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ENTE ITALIANO DI ACCREDITAMENTO

Certification and Inspection Department

Regulation for the accreditation of Certification, Inspection, Validation and Verification Bodies – General Requirements

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TITLE **Regulation for the accreditation of Certification, Inspection, Validation and Verification Bodies – General Requirements**

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NOTE 2 *The present document represents the English version of the document under reference at the specified revision. In case of conflict, the Italian version will prevail.*

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The Director of Certification and Inspection Department

APPROVAL
The Directive Council

AUTHORIZATION
The President

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0. Foreword

The objective of ACCREDIA, through the Department of Certification and Inspection (ACCREDIA-DC) is to contribute towards creating trust in the conformity assessment system – with the task of assessing and attesting the conformity of products, processes, services, management systems, persons, claims and inspection reports to the requirements established by the applicable national and international technical standards – and to ensure the effective and consistent approach adopted by the system's operators, thereby enhancing the growth of competitiveness of the national productive system and the improvement in the wellbeing of the general public. For this purpose, ACCREDIA-DC accredits conformity assessment Bodies, verifying that they possess and maintain over time the required organisational, procedural, technical and professional requirements, in such a way as to foster a high level of confidence among all relevant social and economic stakeholders and, in particular, end users and consumers, in the work of these bodies and in the value of the conformity attestations they issue.

In line with the above objectives and in accordance with the guidance issued by its Statutory Bodies, and with the aim of further ensuring the effectiveness of the accreditation process and guaranteeing the effectiveness and consistency of the practices of accredited bodies, ACCREDIA-DC has developed specific rules and appropriate criteria for the application of the general requirements of the applicable normative references, formalised through the issuance of this General Regulation and of Regulations setting out the specific requirements for the accreditation of:

- Management system certification Bodies;
- Product/service/process certification Bodies;
- Certification Bodies of persons;
- Inspection Bodies;
- Validation and Verification Bodies;

taking into account the development in the applicable normative references, the experiences acquired by ACCREDIA-DC and the indications expressed by ACCREDIA's institutional bodies for the improvement of the national system of accreditation and certification/inspection/claim.

0.1. Introduction

The accreditation of Certification, Inspection, Verification and Validation Bodies is a complex process, the importance of which varies as the object of certification (system, product, person) and the object of inspection activities (project, product, service, process or installation) and the object of verification and validation changes – due to the inevitably general nature of the normative references used.

To promote the effectiveness and credibility of the accreditation process, it is therefore necessary to introduce specific application criteria which, without departing from the spirit and letter of the standard, foster its full and

substantive implementation by accredited bodies, while at the same time providing unambiguous, objective and impartial references for the assessments carried out by the Accreditation Body with respect to them.

This objective can be achieved thanks to the correct and effective application of the present General Regulation and the specific Regulations for each accreditation standard, which have been developed taking into account the best available knowledge and experience in the field (state of the art).

0.2. Scope and field of application

The present Regulation is applicable for the accreditation of:

- Certification Bodies of management systems, of products/services/processes and persons;
- Inspection Bodies;
- Verification and Validation Bodies.

(hereinafter collectively referred to as CABs). In cases where ACCREDIA-DC undertakes assessment activities for the recognition of CABs by public entities and/or by owners of conformity assessment schemes, any additional requirements and/or requirements that may be in conflict with those set out in this General Regulation and in the specific Regulations for each accreditation standard shall be formally communicated to the CAB within the framework of the relevant contractual arrangements.

In particular, this Regulation sets out the conditions and procedures for the granting, surveillance, extension, renewal, reduction, self-reduction, suspension, self-suspension, restoration, renunciation and withdrawal of accreditation of the CAB in accordance with the applicable standards and guidelines, with the relevant specifications and details in cases where the normative references provide only general requirements.

This General Regulation cannot be considered separately from the specific Regulation applicable to the standard for which accreditation is requested.

This General Regulation and the specific Regulations for each accreditation standard constitute a source of contractual obligation in the relationship between ACCREDIA-DC and accredited bodies, by virtue of which:

- ACCREDIA-DC commits to undertake, with competence, objectivity, diligence, impartiality and professional integrity, the assessment of the adequacy of the CAB's system to the requirements of the standards and reference documents, and in the event of a positive outcome, to grant accreditation, as well as its maintenance, extension and renewal, and to ensure the inclusion of the CAB and its relevant data in the ACCREDIA database of accredited bodies;
- The CAB commits to conform with the provisions of the present Regulation, initially and to maintain conformity throughout the period of accreditation which ACCREDIA-DC has established at 4 years (unless otherwise specified by the specific scheme regulations).

Technical circulars issued from time to time by ACCREDIA-DC, specific to each scheme/sector, which will be shared with the relevant stakeholders and included in ACCREDIA document LS-14, shall also be considered a source of contractual obligation in the relationship between ACCREDIA-DC and accredited bodies.

According to the speciality principle, a technical circular issued by ACCREDIA-DC integrates the general provisions of the applicable regulations.

ACCREDIA-DC considers as mandatory:

a) Mandatory documents issued by EA/Global and by the standardisation bodies;
b) Any applicable provisions arising from resolutions adopted by the General Assemblies of the bodies referred to in the previous point (see document EA-INF/17, in its current revision);
c) Documents regarding accreditation issued by the European Commission (CERTIF year-xx);
d) Any provisions issued by Public Authorities;
e) Any applicable provisions issued by ACCREDIA's institutional bodies (e.g. CD, CIG, CSA, etc.).

With regard to the dispositions defined in points b, c, d and e, it is responsibility of ACCREDIA-DC to inform the CAB by means of informative circulars.

ACCREDIA considers as points of reference in cases of disputes:

- FAQs issued by EA Committees and by Global Technical Committees and their respective working groups;
- the interpretations provided by ISO CASCO maintenance groups.

ACCREDIA-DC does not assume any prior obligations regarding the positive outcome of the assessments performed and therefore, with regard to the granting, maintenance, renewal (or extension) of accreditation.

ACCREDIA-DC has the responsibility of verifying – within the limits of assessment usually done by sampling – that the CAB has the necessary expertise (in terms of organisation, procedures and other operative documents, human resources and instruments) to perform its certification, inspection, verification and validation activities in accordance with the requirements of this Regulation and with every other pertinent requirement or regulation.

The present Regulation clarifies the modalities on the basis of which ACCREDIA-DC determines whether a CAB is competent, impartial and consistent with the rules it has established and in carrying out conformity assessment activities.

The CAB shall be responsible for ensuring and maintaining the full and systematic conformity to the requirements outlined above, at all times and for every aspect of its activity.

If a conflict is identified between a mandatory national or international regulation and any provision issued by ACCREDIA (Regulations, Circulars, etc.), the mandatory regulation shall prevail.

Note: Where, within this document and the specific scheme regulations, reference is made to a document issued by IAF and/or ILAC, this shall also be understood to include the subsequent Global version.

The present general Regulation and the specific Regulations for each the accreditation standard are subject to formal approval by the ACCREDIA Directive Council (article 14 of the ACCREDIA Statute) following a favourable opinion of the Committee for Accreditation Activities and issuance under the authority of the President

of ACCREDIA. The Steering and Guarantee Committee is also involved in the process for consultation purposes.

0.3. Normative references

The normative references for the application of the present Regulation and of the specific Regulations for each accreditation standard are given in the ACCREDIA documents LS-02 "*List of reference standards and documents for the accreditation of Certification Bodies",* LS-03 *"List of reference standards and documents for the accreditation of Inspection Bodies"*, LS-12 *"List of reference standards and documents for the accreditation of Verification and Validation Bodies"* in the current version, including the applicable ISO, IAF, ILAC and EA documents.

It follows that – in the context of a given accreditation scheme - the use of the General Part of the Regulation and of the specific Regulation for each accreditation standard is completed by the Technical Regulations (RT)/Technical documents (DT) and technical circulars applicable to the scheme, where such exist.

The general provisions, on the other hand, apply to all certification, inspection, validation and verification activities carried out under ACCREDIA accreditation by the Certification and Inspection Bodies Department, both within and outside the national territory. The application of the requirements set out in the individual RT/DT documents/technical circulars to certification, inspection, validation and verification activities carried out outside Italian territory shall be considered mandatory, unless they conflict with the application of legislative or regulatory requirements applicable in the country where the conformity assessment activity is performed.

The present Regulation and the specific Regulations of the accreditation standard also refer, when and as far as applicable, to the following ACCREDIA statutory standards and regulations in their most recent applicable version:

- ACCREDIA Statute (ST);
- General Regulation for the application of the Statute (ST-01);
- Regulation for the proceedings of the Accreditation Committee (RG-04);
- Regulation for the proceedings of the Sector Accreditation Committees (RG-04-DC);
- Regulation for the proceedings of the Sector Accreditation Sub-Committees (RG-04-01);
- Regulation for the proceedings of the Steering and Guarantee Committee (RG-05);
- Regulation for the proceedings of the Appeals Commission (RG-06);
- Regulation for the use of the ACCREDIA mark (RG-09);
- ACCREDIA Pricelist (TA-00);
- Contractual agreement for accreditation (CO-00);
- Contractual agreement for use of the IAF Mark (CO-05-DC);
- Application for accreditation/extension (DA-00, DA-01, DA-03, DA-04, DA-10, DA-11, DA-13);
- ACCREDIA applicable technical regulations (RT);
- Applicable technical documents (DT);
- Mandatory standards – where applicable;

- Technical/Informative Circulars;

and EA/Global documents and other applicable schemes for certification, inspection, verification and validation Bodies.

For every ACCREDIA document cited only the revision currently in force is valid and can all be downloaded free of charge in the reserved area for accredited CABs in ACCREDIA's website.

General note: It is hereby specified that any timeframes referred to in this Regulation may not be met during periods of business closure, which are published on the ACCREDIA website.

0.4. Terms and definitions

- Accreditation: an attestation by a National Accreditation Body certifying that a conformity assessment Body satisfies the requirements of the applicable harmonized standards and, where appropriate, any other supplementary requirement, including those set down in the relevant sector-specific programmes, to carry out a specific conformity assessment activity (Reg. CE 765/2008 chapter 1, article 2, § 10) and subsequent amendments.

Note: accreditation consists of a declaration of adequacy (an adequacy audit, therefore not a compliance or conformity audit) of the organization and of the CAB's procedures in providing a competent, consistent and impartial service, as resulting from full compliance with the reference standards/regulations.

- National Accreditation Body: The sole Body of a Member State which is authorized by such state to perform accreditation activities in accordance with Reg. CE 765/2008 chapter 1, article 2, § 11 and subsequent amendments.
- Conformity Assessment Body (CAB): a Body performing conformity assessment activities, including calibration, testing, certification and inspection (Reg. CE 765/2008 chapter 1, article 2, § 13 and subsequent amendments). For the purpose of the present Regulation, a CAB is intended as a certification, inspection, verification or validation Body.
- Object of conformity assessment: entity which specified requirements apply. Examples are: product, process, service, system, installation, project, data, design, material, claim, person, body or organization or any combination of these (see ISO/IEC 17000 § 4.2).
- Attestation: issuance of a declaration, based on a decision, that the fulfilment of specified requirements has been demonstrated (see ISO/IEC 17000 § 7.3).
- Certification: an attestation by a third party regarding an element of conformity assessment with the exception of accreditation (see ISO/IEC 17000 § 7.6).
- Certification Body (CB): a Body performing certifications of conformity.

Note: The term "Body", for the provisions of the present Regulation, and in the specific Regulations for the accreditation standard, means that they are equally applicable to certification Bodies of management systems (quality, environment, workplace health and safety, etc.), of product/service/process and persons.

- Inspection: examination of an object of conformity assessment and the determination of its conformity with detailed requirements, or on the basis of a professional judgment in conformity with general requirements (see ISO/IEC 17000 § 6.3).

Note: the inspection of a process may involve persons, facilities, technologies and methodologies (see UNI CEI EN ISO/IEC 17020).

- Inspection Body (IB): a Body which performs inspections (ISO/IEC 17020).

  For the different types of Inspection Bodies, reference is made to the provisions of the currently applicable version of ISO/IEC 17020.

- Validation**:** Confirmation of the plausibility, for a specific intended use or intended application, through the provision of objective evidence, that the specified requirements have been met (see ISO/IEC 17000 § 6.5).

- Verification: Confirmation of the truthfulness, through the provision of objective evidence, that the specified requirements have been met (see ISO/IEC 17000 § 6.6).

- Validation and Verification Body (VB): Body that carries out verifications or validations of the claims in compliance with the programmes (UNI CEI EN ISO/IEC 17029 points 3.4 and 3.5).

- Scope of accreditation or field of application of accreditation: specific conformity assessment activities for which accreditation is required or has been granted (see ISO/IEC 17011 § 3.6).

- Fixed scope of accreditation**:** description of the scope of accreditation which details the applicable Level 5 documents, such as standards, specifics and product schemes, inspection standards and procedures and the standards, procedures and schemes for the certification of persons, standards, procedures and validation and verification schemes.

- Flexible scope of accreditation or flexible field of application of the accreditation: more generic description of the scope of accreditation, regarding management of systems, products, persons, inspection activities, admitting the possibility that the CAB may, on the basis of its competences, which have already been assessed with positive outcome, to modify and/or increase the field of application, use new revisions of standards, procedures and schemes, or to add new products, professional profiles or inspections, provided that the conformity assessment activities require the same skills and resources as those already accredited.

- Accreditation scheme: set of rules, defined procedures and processes performed by ACCREDIA-DC to grant, extend and maintain the accreditations relating to the various categories of certification/inspection/validation/verification activities covered by ACCREDIA accreditation and distinguished by significant differences for the purposes of the accreditation.

- Certification scheme: set of rules, defined procedures and processes performed by the CAB for the declaration of conformity of management systems of products/services/processes and persons.

- Sector of certification: set of rules, defined procedures and activities performed by the CAB for the declaration of conformity as above, specifically regarding:

- the certification of management system: to specific sectors of economic and social activities (IAF sectors and related sub-sectors if they exist, categories and technical areas);
- the certification of products/services/processes: to typology of product/service/processes covered by the technical regulation (mandatory), technical standards (voluntary), specific techniques, rules etc.;
- the certification of persons: professional persons with characteristics defined by the relevant normative references.

Note: When a sector of certification is covered by accreditation, it takes the name of sector of accredited certification.

- Sector of inspection activities: set of rules and procedures adopted and activities undertaken by the CAB to conduct inspection activities in a certain area consisting if typologies of design, products, services, processes and facilities, with reference to technical rules (mandatory), technical standards (voluntary), specific techniques, specifications and requirements in general, expressed in terms (both specific and generic) also defined by the CAB's clients.
- Macro sector/cluster: group of homogeneous and similar certification sectors.

Note: All IAF sectors are grouped in a series of **macro sectors**, in each of which **critical sectors** are identified (for details see the document IAF MD 17 - and subsequent versions - and the Technical Regulation RT-09 in its current revision).

In some schemes the relative standards define the grouping of sectors in technical areas/categories;

- Scheme owner: person or organization responsible for developing and maintaining a conformity assessment scheme.
- Relevant site: in line with the provisions of the previous IAF/ILAC A5 document, ACCREDIA-DC considers a site to be relevant if it carries out one or more of the following "key" activities, unless these are performed fully remotely and the personnel are under the control of another already accredited site:
    - Process development and approval (responsibility of the organization/control of the body, its strategies and policies);
    - Approval of competences and monitoring of auditors, experts, examiners and subcontractors;
    - Review of the contract;
    - Technical review for the ISP scheme;
    - Decision;
    - Management of flexible scope;
    - Definition of activities related to the management of equipment;
    - Laboratory activities supporting accredited / in the process of accreditation conformity assessment (product certification, inspection).

- Assessment: process performed by ACCREDIA-DC to determine the competence of a CAB based on one or more standards and/or other normative documents, for a defined scope of accreditation (see ISO/IEC 17011 § 3.22).
- Assessment programme: set of assessments in line with a specific accreditation scheme which ACCREDIA-DC performs on a CAB during the cycle of accreditation.
- Assessment techniques: methods used by ACCREDIA-DC for performing assessments:

Note: for the purpose of the present Regulation the assessment techniques may include, but are not limited to:

- office assessments;
- witness assessments;
- document review;
- file review;
- unannounced assessments;
- validation assessments (e.g. market surveillance visits);
- interviews;
- mystery audits.

All the above assessment techniques can be carried out remotely, according to the rules and limits of applicability defined by ACCREDIA-DC.

Note: in the case of accreditation of owner schemes, it is specified that the assessment activities carried out by ACCREDIA-DC could also be attended by the scheme owner and also the scheme owner could directly conduct audit activities on the accredited CABs in its conformity assessment scheme.

- Assessments (VI): assessments performed by ACCREDIA-DC (initial, supplementary, scheduled surveillance, unscheduled surveillance, extension, renewal, maintenance until expiry) which are a part of the process of the granting, maintenance, extension and renewal of accreditation.
- Witness assessments (VA): observation of the CAB by ACCREDIA-DC assessors (and technical experts if necessary) at the time of the conduct of the conformity assessment activities contained in the scope of accreditation or in the application for accreditation/extension.
- Remote assessment: Remote assessments by ACCREDIA-DC assessors not physically present at the site of the CAB or of the CAB's client. This is a verification of a physical or virtual site of a CAB or an organization (in the case of witness assessments), using communication techniques/electronic means.

Note: A virtual site is a virtual place where a CAB/organization performs its activities or provides a service using an online environment that allows people regardless of physical locations to perform processes.

- Unannounced assessments (without prior notice): assessments carried out by ACCREDIA- DC without prior notice to the CAB at its head office, or where applicable at its branch offices, or as witnessed assessments at the CAB's clients' premises, based on the schedule provided by the CAB itself. They are intended to assess the continuous maintenance of compliance with accreditation requirements by accredited CABs. For scenarios of application, the provisions set out in this Regulation shall apply.

- Interview: assessment technique by means of which the ACCREDIA-DC assessment team, during the office assessment interfaces with the CAB's auditors/inspectors involved in the conformity assessment process, in order to give an evaluation of the level of the CAB's knowledge and effectiveness.
- Accreditation cycle: period of validity of the accreditation.
- Accreditation certificate: declaration issued by the national accreditation body, based on a decision, which attests the conformity of a conformity assessment body with the requirements of a specific accreditation standard.

Note: A cycle of accreditation starts after the date of the decision for the granting of initial accreditation or of renewal and it shall not last longer than 5 years.

- Decision for accreditation: decision to grant, maintain, extend, reduce, suspend or withdraw accreditation.
- Granting of accreditation: granting of accreditation for a specific scope of accreditation.
- Maintenance of accreditation: confirmation of the continuation of the accreditation for the specific scope.
- Extension of accreditation: the addition of conformity assessment activities to the scope of accreditation.
- Re-assessment: assessment carried out for the renewal of the period of accreditation. For the purpose of the present Regulation re-assessment is referred to as renewal.
- Assessment plan: description of the activities and dispositions regarding an assessment.
- Market Surveillance Visit: assessment usually lasting one day at a certified organization, to determine the level of confidence in the conformity of the management system to the specific requirements and the effectiveness of the process of accredited certification (ref. document IAF ID4).

For the objectives and modalities of the conduct of a market surveillance visit reference is made to the provisions of this Regulation in § 1.5.1.3 and to the details set out in Annex 1 to this Regulation.

- Mystery audit: an audit performed by one or more auditors, appropriately trained, intended to simulate the behaviour and actions of potential or actual client of an organization providing services without being recognized by the personnel in question, with the aim of evaluating the quality of the service including any related products.

Note: the person undertaking the mystery audit is often referred to as "mystery" followed by the type of client (e.g. mystery shopper, mystery guest, mystery traveller, mystery patient).

- Increased surveillance: minor sanction measure caused by non-positive evidence with regard to a CAB which consists of the performance of supplementary or advance assessments with respect to the periodical surveillances - with costs met by the CAB - to ascertain the effective implementation/effectiveness of the necessary corrections and corrective actions within the timeframe given in relation to a scheme/sector of accreditation.
- Block of extensions of accreditation or granting new accreditations: minor sanction measure that provides for the blocking of the granting of extensions or new accreditations, for a defined period of time, in relation to a specific certification scheme included in an accreditation standard. However, in cases of transversal

criticalities, the block may apply to an entire accreditation standard and/or to multiple accreditation standards.

- Reduction of accreditation: major sanctioning measure providing for the elimination of a part of the scope of accreditation of a CAB in a certain scheme.
- Suspension of accreditation: major sanction, which may include partial suspension of the scope of accreditation of a CAB for a specific accreditation scheme, or of the entire accreditation, for a determined period.
- Withdrawal of accreditation: major sanction for the withdrawal of accreditation of a CAB for an entire accreditation scheme.
- Voluntary renunciation of accreditation: request to renounce accreditation presented by the CAB for any given reason (e.g. non-acceptance of changes to the pricelist, non-acceptance of modifications to the provisions governing accreditation activities, etc.). It is submitted for decision as a withdrawal of accreditation requested by the CAB.
- Transfer of accreditation: procedure for transferring the accreditation of a CAB by means of assessments/document reviews from one foreign AB, signatory of the EA, Global MRA agreements, to ACCREDIA.
- Finding: result of an assessment formalized by ACCREDIA-DC and classified as a Nonconformity, Concern or Comment.
- Nonconformity (NC): a finding which results from the presence of a deviation/lack which:
  a) jeopardizes the reliability of the results/performances/services provided by the CAB, and/or;
  b) compromises the capacity of the CAB's management system to maintain the quality level in accordance with the conformity assessment activities or signals a failure in the functioning of the management system and/or;
  c) threatens the credibility of the accreditation procedure or the integrity/honesty of ACCREDIA and/or;
  d) shows failure to respect the applicable mandatory requirements of the scope of accreditation and/or;
  e) derives from a repeated failure to effectively close a previous Concern issued against the CAB.

Note 1: The NC is formulated by ACCREDIA-DC assessors by means of a clear identification of the finding and shall indicate the evidence on which the finding is based and the reference to the specific requirement which was not respected.

Note 2: The NC may result in the imposition of sanctions as defined in § 1.8.

- Concern: a finding which results from the partial implementation of a requirement (referring to a Standard or Circular), the result of which generally does not affect or is not likely to affect, either directly or immediately, the quality of the performances and results of the CAB.

Note 1: a Concern is formulated by ACCREDIA-DC assessors by means of a clear identification of the finding and shall provide an indication of the evidence on which the finding is based and the specific requirement which was not respected.

Note 2: an unresolved Concern at the time of the subsequent assessment may be re-classified as a NC.

- Comment: A finding raised by ACCREDIA against a CAB which is not the consequence of an objective situation of failure to satisfy a requirement but it is intended to avoid this happening in the future (when this is a real possibility), and/or to give suggestions for the improvement of the documents or of the operative modalities of the CAB.
- Management of findings by the CAB: activities to be undertaken by the CAB with respect to findings raised by ACCREDIA-DC

Note 1: Within document reviews, deficiencies are not classified as above (see § 1.8.3).

- Appeal: a request by a CAB to reconsider any adverse decision concerning accreditation regarding the status of accreditation.
- Complaint: a statement, requiring a response, of dissatisfaction made by any person or organization towards ACCREDIA-DC, concerning the activities of ACCREDIA-DC or of an accredited CAB.
- Report: this refers to a communication of either external or internal origin which does not inherently constitute a complaint, but serves as an indication of potentially non-compliant situations concerning accredited CABs and/or their respective clients and/or certified organisations.
- Impartiality: the presence of objectivity.

The typologies of conflicts of interests applicable to the various accreditation schemes, are dealt with in the specific "recommendations" documents prepared together with ACCREDIA's Steering and Guarantee Committee and, where necessary, in the regulations for the accreditation standard.

- Interested parties: person or organization with direct or indirect interest in accreditation.
- Technical Circulars: documents that introduce technical requirements applicable to a specific accreditation/conformity assessment scheme.

Note: before their issuance, ACCREDIA-DC conducts consultation with the interested parties.

- Informative Circulars: documents that treat general interest information for CABs (e.g. transition steps linked to new accreditation standards, decisions taken in the EA/IAF/ILAC area, etc.).
- Risk: the effect on an activity which could derive from certain processes/activities performed by the CAB, including those of its internal staff and/or collaborators.
- Assessor: person qualified and engaged by ACCREDIA-DC, either individually or as a member of a team, to assess the adequacy of a CAB's system and its certification/inspection/validation and verification process according to the applicable reference standards and to ACCREDIA-DC Regulations.
- Technical expert: person qualified and engaged by ACCREDIA-DC working under the responsibility of an assessor, providing specific knowledge or expertise concerning the area of accreditation to be assessed and who does not assess independently. The expert will also be able to work alone exclusively in cases in which the member of the ACCREDIA team is able to interface and communicate with him/her periodically, even if in different places. Therefore, the Expert may liaise directly with the CAB, subject to the authorisation that the RGVI has obtained from the CAB itself.

- Technical Officer: person tasked by ACCREDIA-DC to manage the various phases of the process of accreditation for the purpose of accreditation, surveillance, maintenance, renewal, extension, reduction, suspension or withdrawal and transition of accreditation, coordinating the activities of the assessors.
- Technical and Programming Secretariat: staff ensuring the programming of the verification of the processes of accreditation.
- Adaptation time: period between the date of issuance (first issue or revision) of any ACCREDIA-DC regulatory document and the application date of such documents.

0.5. Acronyms

- ACCREDIA–DC: ACCREDIA Department of Certification and Inspection;
- CSA: Sector Accreditation Committee;
- CdA: Committee of Accreditation Activities;
- DDC: Director of the Department of Certification and Inspection;
- VDDC: Vice Director of the Certification and Inspection Bodies Department;
- dRSG: Departmental Management System Representative
- ATM: Monitoring of assessors;
- FT: Technical Officer;
- ST/PRO: Technical secretariat and programming.

Part 1 – General requirements relating to the accreditation process

1. Criteria and information for accreditation

1.1. General information

1.1.1 Any CAB may send to ACCREDIA-DC a request – written, verbal or electronic – to find out about accreditation.

Upon receipt of the request, ACCREDIA-DC sends to the CAB the website address – www.accredia.it – from which the list of current ACCREDIA documents can be downloaded, including the documentation relevant for accreditation purposes.

For the submission of documentation by email, all communications should be addressed to the specific email boxes indicated in the ACCREDIA website www.accredia.it.

When necessary, it is possible to arrange a preliminary meeting at ACCREDIA-DC's office or by remote mode of not more than half a day to explain the accreditation process to the interested CAB. These meetings do not involve any commitment by either party and they do not involve any form of consultancy (also unintended).

If the applicant CAB proposes a preliminary assessment, this is specified in the cost quotation and invoiced in man-days, in accordance with the conditions set out in ACCREDIA's pricelist, and shall not last longer than an initial accreditation assessment. The preliminary assessment may be requested only in the case of initial accreditation to a Level 3 standard (i.e. a new accreditation standard), and not in cases where there is an interest in potential extensions to new areas of operation for an already accredited scheme.

Activities shall be conducted in such a way as to show the failures, without providing indications for the modalities of correction. ACCREDIA-DC does not provide consultancy for CABs.

In any case, the outcomes of such assessments do not affect the result or the duration of the subsequent application for accreditation. Only one preliminary assessment can be conducted for a CAB per accreditation standard.

It is not possible to transform a preliminary assessment into an initial assessment for first accreditation.

1.1.2 Accreditation and subsequent inclusion in the relevant ACCREDIA database are granted to the CAB in accordance with the applicable reference standards and reported in the ACCREDIA documents LS-02, LS-03 and LS-12.

1.1.3 The conditions for the possible accreditation of a CAB are as follows:

- that it conforms with the requirements as defined in the present Regulation, with the reference documents and standards, reported and/or recalled by the ACCREDIA documents LS-02, LS-03

and LS- 12., and that it operates correctly over time, with transparency and in collaboration with ACCREDIA-DC;

- that if fulfils the minimum specific requirements if contained in the specific regulations for the accreditation standard;
- that it also satisfies any supplementary documents defined by ACCREDIA-DC (e.g. circulars) or by the scheme owner (specific technical owner);
- that it has transferred to its clients, through an appropriate contractual document (regulation or similar), the applicable obligations, including recognition of the right of ACCREDIA-DC's assessors and technical experts to have access, also without prior notice, to the premises of its clients (witnessing assessments at the CAB) otherwise certification may not be issued or it may be suspended or withdrawn if such failure to meet obligations is persistent, unless for justified reasons;
- in the case of activities carried out outside accreditation that may have implications for accredited scopes, it operates in such a way as not to bring disrepute to the accreditation/certification/inspection/validation and verification sector;
- it has at least one stable physical operational site from which to coordinate assessment activities in accordance with the provisions of this Regulation;
- where the interested party is a CAB applying for subsequent authorisations and/or notifications, it shall have at least one operational office in Italy, unless otherwise provided by applicable regulatory requirements;
- demonstrates that it has the financial soundness required to meet accreditation costs and ongoing maintenance fees;

Furthermore:

- where the applicant CAB is constituted by trust companies/holding companies, or where the shareholders include a trust company/holding company/investment fund/other type of organisation, all aspects governed by § 1.5.1.8 below shall be clarified in advance;
- the CAB may not use the term "accreditation" (or equivalent) in its name or in relation to services not covered by a valid accreditation or by an application in progress, nor may it present itself as a provider of accreditation services attributable to ACCREDIA itself. Any proposed use of the term may be subject to a formal request, which must demonstrate the absence of conflicts or potential risks of confusion. ACCREDIA reserves the right, in any case, to reject such a request at its own discretion, without any obligation to provide reasons.

If the CAB becomes aware that other parties with whom it has contractual relations publicise their services in such a way as to facilitate the achievement of its certifications or in any case related to the certification activity carried out, it commits to avoid or, in any case, to intervene promptly to remove situations of this type.

At the time of the initial assessment at the CAB's premises, the CAB shall have completed at least one internal audit of its entire management system and shall have defined the corrective action plan where necessary. The CAB shall also have performed at least one review of the system and have planned the relative preventive and corrective actions, where applicable.

Any possible exemptions are set out in the specific Regulations for the accreditation standard and shall be submitted to the competent CSA for deliberation.

1.1.4. The CAB may indicate, if it wishes, any limitations of the scope of accreditation within the sector requested or certification scheme, unless otherwise provided by the competent authorities. Constraints may also be imposed by ACCREDIA-DC following the outcome of the investigation and/or the assessments where there is no document or applicative evidence of the entire scope requested. In the absence of such limitations, the competence is extended to the entire sector of accreditation requested. Furthermore, any limitations may also be established in terms of the territorial extent of accreditation.

1.1.5 Any sources of finance not deriving from certification/inspection/verification or validation activities shall be made clear and shall not compromise the independence and impartiality of the CAB. Where this cannot be directly deduced from the data of the balance sheet, this information shall be provided through appropriate documentation (e.g. an additional note to the balance sheet or other accounts documents requested by the director or by the ACCREDIA-DC assessors).

The CAB shall identify, the income deriving from every activity which is different from the object activities of the accreditation.

The elements and data relating to the calculation of the above parameters shall be kept available to ACCREDIA-DC and/or its assessors.

As well as the above, the CAB shall send annually, by the expiry date indicated in the communication sent by ACCREDIA-DC, by means of the completion of the relevant module, available in the reserved area for CABs in ACCREDIA 's website, the economic data related to activities carried out under accreditation.

In cases of non-receipt of such data by the end of the set timeframe, also after the sending of reminders, ACCREDIA-DC may impose a minor sanction on the CAB and the relevant CSA shall be informed.

1.1.6. In cases where the CAB assigns one or more activities inherent to the scheme and/or accredited sector or the sector applied for, to an external Body, whether it is a physical or legal person (outsourcing), it shall make sure that such person/entity is in a position to demonstrate that such person/entity is sufficiently competent to provide the service in question and has knowledge and applies the procedures of the CAB and, where applicable, to meet the requirements of the standards of the series ISO/IEC 17000. The names of such persons shall be communicated to ACCREDIA-DC in timely manner in the application and updated regularly where necessary (in the event of multiple changes during the year, the update shall be at least every six months and therefore twice a year).

ACCREDIA-DC reserves the right to access and verify the premises of persons to whom the CAB entrusts parts of its activities; reference to this right shall be included in the CAB's contract with these external collaborators.

1.1.7. ACCREDIA-DC, prior to the start of the accreditation (or extension) activities, carries out a detailed examination of the new scheme in accordance with Procedure PG-13-01 "Procedure for starting the accreditation of new conformity assessment schemes".

In all cases of initiation of accreditation of new conformity assessment schemes, the interest of the interested parties shall be demonstrated and their assessment shall be carried out according to the requirements of the document EA 1/22.

For further details, refer to the requirements contained in PG-13-01 and in Regulation RG-19.

It should also be noted that, in cases where accreditation has been granted against owner schemes, the accreditation will have to transit to the standard that should subsequently be issued, in cases where the field of application is the same. However, this requirement is not applicable for accreditations and certifications issued abroad, if the standard is issued only at a national level (UNI/CEI).

Note: the certification scheme referred to in the documents indicated above is equivalent to the verification/validation programme and inspection activity.

1.2. Submission and processing of the application for accreditation

1.2.1 The application for accreditation of a CAB shall be presented to ACCREDIA-DC using the appropriate modules which are available on ACCREDIA's website, together with all the necessary requested documentation. The application shall be carefully, clearly and fully completed, providing all the information and data required and giving reasons for any inapplicable item. Otherwise, if it is not complete, the application may not be accepted. The application shall be signed by the CAB's legal representative or by an authorized person.

In cases of delegation, for the purposes of the validity of the signing party, ACCREDIA-DC reserves the right to request from the CAB the document certifying the powers of legitimacy of the delegate (e.g. power of attorney, executive decision, decision of the Board of Directors).

The applicant CAB shall be a **legal entity**, i.e. a natural or legal person who assumes the obligations and rights arising out the organization's activities, and in possession of a VAT registration number.

A public legal person is also considered to be a legal entity (e.g. regions, provinces and small local administrative areas, public economic entities, public institutional entities such as INPS, INAIL, universities, etc.).

For foreign CABs the definition of a legal entity applied in the country in question is applicable in accordance with the local national legislation.

Natural persons cannot present an application for accreditation, except for natural persons in possession of VAT registration (see CERTIF. 2012-04 REV4 and subsequent revisions).

In the event that the applicant CAB is constituted by trust companies/holding companies or, in any case, where a trust company/holding company/investment fund/other type of organisation is among its shareholders, ACCREDIA-DC, in order to accept the application, shall carry out all necessary checks as set out in § 1.5.1.8 below.

The Statute, or other equivalent document of the applicant Body, shall expressly provide, as the object of its activities, those of conformity assessment for which accreditation is requested (certification/inspection/validation/verification).

The applicant entity must also have, on a stable and continuous basis, sufficient resources to demonstrate the organisation's ability to oversee and manage effectively the areas for which accreditation is sought.

1.2.2. If the documentation attached to the application is complete and conforms with the requirements, within **30 (thirty) calendar days** from the date of formalization of the receipt, ACCREDIA-DC formally accepts the application and prepares a cost quotation for accreditation activities to be signed by the DDC or VDDC before sending it to the CAB. The minimum criteria for determining the days needed for the assessment are described in the internal ACCREDIA-DC procedures, the principles of which are set out in the specific Regulations for the accreditation standard.

The duration of the office assessment is determined taking into consideration the specifics of the scheme (e.g. number and criticality of the sectors/macro-sectors/technical areas/categories requested, the number of sites to be verified) and other factors such as the number of findings of the document review to close, language issues, transfer times, etc.

If the accreditation assessment is carried out jointly with another scheme, ACCREDIA-DC will evaluate, taking into consideration the critical factors listed above, the possibility of reducing the total time.

If the documents sent by the applicant are not complete or clear or if the applicable conditions are not met, ACCREDIA-DC will not accept the application and, within **30 (thirty) calendar days** ACCREDIA-DC requests the remaining necessary documents in written form. These additional documents shall be sent within 2 months, otherwise the application lapses, and if they are adequate, the application is accepted and the cost quotation is prepared as described above.

If the technical and financial quotation is not returned signed following at least two reminders, the accreditation application shall lapse and the applicant entity will be required to submit a new application.

If the controls reveal that the CAB has provided false information, ACCREDIA-DC will reject the application and not provide the CAB with any other services. Furthermore, if the Body is already accredited for other areas, the file will be submitted to the relevant CSA for the appropriate evaluation.

1.2.3. A CAB (and/or other Body) intending to apply for accreditation for a new conformity assessment scheme, shall comply with the provisions of ACCREDIA procedure PG-13-01 and Regulation RG-19 by sending the documentation in accordance with the timeline and modalities defined in the above documents.

It should also be noted that, in cases where accreditation has been granted against owner schemes, the accreditation will have to transit to the standard that should subsequently be issued, in cases where the field of application is the same. However, this requirement is not applicable for accreditations and certifications issued abroad, if the standard is issued only at a national level (UNI/CEI).

1.3. Process of accreditation

1.3.1. Document review

1.3.1.1 Following acceptance of the technical cost quotation by the applicant CAB, ACCREDIA-DC starts the process of accreditation with an in-depth analysis of the contents of the documents. The document review is carried out, compatibly with the payment necessary for the start of the review process, within **60 (sixty) calendar days** of the date of acceptance of the quotation by the CAB

ACCREDIA-DC will not transmit the result of the document examination carried out until the payment of the payment as stated in the pricelist has been made. If the CAB fails to do so, ACCREDIA-DC interrupts the accreditation process and therefore also the application.

If, on the other hand, the administrative formalities have been completed and the outcome of the review of the documents sent by the CAB is positive, the assessment activities can proceed.

If, however, the outcome is negative and the presence of deficiencies requires sending revised documentation which has to be re-evaluated on a document basis, before proceeding with the planning and performance of assessments ACCREDIA-DC advises the applicant CAB of the need to implement the adaptations to the documents in accordance with the identified deficiencies.

The cost of the first review is met by ACCREDIA-DC, but all further document reviews which may become necessary are paid by the CAB.

At the end of the 3 months after the request for adaptation, if the CAB has not implemented as required, the application for accreditation lapses and a new one has to be presented with all the relevant obligations and costs.

ACCREDIA-DC may decide whether to perform the document review for accreditation at the CAB's head office.

1.3.1.2 If, from the document review, or also after direct contacts with the applicant CAB, it is evident that the applicant CAB does not possess adequate expertise and impartiality, ACCREDIA-DC may interrupt the process of accreditation.

ACCREDIA-DC shall also interrupt the accreditation process where three document reviews have been carried out with a negative outcome, thereby demonstrating an insufficient level of competence and/or impartiality on the part of the applicant CAB.

1.3.2. Assessments

1.3.2.1 After completion of the document review, with a positive result, the Technical Officer arranges the performance of the initial assessment at the CAB's premises.

The purpose of this, is to verify that the operative procedures of the CAB are in conformity with the present Regulation and every other applicable general normative or legal reference by the CAB, as well as the regulations and procedures established by the CAB itself, as formalized in the documentation in its management system documentation (quality manual, regulations, procedures, instructions, control plans, personnel qualifications and so forth.)

The Technical Officer, with the support of the Technical Secretariat and Planning Unit, in agreement with the applicant CAB and the assessors involved, sets the date for the initial assessment.

The Technical and Programming Secretariat (ST/PRO) sends the confirmation to the CAB in order to formalize the composition of the assessment team as well as the date and the objectives of the assessment.

Regarding the choice of the activities to verify, ACCREDIA-DC considers the risks related to the activities, the locations and the personnel who come into the range of application of the accreditation.

The plan for the initial assessment is sent to the CAB at least **3 (three) working days** before the assessment and it shall be set out in such a way that the activities in question of the CAB regarding the process of accreditation are properly verified, including the assessment of the requested accreditation sectors.

If the request for accreditation concerns an activity undertaken in more than one location, a sampling shall be carried out to determine the competence of the CAB to carry out the activities for which accreditation has been requested.

If, on the other hand, from the conclusion of the document review, a period of time of 12 months has elapsed and the CAB has not made itself available to carry out the subsequent assessment activities provided for in the accreditation process, the CAB will be contacted by the FT to understand whether it intends to continue the accreditation process or not. Where the CAB communicates that it intends to continue, the need to carry out a supplementary document review shall be assessed if it communicates that it has made changes to the system documentation assessed at the time. If, on the other hand, the body does not provide a response or does not confirm its intention to proceed with the accreditation process, ACCREDIA-DC proceeds with the interruption of the accreditation process and therefore with the forfeiture of the application.

During the office assessment, in order to allow ACCREDIA-DC to conduct the necessary analyses, the Body is required to organize, if expressly requested, an interview between the ACCREDIA-DC assessors and an agreed sample of its own auditors/inspectors. ACCREDIA-DC must also be granted access to insurance coverage, accounting and administrative documents, including invoices, staff and examination centre expenditure records, and any other relevant administrative documentation. This principle also applies in cases of applications for extension and maintenance of accreditation.

1.3.2.2 If one or more NCs are raised and formalized (as defined in § 0.4), the provisions contained in § 1.3.2.5. below become applicable.

If the overall result of the of the assessment at the CAB's location is positive, planning goes ahead of the witness assessment (WA)as required by the specific scheme regulations. The planning may be annulled if payment conditions are not met regarding the office assessment already performed.

This factor may cause an interruption in the process of accreditation and thus cause the application n to lapse.

The witness assessments have the following objectives:

- to verify the effectiveness of the CAB's procedures especially with regard to the use of auditors (or inspectors, examiners or verifiers) in possession of the necessary experience and expertise;
- to observe the behaviour of the auditors (or inspectors, examiners or verifiers) and the conformity of their conduct with the CAB's procedures and every other reference standard applicable to the CAB.
- to assess whether the CAB itself has, at the time, formulated a correct and consistent judgment with the effective status of the system in the case of surveillance and renewal audits.

The organization where the accreditation witness assessment takes place shall possess a management system, which includes the processes/products sufficiently representative of the sector of the socio-economic activity in question.

Witness assessments (WAs) are performed by at least one ACCREDIA-DC assessor. For accreditation schemes and/or sectors of accreditation for which the necessary expertise is not available with regard to the processes and products of the organization involved in the witness assessment (or relating to the persons assessed, inspection activities, programmes examined) the assessor is assisted by a technical expert who is selected from the list in accordance with § 1.3.2.3.

The composition of the ACCREDIA assessment team will also be determined according to the number of members of the Body's audit team and the complexity of the verification (duration, number of sectors/categories/schemes to be verified).

In the verification activities abroad, the requirements of the ACCREDIA PG-12 procedure shall apply.

In some cases (e.g. PRD, PRS, ISP schemes), the witness assessment may be carried out jointly with the office assessment (where provided for by the accreditation process), provided that this is logistically feasible and that the overall effectiveness of the office assessment is not compromised. This principle also applies to assessments for the purposes of extension and maintenance of accreditation.

In exceptional cases, justified by objective difficulties in organizing the witness assessment the DDC or VDDC may authorize such assessments before the performance of the initial assessment at the CAB's location. In such cases the accreditation process is suspended until successful completion of the office assessment at the CAB's premises.

For witness assessments (WAs) the CAB shall send to ST/PRO the audit plan at least **3 (three) working days** before the performance of the assessment itself.

In cases of a request for accreditation to certain specific schemes/sectors in which the number of audit activities performed by the CAB is limited, the DDC/VDDC may authorize, in agreement with the applicant CAB, as a substitution of the witnessing, the conduct of a supplementary office assessment.

1.3.2.3 The names of the ACCREDIA-DC assessors qualified on the basis of the ACCREDIA procedures, are approved by the CdA following proposal by the DDC.

The references of the assessors and technical experts designated for assessment activities (names and organizations belonged to – if any) are communicated in advance to the CAB which has the right to present objections in the timeframe specified in the notification, giving reasons in written form.

ACCREDIA-DC does not provide CVs of its assessors and technical experts.

Nevertheless, upon request, it may provide information concerning the ongoing collaborations of its assessors and technical experts with CABs potentially in competition.

A CAB which intends to present a reservation regarding the assessors or experts shall do so in writing to ACCREDIA-DC within **3 (three) working days** of receipt of the communication. In the absence of a response in this period the assessment team is considered to be accepted.

CABs may object to an assessor or expert or ask for a substitution for the following reasons:

- unprofessional and improper behaviour (to be demonstrated to ACCREDIA-DC with objective proof concerning behaviour on-site and only after the CAB has expressed reservations regarding the performance of the assessor. Such reservations are evaluated by the DDC and the ATM);
- conflict of interests (to be communicated to ACCREDIA-DC for analysis on the basis of declarations provided by the assessor). If the reasons are considered well founded, the matter will be evaluated in the ACCREDIA-DC/assessor reports. It is hereby specified that recusation is not considered acceptable on the grounds that the ACCREDIA assessor is a self-employed professional who also collaborates with other bodies, as the assessor is in any case bound at all times by confidentiality obligations and the code of professional ethics.

ACCREDIA-DC assessors who are employees may not be challenged by the CAB concerned, except on serious grounds of incompatibility, which must be explicitly set out and submitted directly to the Department Directorate.

1.3.2.4 The CAB shall allow access of the ACCREDIA-DC team to its premises and documentation and shall offer full cooperation.

Similarly, the CAB shall include in its contractual agreements clauses enabling ACCREDIA-DC assessment teams to access the premises of client organisations or the sites where audit activities are carried out, reserving the right to suspend or withdraw certification if the organisation concerned does not make itself available for the assessment with the participation of the ACCREDIA assessment team.

1.3.2.5 If, during the office and/or witness assessment, one or more NCs are raised, the accreditation process is suspended until confirmation of the implementation of the necessary corrections, of the closure of the corresponding CAs and the verification of effectiveness on the part of ACCREDIA-DC. These actions may be verified by ACCREDIA-DC by means of a supplementary assessment.

The deadline for the implementation of CAs and demonstration of their effectiveness shall not exceed 6 months, otherwise the accreditation process lapses, unless the specific scheme regulation specifies differently.

The accreditation process may be interrupted where more than two supplementary office assessments have been carried out with a negative outcome.

1.3.2.6 ACCREDIA-DC may verify autonomously the information received by a CAB, for example by contacting the CAB's auditors or an organization audited by the CAB, both during or after the assessment.

1.3.2.7. If ACCREDIA-DC should obtain knowledge during the accreditation process that the CAB has given false information, the DDC may decide to close the accreditation process. Furthermore, if the Body is already accredited for other areas, the file will be submitted to the relevant CSA for the appropriate assessments.

1.4. Decision-making process and granting of accreditation

1.4.1. Following a positive outcome of the above assessments the FT prepares, in accordance with the procedures and using the applicable modules in force, a summary document of the assessments performed (accreditation file), which is viewed and validated by the DDC or VDDC and submitted to the relevant ACCREDIA-DC CSA for deliberation.

The above assessments shall generally be concluded within **15 working days** of the date of the CSA meeting in order to enable the complete preparation of the documentation.

The granting of accreditation is exclusive responsibility of the CSA which decides, after thorough analysis of the investigation carried out by the personnel and independently of the proposal prepared by the DDC or VDDC. If the decision is negative, the CSA shall give reasons for its decision as well as when it orders additional, supplementary/extraordinary assessments, market surveillance visits/unannounced visits, or imposes other conditions.

Accreditation can be granted only when payment to ACCREDIA-DC is made in accordance with the ACCREDIA quotation and with the ACCREDIA pricelist. In the event of late payments for the amounts indicated above, the DDC or VDDC will assess whether or not it is possible to proceed with the presentation of the file to the relevant CSA.

1.4.2. Accreditation is deemed to be granted exclusively for each specific conformity assessment scheme and any relevant sector-specific specification, category, module, etc., as indicated in the CSA resolution, and it takes effect from the date of the relevant CSA meeting.

1.4.3. Accreditation is formally granted via a contractual agreement (CO-00) between ACCREDIA-DC and the CAB, with the issue of the relative Certificate of Accreditation and its publication on ACCREDIA's website (which shall only report the legal entity to which accreditation was issued) and corresponding attachments containing the list of relevant sites covered by the accreditation and the description of the scope of accreditation. Accreditation certificates shall be generally published within 15 working days from the date of the relevant CSA meeting. These timelines may vary in the event that more CSAs are carried out on nearby dates.

Upon granting accreditation, ACCREDIA-DC formulates the scope of approved accreditation and, for some areas, shall transmit, where applicable, a communication describing the decisions to the competent authorities (e.g. Ministries), for further evaluation.

Upon granting of accreditation, any voluntary certifications issued by the CAB prior to its attainment shall acquire the status of accredited certifications, unless otherwise provided by the CSA. Prior to their re-issuance, the Body shall conduct a review to assess their adequacy with respect to the conformity assessment process approved upon obtaining accreditation, and they shall consequently be re-issued by the CAB, with the relevant accreditation references, within 1 year (unless otherwise specified in dedicated circulars). ACCREDIA reserves the right to carry out specific assessments to verify the adequacy of the review conducted by the Body. With regard to Inspection Bodies, Validation and Verification Bodies, and Bodies accredited for subsequent authorisations and notifications, only reports and/or certificates and/or attestations issued after the date of accreditation shall be considered accredited reports/certificates/attestations.

The declarations (certificates) of conformity or conformity assessment (inspection reports) or declarations of validation and verification issued by CABs with ACCREDIA accreditation, within the scope of accreditation, shall show the ACCREDA Mark as defined in Regulation RG-09, unless otherwise provided by the relevant authorities.

The accreditation is valid for four years from the date of the decision with the exception of annex CSA CI to the V&V scheme accreditation certificate, for which the accreditation is valid for 5 years, always starting from the date of the decision.

Subsequently, the Department Secretariat will send the accreditation agreement, in which all the provisions governing the granting and use of the accreditation are contained and will send a specific communication to the CAB informing it that the digital Accreditation Certificate with QR Code can be downloaded from the ACCREDIA website The accreditation certificate cannot be transferred to third parties. By virtue of this process, which ensures immediate verification of its authenticity, signed copies thereof will not be issued. Furthermore, requests for translation into other languages will not be accepted, as it is already available in a bilingual Italian-English format.

1.4.4. By signing the contractual agreement and inclusion on the ACCREDIA database of accredited CABs, the CAB commits itself to retain its organizational structure and proceedings in conformity with the requirements of the present Regulation and the specific regulations for the accreditation standard and with the applicable general and sector standards and reference standards.

Failure to sign the Accreditation Agreement, following three reminders issued by the Department General Secretariat, shall result in the application being submitted to the next available CSA meeting for the adoption of sanctioning measures as set out in § 1.9.2 below.

1.4.5. With regard to reference to accreditation and, in particular, use of the ACCREDIA Mark, the CAB shall comply with the present Regulation, with the specific regulations for the accreditation standard, and the Regulation for use of the ACCREDIA Mark RG-09.

1.4.6. If accreditation is not granted the DDC or VDDC informs the applicant CAB within approximately 15 working days of the decision, giving reasons and the conditions for continuing the accreditation process, including the documentation to be presented.

1.4.7 ACCREDIA shall have the right to suspend the accreditation process where complaints/reports are received or where situations of particular criticality concerning the Body are identified in relation to the scopes covered by the application in progress. The process may be resumed only following the resolution of the issues identified and, in any case, no later than 12 months from the suspension itself.

1.5. Surveillance and renewal of accreditation

1.5.1. Surveillance of accreditation

1.5.1.1. General

Throughout the accreditation cycle, ACCREDIA-DC implements a programme of assessments to evaluate the entire scope of accreditation and a representative sample of the most important sites of the accredited CABs, in conformity with the requirements of the standards and rules deriving from Reg. (CE) 765/2008 and subsequent amendments (the ISO/IEC standards and EA/Global documents) and, where applicable, by the owners of voluntary conformity assessment schemes.

All accredited CABs shall undergo surveillance activities by means of scheduled assessments (communicated through the sharing of maintenance programmes) and also unscheduled assessments, in order to ensure continued compliance with the present Regulation, the standards and international guidance and all other applicable reference standards.

Where applicable on the basis of the documents, the CAB undertakes to agree that the ACCREDIA assessors carry out assessments of the accredited activities, and other assessment activities provided for by the ACCREDIA Regulations (for example: unannounced visits, mystery audit activities, Market Surveillance Visit etc.) at its own office/s and at its suppliers to which they are subcontracted by including this possibility in the agreements with the latter, in order to ascertain the maintenance of the CAB's compliance with the requirements for accreditation.

The CAB also undertakes to ensure the access of ACCREDIA assessors to the client sites where the CAB performs the activities for which it is accredited, even in the absence of prior notice.

Some assessment activities may be conducted by ACCREDIA also in remote mode.

In the event of extraordinary events that prevent the assessment from being performed, ACCREDIA-DC applies the requirements of the IAF ID3, IAF ID12 documents (and subsequent versions) and any other applicable requirements issued internationally by EA/ ISO/ Global.

The CAB shall communicate, by submitting form MD-24-DC and the relevant supporting documentation, any updates made to its organisation and documentation compared to the information and data provided in the initial accreditation application (and any subsequent extension applications), where such updates entail significant changes in ownership, governance, resources and/or procedures used for conformity assessment activities. Where necessary, it shall update, in the event of changes, the versions of the Quality Manual and of the Certification/Inspection/Validation/Verification Rules. The updated documentation may also be submitted by uploading it to the restricted area of ACCREDIA's website, under the "CAB Structure" section, while form MD-24-DC shall be sent to the Department General Secretariat and to the relevant Technical Officers.

Within the aerospace scheme, where changes have been made to the organizational structure affecting the scheme manager identified during the accreditation phase, the Body is required to transmit to the ACCREDIA technical office a communication containing the references of the new Head Officer and the type of the contract signed with the CAB, attaching an updated copy of his/her CV and of the organization chart and subsequent evidence of its approval by AIAD-RMS (for further details, please refer to the provisions of Technical Regulation RT-18, in its current revision).

In the event of failure to update these data, ACCREDIA-DC may impose minor sanctions against the non-compliant CABs.

The maintenance of accreditation is subject to the payment of the amounts indicated in the invoices issued in relation to the assessment activities carried out, in accordance with the applicable ACCREDIA Pricelist (see § 1.9.2.4).

1.5.1.2. Scheduled surveillance of accreditation

Regarding scheduled assessments (communicated to the CAB through a maintenance programme issued by ACCREDIA-DC for each accreditation cycle, following the risk analysis[1]), the first surveillance activity shall consist of an assessment at the CAB's premises carried out 6 months after the date on which accreditation is granted, unless otherwise decided by the relevant CSA.

In cases where the CAB has not acquired any new contracts, the first surveillance activity may be carried out after 12 months, provided that the renewal process is in any case initiated at least 6 (six) months prior to expiry.

The subsequent surveillances shall be performed at least once every calendar year starting from the date of the first surveillance assessment (unless it has been carried out 12 months after the accreditation decision) and they shall include both office and witnessing activities.

.....

[1] It shall remain valid for the entire accreditation cycle, unless it needs to be reissued due to significant changes in the outcome of the risk analysis, modifications to the scope of accreditation, changes to accredited sites, or critical situations requiring the reassessment of the duration of office assessments, the number of witness assessments and/or their frequency, etc.

The frequency of the surveillances may vary according to the decisions of the CSA depending upon the results of the accreditation, surveillance and renewal assessments.

The planning and performance of the office surveillance assessment are undertaken using similar modalities to those for the accreditation assessment.

If ACCREDIA-DC decides that it is not necessary to perform an office surveillance assessment, it shall use a different assessment technique for the same purpose as for the office assessment which is substituted, and it shall justify the use of this technique. The time period between the performance of one office surveillance assessment and the next shall not exceed 2 years.

The organization where the witness assessment for the maintenance of accreditation is undertaken shall possess a management system which includes the processes/products which are sufficiently representative of the socio-economic activity to which it belongs.

In the preparatory phase for the surveillance or renewal assessment of the CAB which has obtained use of the flexible scope, the ACCREDIA-DC assessors shall apply the provisions of Technical Reg. RT-37 in the current version.

To determine the number of assessment days for the office surveillance/witness assessment, ACCREDIA-DC performs regular risk analyses on the basis of general indications defined in collaboration with ACCREDIA's Steering and Guarantee Committee, which approved them and which include these factors: the results of previous assessments, any sanctions, the issuance of nonconformities/concerns during the assessment of the complaints/reports/dispute management process, the number of complaints/reports, the management of certifications in critical schemes, the number of certificates issued by the body also outside the scope of accreditation but which may have implications for accredited areas (e.g. voluntary certificates in notified fields), the number of pending assessments, etc.

Any reduction to the surveillance programme may be applied by ACCREDIA-DC according to the experience and capacities of the CAB.

During assessments at the Body's premises, the Body shall, where expressly requested, arrange an interview between ACCREDIA-DC inspectors and an agreed sample of its own auditors/inspectors, in order to enable ACCREDIA-DC to carry out the necessary in-depth evaluations.

1.5.1.3. Unscheduled accreditation surveillance

Supplementary and/or extraordinary assessments and/or Market Surveillance visits or other assessment techniques, may be considered necessary by ACCREDIA-DC after the granting of accreditation/extension, following the identification of a critical situation, either directly by ACCREDIA-DC, or after feedbacks and/or complaints, presented in written form and with objective motivations, received by ACCREDIA-DC, or situations of inadequacy which ACCREDIA-DC comes to know about. Any unscheduled surveillance activities may also be carried out by ACCREDIA-DC following requests for further investigation and/or indications of critical or potentially critical situations received from public authorities and supervisory bodies.

These issues are promptly communicated by ACCREDIA-DC to the CAB in question, leading to – where necessary – the performance of a specific assessment and clarification of the motive and origin of the issue (e.g. the context of the issue as well as the area/sector from which it arises and the type of entity which issued it: private, an association, a competitor, the public administration etc.)

For these assessments – which are to all effects unscheduled assessments – advance notice of at least **7 (seven) working days** is given, during which time period the CAB has the right to present a reservation or objection regarding the ACCREDIA-DC team. Such advance notice shall obviously not be given where the assessment activity consists of an unannounced assessment.

In cases of a MSV, ACCREDIA-DC asks the CAB in question (if necessary), for the list of all the audits previously carried out under accreditation (or by limited sampling according to needs), with the indication of the audit teams tasked for each audit, the dates of the performance of the audits and the references of the audited organizations (name, addresses of operative locations and scope of certification).

After choosing the MSV activities to be conducted, ACCREDIA-DC informs the CAB of the date of visit with minimum advance notice of **7 (seven) working days** and the references of the ACCREDIA- DC team, and asks the CAB to send within **3 (three) working days,** all the documents of the certification process (from the informative questionnaire to the 3-year programme, the support checklists, if necessary, but excluding the invoices) of the entire 3-year period, if applicable.

In exceptional and duly justified cases, postponement of the activity shall be permitted for a maximum of three days. Consequently, the CAB shall proceed in accordance with the provisions set out in § 1.11 below.

In cases of a MSV required following a feedback or complaint, or decisive by the imposition of a sanction measure, the ACCREDIA-DC assessment team will probably be assisted by an observer. Upon receipt of the documents by the CAB, ACCREDIA-DC sends the plan to the CAB within **3 (three) working days** before performance of the MSV (in exceptional cases this may be reduced to **1 working day**)**,** specifying to the CAB that a copy of the plan shall also be sent to the organization.

The costs of extraordinary assessments (office, witnessing, MSV, unannounced) required by ACCREDIA-DC for the above reasons, are met by the CAB if any NCs or numerous Concerns are raised, sufficient to lead to a negative result of such activities.

If such conditions are not present, the costs are met by ACCREDIA-DC.

The aims and modalities for conducting a MSV are set out in Annex 1 of the present Regulation.

Unscheduled surveillance activities consist of office and witness assessments and MSVs, required also by ACCREDIA's corporate bodies at CABs operating in sectors/areas where they have identified grave and numerous criticalities related to the effectiveness of the certifications/inspections/declarations of verifications issued. The costs of such assessments are met by the CAB.

Other methods of control may be adopted by ACCREDIA-DC to assess the CAB's operations (e.g. assessments performed directly on auditing companies or other companies operating in outsourcing for a CAB, unannounced assessments at the CAB's head office, whether they are witnessing, mystery shopping, requests

for information by ACCREDIA made to organizations or consultancy companies, contact with certified companies during ACCREDIA audits at the CAB's offices or other control methods).

In cases where these activities are configured as additional activities or as a result of a NC issued or additional activities requested by the CSA, the costs will always be met by the Body regardless of the outcome of the assessments.

1.5.1.3.1 Unannounced assessments

Unannounced assessments are an assessment technique provided for by ISO/IEC 17011 and do not replace routine surveillance and renewal activities. The reasons are related to organisational aspects (e.g. unavailability of all personnel who are normally interviewed during regular surveillance activities, etc.) and/or logistical constraints, and/or their limited duration compared to a surveillance/renewal, which therefore does not allow all the required criteria to be verified, resulting in the consequent risk of not covering the scope of accreditation during the relevant cycle.

Unannounced assessments may be decided:

- in exceptional situations such as to call into question compliance with the requirements for accreditation and/or the competence of the CAB, for example:
    - unannounced assessments (VSP) decided by the Department Directorate following objectively substantiated reports/complaints received by ACCREDIA, especially when originating from public authorities and/or supervisory bodies;
    - delays in the management of assessment outcomes;
    - delays in the planning of assessments resulting in a backlog of pending items;
    - major events (e.g. serious accidents, incidents, environmental damage, etc.);
- unannounced assessments decided by the relevant CSA on the basis of assessments outcomes and/or critical situations submitted by the Directorate. In this case, taking into account, where applicable, the outcomes of the assessment, the related findings management plan proposed by the CAB, the risk analysis of the CAB and the planned surveillance programme, the CSA may decide, at the time of the resolution, to:
    - notify the CAB of the decision to carry out an unannounced assessment, without communicating the date/period in which it will take place;
    - not notify the CAB of the decision to carry out an unannounced assessment, instructing the Technical Office to proceed directly with the organisation of the assessment.

The possible decision options available to the CSA also apply where no assessments have been carried out, but a critical situation has been identified and presented by Management as outlined above.

Unannounced Assessments may also be applied in situations that do not fall within the above-mentioned cases, as they have not shown evident critical issues, but where there are elements of concern arising from document and on-site assessments, such as, for example:

- activity volumes, peaks in the number of assignments, scope of accreditation and requests for extension that appear inconsistent with the size or organisational structure of the CAB;

- activities in market sectors that are potentially high-risk or high-impact, where specific attention is required, or where the CAB has demonstrated a failure to adequately and systematically examine the associated processes and risks;
- activities in very simple sectors, where the CAB has adopted a 'casual' or superficial approach to the selected assessment activities, which could call into question compliance with requirements (e.g. reduced surveillance times, all assessments carried out remotely, etc.);
- aggressive, unclear or misleading commercial policies;
- any other situation or element of concern which, irrespective of the CAB's risk class or of any reports/complaints or non-conforming situation, may give rise to doubts about the proper conduct of the CAB.

In such cases, the decision as to whether to carry out the Unannounced Assessment may be taken by the Department Management, based on the outcomes of the assessment activities (where applicable) and the analysis of CAB data, submitting the case to the relevant CSA, where deemed necessary.

The duration of the assessment is typically one calendar day (although it may be longer in cases of particular criticality and/or complexity), with the participation of at least two ACCREDIA assessors, who may be supported by additional personnel (i.e. other assessors or technical experts), depending on the scope and extent of the assessment activities to be carried out. The participation of Observers may also be envisaged.

The Unannounced Assessment must be conducted in person or at least in a blended format. It may be carried out remotely only in exceptional and duly justified cases (e.g. activities to be performed abroad, access restrictions requiring prior authorisation, etc.).

The costs of Unannounced Assessments, where not requested by the relevant CSA or as supplementary activities, are charged to the CAB only in cases where the reasons for carrying out the assessments are substantiated, non-conformities are identified, or a significant number of Concerns are raised such as to lead to a negative outcome of the assessment. Otherwise, the costs are borne by ACCREDIA-DC.

In the case of unannounced assessments, once the ACCREDIA Assessment Team has arrived at the CAB premises, it will request to liaise with a manager/contact person of the CAB, who does not necessarily need to be the Scheme Manager of the assessed scheme, to whom it will explain the purpose of the assessment and deliver:

- a communication from the Management of ACCREDIA-DC, setting out the reasons for the assessment;
- the Assessment Plan, in which the CAB may record any objections/non-acceptance regarding the plan itself or the names of the ACCREDIA Assessment Team.

The outcomes of Unannounced Assessments are reviewed by the Technical Unit together with the Department Management in order to assess the situation identified, as a result of which it may also be necessary to obtain further information/clarifications on aspects that could not be verified at the time of the assessment. Subsequently, the outcomes are managed in accordance with the methods and timelines defined in this Regulation. Specifically:

- in the event of a negative outcome, additional assessments may be carried out (e.g. document review of evidence, supplementary assessments) or, depending on the critical issues identified, it may be necessary to submit the case to the relevant CSA for the adoption of any sanctioning measures, as set out in section 1.9.2 below. The submission of the case to the relevant CSA as a Critical Case will also apply where the Organisation is not available, for valid reasons, to undergo the assessment;
- in the event of a positive outcome, the findings may be taken into account when planning subsequent scheduled surveillance assessments (for example, through an adjustment of the requirements to be assessed and therefore of the assessment timing, since some of those foreseen in surveillance have already been verified during the VSP). In any case, there must be no time interval of more than 6 months between the two activities.

Unannounced Assessments (VSP) may also be carried out using the witnessing assessment technique. In this case, they are conducted in combination with the assessment at the CAB premises (planned in accordance with the maintenance programme). From an operational perspective, during the opening meeting the Assessment Team Leader (RGVI) requests from the CAB the list of assessments being carried out on that day and selects which ones will be witnessed. The process then continues as follows:

- if the organisation is located nearby (travel time < approximately 1 hour), the team will arrange transfer to the organisation's premises in order to carry out the witnessing activity;
- if the organisation is distant, depending on the relevant scheme, an IT connection may be requested in order to follow the assessment remotely.

Assessments at the organisation's premises (to be carried out with copies of previous reports) are conducted within the time strictly necessary to achieve the audit objectives.

The ACCREDIA Team, during such assessments, is entitled to request specific in-depth analyses deemed necessary to achieve the audit objective. In particular cases, for example where there is a very high number of assessments scheduled on the same day, telephone contacts may also be arranged (not constituting full witnessing activities) at different times during the day in order to verify the actual presence of the CAB assessor at the organisation's premises, in particular at the start and end times of the assessment.

In the absence of an audit on the same day, or where the scope/scheme does not allow for remote witnessing, the assessor may alternatively select assessments for the following day (communicating the selected assessment directly on the day of execution, shortly before the scheduled start time). Under no circumstances shall any information be provided to the organisation concerned. The CAB shall in any case define these situations and their implementation modalities in detail within its contractual documents.

The conduct of these assessments will normally be carried out by an additional member of the team, who will attend by joining the "official" team without prior notification to the CAB or, alternatively, additional days will be scheduled for one of the team members (not communicated in advance to the CAB).

With regard to the management of costs and outcomes of these types of VSP, the provisions set out above shall apply.

1.5.1.3.2 Mistery Audit

This assessment technique is intended to verify the behaviour of CABs, their partners and/or their clients (e.g. certified organisations) with regard to information circulated in the market concerning accreditation and accredited conformity assessment, the use of marks, and the scope of certifications. It also aims to demonstrate the correctness of the conformity assessment process implemented by the CAB.

The primary, but not exclusive, application includes:

- conducting reviews of CAB websites, examination centres, business partners, auditing companies, etc.…
- conducting reviews of certification examinations.

The execution of these assessments may be carried out by ACCREDIA officers / staff members / assessors qualified for the specific scheme, with the possible support of external experts, e.g. potential candidates whose names will not be disclosed to the CAB concerned.

As regards costs, for website review activities, these shall be borne by ACCREDIA, whereas in other cases costs shall be charged to the CAB only where the reasons for the assessments are found to be justified, nonconformities are identified, or a significant number of Concerns is raised such as to lead to a negative outcome of the assessment. Otherwise, the costs shall be borne by ACCREDIA-DC.

With regard to the management of the outcomes of these activities, the provisions set out in the previous § 1.5.1.3.1 shall apply.

1.5.1.4. Remote scheduled and unscheduled surveillance

With regard to the possibility of performing the assessment activities remotely, except for situations attributable to the provisions of the IAF ID 3 document (and subsequent revisions), the performance of the assessment will take place under the following conditions:

- in the surveillance cycle (including renewal) at least one of the assessments shall be performed in presence or in mixed mode;
- in the event that the activity performed remotely proves unsatisfactory at the end of its performance, follow-up activities shall be performed, with costs met by the Body concerned if it is responsible, agreed and recorded in the relative report (e.g., connection problems, lack of collaboration in providing evidence, etc.);
- the Body has in any case the possibility of requesting ACCREDIA to replace the remote assessment, provided this is possible, with one in presence.

ACCREDIA shall in any case have the possibility to increase the frequency of in-person or blended assessments in situations of criticality and/or, based on a risk-based approach, taking into account various factors (e.g. performance of the Organisation, number of pending items, change of premises, etc.).

Where requested by ACCREDIA-DC for in-person or blended assessments, the CAB shall grant access to its premises to all members of the ACCREDIA Assessment Team as required, ensuring that the resources to be interviewed/scheme managers, etc., involved in the assessment activities are also present at the same location

Except for situations related to the provisions of IAF ID 3, ACCREDIA-DC will not carry out assessment activities at the premises of the Body, completely remotely, in the following cases:

- initial assessments where the Body is not already accredited for other areas (however, the mixed mode would be admissible);
- surveillance and/or supplementary assessments in critical cases (e.g. preliminary assessments for the restoration of the suspended accredited activity, etc.) except in exceptional cases;
- extension assessments (limited to cases considered complex) except in exceptional cases.

With regard to witness assessments, ACCREDIA-DC will not perform completely remote assessment activities:

- in cases where the Body carries out its own audit in presence except in exceptional cases to be assessed on a case-by-case basis and except where it concerns an Unannounced Assessment, the execution modalities of which are governed by § 1.5.1.3.2 above;
- in cases where it is not possible for the audited organization to ensure complete verification of all processes and information via the ICT platform;
- for those sectors in which the use of ICT equipment may not be allowed (for example some food, military, hospital, aerospace areas etc.);
- for regulated scopes, non-applicability shall be determined based on the scope and, where applicable, the module under assessment or the specific characteristics of the individual conformity assessment scheme.

Any specific requirements are set out in the individual scheme regulations RG-01-0X.

Remote assessment can in no case be performed:

- where it is not possible to guarantee a stable internet connection;
- for all areas of accreditation in which a Scheme Owner has defined specific limitations;
- where the audited body or organization requests that the assessment activity is performed in a traditional way (on-site);
- where the degree of computerization of the Body, including its system and technical documentation, does not allow for adequate remote assessment.

ACCREDIA-DC will perform an appropriate feasibility analysis in order to determine whether to conduct an assessment remotely or in mixed mode.

For the purposes of this analysis, it may also be necessary to do a prior simulation of how the audit will be performed by the Body, especially in cases where site inspections of external facilities are planned (e.g. laboratories, training centres) or also construction sites.

Finally, it is specified that, in performing the remote witness assessments, the ACCREDIA assessor, in compliance with her/his role as observer, shall retain the right to make any requests to the Body's audit team,

provided that they are indispensable for determining the outcome of the assessment also in terms of its effectiveness (e.g. request for ad hoc video footage, sharing of documents of the audited organization, etc.).

1.5.1.5. Decision-taking process and granting of maintenance of accreditation

The results of the above surveillance activities are analysed by the FT, the DDC and VDDC. If the ACCREDIA-DC performs assessments directly on auditing companies or other companies that operate in outsourcing for a CAB, any findings will be issued with respect to the CAB itself and not to the third-party organization.

Following the results of the surveillance assessments, as well as the subsequent analyses conducted by the DDC or VDDC, the following procedures take place:

a) if there are no NCs: maintenance of accreditation is confirmed by an ACCREDIA-DC FT through the recording of the confirmation of the results within 2 months of the performance of the assessment, with the relative requirements for corrections and CAs for the eventual Concerns that the CAB shall send **within 15 (fifteen)working days;**

b) if one or more NCs are raised, the finding is examined and confirmed to the CAB by the DDC or VDDC within 2 months of the conclusion of the assessment.

In this case, treatment and corrective actions are required, which shall be sent by the CAB **within 15 (fifteen) working days** from the receipt of the communication confirming the findings by the DDC, implemented by the CAB usually within 2 months and in any case in accordance with DDC or VDDC. In the event of unsatisfactory or not effectively implemented corrective actions, the case is referred to the CSA. To verify the implementation of the treatment plan and corrective actions, ACCREDIA-DC carries out an additional assessment activity whose costs are met by the CAB.

c) if a particularly critical NC is raised in terms of number and/or gravity of failures, and/or if the behaviour of the CAB is found to have been professionally improper: the file is submitted directly to the CSA as a “critical case”, without any need for treatments and CAs by the CAB.

1.5.1.6. Variation of the accreditation scope and accreditation standards

1.5.1.6.1. Transition or migration to new accreditation/certification standards

In the event that the accreditation standards/regulatory reference documents for the conduct of conformity assessment activities are updated or amended, it is the CAB’s responsibility to demonstrate that it has adequate rules and competences in the new standard, preparing a transition plan to be made available to the ACCREDIA-DC assessment team before the assessment of the transition, also in accordance with any applicable EA/Global rules.

The transition or transfer is verified during surveillance and renewal activities as programmed in the normal cycle of accreditation (without increased costs) in compliance with the rules issued by ISO/EA/Global etc.). If additional assessments to the normal cycle of maintenance are necessary, the costs are met by the CAB.

The results of these assessments are submitted to the competent CSA for deliberation. When a modification of the field of application takes place, ACCREDIA-DC, for some areas, shall send, where applicable, a communication setting out the decisions to the competent authorities (e.g. Ministries), for further evaluation.

In cases of a negative outcome of the transition/migration to a new edition of the accreditation standard, if the agreed end-date has expired, after submission of the case to the competent CSA, the DDC informs the CAB, within 5 working days of the decision, of the expiry of the accreditation, giving the reasons and the conditions for reapplying for accreditation.

The CAB shall present once again the application for accreditation together, with all the documentation requested and the file will follow the normal process of a new accreditation. However, ACCREDIA-DC, in the context of the risk-based approach, taking into account all the information relating to its previous withdrawn accreditation, will determine the duration of the initial assessment. For these activities, ACCREDIA-DC will issue a technical economic quote, which must be returned for acceptance by the CAB before starting the process.

At the end of the new accreditation process, in the event of a positive decision, the Body will receive a certificate a new accreditation number and the identification of the previous accreditation period may be indicated on the certificate with appropriate wording.

In accordance with the provisions of the document IAF PR 7:2022 "Requirements for Producing IAF Mandatory Documents on Transitions", unless otherwise indicated in specific resolutions and/or Technical Circulars, the following activities must be carried out with related timescales for the management of transitions:

Activity	Duration/Deadline
Overall transition period	2 years from the date of publication of the standard
ACCREDIA carries out assessment activities against the new standard	3 months from the date of publication of the standard
CABs in question that must send to ACCREDIA a specific declaration on the transition status	6 months from the date of publication of the standard
Completion of the transition by accredited CABs	9 months from the date of publication of the standard
Performance of periodic audits by the CABs exclusively against the new edition of the standard	1 year from the date of publication of the standard
Completion of the transition of organizations certified by a CAB	2 years from the date of publication of the new edition of the standard

1.5.1.6.2. Flexible scope of accreditation

For the relative management modalities, see the provisions of the ACCREDIA Technical Regulation RT-37 in the current revision.

In the event of non-compliance with the applicable requirements, sanctioning measures may be taken against the body.

1.5.1.7. Transfer of accreditation between accreditation bodies

A CAB, requesting to ACCREDIA-DC the transfer of accreditation from another foreign AB, signatory to the EA/MLA/Global MRA agreements, shall present the application in accordance with the modalities as set out in § 1.2 together with the documents required, the last assessment report of the previous AB and the active certificate of accreditation.

An indispensable condition for the accreditation transfer process to be initiated if the applicant is a secondary site of a CAB accredited abroad is that the latter is present on the accreditation certificate issued to the accredited legal entity or demonstrates that it applies the same management system as the parent company.

In the event of a request for transfer of accreditation by a CAB already accredited by another Accreditation Body (AB) signatory to the EA/Global MLA/MRA agreements, ACCREDIA shall carry out a pre-transfer review activity, including a document review of the CAB's documentation and of the reports issued by the previous AB relating to the current cycle or to the most recent renewal assessment. Prior to defining the assessment techniques, ACCREDIA shall carry out an initial risk assessment, documented and traceable, aimed at determining the required level of depth of the review.

The transfer may be granted exclusively provided that the scope remains unchanged with respect to that already accredited by the previous AB. Where the CAB simultaneously requests scope extensions, new sectors/methods or new relevant sites not previously assessed, such requests shall be managed by ACCREDIA-DC as extension applications and shall be assessed using appropriate techniques, separately from the transfer process.

Without prejudice to the requirements of Regulation (EC) No 765/2008, as amended, and based on the outcome of the risk assessment, the following approaches shall apply:

- the transfer is managed under a simplified ("light") approach only when the CAB originates from an EA MLA Accreditation Body and all of the following conditions are simultaneously met: unchanged requested scope; absence of major non-conformities in the last two years; absence of suspension, reduction or withdrawal measures in the last three years; absence of relevant pending complaints or appeals; absence of significant changes affecting the legal entity, organisational structure, key personnel or sites; and complete and consistent information provided by the previous AB. In such cases, ACCREDIA shall finalise the transfer based on the positive outcome of the document review and an in-person assessment at the CAB (which may also be conducted remotely), with a targeted evaluation of key competencies (minimum duration: 1 man-day). Any witnessing assessment shall be carried out only if critical elements emerge during the review.

- When at least one of the above conditions is not met, the transfer shall be managed under the regular approach. In this case, in addition to the document review, ACCREDIA shall carry out an office assessment focused on competencies/impartiality (minimum duration: 2 man-days) and at least one witness assessment of a representative activity.
- The transfer shall be managed under an enhanced approach when even one of the following elements is present: request for scope extension or introduction of new sectors/methods; new relevant sites not assessed by the previous AB; recent major non-conformities or a negative trend relating to competence/impartiality; suspension, reduction or withdrawal measures in the last three years; changes affecting the legal entity or transfer requests during the cycle; activities in regulated or high-risk sectors; insufficient or unreliable information from the previous AB, including lack of response. In such cases, ACCREDIA shall carry out an office assessment with a duration proportionate to the complexity of the scope and proportionate witness assessments, up to covering the critical activities necessary to grant the full scope.

The transfer shall also be managed under the enhanced approach in the case of accreditation duplication, which is however not applicable within the EA Region.

The transfer decision shall be taken in accordance with the requirements of ISO/IEC 17011, in particular clause 7.7, and, for cases of cross-frontier accreditation within the EA framework, with document EA-2/13. Any provisions of IAF MD 2 (and subsequent revisions) may be considered solely as technical guidance and shall not be used as a normative basis for the transfer process.

Upon transfer of ownership of the accreditation, ACCREDIA-DC for some areas, shall send, where applicable, a communication setting out the decisions to the competent authorities (e.g. Ministries), for further evaluation.

If a CAB applies to ACCREDIA-DC for the transfer of accreditation from another AB, which is not signatory to the EA/Global MLA/MRA agreements, the complete set of provisions for accreditation shall be applied.

The first surveillance in case of transfer of accreditation will be carried out 12 months from the date of the accreditation decision.

As regards the aerospace scheme, ACCREDIA-DC will apply the provisions of the Technical Regulations RT-18.

1.5.1.8. Transfer of ownership of accreditation and/or changes in the organisational structure

The CAB shall inform ACCREDIA-DC in advance by completing the module MD-24-DC, which can be downloaded from the documents section, Department of Certification and Inspection, if it intends to transfer ownership of accreditation to a new legal entity following some corporate operations such as: modification of the CAB's name, merger, incorporation, ceding of activities/renting of company branch to another CAB etc.

In such cases, ACCREDIA-DC performs an assessment of the maintenance of the required conditions with regard to:

- organizational set-up;
- human resources (in terms of quantities and competences);

- every other applicable condition (through the preparation of specific transition plans detailing times and modalities).

Apart from a request to modify the corporate name, in all other cases ACCREDIA-DC performs an assessment, with the costs being met by the CAB, in the form of a document review or, for more complicated cases (e.g. merger, non-exhaustive list), by means of an office assessment.

The office assessment always takes place in cases of transfer of ownership of accreditation to a non-accredited CAB.

Furthermore, in the case of ownership transfers or the sale of shares to trust companies/holding companies, or where the shareholders include a trust company, holding company, investment fund or other type of organisation, ACCREDIA-DC, in order to accept the transfer request, shall carry out all necessary checks to ensure that there are no activities directly incompatible with those covered by accreditation. To this end, it shall request appropriate declarations/documents relating to companies/organisations within the group to which the applicant CAB belongs. In particular, the names of the shareholders of the trust company/other companies/organisations, senior management, as well as chamber of commerce extracts or equivalent documents providing detailed information, shall be disclosed, in order to assess any potential conflict of interest situations.

In any case, when the CAB notifies ACCREDIA of a change in shareholding structure and/or the transfer of accreditation ownership to another legal entity, it shall be required to submit in advance all necessary information to enable the assessment of:

- the shareholdings held by the new parent or owning organisation;
- the type of activities carried out by the new parent or owning organisation;
- the value creation model;
- the economic and financial situation of the same organisation.

Therefore, documents such as the following may be requested and shall be provided, including but not limited to: Articles of Association, Chamber of Commerce certificate, group organisational chart, financial statements and explanatory notes, detailed list of investee companies with indication of shareholding percentages/shareholders and the activities carried out by subsidiaries/investee companies, intra-group service agreements, governance information (group strategy, operational model – role of the CdA, committees, delegations of authority), risk analysis and related documents.

All the above information shall be provided for any type of incoming/related company and communicated to ACCREDIA prior to the legal completion of the transfer.

It is noted that, in the event of any period during which accreditation is not in force, or where the change in corporate structure has been completed prior to notification to ACCREDIA-DC and/or the relevant decision, no accredited certificates of any kind (e.g. new certificates, renewals, extensions) may be issued by either legal entity, until accreditation has been granted to the new CAB.

The granting of transfer of ownership of accreditation is dealt exclusively by the CSA, which decides after examining (if necessary) the results of the investigations carried out, and the CSA may, if necessary, request the conduct of further assessments.

The request for transfer of accreditation shall be submitted to the first available CSA of the Department in chronological order, and communication shall be provided to the other relevant Committees depending on the scope of accreditation. The same Committees shall be informed of the outcomes of the investigations and assessments carried out, including any aspects to be addressed by the CAB. In the transfer decision, the CSAs may impose specific conditions on the incoming entity.

If the matter regards an organization which is on the official Register of Businesses, the CSA decides that the transfer of ownership of accreditation:

- shall be effective from the date of deposition of the act of variation to the Register of Businesses, provided that such date is after the CSA's meeting at which the file concerning the transfer was presented;
- shall be effective from the date of meeting of the CSA, if the date of deposition in the Register of Businesses coincides with or precedes the date of presentation of the file to the CSA.

If the organization is not on the official Register of Businesses, the transfer shall be effective from the date of the meeting of the CSA which coincides with, or is after, the act of transfer.

Upon transfer of ownership of the accreditation, ACCREDIA-DC for some areas, shall send, where applicable, a communication setting out the decisions to the competent authorities (e.g. Ministries), for further evaluation.

Where necessary, for some specific areas the CAB shall contact the competent authority to define the steps necessary for the transfer of the related authorizations (non-exhaustive example: supervision).

The granting of the transfer of accreditation involves updating the contractual agreement (CO-00) between ACCREDIA-DC and the CAB where a change in VAT number has occurred, as well as updating the certificate of accreditation and, where necessary, of the accreditation number, the ACCREDIA database of accredited Bodies and the relative publication on ACCREDIA's website. This process takes place only after the CAB has sent the deed of transfer.

It is specified that, in the case of lease of a business unit, the duration of the lease agreement shall not be shorter than the remaining duration of the current accreditation cycle.

For CAB's established abroad, evidence shall be produced, applicable in the relevant status.

Upon transfer of ownership of the accreditation, ACCREDIA-DC for some areas, shall send, where applicable, a communication setting out the decisions to the competent authorities (e.g. Ministries), for further evaluation.

1.5.2. Renewal of accreditation

1.5.2.1. Process of renewal of accreditation

Before the expiry of the four-year accreditation period (five years if the annex of the V&V accreditation scheme of the scope included in the annex CSA CI), at least six months before the expiry of the certificate ACCREDIA-

DC starts the procedure for renewal (with the agreement of the maintenance programme on the part of the CAB) which takes place with a document review (with costs met by the CAB) and with the performance (usually 2-3 months before the expiry of the certificate) of an office and a witness assessment if necessary.

Performance of the document review, unless otherwise specified, is limited only to the Certification/Inspection/Verification and Validation Regulations, including those that may be specific to the scheme due for renewal, reference procedures for the conduct of activities for the scheme being renewed, the management system manual and the qualification procedure for assessors/technical experts.

The outcome of the renewal assessment is analysed by the FT, together with a review of the CAB's ongoing operative activities during the accreditation cycle, including the data regarding the monitoring activities carried out by the CAB (situation of client or market complaints etc.)

Note 1: The performance of the document review for renewal of an accreditation scheme shall include any document reviews conducted during the year in certification schemes/sectors for which the CAB is already accredited.

ACCREDIA-DC has the option to evaluate whether to perform the document review during the on- site visit. In cases where at the time of carrying out the renewal assessment, the document review has not yet been performed or completed, the review shall preferably be performed during the renewal, the duration of which will therefore be increased in proportion to the time required for the document review in the annual maintenance programme.

The duration of the office renewal assessment is determined by taking into consideration the specific criticalities of the scheme (e.g. number of sites, number and criticality of the schemes and sectors to be assessed) and other factors such as the management of complaints/feedbacks, number of previous findings to be closed, any sanctions adopted against the CAB, language issues, transfer times, etc.

In the event that the renewal assessment is carried out jointly with another scheme, ACCREDIA-DC will evaluate, taking into account the critical factors listed above, if it is possible to reduce the total time.

1.5.2.2. Decision-making process and granting of renewal of accreditation

Activities are undertaken in the same way as for the process of accreditation, according to § 1.4 "DECISION-TAKING PROCESS AND GRANTING OF ACCREDITATION", except in the following circumstances:

In the event that:

- the renewal assessment is, exceptionally, carried out at a date too close to the meeting of the relevant Accreditation Sector Committee;
- the assessment of the corrective actions submitted by the CAB is still ongoing by ACCREDIA-DC;
- it is necessary, following the outcomes of the renewal assessment or for other reasons (e.g. to further investigate reports), to carry out an additional office or witness assessment or an unscheduled surveillance assessment (e.g. including but not limited to a market surveillance visit);
- the meeting of the relevant sector committee is scheduled too close to the completion of the activities, making it impossible to prepare all the documentation required for the assessment;

The validity of accreditation may be extended by ACCREDIA-DC or by the CSA beyond the expiry date and up to a maximum period of one year from the original expiry date. Such a deferral shall not apply to the V&V accreditation scopes included in the annex entitled CSA CI of the relevant accreditation certificate.

The accreditation certificate is, in any case, never valid for more than five years.

In any case, in order to apply an extension of the validity of accreditation, the renewal assessment shall have been carried out within the original expiry date. Otherwise, accreditation shall lapse and consequently be withdrawn, except in justified and duly substantiated cases, which shall be authorised by the Department Management. Information regarding the extension of accreditation validity shall be published on the website and, where necessary, communicated to the relevant Authority and other interested parties (e.g. Ministries, Scheme Owners, etc.).

If it is not possible, due to lack of availability of the CAB, to verify the entire scope during the accreditation cycle (sectors, macro-sectors, technical areas, categories, etc.) in accordance with the requirements of the relevant scheme/scope ACCREDIA-DC shall reduce the scope accreditation according to the provisions of § 1.8.4.1.

If renewal of accreditation is not issued, the accreditation is withdrawn and the President informs the CAB in question approximately **within 5 working days** of the date of the decision, giving the reasons as well as the conditions for a restart of the accreditation process.

In particular, the CAB will have to re-apply for accreditation, accompanied by all the required documentation and the file will follow the normal process of a new accreditation. However,

ACCREDIA-DC, within the risk-based approach, taking into account all information relating to its previous withdrawn accreditation, will determine the duration of the initial assessment. For these activities, ACCREDIA-DC will issue a technical economic quotation, which shall be returned for acceptance by the CAB before starting the process.

At the end of the new accreditation process, in the event of a positive decision, the Body will receive a certificate with a new accreditation number and the identification of the previous accreditation period may also be indicated on the certificate using appropriate wording.

Following renewal, ACCREDIA-DC prepares the surveillance programme, taking into consideration the risks concerning the CAB and the performance of the previous cycle for the planning of the new one.

1.6. Extension of accreditation

1.6.1. General information

As regards the application for an extension of accreditation to new certification schemes/sectors/inspection activities/programmes (e.g. new product typologies, new IAF sectors, new categories of professional person, new types of inspection of projects, products, plants, new verification/validation sectors etc.) – always within the scheme which is already covered by accreditation – it is obligatory for the CAB to fulfil the minimum requirements set out in the Technical Circulars and regulations for the accreditation standard, where they exist.

1.6.2. Submission and processing of the application for extension

The application for extension of accreditation of a CAB shall be made to ACCREDIA-DC by completing the same modules as the application for accreditation, for the part which is applicable for extension, together with all the necessary documentation.

The application shall be signed by the legal representative of the CAB or by an authorized delegate.

In cases of delegation, for the purposes of the validity of the subscription, ACCREDIA-DC reserves the right to request from the CAB the document certifying the powers of legitimacy of the delegate (e.g. notarial power of attorney, executive decision, decision of the Board of Directors).

The application shall be completed giving all the necessary information and data, giving reasons for any missing details, otherwise the application will not be accepted.

An application for extension cannot be accepted if a sanction blocking extension is in place as defined in § 1.8 except in cases of different provisions which have been approved by the CSA.

The application for extension for accreditation with a flexible scope shall be submitted to ACCREDIA-DC using the DA-10 module, available on the ACCREDIA website, accompanied by all the documentation requested.

The modalities for extension for the flexible scope of accreditation are contained in Technical Regulation RT-37 and, where applicable, in the specific regulation for the accreditation standard.

ACCREDIA shall have the possibility to suspend the extension process where complaints/reports are received or situations of particular criticality affecting the CAB are identified in relation to the scopes covered by the pending application. The process may only be resumed following the resolution of the identified issues and, in any case, no later than 12 months from the date of suspension.

1.6.2.1. If all the documentation attached to the application is complete and compliant, within **30 (thirty) calendar days** from the date of formal receipt, the FT formalizes acceptance and prepares a technical/economic quotation for extension activities to be signed by the DDC or VDDC and sent to the CAB.

During the stage of acceptance of the application for extension, ACCREDIA-DC will take into consideration the results of the last risk analysis with regard to the CAB and its performance

during the accreditation cycle, including the assessment of the status of planning of the maintenance activities.

If the documentation sent by the applicant is incomplete or unclear or not all the conditions are fulfilled, the FT will not accept the application and, within **30 (thirty) calendar days** will ask, in writing, for the outstanding documentation to be sent within 2 months, otherwise the application lapses. If all the necessary documentation is provided and adequate, the application is accepted and the quotation is prepared as described above.

If the technical and financial quotation is not returned signed following at least two reminders, the extension application shall lapse and the applicant shall be required to submit a new application.

1.6.3. Document review

Following acceptance of the quotation by the applicant CAB, the extension process begins with the document review, which is completed within **30 (thirty) calendar days** of the date of acceptance of the quotation.

If the outcome of the document review is negative and if findings are raised requiring revised documentation to be sent and re-evaluated, before going ahead with the planning and the conduct of assessments, ACCREDIA-DC informs the applicant CAB of the need to provide adequate documentation in accordance with such findings. These corrections shall be sent within two months, otherwise the application lapses.

ACCREDIA-DC retains the right to evaluate whether to carry out the document review for extension at the CAB's premises.

ACCREDIA-DC shall also interrupt the extension process in the event that three document reviews have been carried out with negative outcomes, thereby demonstrating an insufficient level of competence and/or impartiality of the applicant CAB.

The above does not apply if a sanction blocking extension is in place as defined in § 1.8 apart from exceptional cases approved by the relevant CSA.

1.6.4. Assessments

1.6.4.1. Following a positive outcome of the document review as above, the process of extension continues in line with the accreditation standard and as set out in the specific regulations.

The organization where the witness assessment for extension takes place shall have a management system which includes processes/products which are sufficiently representative of the relevant socio-economic activity.

In exceptional cases, justified by objective difficulties in the organization of witness assessments (e.g. poor number of certifications in the sector of the extension), ACCREDIA-DC may authorize the conduct of such audits before the document review has been completed.

In these cases, the process of extension is suspended until the document review has been concluded.

In cases of extension of accreditation to certain specific schemes/sectors in which the number of audit activities by the CAB is limited, the DDC may authorize, instead of the witness assessment, the performance of a market surveillance visit.

The modalities defined in § 1.3.2.2. are applicable.

The above does not apply if a sanction blocking extension is in place as defined in § 1.9 apart from exceptional cases approved by the relevant CSA.

1.6.4.2 As regards the composition of the team for the extension assessment, the criteria applied are the same as those for initial accreditation.

1.6.4.3 If, during the witness assessment any NCs are raised and formalized, or if the outcome of the assessment is not positive, the extension process is suspended until the closure of the CAs and the demonstration of effectiveness which ACCREDIA-DC will verify by means of a supplementary assessment. The time limit for the implementation of CAs is usually 2 months.

1.6.4.4. The extension process may be interrupted where more than two consecutive supplementary assessments have been carried out with a negative outcome.

The relevant CSA may decide that it is necessary to perform supplementary assessments or unscheduled surveillances after the granting of extension if there is a significant number of findings classified as Concerns (Observations) or if, for some findings, the effectiveness of the CAs has to be monitored by means of specific assessments.

If, during the extension assessments, situations of inadequacy are found in any way and for any reason, not directly related to the subject of the extension, but in any case, relating to the conformity assessment scheme, or to other accreditation scheme/s covered, the intervention methods specific to surveillance activities apply. The ACCREDIA assessor will therefore have to provide for the inclusion of any in-depth proposals in the assessment report.

If, following the conclusion of the Document Review, a period of 12 months has elapsed and the CAB has not made itself available to carry out the subsequent assessment activities provided for in the extension process, the CAB shall be contacted by the FT in order to ascertain whether it intends to continue with the accreditation process. Where the CAB requests to proceed with the extension process, the need to carry out a Supplementary Document Review shall be assessed in the event that the Organisation has communicated changes to the system documentation previously assessed by ACCREDIA-DC; where, on the other hand, the Organisation does not provide feedback or does not confirm its intention to proceed with the extension process, ACCREDIA-DC shall terminate the process, resulting in the lapse of the application.

1.7. Decision-making process and granting of extension of accreditation

Activities go ahead in the same way as for the process of accreditation, according to § 1.4 “DECISION- MAKING PROCESS AND GRANTING OF ACCREDITATION”.

Upon granting the extension of accreditation, ACCREDIA-DC shall update the relevant annex to the existing accreditation certificate by including the new scope of accreditation (or any new site, where applicable).

The extension of accreditation does not prolong the validity of the accreditation.

1.8. Additional provisions

1.8.1 Cross-frontier accreditations and multiple accreditations

Where ACCREDIA-DC receives accreditation applications concerning certification activities carried out by CABs in foreign sites, the provisions of Regulation (EC) No 765/2008 and subsequent amendments, the ACCREDIA PG-12 “Policy for the application of Cross Frontier accreditations”, the relevant EA/Global documents, as well as documents issued by the European Commission (e.g. CERTIF 2009-06 REV6 – CROSS BORDER ACCREDITATION ACTIVITIES and subsequent revisions), shall apply.

ACCREDIA-DC shall also issue an NC in the event that it becomes aware that a CAB established in Italy does not comply with ACCREDIA Circular No. 3/2016, issued in relation to the implementation of Regulation (EC) No 765/2008 and subsequent amendments, with specific reference to Article 7 (Cross-frontier Accreditation). It is recalled that a CAB established in Italy is prohibited from applying to another Accreditation Body, whether located within or outside Europe, for accreditation in a scheme/sector where such accreditation can be provided by ACCREDIA, whereas if the CAB is already covered by ACCREDIA accreditation in the relevant scheme/sector, it may apply for an additional accreditation only to a non-European Accreditation Body.

Furthermore, the CAB, in application of the above requirements, shall not refuse that assessment activities are carried out by the local AB, as ACCREDIA is obliged to resort to subcontracting where the conditions apply and, at the same time, cannot interfere with the fees applied by other accreditation bodies. Where the CAB does not make itself available for the execution of the activity, ACCREDIA-DC shall proceed with a territorial limitation of the accreditation scope, in implementation of specific indications provided by EA itself. Finally, when carrying out assessment activities under subcontracting to another AB, the CAB shall demonstrate co-operation and provide the requested documentation, which may differ from that generally required where the activities are carried out by ACCREDIA-DC itself.

1.8.2 Management of any violations of legal provisions during Witness Assessments

The ACCREDIA-DC Assessor, in the event that during a Witness Assessment they identify a violation of a legal/contractual provision relevant to the object of certification that has not been identified by the CAB, shall correctly classify the deficiencies found, ensuring they are supported by appropriate objective evidence, in order to enable prompt and proportionate action by the CAB and to reconcile the responsibility of the Assessment Team with the inspection mandate received from ACCREDIA-DC. The following clarifications are provided below.

If the violation of the legal/contractual provision falls within the scope of the audit, the ACCREDIA-DC Assessor shall issue a NC or, in any case, a finding referring to the specific violated requirement of the standard, where this has not already been adequately identified by the CAB (e.g. a breach by the organisation of a safety regulation during an SCR audit). When determining the severity of the finding, it shall be assessed whether the situation has changed compared to the outcomes of previous audits.

Furthermore, the identification of non-compliance with legal requirements relating to the organisation's products/services shall be reported as a non-conformity only where it is relevant to the requirements of the assessed management system, irrespective of the controls and sanctions falling under the competence of the competent Authorities.

If the violation of the legal/contractual provision is only an indirect or related aspect, the ACCREDIA-DC Assessor shall issue a Comment in order to recommend that the CAB concerned keeps such aspects under control during subsequent audits within this scheme (e.g. a potential breach of a safety regulation within the QMS scheme where this may have some influence on product/service conformity, as could occur in a school or a hospital).

If the alleged violation of a legal/contractual provision does not fall within the scope of the assessment, the ACCREDIA-DC Assessor is not required to include it in the audit report, as it is outside the scope of the assessment, and because it is not possible to ensure competence on all regulatory aspects that fall outside the audit scope (e.g. a potential breach of safety or tax regulations within the QMS scheme where this has no impact on product/service conformity).

1.8.3. Management of findings raised by ACCREDIA-DC

All findings formalised by ACCREDIA-DC as Non-conformities/Concerns, in accordance with the criteria set out in this Regulation, shall be duly reviewed by the CAB, which shall submit to ACCREDIA-DC, within **15 (fifteen) working days** from receipt of the findings' confirmation letter (issued by ACCREDIA-DC within 2 months from the date of completion of the assessment), an appropriate findings management plan including:

For non-conformities the correction (where applicable), a root cause analysis, an analysis of the extent of the deficiency, and corrective actions addressing the identified causes, together with the implementation timeframe. Evidence of closure for this type of finding shall be positively assessed by ACCREDIA-DC prior to the decision (granting, renewal or extension of accreditation) by the CSA.

The Sectoral Accreditation Committee may, in exceptional and duly justified cases, issue a positive decision conditional upon the full implementation of the corrective action.

For maintenance purposes, the NC shall be closed within the established timeframe.

An on-site assessment may be required to ensure that the corrective actions have been effectively implemented.

For Concerns: the correction (where applicable), a root cause analysis, an analysis of the extent of the deficiency, and corrective actions, together with the identification of the implementation timeframe.

Implementation shall be verified during the subsequent surveillance assessment. Where deemed necessary by ACCREDIA-DC, evidence relating to the correction and/or corrective actions shall preferably be reviewed in documentary form by ACCREDIA-DC prior to the next surveillance assessment.

For Comments: this type of finding may be addressed through the opening of an improvement action, or it may not be taken into account; in the latter case, the reasons shall be recorded.

The assessment of the adequacy of the root cause analysis, the analysis of the extent of the deficiency, the treatments, the corrective actions and the related timeframes (which shall be as prompt as possible) shall be communicated by ACCREDIA-DC to the CAB within 30 calendar days from receipt of it.

In any case, failure to complete the analysis of the extent of the deficiency shall not be accepted. Where the CAB considers this not applicable, it shall provide adequate justification, which shall be assessed by the ACCREDIA Assessment Team within the proposed findings management plan. Furthermore, the analysis of the extent of the deficiency shall already have been completed, with its outcomes included in its formulation, at the time of submission of the findings management plan to ACCREDIA-DC, since, based also on its outcomes (as well as on the root cause analysis), the CAB shall identify appropriate corrective actions. In addition, the CAB shall submit a root cause analysis structured in such a way as to demonstrate that it has effectively investigated the deficiency raised up to the identification of its primary root cause.

If a CAB fails to submit to ACCREDIA-DC the findings management plan or the required documentary evidence within the applicable deadlines for the different cases, ACCREDIA-DC may submit the case to the relevant CSA for the adoption of sanctioning measures, as provided for in § 1.9.2.1 below.

Findings formalised by ACCREDIA-DC at the end of assessments may be reclassified by the Technical Office following a review of the outcome review.

In the case of document review for accreditation/extension/renewal/transition, etc., deficiencies classified as Comments shall instead be assessed in their entirety and, where appropriate, managed by the Organisation and verified by ACCREDIA-DC, preferably prior to submission of the case to the relevant CSA.

In the case of document reviews for accreditation/extension/renewal/transition, etc., deficiencies are classified as follows:

1. **Comment**: a deficiency that shall be assessed by the CAB for acceptance or for a justified non-acceptance. Where applicable, verification of the analysis carried out shall be assessed directly on-site. In any case, all such items shall be assessed and, where appropriate, managed by the Organisation and verified by ACCREDIA-DC, preferably prior to submission of the case to the relevant CSA;
2. **To be completed, with assessment, during the on-site assessment:** a deficiency that the CAB shall address, but which will be verified by the ACCREDIA Assessment Team during the subsequent on-site assessment (office or witness). This case applies where the finding is such as to still allow planning and execution of the assessment;
3. **To be completed prior to the on-site assessment**: a deficiency requiring submission of the revised document to ACCREDIA-DC, which shall be assessed or reassessed on a documentary basis by

ACCREDIA-DC before proceeding with the planning and execution of the on-site assessment (office or witness).

Where no on-site assessment (office or witness) is foreseen during the process, classification shall follow only cases 1 and 3.

Failure to properly manage ACCREDIA findings may result in the adoption of sanctioning measures, as set out in section 1.9.2 below.

1.9. Suspension, withdrawal and reduction of accreditation

1.9.1. Minor sanctioning measures

If the outcome of assessments, undertaken as part of surveillance activities (scheduled or unscheduled) or extension procedures of the scope of accreditation and any other evaluation activity, provide clear evidence of situations which may compromise the value of the certifications issued by the CAB (without casting any doubt on trust placed in the CAB) - together with the supplementary activities related to the verification of adequacy and effectiveness of the corrective actions - the DDC, shall impose minor sanctions such as, for example:

- block placed on the applications for extension or the applications already underway, for an established period of time;
- block placed on the applications for accreditation referred to other schemes for an established period of time.
- enhanced surveillance activities.

Minor sanctioning measures may also be imposed by ACCREDIA-DC where the Organisation has not allowed ACCREDIA to carry out the scheduled surveillance activities within the required timeframe and manner, resulting in situations of a certain criticality in terms of the effective coverage of the accreditation scope within the reference cycle.

In these cases, it shall be evaluated by the FT in consultation with the Directorate whether the block is applicable to an entire accreditation standard or to a specific certification scheme. The relevant CSA is entrusted with the possibility of providing for any constraints.

The block of accreditation and/or extension applications, or of their submission to the relevant CSA for decision-making purposes, may also be applied in cases where there is a significant number of unperformed assessments (pending items from previous years), taking into account whether the failure to plan is attributable to the CAB itself (e.g. including but not limited to short notice periods or proposals that do not allow the necessary activities to be scheduled).

These minor sanctions shall be communicated to the CAB in a letter signed by the DDC and subsequently published on the ACCREDIA website (without further details) on the ACCREDIA website (but not on the

database of accredited Bodies). They are communicated to the Sectoral Accreditation Committee (which may review the case) together with all the necessary information.

Minor sanctioning measures may also be applied (e.g. in the case of failure by the CAB to submit annual economic data) or decided by the relevant CSA.

In some areas, ACCREDIA-DC informs, where required, the competent authorities (e.g. Ministries) about the minor sanctioning measures adopted against the accredited Bodies.

1.9.2. Major sanctioning measures

1.9.2.1 If critical situations emerge following surveillance, supplementary, extraordinary or renewal assessments, or from other controls (e.g. Unannounced Assessments and Mystery Assessments) and checks (e.g. from feedbacks), of a technical nature, ACCREDIA-DC, depending on the gravity of the case, imposes the reduction, suspension (partial or total) or the withdrawal of accreditation.

Below are some examples of particularly grave situations:

- failure to remove the causes leading to the imposition of minor sanctions and failure to fulfil related obligations;
- failure to resolve NCs in accordance with ACCREDIA-DC's procedures;
- the issuance of non-conformities at first instance that are of a particularly serious nature (e.g. relating to the competence of the CAB, compliance with impartiality principles, etc.);
- failure to resolve a minor sanctioning measure;
- improper use of the Notified Body number and/or the CE marking and/or failure to comply with the provisions of the European Commission Note of 14 September 2022 (ref. grow.d.3(2022)7036064) – and any subsequent amendments – concerning the issuance of voluntary certification for products subject to EU technical harmonisation legislation.
- issuance of voluntary certifications, including where issued outside the accreditation scheme, in the presence of mandatory (binding) certification schemes subject to accreditation for the same scope of application, in accordance with the EU regulatory framework on conformity assessment as defined by the European Commission. This prohibition applies generally and across all sectors, with the sole exception of cases where the accreditation relating to the voluntary certification was obtained prior to the entry into force of the mandatory nature of the certification itself. This provision does not include the cases governed by the previous point.
- failure to transmit to ACCREDIA-DC the management plan of the findings or the documental evidence required, after sending 3 reminders without having received a reply and in any case within 3 months from the confirmation of the findings;
- inadequate management of findings issued by ACCREDIA-DC (e.g. where they are not deemed acceptable on at least three consecutive occasions).
- failure to manage complaints or failure to reply to ACCREDIA-DC regarding any requests for clarification following critical situations/feedbacks;

- failure to comply with the requirements of the accreditation standards or of the present Regulation or of the specific regulations for the accreditation standard and the contractual accreditation agreement;
- failure to implement the corrections/CAs in cases of unduly issued certifications also in terms of the adequacy of the scopes granted with respect to the scheme requirements (a CA could, for example, lead to a decision with respect to a CAB to suspend or withdraw an unduly issued certificate owing to non-coverage by the ACCREDIA accreditation, or because it does not conform with the standards applicable to the certification scheme);
- improper use of the ACCREDIA Mark;
- failure to respect the obligations of the accreditation contract and/or specific regulations for the accreditation standard regarding the sending of data of certified entities in line with the ACCREDIA-DC procedures;
- in cases where the CAB does not permit ACCREDIA-DC to conduct assessments as set out in the present Regulation, including refusal to allow access for ACCREDIA-DC to a location belonging to the CAB or to a third-party organization which takes part in the conformity assessment process on behalf of the accredited CAB;
- inadequate management of the flexible scope;
- failure to notify ACCREDIA-DC of relevant changes affecting its documentation and structure, which may impact the Organisation's compliance status with accreditation requirements;
- dissemination on the market of incorrect information such as to potentially generate legal consequences for ACCREDIA;
- failure to sign the Accreditation Agreement;
- lack of cooperation in the execution of assessment activities entrusted by ACCREDIA-DC to other Accreditation Bodies;
- confirmed performance of third-party conformity assessment activities and/or issuance of attestations or certifications for activities falling within levels 1–4 of the MLA/MRA agreements (for details of the activities, see document EA 1/06;
- failure to respect the requirements of § 1.11.
- where the organisation no longer meets the conditions set out in § 1.1.3

If, from surveillance, supplementary, extraordinary or renewal assessments, or from other controls (e.g. Unannounced and Mystery Assessments) and investigations (e.g. based on reports), situations of particular severity are identified from an ethical standpoint, ACCREDIA-DC shall impose a reduction or withdrawal of accreditation.

It is possible to proceed with the withdrawal of an accreditation at the sole discretion of ACCREDIA for geopolitical reasons in the application of rules concerning international resolutions (e.g. sanctions).

In compliance with the statutory and regulatory standards, major sanctioning measures are imposed following deliberation by the relevant CSA. If considered necessary, the ACCREDIA President or General Director, in collaboration with the DDC, may convene extraordinary meetings of the CSA, also by email.

The decisions of the CSA concerning suspension/reduction/withdrawal, adequately justified and signed by ACCREDIA's President, are communicated to the CAB in question by means of registered post (if the CAB is situated abroad) or by certified email within **5 (five) working days** from the decision and are subsequently published on the website.

The above resolutions are also sent for information to the competent authorities, if requested (e.g. AIAD-CBMC for CABs accredited in the Aerospace scheme, IAF for the cases envisaged in the document MD 7).

The DDC ensures the immediate implementation of the sanction as well as all the related decisions by the CSA.

For CABs operating in some areas, the resolutions of the CSA, where envisaged, must be sent by ACCREDIA-DC for information to the competent Authorities (e.g. Ministries), for further evaluation.

1.9.2.2. The duration of the measure for the partial or total reduction or suspension of accreditation is established by the relevant CSA (in accordance with the constraints detailed below), concurrently with the decision relating to the measure. Reduction and suspension of accreditation do not entail termination of the contractual obligations towards ACCREDIA-DC.

The sanctions provisions are applicable from the date of their receipt by the CAB in question.

With regard to foreign CABs, the measures shall take effect from the date of delivery by ordinary email (followed by delivery via courier service).

If the assessments performed by ACCREDIA-DC to ascertain the effective removal of the cause of the sanction have had positive results, the accreditation is restored after a decision by the CSA, retaining the original certification expiry date.

If, on the other hand, the assessments carried out by ACCREDIA-DC have not established that the causes of the sanction have been effectively resolved, the case is submitted for examination by the relevant CSA for the adoption of further sanctions, communicated to the CAB as set out in § 1.9.2.1.

The maximum duration of suspension is 6 months but the period may be longer to allow for discussion of the case at the first due meeting of the CSA which had imposed the sanction.

At the end of the period as defined above, if conformity has not been re-established by the CAB, partial suspension becomes the reduction and/or total suspension becomes the withdrawal of accreditation, again, following a decision by the CSA.

The DDC ensures the immediate implementation of the provision. Also in this case, the measures take effect from the date of receipt of the measures by the CAB concerned.

The withdrawal of the suspension (partial or total), along with the restoration of accreditation, shall be submitted for consideration by the CSA.

1.9.2.3. Unless otherwise specified in the regulations for the accreditation standard, during the period of suspension (partial or total), the CAB shall not issue new declarations of conformity under ACCREDIA's accreditation. It may, however, perform surveillance and renewal of existing

certifications, issued exclusively within the fixed timeframe of their issue (extension of the scope of certification is not possible), provided that the maintenance and renewal activities of certifications falling within the suspension period are submitted in advance to ACCREDIA-DC, which shall define any related witnessing activities, with costs borne by the CAB.

The CAB may nevertheless manage:

- changes in clients' company name (provided they do not involve transfer to a new certified legal entity);
- changes of address that do not involve the addition of new sites;
- any scope changes, provided that it is clarified to ACCREDIA that these do not constitute scope extensions.

In regulated cases, ACCREDIA-DC shall inform the relevant Authorities.

During this period, the CAB shall conform with the Regulation regarding use of the ACCREDIA Mark (RG-09). Furthermore, the CAB shall promptly inform its clients, providing details on the date and duration of the measure, and shall transmit the relevant communication to ACCREDIA.

During the suspension period, the CAB shall not participate in public tenders or publicly funded projects involving the performance of accredited conformity assessment activities during the validity period of the measure.

During the suspension period, maintenance activities carried out by ACCREDIA shall be aligned with the CAB's operational activity within the suspended scope. Where the CAB continues to carry out maintenance activities, ACCREDIA shall act accordingly; where the CAB does not carry out activities within the suspended scope, ACCREDIA shall likewise not perform maintenance activities, unless otherwise decided by the competent bodies.

1.9.2.4 Total suspension of accreditation may be imposed automatically by the ACCREDIA General Director, without being submitted to the relevant CSA, if payment owed to ACCREDIA-DC is delayed by more than 60 days from the date specified in the contract (payment date specified in the invoice), and also after a reminder has been sent by ACCREDIA-DC after 45 days from the deadline for payment. Exception is made if an agreement for deferred payment has been reached and approved by the ACCREDIA General Director. The same provisions set out in § 1.9.2.3 above shall apply to such administrative suspensions.

1.9.2.5 The imposition of partial or total suspension is published on ACCREDIA's website and recorded in the database of accredited Bodies and elsewhere as applicable.

1.9.2.6 Accreditation shall be reduced or withdrawn at first instance in certain cases, such as by way of example:

- failure to remove the causes which led to the suspension sanction, within the fixed timeframes;
- negative decision regarding the renewal of accreditation by the CSA;

- illegal, damaging or seriously unprofessional conduct in terms of professional ethics (e.g. including but not limited to cases where ACCREDIA-DC is informed of such situations directly by the competent Authorities);
- failure to pay the sums due, if the CAB persists in its failure to fulfil its obligations, 6 months after notification of the automatic suspension;
- where a maximum period of 12 months has elapsed from the positive conclusion of the document review and the Organisation has not made itself available for the renewal assessment, and in any case without exceeding the limit of 5 years from the start of the relevant accreditation cycle;
- misuse of accreditation such as to cause serious damage and discredit to ACCREDIA and/or to the accreditation and certification/inspection/validation and verification system (e.g. including but not limited to cases where activities carried out outside the scope of accreditation are managed in such a way as to create market confusion with what is foreseen within the accreditation scope, with particular reference to notified areas.

Accreditation also lapses in the event that the CAB terminates its activity, for whatever reason, and in cases of legal action brought against the CAB.

Withdrawal owing to failed payments, is imposed if the CAB continues to fail to meet its payment obligations, after 6 months from the communication of the imposition of the sanction of suspension, the President of ACCREDIA authorizes automatic withdrawal of accreditation.

If there is evidence of fraudulent behaviour or if the CAB deliberately provides false information, or if it conceals information, ACCREDIAS-DC shall start the process of withdrawal of accreditation by submitting the case to the relevant CSA for the corresponding decision.

Furthermore, where the CAB is already accredited by ACCREDIA for other schemes, the case shall be submitted to the relevant CSA for the appropriate assessments.

In the event of withdrawal due to fraudulent behaviour/false information, the CAB shall not be allowed to submit a new accreditation application for any accreditation scheme for a period corresponding to one accreditation cycle of 4 years, except where relevant changes have occurred in the governance and ownership of the CAB, and subject to any different decision by the CSA itself.

Therefore, prior to the above-mentioned deadline, no accreditation or accreditation transfer applications shall be accepted from a different legal entity where the governance and/or ownership includes the same natural or legal persons as the entity subject to the accreditation withdrawal measure.

Where the withdrawal measure is adopted by another Department, the Management shall assess the situation and the case may be submitted to the CSAs for the relevant decisions.

Following withdrawal of accreditation, ACCREDIA-DC shall monitor that the Organisation ceases the use of the mark and any reference to accreditation, reserving the right to take action before the competent bodies should this requirement not be fulfilled.

1.9.2.7. Following reduction or withdrawal of accreditation, the CAB shall immediately cease to issue declarations of conformity referring to ACCREDIA accreditation and it shall remove the ACCREDIA Mark:

- for the certification of management systems, certificates issued by the CAB are deemed to be covered by accreditation for 6 months starting from the date of the CAB's loss of accreditation. Within such timeframe, transfers may be carried out in accordance with the provisions of IAF MD 2 (and subsequent versions). The relevant CSA may, however, impose different timelines (and in any case not exceeding the above-mentioned six months) regarding the accreditation coverage and/or the transfer modalities;
- for the certification of product, where the scheme provides for surveillance/renewal, certificates issued by the CAB shall nevertheless be considered as covered by accreditation for a maximum period of 6 months from the date on which the CAB has lost accreditation. Within this period, such certificates may be transferred. The relevant CSA may, however, impose different timelines (and in any case not exceeding the above-mentioned six months) regarding accreditation coverage and/or transfer modalities.

  Where the scheme does not provide for surveillance/renewal, certificates issued prior to the adoption of the measure shall retain their status as accredited certificates, unless otherwise decided by the relevant CSA.

- for certification of persons, reference is made to the provisions set out in Regulation RG-01-02.

The CAB is also required not to use any copies or reproductions of the accreditation certificate and to comply with the provisions set out in the Regulation governing the use of the ACCREDIA mark.

Reduction or withdrawal of accreditation are published on ACCREDIA's website, specifying also, in cases of withdrawal of accreditation of the obligations that the CAB shall respect (e.g. type and duration of assessment) for the transfer of the certificates, if present, depending on the scheme as described above. The CAB's name is removed from database accredited Bodies and all other places as applicable.

1.9.2.8 In the event of withdrawal or reduction of accreditation (excluding the cases set out in § 1.9.2.6 above), the CAB shall not submit a new accreditation application before six (6) months have passed from the date of the decision of the CSA which imposed the withdrawal sanction, unless the CSA decides otherwise or in cases of exceptions stated in the Regulation for the accreditation standard.

1.9.2.9. Withdrawal or reduction of accreditation does not entail the termination of contractual obligations with ACCREDIA-DC, which retains the right to carry out forcible collection and recovery of expenses, with interest, in accordance with the law.

1.9.3. Suspension requested by the CAB

The CAB may make a request for self-suspension for a period of time not exceeding six (6) months, after which self-suspension will become withdrawal unless conformity is restored of the accreditation requirements through the execution of specific assessment activities.

By submitting form MD-XX-DC, the CAB shall provide the reasons given and the duration of the request for self-suspension, that are evaluated by the DDC or VDDC, who may modify the conditions and timeframe for the restoration of conformity by the CAB, taking the necessary measures to ascertain a full return to conformity at the end of the period of self-suspension. A specific communication of these decisions is sent by the Technical Officer to the CAB concerned.

Where a request for self-suspension is submitted by the Organisation in the presence of situations of particular criticality (e.g. the presence of non-conformities that may compromise the effectiveness and confidence in the conformity assessment process adopted by the Organisation, absence of key resources in a specific scheme, etc.), such request shall be temporarily accepted by the Management of ACCREDIA, with written notification to the Organisation concerned, and submitted to the first relevant CSA available for the corresponding decisions. Exclusively in the above cases, the CSA may convert the self-suspension into a suspension of accreditation or modify its duration

The relevant CSA is informed regarding the self-suspension, and the information is published on the ACCREDIA website.

For CABs operating in some areas, the decisions of the CSA, where necessary, shall be sent by ACCREDIA-DC for information to the competent authorities (e.g. Ministries), for further evaluation.

In cases where the self-suspension of accreditation is requested for a specific area of accreditation and therefore not for the entire scope referred to in the field of application, during the period of self-suspension the Body may anyway request the extension to other conformity assessment schemes or other specific modules, categories, sectors, etc. The Management shall assess each request on a case-by-case basis.

1.9.4. Procedural reduction of the scope and renunciation of accreditation

1.9.4.1 Reduction of accreditation is imposed by ACCREDIA-DC, following a decision by the competent CSA, upon specific request by the CAB or by ACCREDIA, in cases where the CAB has not carried out validation, audit, inspection, certification or surveillance activities for the duration of the cycle of accreditation with regard to a certain conformity assessment scheme and sector/module or, only in the case of QMS, EMS, and OHS schemes (as permitted by the IAF MD 17 document), it was not possible to verify the competence of the CAB itself for the entire scope during the accreditation cycle.

The above-mentioned requirements are understood to be applicable unless otherwise specified by Technical Documents, whereby the scope coverage follows criteria based on competence for homogeneity and assimilability, or by other indications from the relevant Authorities.

Where the situations described above occur, the technical structure of ACCREDIA shall provide prior notification to the Organisation.

Reduction of accreditation, imposed by ACCREDIA-DC, is decided upon by the relevant CSA, whereas in the case of a self-reduction, the relevant CSA is only informed.

In the case of a reduction requested by the CAB, it shall take effect from the date of the relevant communication.

The reduction of accreditation is published on ACCREDIA's website, and elsewhere as required by the competent authorities.

1.9.4.2 An accredited CAB may renounce accreditation at any moment in time and for any reason, such as non-acceptance of changes to the pricelist or changes to the regulations for accreditation activities etc.

If the CAB renounces accreditation and in doing so states a date in the future for such renunciation, the following conditions are applicable:

- until the moment of the renunciation, the CAB may operate as under normal accreditation conditions;
- ACCREDIA-DC may decide it is necessary to perform, as well as the normal assessments, other ones (e.g. for maintenance of accreditation until expiry);
- ACCREDIA-DC may request extra assurances that activities undertaken until the effective renunciation of accreditation have been properly conducted (e.g., it may request the list of assessment activities performed, the closure of findings which remained open or it may perform unannounced assessments etc.).

The withdrawal resulting from the CAB's request for renunciation of accreditation shall be decided by the relevant CSA, unless the renunciation is submitted in conjunction with the expiry of the certificate; in such case, ACCREDIA-DC shall take note of the CAB's decision and inform the relevant CSA accordingly.

For CABs operating in some areas, the decisions of the CSA concerning the reduction/renunciation of accreditation, where required, shall be sent by ACCREDIA-DC for information to the competent authorities (e.g. Ministries), for further evaluation.

In cases of renunciation of accreditation, the certifications previously issued by the CAB shall be considered as covered by accreditation for a period of 6 months from the date on which the CAB has lost accreditation. The transfer modalities shall be those described in the section dedicated to accreditation withdrawal.

1.9.4.3 The renunciation of accreditation does not entail the termination of the contractual obligations towards ACCREDIA-DC, which reserves the right to initiate enforcement collection procedures and recovery of costs, plus interest, in the forms provided for by law.

1.9.5. Restoration of accreditation

On the basis of the motivation for the suspension/self-suspension ACCREDIA-DC performs an assessment of the restoration of adequacy of the CAB's system by means of the performance of the previously established assessment activities and communicated to the CAB.

After verification of the adequacy of the CAB system, the Technical Officer prepares a report of the activities performed with the relative results which is submitted for the assessment by DDC or VDDC (in the case of self-suspension) or by the relevant CSA (in the case of suspensions) to establish whether or not the CAB's activity will be resumed.

In cases of self-suspension and if assessments were not necessary (see § 1.9.3) the DDC or VDDC decides directly regarding the resumption of accreditation and the DDC or VDDC informs the CSA of this decision at the CSA's first due meeting.

The list of CAB's on ACCREDIA's website is updated to show the resumption of accreditation.

For CABs operating in some areas, the decisions for the restoration, where required, shall be sent by ACCREDIA-DC for information to the competent authorities (e.g. Ministries), for further evaluation.

1.10. Complaints, feedbacks, reservations and appeals

1.10.1. Complaints/feedbacks

ACCREDIA-DC may receive complaints/remarks regarding:

- the operations of ACCREDIA-DC;
- the operations of accredited CABs;
- for service disruptions caused by clients of accredited bodies;
- improper use of the ACCREDIA Mark.

Within **30 (thirty) working days** of the date of receipt of the complaint/feedback, ACCREDIA-DC, after evaluating the cause of the complaint/feedback, handles it according to the existing procedures which ensure that such process is undertaken by a person who is independent of the object of the complaint/feedback.

Anonymous complaints/feedbacks will not be accepted in order to avoid speculative actions which unfairly affect competition.

Complaints/reports shall be managed within a period of 12 months from the date of receipt by ACCREDIA-DC, unless otherwise provided for by other applicable provisions. Any inadequate handling, including failure to comply with the above-mentioned timeframes, may lead to the adoption of sanctioning measures as set out in § 1.9.2.1.

With reference to the conduct of ACCREDIA-DC Assessors (both internal and external), any complaints/reports shall be submitted in writing within **10 (ten) working days** from the end of the assessment activities. Such complaints shall be clear and properly substantiated.

1.10.2. Reservations

With regard to any findings reported by ACCREDIA-DC assessors, reservations shall be presented within **3 (three) working days** of the end of the assessment. Any reservations submitted shall be clear and properly

substantiated. The above-mentioned timeframe shall be automatically applied also in cases where, following a review carried out by the structure and Management, the classification of a finding has been upgraded. In any case, reservations submitted after confirmation of the assessment outcome by the structure shall not be taken into consideration.

ACCREDIA-DC shall provide to the CAB which presented the reservation the result of the evaluation whether this may be non-acceptance or otherwise, giving the relevant reasons.

The acceptance or rejection of the reservations submitted by the CAB is entrusted to ACCREDIA-DC and VDDC. However, in specific cases (e.g. where the reservations submitted are highly technical in nature and require specific sector competence and expertise, or where Management has taken part in the assessment itself), the FT may agree with DDC or VDDC o assign the evaluation of the reservation to an external assessor, whose name shall be communicated to the CAB concerned, and whose selection shall ensure compliance with competence and independence requirements with respect to the subject of the reservation.

The appointed ACCREDIA-DC assessor shall provide to the Directorate and the Technical Officer a detailed report specifying the documents that have been evaluated, the technical detail of the response to each individual dispute raised by the Body and a clear formulation of the final outcome regarding the acceptance or not, or also partial, of the reservation presented.

Upon receipt of this report, the FT, in agreement with the DDC or VDDC, reviews its contents and transmit the result to the Body concerned. The answer shall normally be provided to the CAB within 2 months of the conclusion of the verification.

The costs of this activity are met entirely by ACCREDIA-DC.

1.10.3. Appeals

If, during the cycle of accreditation, the accredited CAB wishes to ask ACCREDIA-DC to reconsider actions taken against it, it may present an appeal, using the modalities as set out in ACCREDIA document RG-06 which also includes possible cases of inadmissibility.

The handling of an appeal is the task of the Commission of Appeals and it does not require the involvement of the Sector Accreditation Committees which are, nevertheless, informed of the presentation and of the outcome of appeals. During the appeal process, decisions regarding the accreditation of the CAB concerning the certification schemes (e.g. renewals, transitions or extensions) are taken by the Commission of Appeals, operating in place of the CSA.

ACCREDIA-DC undertakes, where required, to report any appeals received from accredited CABs operating in certain areas to the competent authorities (e.g. Ministries) and to provide feedback on the related management.

1.11. Obligations of the CAB

1.11.1 The CAB shall pay the annual accreditation maintenance fee in accordance with the pricelist.

1.11.2 The CAB shall maintain conformity with the applicable accreditation requirements and shall maintain correct behaviour, with transparency and collaboration with ACCREDIA. The CAB shall inform ACCREDIA if it is no longer able to fulfil the accreditation requirements ((e.g. non-exhaustively, absence of key personnel required for its operation, etc.).

1.11.3 Following receipt of the maintenance programmes held by the CAB or confirmation thereof, CABs shall promptly and independently submit to ST/PRO, at the email address programmazione@accredia.it updates to the controlled lists of their Examination Commissioners, the updated and complete schedule of their examination sessions, as well as the list of conformity assessment activities planned under the relevant schemes/macro-sectors/sectors/technical areas/categories/modules subject to Witness Assessment. This information shall be submitted in good time to allow proper planning and shall include the names of the appointed inspection/audit personnel, ensuring a diversification of proposals throughout the accreditation cycle so that ACCREDIA-DC may assess a representative sample thereof. For certification schemes that do not require planning, as in the case of certain mandatory certification and inspection activities, the CAB shall nonetheless provide full cooperation with ACCREDIA-DC in identifying the activities to be subject to Witness Assessment. CABs shall also, upon request by ACCREDIA-DC, submit the list of all audits carried out in the period specified by ACCREDIA-DC, in order to enable the conduct of market surveillance visits.

The CAB shall allow ACCREDIA Assessors to carry out assessments of accredited activities, as well as other evaluation techniques provided for in ACCREDIA Regulations (e.g. unannounced assessments, mystery audits, Market Surveillance Visits, etc.), at its own premises and at those of its clients/suppliers (e.g. auditing companies, laboratories, etc.) to which such activities are subcontracted, including such a possibility in the relevant agreements with the latter, in order to verify that the CAB continues to comply with the accreditation requirements. Certain assessment activities may also be carried out by ACCREDIA remotely.

1.11.4 CABs shall formally and promptly notify ACCREDIA-DC, by submitting form MD-24-DC, of any significant changes to their organisation, such as changes in shareholding structure, transfer of accreditation ownership to a new legal entity following a change of company name or transfer of a business branch to another CAB, changes or activation of new operational sites, and changes in key personnel involved in the conformity assessment process.

1.11.5 The CAB shall state on the certificate issued with ACCREDIA accreditation the reference to the technical regulation (RT) of the applicable scheme or sector, where they exist, using the wording "*Certification issued in conformity with the ACCREDIA technical regulation RT…*" (this obligation is forbidden for CABs not yet accredited).

1.11.6 All CABs accredited in the fields for which the ACCREDIA database is active are required to submit to ACCREDIA-DC the data relating to the holders of certifications issued by them, in accordance with the procedures defined by ACCREDIA-DC in specific instructions and in compliance with applicable legal requirements.

It is the responsibility of the CAB to transmit to ACCREDIA-DC (via the web service SIAC made available by ACCREDIA-DC, in cooperation with a service provider, and accessed directly through the ACCREDIA website) timely and accurate information relating to certificates issued under its responsibility. Any further requirements are set out in the specific scheme Regulations.

CABs, as independent data controllers and having fulfilled the obligations, including information requirements, provided for under European and national legislation on the processing of personal data, are required to collect, update and correct data relating to natural persons and to representatives of legal entities holding certifications issued by them, and to communicate such data to ACCREDIA-DC in accordance with the procedures defined by the latter and in compliance with applicable legal requirements in force. ACCREDIA processes the personal data in question, namely those relating to natural persons and to representatives of legal entities holding certifications issued by CABs, as an independent data controller. CABs undertake to inform certified persons of the availability on the ACCREDIA website of the privacy notice prepared pursuant to Article 14 of the GDPR, via the following link: https://www.accredia.it/banche-dati/#6a14641fe62f0

1.11.7 The Certification Bodies have full ownership and responsibility of the data relating to the certifications issued to their customers. The Bodies are responsible for obtaining authorization from their certified customers to transmit to ACCREDIA information relating to certifications, which in turn ACCREDIA may publish on its website and, if already published, also transmit to third parties (e.g. the Chambers of Commerce, research institutes, CERVED, ANAC, ENEA, IAF/Global, ISTAT, credit institutes etc.), also in their entirety and completeness, so that the relevant recipients may in turn act as intermediaries for their dissemination to the public, including where such information has not already been published by ACCREDIA-DC on its website..

CABs are required to notify ACCREDIA of any withdrawal of consent by data subjects, which shall in any case not affect the processing carried out by ACCREDIA up to that point. CABs shall therefore remain solely liable towards the bodies using the service (e.g. ANAC, SOAs, contracting companies, the market in general, etc.) and towards ACCREDIA-DC for any damage arising from inaccuracies and/or delayed communication and publication of data, and shall accordingly hold ACCREDIA-DC harmless from any liability, claims or requests for damages in relation to such negligence or breaches, including the failure or incorrect acquisition of consent for data disclosure and/or the failure or incorrect notification of consent withdrawal by CABs.

1.11.8 The CAB shall respect the modalities for sending data (related to certified entities) contained in the applicable technical regulations and the specific schemes/sectors or other instructions.

1.11.9 If such data is not received within the given timeframe, ACCREDIA-DC may impose a sanction against the CAB.

1.11.10 In cases of withdrawal of a certification due to be re-issued, CABs shall, irrespective of the motive (technical or administrative), re-issue it with a new date, also if the same certificate number is retained as well as the same date of first issue.

1.11.11 Under no circumstances may CABs acquire or use data communicated by other CABs relating to issued certifications in order to engage in acts of unfair competition pursuant to Article 2598 of the Italian Civil Code against other CABs and/or for marketing or commercial purposes, which are strictly prohibited; ACCREDIA-DC may adopt sanctioning measures against CABs found to be in breach of this obligation.

1.11.12 Where a CAB operates under accreditation in countries designated as prohibited under international sanctions, it shall assume full responsibility (both legal and in respect of any potential limitations in insurance coverage) for compliance with such sanctions.

1.11.13 The CAB commits to respect all the applicable safety rules in accordance with the applicable regulations and to give to ACCRDIA-DC, during the programming of on-site assessment activities, detailed information concerning the prevention, protection and emergency measures adopted by sending the module MD-19 within 10 calendar days from the date of the assessment, except in cases of unscheduled surveillances, for which **7 (seven) working days** are the fixed timeframe.

1.11.14 The CAB shall promptly inform ACCREDIA-DC of any judicial proceedings concerning accredited activities and it shall promptly inform ACCREDIA-DC with regard to any legal and administrative provisions regarding its internal or external staff concerning accredited activities. The CAB shall not send to ACCREDIA-DC any judicial information in accordance with the privacy laws.

1.11.15 The CAB shall undertake a formal document review if it obtains knowledge through official deeds (or other sources) of actions attributable to organizations certified by the CAB revealing breaches of the law, both confirmed and suspected, pertinent to the CAB's scope of certification. The CAB shall inform ACCREDIA-DC in all such cases.

The CAB shall also record sufficient motives for any actions it intends to make. ACCREDIA-DC may request further detailed information but it may not request judicial information in accordance with the privacy laws.

Any further requirements are set out in the individual scheme Regulations.

1.11.16 The CAB shall collaborate in the investigation and resolution of any complaints communicated by ACCREDIA-DC concerning its accreditation.

1.11.17 Where an organisation does not make itself available for ACCREDIA-DC to carry out scheduled and/or unscheduled surveillance activities, the CAB shall assess whether the conditions exist to proceed with suspension and, where necessary, withdrawal of the issued certification. This provision shall also apply in cases of failure to comply with the timeframes defined by ACCREDIA-DC for the execution of extraordinary assessment activities.

1.11.18 The accredited body is objectively liable for the actions, omissions and conduct of its assessors, evaluators, collaborators and any other persons operating, in any capacity, within the scope of the accredited activities. The liability of the body applies irrespective of the contractual relationship with the individuals involved and covers any conduct that may affect the conformity, impartiality or integrity of the assessment process. In the event of ethical breaches or non-conforming conduct by the

aforementioned individuals, ACCREDIA-DC may adopt measures against the accredited body, including suspension or withdrawal of accreditation.

1.11.19 Where the conformity assessment scheme requires that other marks (e.g. standards body, SO, etc.) be displayed on the attestation document issued by the CAB, the CAB shall demonstrate that it holds valid and up-to-date authorisation for their use. Otherwise, failure to meet this requirement may have an impact on the maintenance of accreditation.

1.11.20 The CAB is required to promptly inform ACCREDIA-DC of any significant cyberattacks it may have suffered (e.g. hacking, cyberattacks, etc.), providing details of their impact on system records/documents and of the corrective actions it intends to implement in order to ensure that there is no interruption in the conformity of the accredited conformity assessment process. ACCREDIA will assess the management of the event.

1.11.21 The CAB is required to promptly inform ACCREDIA-DC of the use of Artificial Intelligence, limited to cases where it is systematically applied to processes that have an impact on conformity assessment activities. ACCREDIA-DC may carry out additional assessments to verify that such use does not affect compliance with accreditation requirements. It is further specified that the use of Artificial Intelligence (AI) systems by Conformity Assessment Bodies (CABs) within the scope of accredited activities is permitted, provided that the requirements of the applicable standards are met and the integrity, impartiality and reliability of the conformity assessment process are ensured. The introduction or significant use of AI systems in processes, operational methodologies or tools used for accredited activities shall be considered a significant change to the body's operational system. Therefore, the CAB is required to promptly inform ACCREDIA-DC, providing adequate documentation describing the system used, its functionalities and its field of application.

Where AI systems are used in the technical stages of the conformity assessment process, the body shall demonstrate that such tools have been appropriately validated as technical resources and that their use does not compromise the reliability of the assessment activities, the confidentiality of information, or the proper management of data. In accordance with the principles of the accreditation system and applicable international standards, final decisions relating to conformity assessment shall remain the responsibility of competent personnel within the body and shall not be delegated to automated systems or Artificial Intelligence (AI).

1.11.22 For the performance of its conformity assessment activities, with reference to all geographical areas in which it operates, the CAB shall be able to demonstrate that:

- it has assessed the risks arising from such activities;
- it has taken appropriate measures (e.g. insurance or risk provisions recorded in the balance sheet) to cover the professional risks of its internal staff and collaborators (e.g. auditors, decision-making committees, etc.) arising from its activities, including in relation to its clients' activities.

1.11.23 In line with what is set out in EA TMB Resolution 2026 (25) 02, the description of the certification scope, for the same standard, must be pertinent and consistent with the requirements of the

certification scheme under which the assessment activities were carried out and the certification was issued. It is not permitted to include references or statements relating to a certification scope that does not fall within the applicable certification scheme and which, therefore, has not been subject to assessment activities by the certification bodies.

1.11.24 For all matters not expressly provided for in this Regulation, the provisions set out in Article 4 of the Agreement (CO-00) shall apply.

Failure to comply with the above requirements shall result in the adoption of sanctioning measures referred to in § 1.9.

1.12. ACCREDIA-DC's obligations

1.12.1 ACCREDIA-DC may sub-contract activities to other ABs signatory to the EA MLA Global /MRA agreements, informing the CAB of this possibility.

1.12.2 In cases of variations to the conditions of accreditation such as modifications to reference standards or regulations for accreditation, as well as standards concerning certified entities, ACCREDIA-DC communicates as such to the CAB which has the option of retaining accreditation, adapting accordingly its organization and proceedings to the new references within the timeframe set by ACCREDIA-DC, or else it may renounce its accreditation.

1.12.3. In cases of modifications to the pricelist, even if the quotation has been accepted by the CAB, services will be invoiced at the cost as it stands when the activities are performed. If costs are changed, immediately after approval by the CSI (Inter-ministerial Surveillance Commission), the CAB is promptly informed (by email) of such variations, and the updated pricelist will be published on ACCREDIA's website.

The CAB has the right to renounce accreditation within 6 months of the receipt of such communication.

During this 6-month period of renunciation on the part of the CAB, the pricelist applied is the one which was valid before the modifications, solely for the activities undertaken until the moment of renunciation.

1.12.4 ACCREDIA-DC shall periodically update the database of Accredited Bodies.

1.12.5 For cases of owner schemes, ACCREDIA-DC shall upload on the database all the information regarding accredited CABs (e.g. the OASIS database for the aerospace scheme).

1.12.6 For everything which is not specifically covered by the present Regulation, article 3 of the contractual agreement, CO-00, is applicable.

1.12.7 ACCREDIA-DC performs an internal assessment of the application of the internal procedures regarding the definition and implementation of the duration and range of office and witness assessments which are related to the granting, maintenance and renewal of accreditations.

1.12.8 Any news - in any way relating to the relationships between ACCREDIA-DC and the accredited or applicant CABs or to the relationships between the CABs and the certified/applicant entities/persons

or the clients or objects of inspection - must be kept confidential, i.e. ACCREDIA-DC must not communicate it to third parties unless:

- publication is required by the accreditation or certification rules;
- the communication is required in accordance with this Regulation or is considered necessary by ACCREDIA-DC for the effective performance of its activities, however it must remain limited to the recipients;
- it is otherwise established by law or by the legal authority;
- the motivated request comes from another Accreditation Body signatory of the EA or IAF MLA Agreements;
- disclosure takes place with the explicit and unanimous consent of all interested parties;
- the request is prescribed by the rules defined by a Scheme Owner. In this case, ACCREDIA-DC may need to share the contents of the assessment reports with it.

1.12.9 ACCREDIA does not carry out assessment activities, and therefore does not accredit, in countries subject to sanctions recognised or imposed by the Italian Government where conformity assessment or accreditation activities are prohibited.

1.12.10 Where, for a proprietary scheme approved by ACCREDIA-DC at national level in accordance with the procedure set out in document PG-13-01, it is determined that such scheme is not eligible for accreditation at the end of the international evaluation process (e.g. EA or Global), ACCREDIA-DC shall terminate accreditation in that scope and, consequently, withdraw any previously granted accreditations.

1.12.11 ACCREDIA-DC may accredit conformity assessment schemes that comply with applicable laws and regulations, including antitrust legislation, and that are designed so as not to create barriers to free competition or contribute to any form of inequality or discrimination.

1.12.12 ACCREDIA shall bear no responsibility towards the market and the authorities for activities carried out by accredited bodies outside the scope of accreditation. However, an accredited body is required not to compromise in any way the integrity of accredited activities, avoiding ethically and technically inappropriate conduct when operating outside the scope of accreditation. In such circumstances, should ACCREDIA-DC become aware of such conduct, it reserves the right to adopt measures against the accredited CAB.

1.12.13 In the exercise of its public interest functions, ACCREDIA-DC may share information with other parties (e.g. Authorities, supervisory bodies) and also with partners, such as scheme owners, in the event of doubts regarding potential unlawful situations, in order to carry out effective and targeted investigations.

1.12.14 In compliance with EA TMB Resolution 2026 (25) 01, accreditation according to Level 3, 4 and 5 standards (ref. document EA 1/06) may be granted exclusively with respect to a standard that has completed the formal approval process and has been published. Consequently, ACCREDIA may not reference a draft standard in the accreditation scope, regardless of whether such draft has been

published or not (e.g. DIS or FDIS). For Level 5 standards (ref. document EA 1/06), a draft standard may be included in the accreditation scope only if it is used as a method/procedure developed and validated by the CAB. In such cases, the requirements of procedure PG-13-01 shall apply.

1.12.15 Where identified critical issues arise in relation to approved proprietary schemes (both at national and international level), ACCREDIA may decide to suspend the accreditation service, duly notifying CABs accordingly, so as to enable the appropriate management of any attestations already issued under accreditation.

Annex 1: objectives and modalities of performance of Market Surveillance Visit Activities

The objectives of the Market Surveillance Visit are as follows:

- to understand the actual performance of an audit and consequently, if the relative report reflects the corporate reality, interviewing the organization's top management – the Director or a representative of the Director – reconstructing the records of the last audit report;
- to understand if the audit report is complete with respect to the processes and requirements to be audited because it is on the basis of the report that the CAB takes the decision concerning certification;
- to understand if the management system is consolidated and historic or if it is an ad hoc creation;
- to understand if the three-year programme has been properly managed (if all the corporate processes were audited in the 3-year period and if there is evidence of this in the reports).

In such cases, where applicable, ACCREDIA may, upon selection of a file, request the CAB to submit in advance all documentation relating to the certification process, as well as copies of previous audit reports and any checklists.

It is the CAB's responsibility to establish contacts with the organization for the performance of the market surveillance visit.

Unless otherwise specified, a visit to the site or temporary site to observe directly the activities undertaken by the organization is not expected.

Any findings raised are classified as Nonconformities, Concerns (Observations) or Comments, whilst in the confidential part the audit team shall provide a rating in accordance with the document IAF ID 04.

It is not acceptable that the organization does not provide the requested documents, i.e. the documents which the CAB used as references during its audit.

The ACCREDIA-DC assessor shall communicate, during the opening meeting, whom s/he wishes to interact with during the activity, and shall explain in detail to the organization the aims of the Market Surveillance Visit, requesting transparency and collaboration in the questions asked, and s/he shall respect the organization's work hours.

When asking questions, the ACCREDIA-DC assessor shall try to adhere, as much as possible, to the indications in the IAF document / checklist contained in the confidential report of ACCREDIA-DC.

The report shall be given and described by the ACCREDIA-DC assessor to the CAB's representatives, if present, without disclosing any details to the assessed organization.

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