

**TITLE REGULATION FOR THE ACCREDITATION OF  
CERTIFICATION, INSPECTION, VALIDATION AND  
VERIFICATION BODIES – GENERAL REQUIREMENTS**

**REFERENCE RG-01**

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**NOTE 1** *Errata corrige dated 10<sup>th</sup> November 2022*

**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. To identify the revised parts reference must be made to the Italian version only.*

**PREPARATION**

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**AUTHORIZATION**

**THE PRESIDENT**

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1.5.1.6.1.,1.8.2., 1.8.2.6.***

## 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, management systems, e-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, ensuring that they satisfy and continue to conform with the organizational, procedural, technical and professional requirements in such a way as to foster in all the social and economic parties involved - and in particular, in the end users and consumers - a high level of trust in the work performed by the Bodies and in the value of the declarations of conformity which they issue.

In keeping with the aims indicated above and in compliance with the policies followed by its institutional Bodies – with the objective of better assuring the effectiveness of the accreditation process and to guarantee the effectiveness and consistency of the operations of the accredited Bodies, ACCREDIA-DC has drawn up specific rules and appropriate criteria for the application of the general requirements of the applicable normative references, as set out in the present General Regulation and in Regulations containing the specifications concerning 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 or plant) and the object of inspection activities (project, product, service, process or plant) and the object of verification and validation changes – due to the inevitably generic nature of the normative references used.

To enhance the effectiveness and the credibility of the accreditation process, it is necessary to implement specific criteria which, without overstepping the intention and the words of the standard, foster full and substantial application on the part of accredited Bodies, at the same time providing unambiguous, objective and impartial references for the assessments performed on such Bodies by the Accreditation Body.

This objective can be achieved thanks to the correct and effective application of the present General Regulation and the specific Regulations for the accreditation standard which have been prepared, taking into account the best level of knowledge and state-of-the-art experience gained in the sector.

## 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.

(hereafter such Bodies are 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 provisions which are additional and/or in conflict with the requirements of this General Regulation and the requirements of the Regulations for the accreditation standard, shall be formalized for the CAB in the relevant contract.

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.

**The present Regulation - General Part, shall not be used separately from the specific regulation of the standard for which accreditation is made.**

The present General Regulation and the specific Regulations for the accreditation standard are contractually binding in relations between ACCREDIA-DC and the accredited Bodies whereby:

- 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, maintenance, extension or renewal of accreditation and to enter the CAB and the relative 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).

Also to be considered as contractually binding between ACCREDIA-DC and accredited CABs are the circulars/provisions issued over time by ACCREDIA-DC, specific to the scheme/sector to be shared with the interested parties and included in the ACCREDIA document LS-14.

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

ACCREDIA-DC considers the following to be obligatory:

- a) Mandatory documents issued by EA/IAF/ILAC and by the standardisation bodies;

- b) Applicable dispositions deriving from decisions adopted by the General Assembly of Bodies regarding the above point (see EA-INF/17 in the current version);
- c) Documents regarding accreditation issued by the European Commission (CERTIF year-xx);
- d) Dispositions issued by the Public Authorities;
- e) Applicable dispositions issued by the ACCREDIA 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:

- the FAQs arising from EA's Committee of Certification and Inspection and from the IAF Technical Committee and relative working groups;
- the interpretations provided by the maintenance groups of ISO CASCO.

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 in respecting the rules and in the performance of 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.

The present general Regulation and the specific Regulations for the accreditation standard are submitted for approval of the ACCREDIA Directive Council (article 14 of the ACCREDIA Statute) following a favourable opinion of the Committee for Accreditation Activities and issuance with the authority of the President of ACCREDIA. The Steering and Guarantee Committee is also involved in the processing a role of consultancy.

### 0.3 NORMATIVE REFERENCES

The normative references for the application of the present Regulation and of the specific Regulations for the 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 the accreditation standard is completed by the Technical Regulations (RT)/Technical documents (DT) and technical circulars applicable to the scheme, where such exist.

The general requirements are applicable to all activities of certification, inspection, verification and validation undertaken with the accreditation of ACCREDIA's Department of Certification and Inspection, both in Italy and abroad. The application of the requirements of the individual RT/DT/circulars to activities of certification/inspection/verification and validation undertaken outside Italy are to be considered optional, except where the application of these laws or standards is not required (e.g. implementation of EA/IAF documents) at an international level.

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/Information Circulars;

and EA/IAF/ILAC 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 should be noted that the times indicated in these Regulations may not be respected during the periods when the organization is closed; this information is 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 programs, 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 (OdC):** 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, h 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 (OdI):** a Body which performs inspections (UNI CEI EN ISO/IEC 17020).
- **Type "A" Inspection Body:** a third party IB which shall fulfil the requirements contained in Appendix A1 of the standard UNI CEI EN ISO/IEC 17020.
- **Type "B" Inspection Body:** an IB which carries out first or second party inspections, or both, constituting a separate and identifiable part of an organization which operates in the design, manufacture, supply, installation, use or maintenance of items which it submits for inspection and which provides inspection services to its own parent organization or to other parties (or both) and which shall meet the requirements contained in Appendix A2 of UNI CEI EN EIC/ISO 17020.
- **Type "C" Inspection Body:** an IB which performs first or second party inspections, or both, constituting an identifiable but not necessarily separate part of an organization which operates in the design, manufacture, supply, installation, use and maintenance of items which it submits for inspection and which provides inspection services to its own parent organization or to other parties, or both, and which shall meet the requirements contained in Appendix A3 of UNI CEI EN EIC/ISO 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 programs (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 fully the 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 of 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.
- **Macrosector/cluster:** group of homogeneous and similar certification sectors.

**Note:** All IAF sectors are grouped in a series of **macrosectors**, in each of which **critical sectors** are identified (for details see the document IAF MD 17 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.
- **Appropriate site:** similarly with the provisions of the document IAF ILAC A5, ACCREDIA-DC considers a location that carries out one or more of the following "key" activities to be relevant:
  - 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;
  - Decision.

- 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 program: 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:

- on-site 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, programmed surveillance, non-programmed 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 advising the CAB, at its premises or, where applicable, at its secondary locations or by witnessing at the CAB's clients on the basis of the program received by the CAB.
- Interview: assessment technique by means of which the ACCREDIA-DC assessment team, during the on-site 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).

**Note:** In these cases, where applicable, ACCREDIA, having chosen a file, may request the CAB to send in advance all the documentation regarding the process of certification as well as a copy of the previous audit reports and any checklists.

For the objectives and modalities of the conduct of a market surveillance visit see the contents of Annex 1 of the present 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 concern an entire accreditation standard.
- Reduction of accreditation: sanction measure providing for the elimination of a part of the scope of accreditation of a CAB in a certain scheme.
- Suspension of accreditation: sanction measure of 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: provision 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.).
- 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, IAF MLA/BLA or ILAC 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.

ACCREDIA-DC shall also issue a NC if it obtains knowledge that a CAB, established in Italy, does not respect the ACCREDIA Circular n. 3/2016, issued regarding the application of the Regulation CE 765/2008 and subsequent amendments, with specific reference to article 7 (Cross Frontier accreditation).

A CAB established in Italy is not permitted to apply to another AB in or outside Europe for accreditation in a scheme/sector if such accreditation can be provided by ACCREDIA. If the CAB is already covered by ACCREDIA accreditation in this scheme/sector, it is possible for this CAB to request further accreditation, but only from a non-European accreditation body.

Furthermore, the identification of non-compliance with the legal requirements, relating to the organisation's products/services, is raised as a Nonconformity only if relevant to the requirements of the management system assessed, regardless of the controls and sanctions of the competent authorities.

**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 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.

**General note:** If the ACCREDIA-DC assessor finds during a witness assessment, a violation of a legal/contractual provision, relevant to the subject of the certification, not raised by the CAB, s/he shall classify the findings in the correct way, to allow prompt and correct management by the CAB, and to reconcile the responsibility of the assessment team with the assessment mandate received from the DDC. Some clarifications are provided below.

If the violation of the legal/contractual requirement comes within the scope of the audit, the ACCREDIA-DC assessor issues a NC or in any case a finding referring to the specific requirement of the rule violated, if it had not already been adequately reported by the CAB (e.g. violation by the organization of a safety standard during an OH&S audit). In defining the grading of the finding, it will be necessary to check whether the situation has changed with respect to the results of the previous audits.

If the violation of the legal/contractual requirement is only a related aspect, the ACCREDIA-DC assessor issues a Comment to suggest to the CAB concerned to keep these aspects under control during subsequent audits in this scheme (e.g. possible violation of a safety standard in the QMS scheme when this can have some influence on the conformity of the product/service, as could happen in a school or hospital).

If the alleged violation of the legal/contractual requirement does not come within the scope of the assessment the ACCREDIA-DC assessor is not required to indicate it in the audit report, because it does not come within the scope of the assessment, and because it is not possible to guarantee his

competence in every regulatory aspect not falling within the scope of the audit (e.g. possible violation of a safety or tax regulation in the QMS scheme when this has no influence on the conformity of the product/service).

- Management of findings by the CAB: activities to be undertaken by the CAB with respect to findings raised by ACCREDIA-DC

All the findings formalized by ACCREDIA-DC as NCs/Concerns, on the basis of the above criteria, shall be reviewed by the CAB which shall send to ACCREDIA-DC **within 15 (fifteen) work days** from receipt of the communication confirming the findings (sent by ACCREDIA-DC within 2 months of the conclusion of the assessment), an adequate plan for the management of the findings which includes as follows:

For Nonconformities: the correction (where applicable), an analysis of the root cause and the relative corrective actions regarding the identified causes with an indication of the timeframe for implementation. The evidences of closure for this type of finding shall be positively evaluated by ACCREDIA-DC before the decision (for granting, renewing or extending accreditation) by the CSA.

The Sector Accreditation Committee may issue a positive decision on condition that the corrective action has been fully implemented.

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

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

For Concerns: the correction (where applicable), an analysis of the root cause and the relative corrective actions, regarding the identified causes with an indication of the timeframe for implementation.

The implementation is verified during the next surveillance visit. If considered necessary by ACCREDIA-DC, the evidences regarding the correction and/or corrective actions, are evaluated in document form before the next surveillance visit.

For Comments: this type of finding may be managed with the opening of an improvement action or it may not be accepted, in which case the reasons for non-acceptance shall be recorded.

The evaluation of the analysis of the causes, of the treatments, of the corrective actions and of the relative timing, shall be sent by ACCREDIA-DC to the CAB within 30 calendar days of receipt of the evaluation.

If a CAB does not send to ACCREDIA-DC the plan for the management of the findings or the requested document evidences within the relevant timeframe for each one, DDC may send the file to the CSA for the imposition of sanctions.

The findings raised by ACCREDIA-DC at the conclusion of assessments may be reclassified by the Technical Office after a review of the results.

In the case of documentary reviews for accreditation/extension/renewal/transition, etc., the findings classified as Comments shall instead all be assessed and managed by the Body and verified by ACCREDIA-DC, possibly before submitting the file to the CSA.



In case a CAB does not provide the plan for corrective actions and the management of the Comments already completed and in a format which can be copied during the surveillance, ACCREDIA-DC may decide to increase the duration time of the assessment.

If the CAB does not provide the corrective action plan and the management of the Comments already completed and in copyable format during the surveillance assessments, ACCREDIA-DC may increase the verification times.

- 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.
- 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.

The CAB should identify risk indicators proportional to the expected effect and to the probability of occurrence of a certain situation.

- 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.
- 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;
- ATM: Monitoring of assessors;
- FT: Technical Officer;
- ST/PRO: Technical secretariat and programming.

# PART 1 – GENERAL REQUIREMENTS RELATING TO THE ACCREDITATION PROCESS

## 1. REQUIREMENTS 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](http://www.accredia.it) – which includes documentation useful for accreditation purposes.

Unless otherwise indicated the references for ordinary contacts are:

Registered head office: ACCREDIA, Via Guglielmo Saliceto, 7/9 - 00161 Roma;

Operative head office: ACCREDIA Department of Certification and Inspection, Via Tonale 26, 20125 Milano.

For emails, all communications should be addressed to the specific email boxes indicated in the ACCREDIA website [www.accredia.it](http://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.

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 it 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;

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. 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.
- 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. If ACCREDIA-DC receives an application for accreditation regarding certification activities carried out by a CAB located abroad, Regulation (CE) 765/2008 and subsequent amendments is applicable as well as the ACCREDIA Procedure PG-12 "Policy for the application of Cross Frontier accreditations" and also the relevant EA/IAF/ILAC documents as well as documents issued by the European Commission (e.g.: CERTIF 2009-06 REV6 - CROSS BORDER ACCREDITATION ACTIVITIES and subsequent revisions).
- 1.1.8. In all cases in which the conformity assessment scheme has international validity (in cases of inspection) or is not based on a law, official standard or on para or pre-normative documents

issued by official Standardization Bodies, the scheme shall be presented to ACCREDIA-DC by the scheme owner.

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 program and inspection activity.

## **1.2. PRESENTATION AND INSTRUCTION OF THE APPLICATION FOR A CCREDITATION**

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).

If an applicant CAB is a trust company or, among its partners, there is a trust company, ACCREDIA-DC, in order to accept the application, will have to perform all the necessary checks, asking for declarations by the applicant CAB and the names of the trust company partners shall be made known for evaluation of any situations of potential conflicts of interests.

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).

- 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 on-site 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 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 (e.g. suspension or withdrawal of accreditation).

- 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 findings 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 findings reported.

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.

### 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, 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) work 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.

In the case of both an on-site and a remote assessment, the team shall hold an initial meeting to define clearly to the CAB the scope of the assessment and the relative requirements of accreditation, and the assessment plan is confirmed.

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 the Body does not confirm its willingness to continue with the accreditation process, ACCREDIA-DC proceeds with the interruption of the accreditation process and therefore with the forfeiture of the application.

During the on-site 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 shall also be allowed to view the accounts documents.

- 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 on-site 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 on-site assessment already performed.

This factor may cause an interruption in the process of accreditation and thus cause the application 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 (the certification of auditors is not obligatory but it is strongly recommended in that it enables the demonstration of the expertise of auditors thereby minimizing the times and modalities of the assessment by ACCREDIA-DC's assessors;

- to observe the behavior 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, programs 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 apply

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) work 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 on-site 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) work 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.

Dependent ACCREDIA-DC assessors cannot be objected to by the CAB other than for grave reasons of incompatibility which shall be explained directly to the DDC.

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 incorporate in its certification regulations clauses guaranteeing access for the ACCREDIA-DC team to the locations of the organizations which are certified or certifying or to locations where audit activities are taking place.

1.3.2.5 If, during the on-site 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.

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 (e.g. suspension or withdrawal of accreditation).

## 1.4. DECISION TAKING 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 work 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 it shall also do when it decides that supplementary/extraordinary assessments or a market surveillance visit are required or if other conditions are imposed.

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 to be understood as granted only and exclusively for each specific certification scheme and sector stated in the decision made by the CSA.
- 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 (which shall only report the legal entity to which accreditation was issued) and corresponding attachment containing the description of the scope of accreditation and its publication on the ACCREDIA website. Accreditation certificates shall be published within 15 work 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.

With the granting of accreditation, any voluntary certifications issued by the CAB before obtaining the status of accredited certifications, acquire the status of accredited certifications unless otherwise specified by the CSA and therefore they must be promptly reissued by the CAB with the relative references to accreditation. As regards the OdI and the accredited Bodies for the purposes of subsequent authorizations and notifications, only the reports and/or certificates issued after the accreditation date will have the status of accredited reports/certificates.

The declarations (certificates) of conformity or conformity assessment (inspection reports) or declarations of validation and verification of GHG inventories in the voluntary area issued by CABs with ACCREDIA accreditation, within the scope of accreditation, shall show the ACCREDA Mark as defined in Regulation RG-09, except if the CAB holds a number of accreditations issued by ABs signatory to the IAF MLA or ILAC MRA agreements, in which case the CAB may choose the Accreditation Mark to use.

The accreditation is valid for four years from the date of the decision with the exception of the annex to the V&V scheme accreditation certificate, relating to environmental areas, 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.

- 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.
- 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 15 work days of the decision, giving reasons and the conditions for continuing the accreditation process, including the documentation to be presented.

## **1.5. SURVEILLANCE AND REWEAL OF ACCREDITATION**

### **1.5.1. SURVEILLANCE OF ACCREDITATION**

#### **1.5.1.1. GENERAL**

Throughout the accreditation cycle, ACCREDIA-DC implements a program 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/IAF documents) and from the owners of voluntary certification schemes.

All accredited CABs shall undergo surveillance activities by means of programmed assessments (formally communicated through an annual surveillance program) and also non-programmed assessments, in order to ensure continued compliance with the present Regulation, the standards and international guidances 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 any other applicable requirements issued internationally by EA/IAF/ISO.

The CAB shall enter in the reserved area of ACCREDIA's website, in the section "Structure of the CAB", the updates carried out in its organization and documents with regard to the information and data provided in the initial application for accreditation (and subsequent applications for extension), which involve significant changes of resources and procedures for certification/inspection/assessment activities. In particular, it is required to update, in the event of changes, the editions of the Quality Manual and the certification/inspection/validation/verification regulations.

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.

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

The maintenance of accreditation is subject to the payment of the costs as contained in the ACCREDIA-DC quotation in accordance with the ACCREDIA pricelist (see § 1.8.2.4).

### **1.5.1.2. PROGRAMMED SURVEILLANCE OF ACCREDITATION**

Regarding programmed assessments (agreed with the CAB by means of a technical and economic program sent by ACCREDIA-DC usually in December or before the end of January), the first surveillance activity consists of an office assessment at the CAB carried out 6 months after the granting of accreditation.

In exceptional cases the DDC or VDDC may authorize the performance of the first surveillance activity after 12 months, e.g. if the CAB has not signed any new contracts.

The subsequent surveillances shall be performed at least once every calendar year starting from the date of the first surveillance assessment and they shall include both on-site and witnessing activities.

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 on-site surveillance are undertaken using similar modalities to those for the accreditation assessment.

If ACCREDIA-DC decides that it is not necessary to perform an on-site surveillance, it shall use a different assessment technique for the same purpose as for the on-site assessment which is substituted, and it shall justify the use of this technique. The time period between the performance of one on-site 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 on-site surveillance/witness assessment (WAs) and the specific surveillance modalities, 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 outcomes of previous assessments; any sanctions imposed; the issuance of any NCs/Concerns during the management of complaints/feedbacks, the management of certifications in critical schemes, the number of certificates issued etc.

The parameters indicated by the Steering and Guarantee Committee in a general sense are published in the area reserved for CABs in ACCREDIA's website.

Any reduction to the surveillance program may be applied by ACCREDIA-DC according to the experience and capacities of the CAB in cases as set out in the specific regulations for the accreditation standard.

### **1.5.1.3. NON-PROGRAMMED ACCREDITATION SURVEILLANCE**

Supplementary and/or extraordinary assessments or Market Surveillance visits, 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.

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 non-programmed assessments – advance notice of at least **7 (seven) work days** is given, during which time period the CAB has the right to present a reservation or objection regarding the ACCREDIA-DC team.

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) work days** and the references of the ACCREDIA-DC team, and asks the CAB to send within **3 (three) work days**, all the documents of the certification process (from the informative questionnaire to the 3-year program, the support checklists, if necessary, but excluding the invoices) of the entire 3-year period, if applicable.

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

The costs of extraordinary assessments (on-site, 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.

Non-programmed surveillance activities consist of on-site 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.

The unannounced assessments may also be ordered by the CSAs to verify the effectiveness of the corrective actions to the findings issued by ACCREDIA, for which the CSA expressed doubts or need for monitoring during the decision stage or ordered by the DDC following receipt of reports from the market/competent authorities or for a response to the mystery audit activities that cast doubt on the reliability of the certification/inspection/validation/verification process of the CAB. The costs will be charged to the Body, in the event that Nonconformities emerge, or in the presence of numerous Concerns (Observations) such as to determine a negative outcome of this activity. Otherwise, the costs shall be met by ACCREDIA.

In the case of unannounced audits, the ACCREDIA assessment team, once it arrives at the CAB's premises, will ask to be able to interface with a manager/contact person, who will not necessarily be the manager of the scheme being assessed, to whom ACCREDIA will explain the aims of the assessment and to whom it will deliver:

- a communication from the ACCREDIA-DC management, containing the reasons underlying this assessment;
- the assessment plan to which the CAB can present any objections/non-acceptances regarding the plan itself or the names of the ACCREDIA Verification Group.

#### **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, 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.

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.);
- extension assessments (limited to cases considered complex).



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;
- 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 the PRS scheme, non-applicability will depend on the professional person being examined (e.g. in cases where a practical test is required with the use of instruments);
- for the regulated area, non-applicability shall be determined according to the scope and, where applicable, the module being assessed.

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.

ACCREDIA-DC, where applicable, may also perform unannounced assessments and mystery audits remotely.

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 VDCC, 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) work days**;
- b) if one or more NCs are raised, the finding is examined and confirmed to the CAB by the DDC or VDCC 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) work 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 VDCC. 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 SCOPE OF ACCREDITATION AND OF THE ACCREDITATION STANDARDS**

##### **1.5.1.6.1. TRANSITION OR MIGRATION TO NEW ACCREDITATION/CERTIFICATION STANDARDS**

If an accreditation/certification standard is updated or modified, 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/IAF/ILAC 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/IAF/ILAC 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 15 working days of the decision, of the expiry of the accreditation, giving the reasons and the conditions for a resumption of the accreditation process.

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**

A CAB may request accreditation with flexible scope (for certification of product, management system, person and for inspection activities) only if it has obtained accreditation with fixed scope for a specific accreditation standard from at least 2 years (see § 1.6.2 concerning extension of accreditation).

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

**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/IAF MLA/BLA 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.

Two cases may be presented in the requests for accreditation transfers:

- straightforward transfer (i.e. with the transfer the CAB loses its original accreditation, usually within two years, to allow the reissue of certificates with ACCREDIA accreditation);
- duplication of accreditation (not applicable for requests coming directly from the accredited legal entity and located in the states in which the EC Regulation 765/2008 and subsequent amendments is in force, for which the duplication would be a violation of Article 6 of the above Regulation which governs the principle of non-competition between ABs).

For the transfer of accreditation the following activities are undertaken:

- straightforward transfer:
  - in compliance with the requirements of the document IAF MD 2, ACCREDIA-DC will carry out a pre-transfer review which will consist of a document review at least 1 man-day during which a series of documents including the reports of the audits carried out shall be assessed from the previous accreditation body in the cycle or starting from the last renewal assessment;
- duplication of accreditation:
  - performance a document review of at least 1 day during which an evaluation of the reports of the assessments conducted by the other Accreditation Body shall also be conducted in the cycle or starting from the last renewal verification;
  - performance of the on-site assessment of a duration equal to that of a renewal assessment;
  - performance of 50% of the witness assessments necessary to grant the entire scope requested.

However, depending on the results of the risk assessment associated with the transfer activity to undertaken, which will include contact with the outgoing AB, ACCREDIA-DC will establish the possible need to increase the assessment activities indicated above.

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/IAF MLA 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**

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 - sub-section procedures and modules - from ACCREDIA's website, 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), by means of an on-site visit.

The on-site visit always takes place in cases of transfer of ownership of accreditation to a non-accredited 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.

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, as well as updating the certificate of accreditation, 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.

If there is a period during which there is no active accreditation, i.e. if the variation was completed before communication to ACCREDIA-DC and/or before the relative decision, no form of accredited certifications shall be granted (e.g. regarding new certificates, renewals, extensions etc.) by neither of the two legal entities until accreditation has been obtained for the new CAB.

In cases of the hiring out of a corporate branch, the duration of the hiring contract shall not be less than the remaining duration of the existing agreement (CO-00) between ACCREDIA-DC and the CAB.

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 regarding environmental scopes), at least six months before the expiry of the certificate ACCREDIA-DC starts the procedure for renewal (with the agreement of the technical program 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 on-site 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 program.

The duration of the on-site renewal assessment is determined by taking into consideration the specific criticalities of the scheme (e.g. number and criticality of the schemes and sectors to be assessed, number of sites 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-TAKING 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:

If – exceptionally – the renewal assessment is done at a date which is too near to that of the relevant CSA meeting and if the assessment being undertaken by ACCREDIA-DC is still underway with regard to the corrective actions formulated by the CAB; or if, following the outcome of the renewal assessment, it is necessary to perform a supplementary assessment on-site or a non-programmed surveillance assessment (e.g. a market surveillance visit), the validity of the accreditation may be prolonged by

the DDC or by the CSA beyond the expiry date until the date of the first CSA meeting subsequent to the expiry.

Further prolonging of accreditation may be deliberated by the CSA.

The certificate of accreditation does not ever last for more than 5 years.

If it is not possible, due to lack of availability of the CAB, to verify the CAB's competence for the entire scope during the accreditation cycle (sectors, macro-sectors, technical areas, categories, etc.) 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 **within 15 work 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 program, 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/programs (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. PRESENTATION AND EXPLANATION 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 in the specific regulation for the accreditation standard.

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 analysis with regard to the CAB and its performance during the accreditation cycle.

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.

### 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.

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 documentary 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 § 1.8 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.

The relevant CSA may decide that it is necessary to perform supplementary assessments or non-programmed 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.

## 1.7. DECISION-TAKING PROCESS AND THE GRANTING OF EXTENSION OF ACCREDITATION

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

When extension of accreditation has been granted ACCREDIA-DC updates the existing accreditation certificate and includes the new scope of accreditation.

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

## **1.8. SUSPENSION, WITHDRAWAL AND REDUCTION OF ACCREDITATION**

### **1.8.1. MINOR SANCTIONS MEASURES**

If the outcome of the on-site and witness assessments, undertaken as part of surveillance activities 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.

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

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 Sector Accreditation Committee (which may review the case) together with all the necessary information.

Minor sanctions may also be imposed by the competent CSA (e.g. in cases of failure by the CAB to send the annual economic data).

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

### **1.8.2. MAJOR SANCTIONS MEASURES**

1.8.2.1 If critical situations emerge following surveillance, supplementary, extraordinary or renewal assessments, or from other controls and checks (e.g. from feedbacks), either of a technical or of a professional 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;
- 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;

- 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 (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;
- failure to respect the requirements of § 1.10.

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 sanctions 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) work 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.

1.8.2.2. 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.

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 § 1.8.2.1.

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.

- 1.8.2.3. 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). Maintenance and renewal certification activities during suspension shall be submitted in advance to ACCREDIA-DC, which defines any witnessing activities, with costs to be met by the CAB.

During this period, the CAB shall conform with the Regulation regarding use of the ACCREDIA Mark (RG-09).

- 1.8.2.4 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.

- 1.8.2.5 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.

- 1.8.2.6 Some examples of situations in which accreditation is reduced or withdrawn are given below:

- 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;

- 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;
- use of accreditation such as to cause serious damage and discredit to ACCREDIA and/or to the system of accreditation and certification.

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.

1.8.2.7. 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 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 MLA agreement signatory status;
- for the product scheme, at the first due surveillance or renewal assessment or at the time of the first modification to the product requiring the CAB's intervention.

The CAB shall also return to ACCREDIA-DC the original certificate (if the paper version still exists); it shall not use any copies or reproductions of the certificate and it shall comply with the Regulation for 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.

1.8.2.8 In the event of withdrawal or reduction of accreditation, 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.

1.8.2.9. 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.

### **1.8.3. SUSPENSION REQUESTED BY THE CAB**

The CAB may make a request for self-suspension for a period of time not exceeding 12 months, after which self-suspension will become withdrawal unless conformity is restored of the accreditation requirements.

The reasons given and the duration of the request for self-suspension 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.

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

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.

However, it should be noted that, in cases where the self-suspension requested by the Body is of the maximum allowed duration (12 months) and that, within this deadline, there is a time period of 2 years from the last assessment activity carried out on the CAB, ACCREDIA-DC shall conduct, before the end of the two years indicated above, the normal surveillance assessment provided for in the accreditation cycle, the duration of which may be increased according to specific needs (e.g. a CAB with one surveillance carried out in January 2020, requests in January 2021, a period in which the second surveillance should be performed, the self-suspension for 12 months. ACCREDIA-DC will carry out in January 2022, before the end of the self-suspension and before two years have elapsed from the last on-site verification, the third surveillance that can be increased in terms of duration).

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 request the extension to other conformity assessment schemes.

### **1.8.4. PROCEDURAL REDUCTION OF THE SCOPE AND RENUNCIATION OF ACCREDITATION**

1.8.4.1 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 audit, inspection or surveillance activities for the duration of the cycle of accreditation with regard to a certain certification scheme and sector or it was not possible to verify the competence of the CAB itself for the entire scope during the accreditation cycle.

Reduction of accreditation, imposed by ACCREDIA-DC, is decided by the competent CSA, whilst only the CSA in question is informed of the voluntary or self-reduction.

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

1.8.4.2 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 audits performed, the closure of findings which remained open or it may perform an unannounced assessment etc.).

The relevant CSA is informed of the withdrawal of accreditation at the first due meeting.

Withdrawal is published on the ACCREDIA website and in the database of accredited Bodies.

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 for management system certification, the certificates issued are deemed to be covered by accreditation for 6 months from the date of renunciation by the CAB of its MLA agreement signatory status.

1.8.4.3 Renunciation of accreditation does not entail the termination of contractual obligations with ACCREDIA, which has the right to carry out forcible collection and recovery of expenses, with interest, in accordance with the law.

### **1.8.5. 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.

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 § 1.8.3) 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.



## 1.9. COMPLAINTS, FEEDBACKS, RESERVATIONS AND APPEALS

### 1.9.1. COMPLAINTS/FEEDBACKS

ACCREDIA-DC may receive complaints/remarks regarding:

- the operations of ACCREDIA-DC;
- the operations of accredited CABs;
- poor services by certified Bodies under accreditation;
- 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/remarks concerning ACCREDIA-DC's assessors (internal or external) shall be presented within **10 (ten) work days** of the conduct of the assessment activity in question.

### 1.9.2. RESERVATIONS

With regard to any findings reported by ACCREDIA-DC assessors, reservations shall be presented within 3 (three) work days of the conduct of the assessment.

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.

Acceptance or non-acceptance is left to the DDC and VDDC. However, for particular cases (e.g. in cases where the reservations presented are of a very technical nature for which specific sectoral competence and knowledge is required, or in cases where the DDC or VDDC has taken part in the evaluation itself), the FT can agree with DDC or VDDC to entrust the evaluation of the reservation to an external assessor (whose name will be communicated to the CAB concerned), whose choice shall guarantee compliance with the competence and independence requirements with respect to the object for which the reservation was formulated.

The appointed ACCREDIA-DC assessor, within 10 work days, shall provide to the DDC or VDDC and the FT 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.



### 1.9.3. 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.

### 1.10. OBLIGATIONS OF THE CAB

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

1.10.2 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.

1.10.3 CABs shall send, in a timely manner to the ST/PRO, when requested, to the email address [programmazione@accredia.it](mailto:programmazione@accredia.it) the updates of the controlled lists of their examiners, the updated and complete programming relating to their exam sessions, as well as the list of audits/inspection activities in planning relating to the schemes/macro-sectors/sectors/technical areas/categories covered by the assessment. This information shall be sent in time for the relative planning and ACCREDIA-DC shall also be allowed to choose the audit group proposed by the CAB, and/or the organization where the witness assessment will be performed. For certification schemes, for which planning is not foreseen, as for some certifications and inspections in the regulated area, the CAB shall collaborate fully with ACCREDIA-DC to identify the activities to be the object of the witness assessment. CABs shall also send, upon request of ACCREDIA-DC, the list of audits performed in the period specified by ACCREDIA-DC in order to enable the performance of the MSV activities.

Where necessary, in accordance with the documents, the CAB undertakes to agree that the ACCREDIA assessors perform assessment visits of the accredited activities, and other assessment techniques provided for by the ACCREDIA Regulations (for example: unannounced visits, mystery audit activities, Market Surveillance Visit etc.) at its premises and at the customers/suppliers to which they are subcontracted by including this possibility in the agreements with the latter, in order to verify that the CAB itself complies with the requirements for accreditation. Some assessment activities may be carried out by ACCREDIA also in remote mode.

1.10.4 The CAB shall promptly communicate formally to ACCREDIA-DC any significant changes in its corporate structure, or transfer of ownership of accreditation to another legal entity following changes to its legal status or sale of a branch to another CAB.

1.10.5 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), except for certifications issued abroad where the application of ACCREDIA technical regulations is optional unless they provide for the application of legislative or regulatory requirements (e.g. implementation of EA/IAF documents) applicable internationally.

1.10.6 All CABs accredited for management system, product and person schemes shall send to ACCREDIA-DC the data regarding entities/organizations possessing certifications which they have issued, in compliance with the procedures defined by ACCREDIA-DC in the relevant instructions and with the existing legal requirements.

The CAB shall send to ACCREDIA-DC (using the web service - SIAC – made available by ACCREDIA-DC with the collaboration of a service company, directly through access to the ACCREDIA website or third parties as indicated by ACCREDIA-DC) timely and correct information concerning certificates issued under its responsibility. The CAB shall also communicate promptly all information related to the withdrawal of certification in the QMS scheme, IAF sector 28, also in compliance with the law. Any further requirements are contained in the specific scheme regulations.

1.10.7 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, CRIF, CERVED, ANAC, ENEA, IAF, ISTAT, credit institutes etc.). The information may be provided in its entirety so that Bodies which receive it may themselves divulge it to the public when it has already been disclosed by ACCREDIA-DC.

CABs are solely responsible with respect to entities benefiting from the service offered (e.g. ANAC, SOA, tender contract companies, the market in general etc.) and with respect to ACCREDIA-DC for any damage arising from inexact or untimely publication of data; therefore ACCREDIA-DC has no financial commitment, dispute or claim for damages resulting from such negligence or failures.

1.10.8 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.

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

1.10.10 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.

1.10.11 With regard to the contents not specifically provided by the present Regulation, article 4 of the contractual agreement (CO-00) is applicable.

1.10.12 The CAB shall have in place an internal procedure which identifies the responsibilities and operative modalities for the inclusion of a new element in its flexible scope. The CAB shall

demonstrate possession and application of a “design” process of its flexible scope regarding the introduction of new products/services, professional persons, inspection activities within the flexible part of the scope of accreditation.

- 1.10.13 The CAB commits to respect all the applicable safety rules in accordance with the applicable regulations and to give to ACCREDIA-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 non-programmed surveillances, for which **7 (seven) work days** are the fixed timeframe.
- 1.10.14 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.
- 1.10.15 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.

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

Failure to comply with the above requirements leads to the imposition of sanctions as referred to in § 1.8.

## **1.11. ACCREDIA-DC’S OBLIGATIONS**

- 1.11.1 ACCREDIA-DC may sub-contract activities to other ABs signatory to the EA/IAF MLA/BLA and ILAC/MRA agreements, informing the CAB of this possibility.
- 1.11.2 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.
- 1.11.3. 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.

- 1.11.4 ACCREDIA-DC shall periodically update the database of Accredited Bodies.
- 1.11.5 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).
- 1.11.6 For everything which is not specifically covered by the present Regulation, article 3 of the contractual agreement, CO-00, is applicable.
- 1.11.7 ACCREDIA-DC performs an internal assessment of the application of the internal procedures regarding the definition and implementation of the duration and range of on-site and witness assessments which are related to the granting, maintenance and renewal of accreditations.
- 1.11.8 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.

**PART 2: ACCEPTANCE CLAUSE**

The present Regulation constitutes an integral part of the Contractual Agreement between ACCREDIA-DC and the CAB (Accreditation Agreement).

By undersigning this document, the CAB declares that it accepts de facto all the conditions contained in the present Regulation, as well as the specific regulations for the accreditation standard and the standards, guides and reference documents cited in the Regulation.

Stamp of the CAB and signature of the legal representative or empowered attorney

Date .....

In accordance with articles 1341, 1342 of the Civil Code, the conditions of the present Regulation and the conditions of the specific regulations for the accreditation standard are duly approved.

Stamp of the CAB and signature of the legal representative or empowered attorney.

## **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 program 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).

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.