ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

**TITLE** **REGULATION FOR THE ACCREDITATION OF REFERENCE MATERIAL PRODUCERS**

**REFERENCE** **RG-18**

**REVISION** **03**

**DATE** **05-10-2022**

**PREPARATION**
**THE DIRECTOR OF CALIBRATION LABORATORIES DEPARTMENT**

**APPROVAL**
**THE DIRECTIVE COUNCIL**

**AUTHORIZATION**
**THE GENERAL DIRECTOR**

**APPLICATION DATE**
**01-02-2023**

## INDEX

# 0. FOREWORD

ACCREDIA's purpose through the Calibration Laboratory Department is to favour the development of confidence in the compliance assessment system - called to assess and attest conformity of 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 Laboratory Department, accredits:

- Reference Material Producers, including certified reference materials, operating in compliance with the requirements of UNI CEI EN ISO 17034 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 Laboratory Department (DT) has developed appropriate rules and appropriate criteria for applying the general requirements of the regulatory references applicable, formalized through the issuance of this Regulation (as well as through other documentation to be used in conjunction with the Regulation itself).

This document 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 UNI CEI EN ISO 17034 standard and other applicable documents has the purpose of favouring 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.

The accreditation in compliance with UNI CEI EN ISO 17034, replacing the ISO Guide 34 and aligned with UNI CEI EN ISO/IEC 17025:2018, attests the competence of the accredited Producers to produce those reference materials or specified types of reference materials as set out in the scope of accreditation and the implementation of a management system by which it operates generally in accordance with the principles of UNI EN ISO 9001.

Where the reference materials producer works in the medical field, UNI EN ISO 15189 standard may be used as a regulatory reference as an alternative to UNI CEI EN ISO/IEC 17025:2018 standard. The UNI EN ISO 15195 standard provides specific requirements for reference measurement laboratories in the field of laboratory medicine and can be used by the Reference Material Producers for calibration in conjunction with UNI CEI EN 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 deemed competent to produce materials to support the activity of Proficiency Testing Providers, of Calibration, Testing and Medical Laboratories and accredited Certification, Inspection, Verification and Validation Bodies.

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 UNI CEI EN 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;
- collaborate on the subsequent activity of monitoring and maintaining accreditation;
- submit applications for extension, variation and renewal of accreditation;
- implement ACCREDIA DT requirements in case of suspension, reduction, renunciation and withdrawal of accreditation.

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.

Also to be considered a source of contractual obligation in the relationship between ACCREDIA DT and the Reference Material Producers accredited and under accreditation are the technical circulars issued by ACCREDIA DT, which will be shared with interested parties and included in the ACCREDIA document LS-18.

According to the principle of speciality, a technical circular issued by ACCREDIA DT supplements the general provisions 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 of points b), c) and d), it will be the task of ACCREDIA DT to inform Reference Material Producers about the issuance of appropriate circulars.

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

- the FAQs issued by the EA Laboratories Committee and the ILAC Technical Committee and their 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 Laboratory 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 Provisions 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 should be noted that the timeframes in this Regulation may not be adhered to during company closure periods that are published on the ACCREDIA website.

## 0.3. NORMATIVE REFERENCES

The 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 Sector Accreditation Committees of the Department of Calibration (RG-04-DT);
- Regulation for the procedures of the Steering and Guarantee Committee (RG-05);
- Regulation of the Appeals Commission (RG-06);
- Regulation for the use of the ACCREDIA Mark (RG-09);
- ACCREDIA Price-list (TA-00);
- Accreditation contractual agreement (CO);
- Application for Accreditation (DA-00);
- Accreditation Application for Reference Material Producers (DA-09);
- Applicable ACCREDIA Technical Regulations;
- Technical circulars

EA, ILAC documents and other documents applicable to reference materials and their Producers.

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

## 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, conformity assessment body (or conformity assessment body, CAB) means the 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 (UNI CEI EN ISO 17034 3.1).

In this document it is also called only "Producer" or "RMP" (UNI CEI EN 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 1 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:** it is defined as 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 Materials 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.

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

NOTE 2: Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guide 35.

NOTE 3: The ISO Guide 31 gives guidance on the contents of certificates.

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

**Certified value:** value, assigned to a property of a reference material that is accompanied by an uncertainty statement and a statement of metrological traceability, identified as such in the reference material certificate (UNI CEI EN ISO 17034, 3.4).

**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 1 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 (Technical Sheet):** document containing all the information that is essential for using an RM other than a CRM.

**Operationally defined measurand:** measurand that is defined by reference to a documented and widely accepted measurement procedure to which only results obtained by the same procedure can be compared.

Note 1: Examples include crude fibre in foods, impact toughness, enzyme activities and extractable lead in soils (UNI CEI EN ISO 17034, 3.7).

**Site:** facility where the RMP's activities are carried out. A site may be a permanent, temporary or mobile facility of the RMP or a site outside the permanent facilities of the RMP.

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

**Finding:** an assessment result formalised by ACCREDIA DT and classified as Non-conformity, Concern and Comment.

**Non-conformity (NC):** finding indicating the presence of a deviation/shortage 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.

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

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

Non-compliance with legal requirements is also highlighted as a non-Conformity if it is relevant to the requirements of the management system, irrespective of the controls and sanctions of the authorities in charge.

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

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

**Concern:** a finding caused by a partial implementation of a requirement (of a standard or referred to in the Accreditation Regulations/Technical 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.

NOTE 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**.**

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

- **For Non-Conformity**: Correction (where applicable), Root Cause Analysis, and Corrective Actions related to the identified causes, indicating the timing of implementation. Closing evidence for this type of findings should be evaluated positively by ACCREDIA DT prior to the approval (grant or extension of accreditation) of the CSA. For maintenance and renewal, the CSA may issue a positive resolution based on sufficient information showing that the response to these findings is satisfactory. An assessment may be required to ensure that Corrective Actions are implemented effectively.
- **For Concerns:** the correction, an analysis of the root cause and, when determined by the Laboratory in relation to the identified causes, the Corrective Actions, with an indication of the timeframe for implementation. Evidence of corrections and/or Corrective Actions is evaluated in documentary form, prior to the next visit. Depending on the nature and number of Concerns, ACCREDIA DT may establish that, also for this type of findings, the evidence of closure must be positively evaluated before the resolution (of granting or extension) of the CSA.
- **For Comments**: this type of finding may be handled with the opening of an Improvement Action or it may not be acknowledged. In the first case the degree of implementation is verified by ACCREDIA DT during the first suitable assessment while in the second case the reasons for non-implementation must be communicated by RMP.

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

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

**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 UNI CEI EN ISO 17034.

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

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

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

**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;
- unscheduled visits;
- interviews;
- measurement audit (including drafting of the Comparison Report);
- experimental on-site assessment (including the drafting of the Comparison Report).

**On-site assessments:** assessments carried out in presence at the Laboratory's premises.
**Remote assessments:** assessments carried out remotely using electronic means.

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

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

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

**Accreditation cycle:** validity period of accreditation.

Note: The accreditation cycle begins on the date of the decision to grant initial accreditation or renewal of accreditation and shall not exceed 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:** addition of conformity assessment activities to the scope of accreditation.

**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**.**

**Suspension of accreditation**: implementation of temporary restrictions on all or part of the scope of accreditation of an RMP.

**Withdrawal of accreditation:** cancellation of an RMP's accreditation for the entire scope of accreditation.

**Accreditation Table:** a document attached to the Accreditation Certificate that contains the scope of accreditation of the RMP by describing the following fields:

- type of reference material (CRM, RM, or both);
- the matrix of reference material or artefact;
- the characterized property/ies;
- the method used to assign these properties.

Note: The description of the categories and subcategories of the reference materials can be made using the ISO/TR 10989: 2009 "Reference Materials - Guidance on, and keywords used for, RM categorization" guidelines

**Reference Material Category/ 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.

**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/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 a Laboratory with reference to the categories for which RMP is accredited or has applied for accreditation.

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

**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.

**Experimental Assessment Report:** a document that reports the results of on-site experimental assessment.

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

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:** Sector Accreditation Committee for the Calibration Laboratory Department;
- **CdA:** Committee for Accreditation Activities;
- **DDT:** Direction of Department of Calibration Laboratories;
- **ATM:** Assessors' Monitoring;
- **FT:** Technical Officer;
- **STD:** : Department Technical Secretariat;
- **CAB:** Conformity assessment body;
- **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 Dipartimento Laboratori di Taratura, 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 section 1.2 below, 'Submission and assessment of the application for accreditation' and complete with all the annexes required therein in the appropriate form.

### 1.1.1. PRELIMINARY MEETING

When necessary, and at the request of the 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 VISIT

When necessary and at the request of the RMP interested in accreditation, a preliminary visit may be organised for which a special technical-economic quotation expressed in man-days is issued, in accordance with the conditions set out in ACCREDIA's current price-list. This visit may result in the identification of deficiencies in the system or in the 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 visit will not influence the outcome and duration of any subsequent request for accreditation. Only one preliminary visit may be conducted against a single RMP.

## 1.2. SUBMISSION AND ASSESSMENT OF THE APPLICATION FOR 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 applicant Organisation must expressly provide for calibration activities as the object of its activities.

Accreditation may cover the production of different reference materials, in different matrixes and of different types carried out at the organisation's site(s).

Any requests for accreditation by Category/Sector of the reference material not present in the Annex to DA-09 "Correspondence Quantities - Sectors", or in any case differing from the existing ones, are reviewed by DDT in order to proceed with their inclusion in the Annex to DA-09 at the first suitable meeting of CSA DT.

If ACCREDIA DT receives applications concerning the production of reference material based abroad, the provisions of Regulation (EC) 765/2008 and subsequent amendments, of PG-12 "Policy for the application of Cross Frontier Accreditations", of the relevant EA and ILAC documents, as well as of the documents issued by the European Commission apply. Accreditation may be performed in cooperation with another accreditation body recognised within EA and ILAC. In this case, the document review and on-site assessment phases may also be performed using assessors appointed by the other Accreditation Body. A copy of the relative documentation, in Italian or English, must be provided to ACCREDIA DT by the other Accreditation Body.

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.

**Against the above, an application from a company dealing exclusively with services, such as the assignment of a reference value to the candidate RM, cannot be accepted because it does not meet the requirements of RMP.**

Accreditation as a Calibration/Testing/Medical Laboratory does not guarantee its compliance with UNI CEI EN 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 UNI CEI EN ISO/IEC 17034 standard accepts accreditation as Calibration/Testing/Medical Laboratory.

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

- if this assessment is positive: STD formalises 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 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.

The only exceptions allowed, in the case of applications submitted for CRM production, for which ACCREDIA DT conditionally accepts the accreditation file, are:

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

Upon acceptance of the application

- SDT informs the administration of ACCREDIA which 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 following the accreditation and then the ordinary maintenance operations, the appointed FT will follow up on any extensions or changes in the scope of accreditation. The appointed FT will normally follow an RMP at least until the next renewal.

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

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

## 1.3. QUOTATION

Within **60 (sixty) calendar days** from the date of acceptance of the application, the appointed FT will prepare the technical and economic 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 economic 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 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 Board of Directors, 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 recuse Assessors (or request that they are replaced) in the event of a conflict of interest, to be communicated to ACCREDIA DT, which will verify the conflict on the basis of prior declarations provided by the Assessor. If the reasons given are considered valid, the Assessor/Expert is replaced and the matter will be subject to assessment within the framework of the relationship between ACCREDIA DT and the Assessor/Expert. Assessors employed by ACCREDIA DT may not be recused by the RMP concerned except for serious reasons of incompatibility, which must be made explicitly clear to DDT.

Assessors may be replaced by other Assessors with the same qualification, subject to 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.

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

## 1.4. ACCREDITATION PROCESS

Upon receipt of the 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/mixed assessments (visits);
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 assessed as critical by ACCREDIA DT (e.g., the characterisation of a CRM) and the qualification is performed by means of a second-party audit, ACCREDIA DT will attend such an audit for the scope of assessing how the RMP qualifies the subcontractor on site.

If the RMP performs internal calibrations, these will also be subject to documentary assessment and evaluated during the visit.

## 1.5. PRELIMINARY OPERATIONS

Once the RMP has received the order/acceptance of the quotation, the appointment of the assessment team members 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 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.

## 1.6. 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.

Where the participation to proficiency tests and/or interlaboratory comparisons is expected, the Technical Assessors evaluate the relative documentation both in terms of the validity of the comparison with the type and category of material produced and of the effectiveness of any corrective actions implemented (where applicable).

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

If the results of the participation in assessment tests and/or interlaboratory comparisons have not been attached to the DA-09, ACCREDIA DT awaits them for **12 (twelve) months** (case admitted under 1.2 SUBMISSION AND ASSESSMENT OF THE APPLICATION FOR ACCREDITATION however the analysis of the remaining documentation can be started. The specific assessment of PTs and/or ILCs, when conferred, is notified to the RMP within **30 (thirty) calendar days** from its receipt.

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

- if the outcomes are positive, it prepares for the next accreditation phase;

- if the results are not positive and documentary changes are necessary, it arranges for the document assessment to be repeated, no more than two more times. The Laboratory must implement corrections/corrective actions within a maximum period of **12 (twelve) months** from the first adjustment request and **6 months** from the next 2;
- if the negative outcomes are referred to the assessment of the participation and results in proficiency testing and/or interlaboratory comparisons, requests RMP to analyse the causes and propose Corrections and Corrective Actions. For the assessment of the effectiveness of these Actions ACCREDIA DT reserves the right to propose a possible supplement to the quotation;

If the negative results from the third assessment persist, it proposes to DDT to discontinue the accreditation process by applying the provisions of 1.8.3. CLOSURE OF THE ACCREDITATION PROCESS

- 12 (twelve) months after the last request for adjustment without the RMP having done so, it proposes to DDT to terminate the accreditation process, applying the provisions of paragraph 1.8.3. CLOSURE OF THE ACCREDITATION PROCESS.

In the presence of positive outcomes with comments the RMP must:

- in the event of their acknowledgement, forward the revised documentation to the FT and the assessment will be carried out in the next phase;
- in the event of non-acceptance, forward the justifications to the FT.

Should the examination of the submitted documentation - as well as any direct contact with the requesting RMP - reveal that the RMP does not have a sufficient degree of competence and impartiality, ACCREDIA DT shall interrupt the accreditation process, applying the provisions of Section1.8.3. CLOSURE OF THE ACCREDITATION PROCESS.

## 1.7. ASSESSMENT

### 1.7.1. GENERAL

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

ACCREDIA DT may carry out in-person, remote and mixed visits, possibly using the RMP's Information Technology (IT) systems. In any case ACCREDIA DT will carry out a preliminary feasibility analysis in order to determine whether or not a fully remote or mixed visit activity can be carried out.

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.

## 1.7.2. ASSESSMENT PLAN

### *1.7.2.1. PREPARATION AND NOTIFICATION*

FT agrees, with the RMP and the assessors involved, the date for the visit, 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.

In the event that the RMP subcontracts activities assessed as critical by ACCREDIA DT and the qualification takes place by means of a second-party audit, ACCREDIA DT reserves the right to include an Assessor in the plan in order to attend such an audit in scope to assess 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 mixed: at least 10 (ten) calendar days prior to the date of the assessment, the RMP must send ACCREDIA DT the MD-19 form "Information on specific risks existing in the workplace and protective 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 1.7.4.2), the RMP must hand over the duly completed document to the Assessment Group 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 visit, as recalled in the assessment plan.

### *1.7.2.2. 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 1.8.3 "CLOSURE OF THE ACCREDITATION PROCESS" shall apply.

### 1.7.3. ASSESSMENT PREPARATION

In particular cases (e.g., in cases of unscheduled accreditation, renewal and surveillance and for those RMPs that have a high number of categories of reference materials produced) the FT in agreement with DDT assesses, on the basis of the results of previous assessments, whether the participation of the appointed FT in attendance is necessary.

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

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

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

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

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

The assessment, conducted by the appointed assessors in accordance with the UNI EN 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 must make available a reserved room to the assessment team, preferably with computer and internet connection, for the preliminary, intermediate and final internal meetings of the Assessors.

The 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 visit. 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.

## 1.7.4. OPENING OF THE ASSESSMENT

### *1.7.4.1. 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.

### *1.7.4.2. 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;

c) clarify the roles and responsibilities of possible assessors ACCREDIA DT (EVA), FT, guides (i.e., those responsible for the RMP to accompany the Assessors), training assessors and observers;

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

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

c) define the possible production process of reference material, or part of it, to be carried out in the presence of the Assessor;

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

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

f) agree on the timing and modalities for the assessment of any off-site tasks;

g) agree on possible variations in the Assessment Plan;

h) illustrate the assessment process and the possibility of the RMP to make reservations;

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

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

k) request confirmation of the presence of the Director of the RMP or of a Representative at least at the final meeting and to complete and sign the list of persons taking part in the assessment;

l) offer the RMP the opportunity to ask for further clarification;

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

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

## *1.7.5.* CARRYING OUT THE ASSESSMENT

### *1.7.5.1. GENERAL*

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

The checklist used by the System Assessor, which can be found on the website www.accredia.it, is the same as that used by the RMP for the self-assessment attached to Application DA-09.

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

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

It is reminded that the purpose of assessments for accreditation is to verify the compliance of the Reference Materials Producer with the requirements of the reference standards, EA, ILAC, ACCREDIA DT application documents, for the attestation of technical competence of the RMP for the execution of RM production indicated in the scope of accreditation. Binding rules, such as security, privacy, administrative responsibility, etc. do not fall within the requirements for accreditation and are not subject to verification, unless expressly stated in the reference standard. The behaviour that ACCREDIA DT Assessors have to keep against potentially violating binding requirements is reported in paragraph §1.7.5.4.

Assessment of the management system will be extended to all applicable requirements, in accreditation and renewal on-site assessment. In surveillance and renewal, the implementation and effectiveness of corrective actions opened following the previous assessment is always checked.

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 measurement results comparisons (PT/ILC) to demonstrate testing/calibration compliance. Where such activities have an impact on the uncertainty of the value assigned to the property, participation in such activities is assessed in accordance with Technical Regulations RT-36 (calibration activities) or the Technical Regulations RT-24 (testing activities).

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 reference 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.

### *1.7.5.2. TASKS OF THE SYSTEM ASSESSOR*

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

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 Regulations for the use of the ACCREDIA mark RG-09.

### *1.7.5.3. TASKS OF THE TECHNICAL ASSESSOR*

The Technical Assessor must verify the technical competence of the RMP in compliance to the requirements of the UNI CEI EN ISO 17034 standard, of UNI CEI EN 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 UNI CEI EN 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.

If the property of the material is quantitative: the metrology traceability policy always applies to measures that have a direct and/or indirect impact on the assigned value (an example of an indirect impact is the environmental conditions). For the estimation of uncertainty, refer to ISO Guide 35. The evaluation of the uncertainty budget of the assigned value is carried out in compliance to ILAC P14 if the assignment is carried out by calibration or in compliance to EA-4/16 if the assignment is done through testing.

If the property of the material is qualitative: metrological traceability should be assessed case by case taking into account the methods (shared by the scientific community) and the information used to identify the property and the traceability of the 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 air conditioning systems;
- 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.

### *1.7.5.4. FORMULATION OF FINDINGS*

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

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

- any violations found by the Assessors on binding requirements not covered by the audit are not to be included in the assessment report;
- any violations encountered by the Assessors on binding requirements linked to the purpose of the audit should be reported as comments to prompt the affected 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.

### *1.7.5.5. 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 Director of the RMP.

In case of acceptance by the RMP, the Assessors will carry out the scheduled meetings formalizing the findings so far emerged and reporting in the ACCREDIA DT checklist that the evaluation was interrupted with the relevant motivations.

If, on the other hand, the Direction 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 Direction 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 price-list (see 7 "Specific cases" of the TA-00 document in force).

## 1.7.6. FINAL MEETING AND TAKING NOTE 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 submitted by the RMP; alternatively, the RMP may make reservations by completing its form (DT-Mod-007) **within 3 working days**; the acceptance of the reservations made by the RMP is subject to the DDT.
- request from the RMP evidence of acceptance of the report containing the findings and summary report of the assessment;
- issue a copy of the Report to the RMP, containing both the list of findings and the Summary Report, specifying that ACCREDIA DT reserve the right to confirm or not the contents.

## 1.7.7. ACTIONS FOLLOWING THE ASSESSMENT

### *1.7.7.1. REQUEST OF FINDINGS MANAGEMENT PLAN*

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

- **For Non-Conformities**: correction (where applicable), a root cause analysis and corrective actions related to the identified causes, with an indication of the timeframe for implementation;

- **For Concerns**: the correction, a root cause analysis and, when determined by the RMP in relation to the causes identified, corrective actions, with an indication of the timeframe for implementation
- **For Comments**: the reasons for any non-implementation. If, however, the RMP intends to acknowledge the comment, the consequent actions implemented will be verified by ACCREDIA DT during the first suitable 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 paragraph 1.8.3 CLOSURE OF THE ACCREDITATION PROCESS below.

#### *1.7.7.2. ASSESSMENT OF 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 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 section**

**CLOSURE OF THE ACCREDITATION PROCESS.**

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.

#### *1.7.7.3. 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 Laboratory, **within 15 (fifteen) working days** from their receipt.

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

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

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

The evidence required for **non-Conformities** shall be positively evaluated prior to the meeting of the CSA DT.

## 1.8. DECISION-MAKING PROCESS

### 1.8.1. ASSESSMENT OF RESULTS

Upon completion of the above assessments and the final outcome of the same, FT collects all the documentation relating to the file, in particular the results of the document review, the technical reports, the outcomes of the assessment visit, the experimental assessment reports and/or technical reports, and prepares

- the accreditation table
- the assessment report.

It is possible that during the assessments

- the RMP requests reductions in the scope of accreditation within the requested metrology area and/or metrology sector that must be formalised through the submission of the DA-09;
- ACCREDIA DT imposes reductions in scope following the outcomes of the assessments (documentary assessments and/or PT and/or ILC outcomes and/or on-site assessments) which FT formalises to RMP by means of a registered letter.

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

### 1.8.2. CSA DT RESOLUTION ON ACCREDITATION

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

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

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 resolution, but performs its legal effects by the RMP signing the agreement with ACCREDIA (CO-00).

The RMP is required to return the signed Accreditation Agreement within **30 days of transmission**. Otherwise, the CSA may apply one of the sanctions provided for in paragraph 5.1. SUSPENSION.

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 these Regulations, 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.

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

If the CSA DT decides not to release the accreditation and considers necessary to have further assessments, DDT shall notify the RMP, within 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 1.8.3 CLOSURE OF THE ACCREDITATION PROCESS shall apply.

### 1.8.3. CLOSURE OF THE ACCREDITATION PROCESS

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

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

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

# 2. SURVEILLANCE AND MAINTENANCE OF ACCREDITATION

## 2.1. SURVEILLANCE

### 2.1.1. GENERAL

During the period of validity of the accreditation, ACCREDIA DT is obliged to implement an assessment programme to evaluate the scope and sites of the accredited RMPs, in accordance with the requirements of the standards and rules deriving from EC Regulation 765/2008 as amended (ISO/IEC Standards and EA/ILAC documents).

Therefore, all accredited RMPs must undergo surveillance activities both through scheduled and unscheduled assessments, in order to ascertain continuous compliance with the requirements of these Rules, international standards and guides and any other applicable regulatory reference, using all the assessment techniques envisaged by the ACCREDIA DT Rules (for example: unscheduled visits, mystery audits, etc.) at their own site(s) and at their clients' sites. In the event of extraordinary events that prevent assessments from taking place, ACCREDIA DT applies the requirements of the IAF ID3 documents and any other applicable requirements issued at international level by EA/IAF/ISO.

The on-site surveillance activities are described in a quotation specifically prepared by FT, approved by DDT and transmitted by STD to the RMP.

If the RMP is also an accredited Calibration Laboratory, ACCREDIA DT, where possible, organises the surveillance visits in conjunction with those scheduled for the Laboratory.

### 2.1.2. SCHEDULED SURVEILLANCE ASSESSMENT

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

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

In the accreditation cycle, activities at all RMP sites must be evaluated.

Assessments may also be carried out remotely, with the exclusion that all surveillance visits in the accreditation cycle may be performed in this single mode.

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

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

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

For the purposes of this analysis, it may also be necessary to conduct a prior simulation of how the assessment will be carried out by the RMP, especially in cases where experimental activities or assessments at the supplier's premises are envisaged.

In order to determine surveillance assessment man-days, ACCREDIA DT conducts periodic risk analyses, which include factors such as: the outcomes of previous assessments, outcomes of internal corrective actions taken by the RMP against internal technical NCs, possible sanctioning measures, particularly small uncertainties, traceability of measures resulting from supplier qualifications directly from the RMP, the presence of well-founded complaints/reports, the presence of critical accreditations, the number of documents associated with issued reference materials, etc...

ACCREDIA DT can apply any lightening of the surveillance programme depending on the experience and capacity of the RMP.

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

In general, within the period of validity of the accreditation, each category of reference material must be assessed at least once, as well as any aspect of the management system. Furthermore, in the course of each surveillance, the set of reference materials categories and sampled sites must nevertheless allow the assessment of a representative set of accredited activities.

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

Particular attention must then be paid to examining the results of participation in proficiency tests and/or interlaboratory comparisons (where applicable), internal audits, reviews, complaints, documents associated with reference material, maintenance and improvement of the Management system, conformity of technical activity and the correct use of the ACCREDIA mark and/or the reference to accreditation.

Whenever possible, the Technical Assessor, based on the FT's indications in the Notification, has the right and the duty to require that calibration, when applicable, and the production of reference materials be carried out by approved operators other than those verified during the previous assessment.

The planning and implementation of the surveillance assessment are carried out in the same way as for the accreditation assessment.

In the event of interruption of the assessment (see Section 2.4.4.5 "Interruption of the on-site assessment") ACCREDIA DT reserves the right to submit the case to the CSA DT for the adoption of any sanctioning measures, as per Section 5. "SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION".

Following the assessment, FT and/or DDT conduct a review of the findings made by the Assessors and reserve the right to amend and/or classify them differently, and FT officially transmits the final version of the findings to the RMP, with the corresponding management plan request.

The RMP must inform FT **within 10 (ten) working days** from the sending of the request of its findings management plan and the implementation timeframe. The implementation time for **corrections and corrective actions** may not exceed **3 (three) months** from the date of confirmation of the findings by FT, 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. The assessment of the plan is communicated by FT to the RMP, **within 15 (fifteen) working days** from receipt of the findings management plan

If the assessment of the findings management plan by the Assessment Team is not positive, FT will re-submit a new proposal to the RMP which must be received **within 10 (ten) working days**.

Should the second proposal of the findings management plan and/or the documentary evidence prove to be unsuitable, DDT may proceed to submit the case directly to the CSA DT for the adoption of sanctioning measures such as suspension, reduction or withdrawal of accreditation, applying the provisions set out in §5 SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION.

## 2.1.3. UNSCHEDULED SURVEILLANCE ON-SITE ASSESSMENT

### *2.1.3.1. SUPPLEMENTARY SURVEILLANCE ASSESSMENT*

The RMP is required to inform the concerned FT on any changes that have occurred since the Accreditation Application has previously communicated (e.g., change of key figures in the organization, change of legal name, change of location).

On the basis of these notifications and/or following the identification of inappropriate situations by ACCREDIA DT, during the scheduled assessments or from indications by DDT and/or the CSA DT, the above-mentioned surveillance activities may be intensified, after the accreditation/extension/renewal has been granted, by carrying out supplementary unscheduled surveillance.

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

The RMP is informed promptly and must accept the technical quotation **within 10 (ten) working days;** within this timeframe, the RMP may, where appropriate, exercise the right to refuse the members of the assessment team based on the provisions of paragraph 1.3 QUOTATION.

If such a quotation is not accepted:

- CLOSURE OF THE ACCREDITATION PROCESS shall apply;
- in the event of maintenance of accreditation, the provisions of 5.1 SUSPENSION shall apply.

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

-

- CLOSURE OF THE ACCREDITATION PROCESS;
- if the assessment has been determined by numerous and serious non-conformities that undermine the competence of RMP, it may decide to withdraw accreditation, as set out in § WITHDRAWAL OF ACCREDITATION
- if the assessment has been decided for specific categories/sectors of the reference material, it may decide to grant the maintenance/renewal of accreditation, excluding those categories/sectors, as set out in the section REDUCTION OF ACCREDITATION.

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

#### *2.1.3.2. EXTRAORDINARY SURVEILLANCE ASSESSMENT*

ACCREDIA DT imposes an extraordinary assessment on RMP in the event of customer and/or user complaints or objectively motivated reports received by ACCREDIA DT questioning the compliance of the RMP competence.

The RMP is informed promptly and must accept the technical quotation **within 10 (ten) working days**; within this timeframe, the RMP may, where appropriate, exercise the right to refuse the members of the assessment team on the basis of the provisions of paragraph 1.3 QUOTATION. If this quotation is not accepted, the provisions of paragraph 5.1 SUSPENSION shall apply.

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

The costs of such assessments are only charged to the RMP if non-conformities are identified or a large number of concerns are found. Otherwise, the costs are borne by ACCREDIA DT.

In the case of unscheduled assessments, the Assessment Team, once it has arrived at the RMP premises, will ask to be allowed to interface with an RMP Manager or Contact Person to whom it will explain the purpose of the audit and to whom it will deliver:

- a communication from ACCREDIA DT Management containing the reasons for the assessment;
- the Assessment Plan where the RMP may record any objections/unacceptance regarding the plan itself or the names of the ACCREDIA Assessment Team.

## 2.2. MAINTENANCE

The maintenance activity includes:

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

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

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

Documentation that the RMP may deem convenient or necessary to update must be sent in advance for assessment to ACCREDIA DT. Changes to the management system that do not affect the RMP's fulfilment of the requirements may also be communicated immediately after their implementation.

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

In the event that the changes to the documentation result in changes to the scope of accreditation of the RMP, the requirements of section 4 EXTENSION OF ACCREDITATION and section 5.3 REDUCTION OF ACCREDITATION respectively shall apply

d) the control of documents associated with reference materials issued in the case of first accreditation and extension.

In this case, the RMP must send the first 10 Reference Material Certificates issued to the reference FT and the first 10 Product Information Sheets and their technical records will be examined during the first surveillance assessment.

e) examination of the update of the documentation following the implementation by RMP of updates of standardised methods due to reissue of the reference standards. The update must be formalised by RMP by sending the Application for Accreditation DA-09 duly completed and complete with the relevant annexes.

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

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

The costs of the above-mentioned activities are normally included in the annual maintenance fee that the RMP is required to pay, with the exception of cases in which a specific quotation is explicitly provided for.

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

### 2.2.1. ASSESSMENTS FOR REGULATORY ALIGNMENT

Upon receipt of the documentation by the FT, the Technical Assessors and/or Technical Experts carry out the examination thereof, the outcome of which is notified to RMP within **60 (sixty) calendar days** from receipt of the order/acceptance of the quotation. If the results are not positive, RMP shall propose corrections within **30 (thirty) working days**.

### 2.2.2. MAINTENANCE DECISION-MAKING PROCESS

Following the outcomes of the surveillance and maintenance assessments (reports of the ACCREDIA DT Assessors), as well as the subsequent assessments conducted by FT on the findings management plans submitted by the RMP and approved by the assessment teams, the following steps are taken:

- in case of absence of Non-Conformities: FT confirms the maintenance of accreditation, and waits for the completion of treatments and corrective actions for findings classified as Concerns;

- in the case of one or more Non-Conformities, DDT decides whether to confirm the maintenance of accreditation or to submit the case to the CSA DT with a proposal for a supplementary assessment in order to verify the effectiveness of the closure of the findings;
- if a particularly critical non-conformity situation is found, in terms of the number and seriousness of the non-conformities detected, of absent, deficient, untimely or doubtful recovery actions, FT, having heard DDT, shall submit the file to the CSA DT for the adoption of sanctioning measures such as suspension, reduction or withdrawal of accreditation, applying the provisions of paragraph 5.

#### *2.2.2.1. DECISION-MAKING PROCESS FOR REGULATORY ALIGNMENT*

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

- on a documentary basis, if no assessment is planned. If the results are positive, the file is submitted to the CSA DT with a proposal for accreditation maintenance with modification of the table. If the negative results persist after the second assessment, the maintenance file is submitted to the CSA DT with a proposal to suspend accreditation, applying the provisions of point 3;
- during the assessment. If the results are positive, the file is submitted to the CSA DT with a proposal to maintain accreditation with modification of the table. If there are findings classified as non-conformities and/or numerous concerns that have not been effectively resolved, the maintenance file is submitted to the CSA DT with a proposal to carry out a supplementary assessment as per section 2.1.3.1 and/or the adoption of a sanction measure referred to in section 3.

# 3. RENEWAL OF ACCREDITATION

## 3.1. PROCEDURE FOR THE RENEWAL OF ACCREDITATION

The accreditation renewal process shall be carried out in the same manner as for accreditation as set out in paragraphs 1.4 and following, with the exception of the following paragraphs.

### 3.1.1. SUBMISSION OF APPLICATION

If the RMP intends to renew the accreditation, at least **8 (eight) months** prior to the expiry of the accreditation itself, it must send the Application for Renewal (DA-00 and DA-09) to STD, accompanied by the documentation required therein, possibly including the results of participation in PT/ILC, where applicable).

When submitting an application, it is permissible

- that the RMP formally requests variations to the scope of accreditation in terms of extending the scope and/or improving the accreditation uncertainty. Such variations are not considered as extensions and the file is processed as follows on the understanding that the procedures leading to such variations are positively assessed during the document review or assessment. In the event of a negative assessment, the relevant variations will not be included in the

Renewal dossier submitted to CSA DT: for such variations RMP must therefore submit a subsequent application for Extension of Accreditation.

- that, when requested, the RMP does not submit PT/ILC participation results for categories/sectors for which it has obtained extensions in the previous 2 (two) years.

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

- if this assessment is positive, STD formalises its acceptance and informs the relevant FT, which prepares the technical and economic quotation for the renewal activities
- if this assessment is negative, STD formalises the non-acceptance of the same and requests, in writing, the necessary documentary integrations. The acceptance of the application and the subsequent preparation of the relative technical and economic quotation can only take place following the positive assessment of the integrations requested.

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

### 3.1.2. QUOTATION

Upon acceptance of the application, the RMP's reference FT prepares the technical economic quotation for the accreditation renewal activities, in the manner set out in Section 1.3 QUOTATION.

In the event that the RMP has obtained extensions in the past calendar year, it is allowed not to proceed with the assessment for the sectors subject to these extensions, however these assessments will be carried out at the first scheduled surveillance.

Among the reasons for rejecting the assessors/Experts proposed in the Quotation, in addition to what is already indicated in 1.3 QUOTATION, the RMP may invoke the deontologically incorrect behaviour of the Assessor. This justification must be demonstrated to ACCREDIA DT with relative objective evidence and in any case only after the RMP has expressed reservations about the actions of said Assessor/Expert.

### 3.1.3. DOCUMENT REVIEW

The examination of the documentation (analogous to the first accreditation, section 1.6 DOCUMENT REVIEW) includes assessments of the results of any Proficiency Testing and/or Interlaboratory Comparisons in which the RMP participated during the accreditation cycle.

The outcome of the examination of the documentation (carried out by the appointed assessors) is notified by FT to the RMP within **60 (sixty) calendar days** from receipt of the order/acceptance of the quotation.

If the outcome of the documentary assessment

- is positive: FT prepares the next step in the accreditation renewal process;

- is negative: the RMP must propose appropriate corrections **and implement them and transmit them to FT within 30 (thirty) working days**. The effectiveness of the corrections will be assessed by the assessors during the assessment.

If the negative outcome relates to the assessment of participation in PT and/or ILC, RMP must analyse the causes and propose corrections and corrective actions. For the assessment of the effectiveness of these actions, ACCREDIA DT reserves the right to propose possible integrations to the quotation.

### 3.1.4. PREPARATION AND NOTIFICATION OF THE PLAN

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

ACCREDIA DT can carry out in-person, remote and mixed assessments, possibly using RMP's Information Technology (IT) systems. In any case, ACCREDIA DT will carry out an appropriate preliminary feasibility analysis in order to determine whether or not a fully remote or mixed visit activity can be carried out.

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 both at their own premises and, when applicable, at suppliers' premises.

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 the follow-up activities are borne by the RMP if the RMP is responsible for the causes of the ineffective assessment.

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

Particular attention must then be paid to how the RMP has managed the implementation of any programme of participation in proficiency testing and/or interlaboratory comparisons, and any review of their outcomes, the management of reference material production plans, records of data used for stability and uniformity determinations, internal audits, reviews, complaints, Certificates and Information Sheets issued, maintenance and improvement of the management system, compliance of technical activity and the correct use of the ACCREDIA mark and/or references to accreditation.

### 3.1.5. ACCEPTANCE OF THE PLAN

Should the RMP fail to make itself available despite the FT's implementation of all the provisions of paragraph 1.7.2.2 ACCREDIA DT proceeds with the adoption of the sanction measures set out in paragraph 5.

### 3.1.6. ASSESSMENT

The assessment activities are performed according to the provisions of Section 1.7 ASSESSMENT.

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

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

### 3.1.7. INTERRUPTION OF ASSESSMENT

In the event of an interruption of the assessment (see section 2.4.4.5) ACCREDIA DT may proceed to take the sanctioning measures set out in section 5.

### 3.1.8. ASSESSMENT OF THE FINDINGS MANAGEMENT PLAN AND EVIDENCE

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

In the presence of findings classified as non-Conformities, the submission of the file to the CSA DT is allowed provided that the findings management plan submitted by the 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.

### 3.1.9. ASSESSMENT OF RESULTS

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

### 3.1.10. 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 of the same, the following procedure shall be followed:

- if the supplementary assessment was triggered by numerous serious non-conformities which affect the competence of the RMP: the CSA DT may decide to withdraw accreditation, as stated on Section 5.3 WITHDRAWAL OF ACCREDITATION

- 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 section REDUCTION OF ACCREDITATION

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 price-list (TA-00).

### 3.1.11. CSA DT RESOLUTION ON RENEWAL

The operations are carried out in the same manner as for the accreditation process, referred to in Section 1.8.2 CSA DT RESOLUTION ON ACCREDITATION with the exception of the following.

The CSA DT also deliberates on the frequency of scheduled surveillance for the new accreditation cycle, taking into consideration the risks related to the RMP and the performance of the previous cycle.

In the event of a negative decision by the CSA DT, accreditation is either reduced or withdrawn, applying the provisions of Sections 5.2 and 5.1 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 years from the accreditation decision or the last renewal is not exceeded.

## 4. EXTENSION OF ACCREDITATION

### 4.1. PROCEDURE FOR THE EXTENSION OF ACCREDITATION

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

- add further Categories/Sectors of reference materials;

  Any extension requests by Category/Sector of reference material not covered by ACCREDIA DT (not present in the Annex to the DA-09 "Correspondence Quantities - Sectors"), or in any case differing from the existing ones, are submitted to the DDT in order to carry out the review of the resources and then proceed with their inclusion in the Annex to the DA-09 at the first suitable meeting of the CSA DT.
- extend properties and measurement fields and/or improve uncertainties.
- add new sites.

In the event that the RMP intends the extension on-site assessment to coincide with that of the first useful surveillance, the extension application must be submitted at least **eight (8) months** before the expiry of the surveillance. In any case, a joint on-site assessment will only be possible if the document review is successfully concluded before the surveillance expires.

The accreditation extension process is carried out in the same way as for accreditation as set out in section 1.2 SUBMISSION AND ASSESSMENT OF THE APPLICATION FOR ACCREDITATION and following, with the exception of the following paragraphs.

### 4.1.1. 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 the acceptance of the same and informs the reference FT which prepares the relative technical economic quotation for the extension activities.
- if said assessment is negative, STD formalises to the RMP the non-acceptance of the same and requests in writing the necessary integrations that the Laboratory must send within 2 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 by that time:

- STD has not received the necessary documentation, the provisions of Section 1.8.3. CLOSURE OF THE ACCREDITATION PROCESS shall apply and, in this case, the RMP wishing to restart the accreditation process must submit a new formal request for extension.

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

Upon acceptance of the application SDT notifies ACCREDIA administration that prepares the invoicing of the acceptance of the application as per TA-00.

However, the examination of the documentation will not be completed until the RMP forwards the missing results

### 4.1.2. CSA RESOLUTION ON EXTENSION

The operations are carried out in the same way as for the accreditation process, referred to in Section 1.8.2 CSA DT RESOLUTION ON ACCREDITATION. In the event of a positive resolution by the CSA DT, ACCREDIA DT updates the annex to the accreditation certificate accordingly on the basis of the accreditation extension resolved.

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

## 5. SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION

ACCREDIA DT can order sanctions for suspension (partial or total), reduction, or withdrawal of accreditation, in the event of particularly serious situations emerging, both technically and deontologically, following supplementary, extraordinary, renewal, surveillance audits or other checks and assessments (e.g., from reports and complaints).

In accordance with the provisions of the statutory and regulatory provisions, the sanctioning measures and the relative duration are adopted on the deliberation of the CSA DT.

The resolutions of the CSA DT relating to suspension/withdrawal/reduction are communicated to the RMP concerned by registered letter with return receipt, or by PEC and subsequently published on ACCREDIA's website.

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

## 5.1. 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 visits. 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.

The suspension does not entail the forfeiture of contractual obligations towards ACCREDIA.

### 5.1.1. SUSPENSION REQUESTED BY REFERENCE MATERIAL PRODUCER (SELF-SUSPENSION)

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

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

- exceptional temporary lack of significant equipment;
- temporary unavailability of the RMP premises (e.g., in the case of failure to control environmental conditions);
- relocation of the RMP premises;
- changes in the legal entity (e.g., change of company name, transfer of ownership).

In particular, self-suspension must always be requested by the RMP in the case of non-conformities/shortcomings that could call into question the validity of the results (e.g., negative assessments of participation in interlaboratory circuits, etc.) or in the case of temporary unavailability or deterioration of resources (e.g., personnel, premises, equipment, etc.).

The RMP transmits to the relevant FT the written request for self-suspension (using form MD-08-04-DT prepared for this scope by ACCREDIA DT) specifying the reasons, and reporting the activity resumption plan also containing the presumed duration of the suspension and attaching DA-00 and/or DA-09 if necessary.

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 reinstatement 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 economic 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 FT by means of written communication of the assessment activities envisaged for the reinstatement of compliance and of the maximum period granted, which may not exceed **12 (twelve) months** and in any case the end date of the self-suspension may not be later than the end of validity of the accreditation certificate.

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

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

- in the case of partial self-suspension: the reduction of accreditation (section 5.2) 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 Section 5.3.

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

### 5.1.2. SUSPENSION DECIDED BY ACCREDIA DT

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

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

b) non-acceptance of the Accreditation Agreement;

c) unavailability of the RMP to undergo scheduled surveillance assessment within the time limits specified by ACCREDIA DT;

d) negative assessment outcome;

e) unavailability of the RMP to undergo unscheduled assessment;

f) contractual insolvency (see Section 5.1.2.1);

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 unduly issued reference materials (a corrective action could for example also lead to a decision for the RMP to withdraw such unduly issued documentation, because outside the accreditation of ACCREDIA DT, or because it does not comply with the accreditation rules);

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

k) failure to handle complaints;

l) failure to promptly notify ACCREDIA DT of the loss of key personnel identified by the RMP;

m) exceptional temporary lack of significant production equipment;

n) exceptional temporary unavailability of significant characterisation equipment (excluding unavailability of instrumentation for 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 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 counter-deductions **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 economic quotation for the assessments necessary to reinstate the activities subject to suspension and STD sends the quotation to RMP.

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

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 partial suspension, this may be converted, by resolution of the CSA DT, into a reduction for the part of the scope and/or locations affected by the suspension
- in the case of total suspension, this may be changed to revocation, again by resolution of the CSA DT.

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

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

#### *5.1.2.1. SUSPENSION FOR CONTRACTUAL INSOLVENCY*

Total suspension of accreditation may be ordered ex officio by 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 day** of delay. This is without prejudice to any payment deferral agreements, which must be authorised by ACCREDIA DT.

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 paragraph 5.3.

## 5.2. ASSESSMENTS ON THE CANCELLATION OF THE SUSPENSION

When the RMP considers that the reasons for suspension or self-suspension have been overcome, it

- accepts the technical economic quotation;
- formally notifies the relevant FT of its readiness to resume operations;
- transmits the documentation proving full restoration of compliance.

Depending on the reason for the suspension or self-suspension, FT will carry out the verification of the restoration of compliance through one or more of the following actions (as provided for 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 activities, FT prepares the relevant report which it transmits to DDT. In case of

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

## 5.3. REDUCTION OF ACCREDITATION

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

- reduce the number of materials or categories of materials
- reduce the number of accredited sites;
- reduce measurement fields and/or worsen uncertainties.

The reduction may also be ordered by ACCREDIA DT (p. 5.2). However, the reduction is always only relative to a part of the scope of accreditation.

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

### 5.3.1. 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.

Section 4.1 PROCEDURE OF EXTENSION OF ACCREDITATION applies for RST competence evaluation.

Upon acceptance of the application, FT examines the reduction request and, with the possible support of Technical Assessors and/or Experts, checks for possible effects on other accredited fields. If such effects are identified, the RMP is asked to implement appropriate corrective actions in advance. If necessary, FT arranges for additional assessments to be carried out by the RMP

(issuing a quotation), through, for example, documentation reviews, supplementary assessments or measurement comparisons.

### 5.3.2. REDUCTION REQUESTED BY ACCREDIA DT

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

a) negative outcome of assessments;

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

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

d) unavailability of key figures identified by the RMP;

e) unavailability of significant production equipment;

f) unavailability of RMP 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-deductions, if any, 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 reduction, assesses the respective reasons and the correctness of the procedures followed and decides on the measure.

## 5.4. WITHDRAWAL OF ACCREDITATION

### 5.4.1. GROUNDS FOR WITHDRAWAL

The reasons why ACCREDIA DT may decide to withdraw the accreditation of the RMP are related to the persistence and seriousness of the failure in compliance with 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 self-suspension of accreditation lasting more than one year;

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

d) non-compliance with the Accreditation Agreement;

e) objective situations that would have prevented the Accreditation Agreement from being concluded;

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

g) negative result of the supplementary assessment;

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

i) expiry of the accreditation if the RMP has not applied for renewal of accreditation by the date of expiry of the accreditation";

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

k) unlawful or malicious conduct or gross misconduct in terms of professional ethics by the RMP;

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

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

n) the bankruptcy of the RMP

o) the cessation of operations of the organisation in which the RMP operates, for whatever reason;

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

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

The accreditation withdrawal procedure entails, with immediate effect

- the removal of the RMP from the list published on the ACCREDIA DT website;
- the loss of the right to be called Accredited RMP
- the suspension of the issue of Reference Material Certificates and Product Information Sheets
- the loss of the right to use the ACCREDIA mark.

### 5.4.2. WITHDRAWAL MEASURE

If the FT detects the occurrence of any of the conditions referred to in paragraph 5.3.1 above, it informs DDT, which in turn informs (where applicable) the RMP in writing of the possible withdrawal measure.

The RMP, informed of the possible withdrawal measure and its reasons, shall send ACCREDIA DT in writing its counter-deductions, if any, **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 withdrawal, assesses the respective reasons and the correctness of the procedures followed and decides on the measure.

Following the resolution of the CSA DT, the withdrawal communication shall be signed by the President of ACCREDIA and sent **within 5 (five) working days** to the RMP by registered letter with return receipt or certified electronic mail (PEC). This communication shall contain 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 RMP accreditation table shall remain published on the ACCREDIA website, indicating the withdrawal measure and its effective date.

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

## 5.5. 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 price list, 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 by indicating a future date for discontinuing accreditation, the following conditions apply:

- until the indicated date of discontinuation, the RMP may continue to operate under accreditation;
- ACCREDIA DT may decide whether, in addition to the normal verifications already scheduled for that period, it must carry out other assessments
- 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.).

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

# 6. COMPLAINTS/OBSERVATIONS, RESERVATIONS AND APPEALS

## 6.1. COMPLAINTS AND OBSERVATIONS

ACCREDIA DT may receive complaints/observations

- 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.

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

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

## 6.2. RESERVATIONS

With reference to the assessments 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 paragraph 1.7.7.1 REQUEST OF FINDINGS MANAGEMENT PLAN.

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

The Technical Assessor/Expert in charge, **within the term of 10 (ten) working days**, shall provide DDT and FT with a detailed report specifying the documents that have been subject to assessment, the technical detail of the response to each single objection made by the RMP and

a clear formulation of the outcome. The costs of these assessment activities are 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.

### 6.3. 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.

## 7. OBLIGATIONS TO BE BORNE BY THE RMP

For everything not expressly provided for in this Regulation, the provisions of Article 4 of the "Accreditation Agreement between ACCREDIA and Bodies performing conformity assessment services (CABs)" (CO).

### 7.1. REGISTRY VARIATIONS

The organisation must communicate to the STD, using the appropriate forms (DA-00, DA-09 and the applicable annexes), any changes in the organisation's 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 section 5.1.2 and/or order an unscheduled assessment (with the issue of the relevant quotation).

### 7.1.1. CHANGE OF COMPANY NAME

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

This category includes 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 point 5.3 WITHDRAWAL OF ACCREDITATION.

#### *7.1.1.2. 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.

For the transfer of ownership of the accreditation to a different legal entity, see section 7.2 below.

### 7.1.2. CHANGES OF LOCATIONS AND/OR CONTACT NUMBERS

This type of change includes, for example, changes in the address of the registered office and/or other locations, whether due to toponymy changes 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 on section 5.1.1 of this document.

### 7.1.3. CHANGE OF THE ORGANIZATIONAL STRUCTURE OF THE PRODUCER

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

## 7.2. TRANSFER OF ACCREDITATION OWNERSHIP

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

The organisation must 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 (section 5.1.2), until the subsequent decision of the CSA DT on the transfer of ownership of the accreditation
- issues economic quotations for assessments as provided for in section 3.3.2 of the ACCREDIA Price List (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 quantity 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 (as established in Section 5.3, except in cases where accreditation can be confirmed to the previously accredited party.

## 7.3. TRANSFER OF ACCREDITATION BETWEEN ACCREDITATION BODIES

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

The accreditation transfer process is carried out in the same way as the accreditation process (section1.4), except for the assessments, for which a sampling of the categories of reference materials is carried out, taking into account their criticality.

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

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

# 8. 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.

## 8.1. VARIATIONS OF ACCREDITATION CONDITIONS

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

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

## 8.2. MODIFICATIONS TO THE PRICE-LIST

The tariffs for accreditation activities are established by the ACCREDIA Board of Directors (and approved by the Interministerial Supervisory Commission) and are listed in the ACCREDIA Price List (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 -List 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 Section 5.4 " Renunciation of Accreditation" shall apply.

During the period of notice, the RMP that avails itself of the right to renounce shall be charged the tariffs prior to the change, for only those activities performed up to the time of renunciation.