4.2.3).
h. Management of requests for changes to the scope of accreditation, including, by way of example: addition or removal of one or more analytes, addition or removal of one or more materials in a different matrix, addition or removal of one or more properties, changes to the property value range, changes to the uncertainty, changes to a method, or addition of a new site. For the procedural process, see § 4.2.4.

The costs of the activities listed above are generally included in the annual maintenance fee that the RMP is required to pay, except in cases where the issuance of a dedicated quotation is explicitly required.
The annual maintenance fee also covers all training activities provided by ACCREDIA DT for the benefit of the RMPs.

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 RMP sites must be assessed. Assessments may also be carried out remotely, but not all surveillance assessments within the accreditation cycle can be performed solely using 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 follow the experimental calibration activities remotely;
- where the RMP requests that the assessment be carried out on-site;
- where the level of digitalisation of the RMP, including its system and technical documentation, does not allow for an effective remote assessment.

ACCREDIA DT will carry out an appropriate preliminary feasibility analysis to determine whether an assessment can be conducted entirely remotely or using a blended approach. For this analysis, it may also be necessary to perform a prior simulation of how the assessment will be conducted by the RMP.

In order to determine the man-days required for surveillance assessments, ACCREDIA DT conducts periodic risk analyses based on general guidelines defined in collaboration with the ACCREDIA Steering and Guarantee Committee.

Any adjustments to the surveillance programme may be applied by ACCREDIA DT depending on experience and the RMP.

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 sector must be assessed at least once, as must every aspect of the management system. During each scheduled surveillance, the selection of sectors must still allow the evaluation of a representative set of the RMP'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 to the review of internal audit results, reviews, complaints, reference material certificates, and product information sheets, 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.

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

Scheduled surveillance activities are detailed in a quotation specifically prepared by FT, approved by DDT, and sent by STD to the RMP 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.

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 RMP, together with a request for the management plan to address them.

The RMP 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 RMP 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 RMP, 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 § 7.

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 RMP 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 withdrawal from accreditation by the RMP.
- Accreditation standard transition assessments, where these are not carried out in conjunction with scheduled surveillance assessments or renewal.
- Assessments decided by the CSA in order to evaluate the effectiveness of the corrective actions implemented by the RMP following findings issued by ACCREDIA.
- Assessments decided by the CSA, prior to expressing a decision on the granting of accreditation, in order to evaluate the effectiveness of the corrective actions implemented by the RMP 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 RMP. 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 RMP'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 shall apply;
- where the assessment was triggered by numerous and serious non-conformities affecting the competence and reliability of the RMP, the CSA DT may decide to withdraw the accreditation, as set out in § 7.3.2;
- where the assessment was decided for specific sectors, the CSA DT may decide to grant maintenance/renewal of accreditation, excluding those sectors, as set out in § 7.2.2.

Where the RMP 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 RMP 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 RMP'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, outstanding issues or delays; 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 RMP, 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 RMP 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. documentary 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 and maintenance 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 § 7.2.2 and § 7.3.2.

4.2.3. Regulatory Alignment

4.2.3.1. Submission of the Application

The RMP is required to submit to ACCREDIA DT the Accreditation Application DA-09, 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 RMP of the outcome using the procedures established for accreditation cases (§ 2).

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

4.2.3.2. Conduct of Assessments

Where, following verification by ACCREDIA DT, the regulatory update does not impact the technical competence of the RMP, 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 RMP 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 through documentary review, or
- through documentary review combined with an 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 RMP within **60 (sixty) calendar days** from receipt of the order or acceptance of the quotation.

In the event of a negative outcome, the RMP 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 documentary review, and where an 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 documentary 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.

In the event of a second negative outcome of the documentary review, the case shall be submitted to the CSA DT with a proposal to suspend the accreditation, in accordance with § 7.

Where, in addition to the documentary review, an 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 RMP is required to submit to ACCREDIA DT the Accreditation Application DA-09, 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 RMP of the outcome using the procedures established for accreditation cases.

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

4.2.4.2. Carrying out the assessments

Assessments may be conducted:

- exclusively through documentary review, or
- through documentary review combined with an assessment.

Assessments shall follow, in terms of timing and methods, the process established for accreditation procedures (§ 2).

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 documentary review and the outcome is positive, the case shall be submitted to the CSA DT with a proposal to maintain accreditation and to change the scope of accreditation.

If, in addition to the document review, an assessment has also been carried out and the outcome is positive (i.e., all findings have been satisfactorily addressed), the application shall be submitted to the CSA DT with a proposal to maintain accreditation and to change the scope of accreditation.

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

If the RMP intends to renew accreditation, at least **8 (eight) months** before the expiry of the accreditation itself, it must submit to STD the Renewal Application (DA-00 and DA-09), together with the documentation required therein.

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

- that the RMP formally requests changes to the scope of accreditation, for example in terms of extending the measurement range and/or improving the accreditation uncertainty. Such changes do not constitute a change to 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 RMP must therefore submit a subsequent application for a change to the scope of accreditation.

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 the assessment is positive, STD formalises its acceptance and informs the relevant FT, which prepares the technical and financial quotation for the Renewal activities;
- if the assessment is negative, STD formalises its non-acceptance and requests in writing the necessary additional documentation. Acceptance of the application and the subsequent preparation of the related technical and financial quotation can take place only after a positive assessment of the requested additions.

In the event that the late submission of the Renewal application, complete with all required annexes, or of the requested additions, results in the acceptance of the application at a time such that the assessments by ACCREDIA DT begin later than **4 (four) months** before the expiry of the Certificate, ACCREDIA DT does not guarantee the continuity of the accreditation. Consequently, upon expiry of the accreditation, the RMP 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.

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

If the RMP 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 RMP and the effectiveness of any corrective actions implemented by the RMP 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 RMP 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 RMP has obtained extensions in the past calendar year, it is permitted not to carry out the assessment for the areas covered by such extensions; however, these assessments will be conducted during the first scheduled surveillance.

Among the reasons for rejecting the Assessors/Experts proposed in the quotation, in addition to those already indicated in Section § 2.2, the RMP 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 RMP has raised substantiated reservations regarding the performance of the Assessor/Expert.

5.1.3. Document Review

The outcome of the document review (carried out by the appointed Assessors) is notified by the FT to the RMP 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 RMP 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.

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 RMPs, it is possible, during the Renewal process, not to carry out assessments at all sites where the RMP 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 RMP'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 RMP, particularly in cases where experimental activities are planned both at the RMP's own sites and, where applicable, at supplier 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 RMP by the assessment team and recorded in the corresponding assessment report. The costs of the follow-up activities will be borne by the RMP if it is responsible for the causes that led to the ineffective conduct of the remote assessment.

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 be paid to how the RMP has managed the implementation of the participation programme in proficiency tests and/or interlaboratory comparisons, any review of the results if required, the management of reference material production plans, the records of data used for stability and homogeneity determinations, internal audits, reviews, complaints, issued Certificates and Information Sheets, the maintenance and improvement of the management system, the conformity 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 RMP fails to be available despite the FT having implemented all the required actions, ACCREDIA DT will proceed with the adoption of the sanctions referred to in § 7.

5.1.6. Assessment

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

If the RMP fails to make itself available to undergo the assessment before the expiry of the accreditation, ACCREDIA DT will nevertheless continue the Accreditation Renewal procedure; however, the current accreditation will lapse at the expiry date. In this case, the RMP will be removed from the list of accredited

RMPs 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, ACCREDIA DT may impose the sanctioning measures referred to in § 7.

5.1.8. Assessment of the Findings Management Plan and Evidence

With reference to the provisions of § 2.6.7.1 and § 2.6.7.2, 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 § 7.

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 RMP 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 (§ 4.2.2.1) and/or the adoption of a sanction measure as per § 7.

5.1.10. Supplementary Assessment

If RMP 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 RMP: the CSA DT may decide to withdraw accreditation, as stated in § 7.3;
- if the supplementary assessment has been decided on for specific categories/sectors: the CSA DT may decide to grant the renewal of accreditation, excluding these categories/sectors, as set out in § 7.2.

If the RMP 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 RMP 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 or 7.3, 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 RMP may extend its scope of accreditation in order to add additional Categories/Sectors of reference materials.

Any requests for extension for a Category/Sector of reference material not covered by ACCREDIA DT (not listed in the Annex to DA-09 “Correspondence of Quantities – 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-09 at the next available CSA DT meeting.

If the RMP intends to coincide the extension assessment with the first scheduled surveillance, the extension application must be submitted at least **8 (eight) months** before the expiry of the surveillance. In any case, the joint assessment will only be possible if the documentary review has been positively completed before the surveillance expiry date.

The accreditation extension procedure is carried out in the same manner as the accreditation process provided in § 2.1 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 RMP must send the Application for Extension (DA-09) 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 RMP its non-acceptance and requests in writing the necessary integrations that the RMP 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 RMP 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, an RMP 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.

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. In the event of a favourable decision by the CSA DT, ACCREDIA DT will accordingly update the annex to the accreditation certificate based on the approved accreditation extension.

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

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 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 RMP via certified email (PEC) and subsequently published on the ACCREDIA website.

The RMP 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 RMP, may affect one or more of the accredited sites.

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

The partial suspension implies, for the RMP, the prohibition to issue documents associated with the reference materials under ACCREDIA accreditation, for the activities subject to suspension. The total suspension implies, for the RMP, the prohibition to declare itself accredited and to issue documents associated to the reference materials under ACCREDIA accreditation.

Moreover, in the period of validity of the suspension, the RMP 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 RMP's contractual obligations towards ACCREDIA.

7.1.1. Suspension Requested by the Reference Material Producer (Self-Suspension)

The RMP 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;
- temporary unavailability of the RMP's premises (e.g., in the event of of failure to control environmental conditions);
- relocation of the RMP's premises;
- non-conformities/deficiencies that could cast doubt on the reliability of the RMP;
- temporary unavailability or deterioration of resources (e.g., personnel, premises, equipment, etc.).

The RMP 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 RMP 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 RMP.

The RMP 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 RMP 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.

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 (§ 7.2) 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 as described in § 7.3.

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 (RT), and the Accreditation Agreement;
b. failure to return the signed Acceptance of the Accreditation Agreement;
c. the RMP'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 RMP in carrying out activities under accreditation);
e. unavailability of the RMP 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 documents associated with reference materials improperly issued;
j. ineffective handling of unsatisfactory results in participation in PT/ILC, where applicable;
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 RMP;
m. exceptional temporary unavailability of equipment essential for production;
n. exceptional temporary unavailability of equipment essential for characterisation (excluding unavailability of instrumentation due to scheduled calibration), where applicable;
o. temporary unavailability of RMP premises where applicable (e.g., in case of failure to control environmental conditions);
p. relocation of the RMP's premises ;
q. change of legal entity (e.g., change of company name, transfer of ownership);
r. failure of the RMP to check the subcontractor's use of the accreditation or certification reference;
s. use by a subcontractor of RMP assessments as an attestation of its own accreditation or certification.

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 RMP in writing of the possible suspension measure if the detected non-conformity situation persists.

The RMP, 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 RMP 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 RMP.

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.

If the RMP 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), also by decision of the CSA DT.

The RMP, 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 RMP for submission of the case to CSA DT by DDT.

The RMP 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 RMP 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 RMP 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.

7.1.3. Assessments on the Cancellation of the Suspension

When the RMP 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 RMP may request ACCREDIA DT to modify its accreditation scope in order to reduce the number of materials or sectors.

The reduction may also be decided by ACCREDIA DT.

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 Reference Material Producer

In order to apply for a reduction of accreditation, the RMP must send the Application for Reduction (DA-09) to STD together with the documentation requested therein.

For the competence assessment of RST, the provisions of § 6.1.1 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 RMP's expense (with issuance of a quotation), through, for example, document review, supplementary assessments, or measurement comparisons. In cases where the RMP has issued Certificates and/or information sheets 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 Requested 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 RMP 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 RMP;

e. unavailability of equipment essential for production;
f. unavailability of the RMP'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 RMP in writing of the possible reduction measure.

The RMP, 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 RMP 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 RMP 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 RMP persists in its non-compliance **6 (six) months** after notification of the suspension measure;
f. negative outcome of the supplementary assessment;
g. evidence showing that the assumptions of the RMP's competence, impartiality, and integrity have not been met;
h. unlawful, intentional, or seriously unethical behaviour by the RMP in terms of professional ethics;
i. evidence of fraudulent behaviour, or that the RMP deliberately provides false information or conceals information;
j. use of the accreditation by the RMP that causes serious harm or disrepute to ACCREDIA and/or to the accreditation and certification system;
k. the RMP's bankruptcy;
l. the cessation of operations of the Organisation in which the RMP operates, whatever the reason.
m. 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 RMP will no longer be allowed to submit an accreditation application.

The accreditation withdrawal procedure entails, with immediate effect:

- removal of the RMP from the list published on ACCREDIA DT's website;
- loss of the right to be called an Accredited RMP;
- suspension of the issuance of Reference Material Certificates and product information sheets;
- 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 § 7.3.1 above, it informs the DDT, who in turn notifies the RMP in writing, where applicable, of the potential withdrawal measure.

Once informed of the potential withdrawal measure and its reasons, the RMP 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 Concerns received from the RMP, 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 RMP within **5 (five) working days** by registered mail with return receipt or 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 declaration that the RMP is no longer part of the ACCREDIA List of Reference Material Producers;
- the prohibition to continue issuing documents associated with reference materials bearing the ACCREDIA mark;
- the prohibition of any further use of the ACCREDIA mark and reference to accreditation;
- the obligation for the RMP to inform the clients involved and, where appropriate, the interested parties of the measure.

The table attached to the RMP'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 RMP 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 RMP 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 RMP intends to discontinue the accredited activities.

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

- until the indicated termination date, the RMP 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 renunciation of accreditation does not release the RMP 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 RMPs;
- on the activities of third parties that are connected with the activity of accredited RMPs or those undergoing accreditation.
- on the improper use of the ACCREDIA mark.

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/reports submitted anonymously will not be accepted.

RMPs 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 RMP 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 RMP **within 3 (three) working days** of the assessment. The submission of a reservation does not exempt the RMP from managing the findings not subject to a reservation according to § 2.6.7.1.

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 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 RMP).

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 RMP, 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 RMP 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 RMP **within 30 (thirty) working days** from receipt of the reservation.

8.3. Appeals

If the accredited RMP, 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 RMP 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-09 and applicable annexes), of any changes to its registry details concerning the aspects described in the following paragraphs.

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

Upon receipt of the documentation sent by the RMP, 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 RMP.

In the event of significant changes affecting the management system and/or the technical competence of the RMP, the FT shall inform DDT, which may determine the measures referred to in § 7 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 RMP, liquidation, etc.).

Following the positive assessment of the documentation submitted by the RMP, ACCREDIA DT, updates the RMP'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 § 7.3.

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

A change in the company name of the RMP 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 RMP, ACCREDIA DT, updates the RMP 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 RMP's activities are performed entails self-suspension as described in section 7.1.1 of this document.

9.1.3. Change in the Organisational Structure of the Producer

The RMP 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 documentation associated with the reference material, 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-09 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, 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 section 3.3.2 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 RMP:

- Chamber of Commerce certificate or equivalent document proving the legal identity of the RMP;
- 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 RMP's accreditation and will initiate the accreditation withdrawal procedure (§ 7.3), except in cases where accreditation can be confirmed to the previously accredited party.

9.3. Transfer of Accreditation between Accreditation Bodies

An RMP 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, 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), except for the assessments, for which a sampling of the categories of reference materials shall be conducted, taking into account their criticality.

Where the RMP 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 accreditation transfer shall be approved by the CSA DT. Upon transfer, the RMP shall cease to use the original accreditation and shall commence accreditation with ACCREDIA.

9.4. Cyberattacks Suffered by the RMP

The RMP 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 RMP shall have a transitional period of **3 (three) months**, unless otherwise indicated in the variation notice, to adjust 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 RMP may, within the transitional period granted by ACCREDIA, decide not to comply and thereby withdraw from accreditation. In such a case, the provisions of § 7.4 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 RMP, the services will be invoiced at the rates in force at the time of the service performed. Therefore, should the rates change, the RMP 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 RMP 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 § 7.4 shall apply.

During the notice period, an RMP 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.

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