ACCREDIA
ENTE ITALIANO DI ACCREDITAMENTO

Certification and Inspection Department

Regulation for the accreditation of Product/Service/Process Certification Bodies

RG-01-03

REVISION

04

DATE

15-04-2026

TITLE **Regulation for the accreditation of Product/Service/Process Certification Bodies**

REFERENCE **RG-01-03**

REVISION **04**

DATE **15-04-2026**

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

PREPARATION

The Director of Certification and Inspection Department

APPROVAL

The Directive Council

AUTHORIZATION

The President

APPLICATION DATE

01-11-2026

Contents

0. Foreword

0.1. Scope and field of application

The present Regulation is applicable to the accreditation of Certification Bodies of product/service/process (hereafter referred to as CBs), setting 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 CBs in accordance with the applicable standards and guides, with the relevant clarifications and details in cases where the reference standards for the scheme provide only general requirements which are not covered by the General Regulation, RG-01.

The present regulation shall not be applied separately from the application of the General Regulation RG-01.

0.2. Normative references

The normative references to be considered for the application of the present Regulation are detailed/referred to in the version in force of the ACCREDIA LS-02 document: “Reference standards and documents for the accreditation of certification bodies”.

It follows that – in the framework of a given accreditation or certification scheme or sector, the use of this Regulation is integrated by the specific regulations and technical documents (RT and DT) and technical circulars, if any.

0.3. Terms and definitions

The terms and definitions contained in the General Regulation RG-01, of the applicable standards and the following scheme specific definitions shall apply:

- Homogeneous product categories: a set of products whose certification requires similar technical competence of personnel, testing equipment and certification rules.

0.4. Acronyms

- ACCREDIA–DC: ACCREDIA Department of Certification and Inspection Bodies;
- CSA: Sectoral Accreditation Committee;
- DDC: Director of the Department of Certification and Inspection;
- VDDC: Vice Director of the Department of Certification and Inspection;
- FT: Technical Officer.

Part 1 – General requirements regarding the accreditation process

1. Criteria and information for accreditation

1.1. General information

Accreditation and subsequent listing on the database are granted to CBs that perform the certification of a product/service/process in accordance with the standards and reference documents applicable to them and detailed/referred to in the ACCREDIA document LS-02.

Accreditation regarding product/service/process (PRD) certification activities is issued referring to the applicable single standards or reference standards. Within this scheme ACCREDIA-DC may define appropriate homogeneous accreditation categories.

1.1.1. Accreditation of CBs related to specific areas

For the accreditation of certain product/service/process schemes, ACCREDIA-DC may define guidance in support of the specific scheme, as well as requirements for applying for and maintaining accreditation, set out in issued documents, typically in the form of circulars. In such cases documents issued by ACCREDIA-DC as above are an integral part of the contractual obligations between the CB and ACCREDIA-DC.

1.2. Submission and processing of the application for accreditation

The provisions of General Regulation RG-01 shall apply, with the clarification that an application for accreditation of a CB must be submitted to ACCREDIA-DC using the relevant forms DA-00 and DA-01, available on the ACCREDIA website, together with all the documentation required therein. Where the CB applies for accreditation with a flexible scope in accordance with ACCREDIA Regulation RT-37, the application shall be submitted to ACCREDIA-DC using form DA-10, also available on the ACCREDIA website. ACCREDIA-DC shall assess compliance with the admissibility requirements in accordance with the provisions set out in the aforementioned Technical Regulation.

The CB shall propose the formulation of the accreditation scope for the requested product/service/process certifications. ACCREDIA-DC shall assess the accuracy and completeness of such scope from the application acceptance stage onwards. The final formulation shall be defined at the time of granting accreditation by the relevant CSA.

The accreditation application aimed at subsequent public authorisation for notification purposes under the New Approach Community Directives, or other regulations requiring accreditation as a condition for public

authorisation measures, shall be submitted to ACCREDIA-DC using forms DA-00 and DA-04 or DA-13, available on the ACCREDIA website, together with all the documentation required therein.

1.3. Accreditation process

1.3.1. Document review

The provisions of General Regulation RG-01 shall apply.

1.3.2. Assessments

If the findings raised following the initial assessment do not necessitate supplementary assessment activities the process of accreditation proceeds with one or more than one witness assessment, if provided for and in accordance with the modalities of the specific accreditation scheme or documents issued by ACCREDIA-DC.

In specific cases (e.g. notifications, Organic sector, designations of origin, etc.), witness assessments may be carried out following the granting of accreditation and the relevant ministerial authorisation. In such cases, the CB shall be required to inform ACCREDIA-DC well in advance of the first assessment activity, during which the witnessing assessment will be organised.

For accreditation areas intended for notification purposes, this activity must be carried out within 18 months from the issuance of the specific accreditation. If this is not possible, the provisions of the current revision of document DT-01-DC will apply (see § 1.9.2 below). The 18-month timeframe shall also apply to other possible accreditation fields where it has not been possible to conduct the witnessing assessment prior to the accreditation decision, without prejudice to cases in which different timelines have been agreed with the relevant Authority and/or established through specific circulars and/or set out in applicable EA/Global documents.

The witness assessment involves observing the behavior of the CB's Evaluators during the activities related to the product certification (e.g. inspection of sampling, presence during tests, examination of manufacturer's records etc.).

Witness assessments have the following objectives:

- to verify the effectiveness of the CB's procedures with particular reference to the deployment of Evaluators, ensuring that they possess the necessary experience and competence;
- to observe the performance of the Evaluators and their compliance with the CB's procedures and any other applicable normative requirements governing the CB itself.

1.4. Decision-making process and granting of accreditation

The provisions of General Regulation RG-01 shall apply with the following clarification:

- for some specific schemes (e.g. Organic, designations of origin, etc.) a general accreditation scope can be issued which will be subsequently detailed, after carrying out the witness assessments and decision of the relevant CSA.

The provisions of Technical Document DT-01-DC, in its current revision, shall also apply to the maintenance of accreditations for notification purposes relating to CE marking.

1.5. Surveillance and renewal of accreditation

1.5.1. Surveillance of accreditation

1.5.1.1. General

The provisions of General Regulation RG-01 shall apply.

1.5.1.2. Scheduled surveillance of accreditation

The provisions of General Regulation RG-01 shall apply with the following clarification:

- the office and witness assessments shall be planned so as to allow a representative sampling of the accreditation scope over the accreditation cycle.

1.5.1.3 Unscheduled surveillance of accreditation

The provisions of General Regulation RG-01 shall apply.

1.5.1.4. Scheduled and unscheduled surveillance of accreditation

The provisions of General Regulation RG-01 shall apply.

1.5.1.5 Decision-making process and granting of maintenance of accreditation

The provisions of General Regulation RG-01 shall apply, as well as those of Technical Document DT-01-DC, in its current revision, for the maintenance of accreditations for notification purposes relating to CE marking.

1.5.1.6 Changes to the accreditation scope and accreditation standards

The provisions of General Regulation RG-01 shall apply.

1.5.1.7 Transfer of accreditation between accreditation bodies

The provisions of General Regulation RG-01 shall apply.

1.5.1.8 Transfer of ownership of accreditation

The provisions of General Regulation RG-01 shall apply.

1.5.2. Renewal of accreditation

1.5.2.1 Conduct of the process of renewal of accreditation

The provisions of General Regulation RG-01 shall apply.

1.5.2.2 Decision-making process and granting of renewal of accreditation

The provisions of General Regulation RG-01 shall apply, as well as those of Technical Document DT-01-DC, in its current revision, for the maintenance of accreditations for notification purposes relating to CE marking.

1.6. Extension of accreditation

1.6.1. General information

The provisions of General Regulation RG-01 shall apply.

1.6.2. Submission and processing of the application for extension

An application for extension of a CB's accreditation must be submitted to ACCREDIA-DC using the relevant forms DA-00 or DA-01, available on the ACCREDIA website, together with all the documentation required therein.

The application shall be fully and clearly completed, providing all required data and information, giving reasons for any inapplicability if not fully completed; any failure to do so to may result in non-acceptance of the application. Given the specificity of this accreditation scheme, ACCREDIA-DC reserves the right to ask for further documentation when necessary for the application for extension.

An application for extension of accreditation aimed at subsequent public authorisation for notification purposes under the New Approach Community Directives, or other regulations requiring accreditation as a condition for

public authorisation measures, shall be submitted to ACCREDIA-DC using forms DA-00 and DA-04 or DA-13, available on the ACCREDIA website, together with all the documentation required therein.

Where the CB applies for an extension with flexible scope in accordance with ACCREDIA Regulation RT-37, the application shall be submitted to ACCREDIA-DC using form DA-10, also available on the ACCREDIA website. ACCREDIA-DC shall assess compliance with the admissibility requirements in accordance with the provisions set out in the aforementioned Technical Regulation.

1.6.2.1. Flexible scope

For the extension of accreditation to flexible scope, the requirements set out in the General Regulation RG-01 and in the Technical Regulation RT-37 in current revision shall apply.

1.6.3. Document review

The provisions of General Regulation RG-01 shall apply, with the clarification that ACCREDIA-DC shall take into account any document reviews carried out during the year for the same accreditation standard.

1.6.4. Assessments

Following the positive outcome of the above document review, the extension process shall normally proceed with the carrying out of one or more office and/or witness assessments, to be conducted only following an evaluation of their necessity, in relation to the novelty and criticality of the extension compared to the existing scope, and in any case in accordance with the specific accreditation rules (where applicable).

In some cases (e.g. some Designations of Origin) the application for extension may be evaluated only on the basis of a document review, without an assessment at the premises of the CB or a witness assessment, if this possibility is expressly provided for by ACCREDIA-DC.

In specific cases (e.g., notifications, the Organic sector, designations of origin, etc.), witness assessments may be carried out following the granting of accreditation and the corresponding Ministerial authorization. In such cases, the CB shall inform ACCREDIA-DC of the execution of the first assessment activity, during which the witness assessment will be organized.

For accreditation areas intended for notification purposes, this activity must be carried out within 18 months from the issuance of the specific accreditation. If this is not possible, the provisions of the current revision of document DT-01-DC will apply (see § 1.9.2 below). The 18-month timeframe shall also apply to other possible accreditation fields where it has not been possible to conduct the witness assessment prior to the accreditation decision, without prejudice to cases in which different timelines have been agreed with the relevant Authority and/or established through specific circulars and/or set out in applicable EA/Global documents.

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

The provisions of General Regulation RG-01 shall apply, with the following clarification:

- for certain specific schemes (e.g. Organic, Designations of Origin, etc.), a general accreditation scope may be issued, which shall be subsequently detailed following the relevant witness assessments and the decision of the relevant CSA.

The provisions of Technical Document DT-01-DC, in its current revision, shall also apply to the maintenance of accreditations for notification purposes relating to CE marking.

1.8. Additional provisions

The provisions of the General Regulation RG-01 shall apply.

1.9. Suspension, withdrawal and reduction of accreditation

1.9.1. Minor sanctioning measures

The provisions of General Regulation RG-01 shall apply.

1.9.2. Major sanctioning measures (suspension, reduction, withdrawal)

The provisions of General Regulation RG-01 shall apply, with the following clarifications:

The identification of serious deficiencies in the oversight of the internal management system and/or in product/service/process certification schemes shall result in the adoption of the most severe sanctioning measures.

In the event that a CB loses accreditation (for its own reasons or as a result of a sanctioning measure), the certificates issued shall retain the value of accredited conformity assessment for six months, except in cases where the relevant sector Authorities issue specific instructions or where their opinion must be obtained to determine the validity status of the issued certifications.

In such cases, another CB accredited for the same scheme, having evidence of the possession of a valid accredited certificate, may carry out renewal or surveillance activities and transfer the certificate in accordance with the rules of the specific certification scheme, even where the previous documentation held by the former CB is not available.

For CBs operating in the mandatory/regulated area the decisions of the CSA, where provided for, shall be sent by ACCREDIA-DC in copy to the competent authorities (e.g. the ministries), for their further evaluation.

In cases where a CB requests accreditation for the purpose of subsequent initial authorization for Notification or another form of public authorization in regulated areas, ACCREDIA shall carry out at least one witness

assessment, selected among those provided for, during the first conformity assessment activity performed by the Body.

Such witness assessment (including, where applicable, the evaluation of a Module B) must be carried out within a maximum period of 18 months from the granting of the accreditation/extension. If the assessment is not conducted within this period, the accreditation for that specific conformity assessment activity shall be revoked. The 18-month timeframe shall also apply to other possible accreditation fields where it has not been possible to conduct the witness assessment prior to the accreditation decision, without prejudice to cases in which different timelines have been agreed with the relevant Authority and/or established through specific circulars and/or set out in applicable EA/Global-ACI documents.

Once the accreditation has been revoked, the CAB may submit a new application. With regard to fields for notification purposes the option to be accredited with the deferral of the witness assessment activity (i.e., after receiving the first client requests) will no longer be applicable. In such cases, the standard accreditation process shall apply, meaning that a (obviously simulated) witness assessment must be carried out prior to the decision on accreditation or extension.

The effects on the market of a suspension or withdrawal of accreditation do not depend on ACCREDIA-DC but on the competent authorities, when they use the accreditation for the purpose of notification or authorization.

1.9.3. Suspension requested by the CB

The provisions of General Regulation RG-01 shall apply.

1.9.4. Procedural reduction of scope, withdrawal and renunciation of accreditation

The provisions of General Regulation RG-01 shall apply.

The provisions of Technical Document DT-01-DC, in its current revision, shall also apply to the maintenance of accreditations for notification purposes relating to CE marking.

1.9.5. Restoration of accreditation

The provisions of General Regulation RG-01 shall apply.

1.10. Complaints/reports, reservations and appeals

1.10.1. Complaints

The provisions of General Regulation RG-01 shall apply.

1.10.2. Reservations

The provisions of General Regulation RG-01 shall apply.

1.10.3. Appeals

The provisions of General Regulation RG-01 shall apply.

1.11. Obligations of the CB

The provisions of General Regulation RG-01 shall apply with the clarification, where required by the rules of the scheme, the CB must allow the scheme owners to conduct any checks without prior notice (e.g. Textile Exchange, etc.).

1.12. Obligations of ACCREDIA-DC

The provisions of General Regulation RG-01 shall apply.

2. Part 2 - Requirements for Product/Service/Process Certification Bodies

Part 2 contains a series of requirements regarding the organization and proceedings of the Certification Bodies of Product/Service/Process, with which the CBs are required to comply in the context of conformity with the applicable reference regulations.

2.1. Organization and operation of a Certification Body

2.1.1. Composition and characteristics of the bodies/functions involved in the activities of the Body and in the issuance of certifications

The following requirements — consistent with the accreditation standards and guidance documents — apply to the bodies/functions of the CB responsible for decision-making tasks or otherwise significant activities relating to the management of the CB and the issuance of certifications.

For the purposes of broadest application, consideration is given to the general case of a CB in which separate bodies/functions exist, all of which are competent — albeit to different extents and in different ways — in matters relating to the management of the CB and the issuance of certifications, and requirements are provided for each of the above-mentioned bodies/functions.

ACCREDIA-DC reserves the right to access not only the records of the above-mentioned bodies/functions, but also their meetings, in order to verify that their actual composition during meetings and their operation comply with the applicable provisions.

The composition and rules of procedure of the aforementioned bodies shall comply with the provisions of ISO/IEC 17065 and with any requirements laid down in applicable Directives, Regulations, national laws/Authority provisions, etc., relevant to the specific scheme.

2.1.1.1. Technical function for certification decision-making

The requirements of ISO/IEC 17065 shall apply, supplemented by any specific rules defined by the relevant scheme/technical circulars/Directives/Regulations/national laws/provisions issued by the Authorities.

2.1.1.2. Formulation of certification scopes

The provisions of Regulation RG-01 shall apply, together with the following requirements arising from the application of EA TMB Resolution 2026 (25) 02.

The description of the certification scope, in accordance with ISO/IEC 17065, as stated on certificates, shall be relevant and consistent with the requirements of the certification scheme under which the assessment activities were carried out and the certification was granted.

It shall not be permitted to include references or statements relating to a certification scope that does not fall within the scope of the applicable certification scheme and which, therefore, has not been subject to assessment activities by the certification bodies.

Note: This implies, for example, that it is not permitted to include a Protected Designation of Origin (PDO) and/or Protected Geographical Indication (PGI) claim in a food safety process certificate, where PDO/PGI requirements are not explicitly included among the elements assessed within the certification scheme.

2.2. Conduct of certification activities

Documents, or parts thereof, specifying the rights and obligations of the client and those of the CB shall be made available to the client prior to, or at the same time as, the signing of the formal application for certification.

The CB shall make available general information concerning the fees applied to the applicant and the clients as set out in the standard ISO/IEC 17065.

For the performance of its certification activities concerning the geographical areas in which it operates the CB shall be able to demonstrate that it:

- has evaluated the risks deriving from its activities;
- has taken adequate measures (for example insurance coverage or provisions for risks entered in the accounts) to cover the professional risks of internal personnel and collaborators (e.g. Evaluators, certification decision-making committees) arising from its activities, including in relation to the activities of its clients.

For mandatory/regulated areas for which the existence of a signed insurance policy is required by regulations/laws, it is mandatory to refer to the requirements set out therein.

To increase the effectiveness of the assessment and certification activities, CBs may use, also depending upon the type of organization requesting certification (e.g. services delivered to the public/consumers) special techniques such as mystery or undeclared audit.

This type of assessment activity shall be agreed with the client, contractually specified and, where applicable, included in the audit plan/programme, indicating at least: the sampling carried out (processes, sites, etc.), the possible period of intervention and the organisational logistics.

2.3. Separation between certification activities and consultancy activities

The CB shall keep documents available to ACCREDIA-DC which constitute objective evidence of the absolute separation between the certification activities and any consultancy activities or other incompatible activities carried out by entities (individuals and legal entities) affiliated in any way. Such separation shall be ensured in

relation to every aspect and stage of the CB's activities, from the definition of policies and strategic directions, through the entire certification process, up to the granting, maintenance and renewal of certifications.

To this end, the CB shall conduct an appropriate analysis of the associated risks in order to issue certifications ensuring the principles of competence, independence and impartiality, documenting the results and motivating the conclusions drawn and the solutions adopted, with particular regard to the problems related to the use of Evaluators also working as consultants.

CBs shall define risk indicators to be monitored periodically in order to ensure that the level of risk is eliminated or minimized.

To this end, a useful guide is represented by the Recommendations made by ACCREDIA's Steering and Guarantee Committee (CIG) relating to the definition of homogeneous criteria for the verification of some requirements of the standard ISO/IEC 17065 during the assessment and surveillance of the accredited CBs. It is recommended to use the document issued by the Steering and Guarantee Committee as a basis for developing the risk analysis document, or as a checklist for carrying out internal or external audits.

3. Part 3 – Provisions relating to the conformity assessment process for Product/Service/Process

3.1. Requirements for Product/Service/Process Certification Bodies

For the definition of the certification scheme, the CB shall demonstrate that it applies the guidelines of ISO/IEC 17067 in its current version, including:

- Type of scheme applied (e.g. Type 5);
- Assessment methods for granting, maintaining, renewing (where applicable), extending, modifying, reducing scope, suspending and withdrawing certification;
- Duration/effort required for the assessment stages;
- Competence of personnel and resources;
- Content of the certificate of conformity.

The CB shall keep available to ACCREDIA-DC all records relating to the activities carried out, with particular reference to: legally valid contracts, execution timelines and plans/programmes, characteristics of the sampling carried out, adopted acceptance criteria, outsourced activities (e.g. laboratories, audit/inspection bodies, etc.) and the relevant accreditation status or qualification outcomes of the subcontractors used (with the exception of bodies accredited by ACCREDIA), etc.

Where the certification scheme includes testing or calibration activities performed by laboratories, these shall operate in accordance with the relevant requirements of ISO/IEC 17025.

Accreditation of the laboratory for the specific activity shall be sufficient to demonstrate its competence.

Where a laboratory is not accredited for the specific activities, the CB shall carry out first/second-party assessments at the laboratory, preferably using the applicable parts of the ACCREDIA Laboratory Department checklist, which is publicly available on the ACCREDIA website. This checklist should also be sent in advance to the laboratory so that it may evaluate its use for its internal audits. The evidence of the CB's assessment of the laboratory is subject to review by ACCREDIA-DC, which may also decide to witness first/second-party audits carried out by the CB at the laboratory premises.

It is noted that, in accordance with IAF MD-07, CBs shall not perform third-party conformity assessment activities for activities falling within MLA Level 1–4. Therefore, in relation to the assessments performed, CBs shall not issue statements or certifications to the laboratory in accordance with ISO/IEC 17025. Failure to comply with this requirement shall result in the adoption of sanctioning measures as set out in § 1.9.2.

Such audits shall be conducted, where possible, with the use of the applicable parts of the control list of the ACCREDIA Department of Laboratories. The list should be sent in advance also to the laboratory so that it can evaluate its use for its own internal audits. Such documentation is publicly available on the ACCREDIA website.

The CB is also encouraged to promote, for laboratories which are not yet accredited for the tests in which the Body is interested, a programme to support progression towards accreditation, starting with laboratories performing tests related to health, safety and environmental protection aspects.

Where the CB grants the manufacturer of the product or the provider of the service a licence to use its conformity mark, it shall ensure that the mark is clearly and unambiguously linked to the quality characteristics covered by the certification. In any case, the conditions for affixing the conformity mark shall not contravene the provisions of applicable EU requirements for mandatory product marking (e.g. CE marking).

With regard to the competence of personnel involved in conformity assessment activities (internal functions managing certification files and evaluators), the CB shall ensure, through the definition of requirements and the demonstration of compliance with them, that:

- personnel possess the required competence and/or experience, as well as any other applicable requirements where required by current legislation;
- the personnel have adequate knowledge of the audited products, including, if applicable, any criticalities related to their use, if there is awareness of this situation;
- the personnel have the necessary knowledge regarding the tests performed and the analysis of the results and their application concerning the declaration of conformity. This involves, among other things, technical knowledge of sampling, validity and validation of testing methods and management of uncertainties related to the results.

The grade of extension and depth of knowledge and activities as defined above shall be related to the task undertaken and may be different for the Body's personnel and for audit personnel, including personnel responsible for final review and decision-making.

3.1.1. Remote assessment activities

Conformity assessment activities shall be carried out on-site, except where clearly permitted otherwise in scheme documents defined by ACCREDIA circulars, the Scheme Owner, normative documents, or the relevant Authorities.

In such exceptional cases, the CB shall conduct a suitably structured risk analysis to determine the feasibility of carrying out the assessment activity remotely (in full or in part), also taking into account requirements arising from international documents (e.g. the current revision of IAF MD 4). Records shall be kept available to ACCREDIA. Force majeure cases governed by EA/Global documents shall also apply as exceptions. Even in the application of such derogations, the CB is responsible for maintaining appropriate evidence and records and making them available to ACCREDIA upon request.

ACCREDIA

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

Certification and Inspection Department

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

Testing Laboratories Department

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

Calibration Laboratories Department

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