ACCREDIA
ENTE ITALIANO DI ACCREDITAMENTO

Certification and Inspection Department

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

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

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

PREPARATION

The Director of Certification and Inspection Department

APPROVAL

The Directive Council

AUTHORIZATION

The President

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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/voluntary reduction, suspension/voluntary suspension, restoration, renunciation and withdrawal of accreditation of the CB in accordance with the applicable standards and guides, with the relevant specifications 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 reference standards 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 are applicable:

- Homogeneous product families: certification of products requiring technical competences of personnel, testing equipment, certification rules and similar.

0.4. Acronyms

- ACCREDIA–DC: ACCREDIA Department of Certification and Inspection Bodies;
- CSA: Sector 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. Requirements and informations for accreditation

1.1. General informations

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. In the ambit of this scheme ACCREDIA-DC may define appropriate homogeneous accreditation families.

1.1.1. Accreditation of CBS related to specific areas

In defining some product/service/process schemes, ACCREDIA-DC may establish the rules of the scheme as well as the requirements to apply for and maintain accreditation in documents issued for the scope, normally in the form of circulars (for example for the END OF WASTE scheme). 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. Presentation regarding the application for accreditation

The provisions of General Regulation RG-01 are applicable with the specification that the application shall be presented to ACCREDIA-DC using the modules DA-00 and DA-01 which are available on ACCREDIA's website, together with all other necessary documents.

The CB shall propose the scope of accreditation for the certification of the products/services/process in question. ACCREDIA-DC, starting from the phase of acceptance of the application, evaluates the correctness and completeness of the scope. The definitive version will be established during the phase of issue of the accreditation, undertaken by the relevant CSA.

The application for accreditation for public authorization for notification concerning the EU directives of the New Approach or other standards which include public authorization provisions, shall be presented to ACCREDIA-DC using the modules DA-00 and DA-04 or DA-13, available on ACCREDIA's website, together with all the requested documentation.

1.3. Accreditation process

1.3.1. Document review

The provisions of General Regulation RG-01 are applicable.

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 (WA), 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 can be carried out following the granting of accreditation and the related ministerial authorization. In such cases, the CB shall inform ACCREDIA-DC about performance of the initial assessment, during which the witness assessments 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 § 1.8.2 below).

Witness assessments (WA) involve observing the behavior of the CB's audit team during the activities related to the product certification (e.g. inspection of sampling, presence during tests, examination of manufacturer's records etc.).

Witness assessments (WA) have the following objectives:

- to verify the effectiveness of the CB's procedures, especially the use on-site of auditors who possess the necessary experience and expertise;
- to observe the behavior of the auditors and the conformity of their behavior with the CB's procedures and with every other reference standard/requirement applicable to the CB.

1.4. Decision-making process and granting of accreditation

The provisions of General Regulation RG-01 are applicable with the following specification:

- 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 assessment (WA) and decision of the relevant CSA.

For the maintenance of accreditations related to notifications concerning CE marking, the provisions of the current revision of Technical Document DT-01-DC shall also apply.

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 are applicable.

1.5.1.2. Programmed surveillance of accreditation

The provisions of General Regulation RG-01 are applicable with the following specification:

- the on-site and witness assessments are planned in such a way as to permit a representative sampling of the scope of accreditation, during the entire cycle of accreditation;

1.5.1.3 Unprogrammed surveillance of accreditation

The provisions of General Regulation RG-01 are applicable.

1.5.1.4. Programmed and unprogrammed surveillance of accreditation

The provisions of General Regulation RG-01 are applicable.

1.5.1.5 Decision-making process and granting of maintenance of accreditation

The provisions of General Regulation RG-01 are applicable, as well as the provisions of the current revision of Technical Document DT-01-DC, for the maintenance of accreditations intended for notifications related to CE marking.

1.5.1.6 Changes to the scope of accreditation and to the accreditation standards

The provisions of General Regulation RG-01 are applicable.

1.5.1.7 Transfer of accreditation between accreditation bodies

The provisions of General Regulation RG-01 are applicable.

1.5.1.8 Transfer of ownership of accreditation

The provisions of General Regulation RG-01 are applicable.

1.5.2. Renewal of accreditation

1.5.2.1 Performance of the process of renewal of accreditation

The provisions of General Regulation RG-01 are applicable.

1.5.2.2 Decision-making process and granting of renewal of accreditation

The provisions of General Regulation RG-01 are applicable, as well as the provisions of the current revision of Technical Document DT-01-DC, for the maintenance of accreditations intended for notifications related to CE marking.

1.6. Extension of accreditation

1.6.1. General information

The provisions of General Regulation RG-01 are applicable.

1.6.2. Presentation and explanation of the application for extension

A CB shall present its application for extension of accreditation to ACCREDIA-DC using the modules DA-00 and DA-01, available on ACCREDIA's website, together with all the necessary documents.

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.

For an application for extension of accreditation of an accredited CB for the purpose of public authorization for notification concerning the EU directives of the New Approach or other standards for which the public authorities require accreditation, the application shall be presented to ACCREDIA-DC using the modules DA-00 and DA-04 or DA-13, available on ACCREDIA's website, together with all the necessary documents.

The application cannot be accepted if a sanction blocking extension is in place in accordance with § 1.8.

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 apply.

1.6.3. Document review

The provisions of General Regulation RG-01 are applicable with the specification that ACCREDIA-DC will take into account any document reviews carried out during the year for the same accreditation standard.

1.6.4. Assessments

After positive outcome of the document review, the process of extension normally continues with the performance of one or more on-site and/or witness assessments, when necessary, related to the novelty and criticalities of the extension with respect to the pre-existing scope, in accordance with the modalities of the accreditation rules (where such exist).

In some cases (e.g. the End of Waste scheme, Industry 4.0) 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 § 1.8.2 below).

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

The provisions of General Regulation RG-01 are applicable with the following specification:

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

For the maintenance of accreditations granted for the purpose of notification under CE marking, the applicable provisions of the current revision of Technical Document DT-01-DC shall apply.

1.8. Suspension, withdrawal and reduction of accreditation

1.8.1. Minor sanctions measures

The provisions of General Regulation RG-01 are applicable.

1.8.2. Major sanctions measures (suspension, reduction, withdrawal)

The provisions of General Regulation RG-01 are applicable with the following specifications:

The presence of grave failures in the management of the systems/product/process certification schemes involves the imposition of major sanctions.

If a CB's accreditation is terminated, either due to voluntary renunciation or to the imposition of a sanction, the certificates already issued remain valid until their original expire date (if valid annually) or until the next first surveillance audit (if applicable), except in areas in which the relevant authorities for the sector give specific indications or it is necessary to obtain the opinion of the authorities for the determination of the validity status of the certifications issued.

In such cases in which the certificates already issued remain valid until their natural expiry date (if valid annually) or the next first surveillance visit, another CB accredited for the same scheme, with evidence of possession of a valid accredited certificate, may perform renewal or surveillance activities by transferring the certificate and respecting the rules for renewal/surveillance as set out in the specific certification scheme, also in the absence of the documentation previously possessed by the previous CB.

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 Certification Body 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 (suspended first, if applicable).

Once the accreditation has been revoked, the CAB may submit a new application; however, 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 above-mentioned provisions are intended to apply to all regulated areas.

However, the timing for conducting witness assessments may differ if established by the relevant National Authority or by applicable EA/IAF documents (e.g., a 24-month period applies for the field of DOP, IGP, STG products, and a 48-month period for the organic sector).

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.

1.8.3. Suspension requested by the CB

The provisions of General Regulation RG-01 are applicable.

1.8.4. Reduction of scope and renunciation of accreditation

The provisions of General Regulation RG-01 are applicable.

For the maintenance of accreditations related to notifications concerning CE marking, the provisions of the current revision of Technical Document DT-01-DC shall also apply.

1.8.5. Restoration of accreditation

The provisions of General Regulation RG-01 are applicable.

1.9. Complaints, reservations and appeals

1.9.1. Complaints

The provisions of General Regulation RG-01 are applicable.

1.9.2. Reservations

The provisions of General Regulation RG-01 are applicable.

1.9.3. Appeals

The provisions of General Regulation RG-01 are applicable.

1.10. Obligations of the CB

The provisions of General Regulation RG-01 are applicable with the specification, 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).

1.11. Obligations of ACCREDIA-DC

The provisions of General Regulation RG-01 are applicable.

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 systems/product/process, with which the CBs are required to comply in the context of conformity with the applicable reference regulations.

2.1. Organization and proceedings of a Certification Body

2.1.1. Composition and characteristics of CB's Bodies/Personnel involved in the granting of certifications

The following provisions, in line with the accreditation standards and guides of accreditation, are applicable to the CB's bodies and personnel who are responsible for decision-taking tasks or other important decisions with regard to the CB's management and the granting of certifications.

For a fuller application, a general case of a CB is considered whereby the CB which possesses a number of competent staff performing different tasks, involved in management of the CB and in the granting of certification, with different operative rules for each personnel member or body.

ACCREDIA-DC retains the option to access, as well as the official files of these personnel members, also their meetings, in order to ascertain that the persons present at meetings and that the proceedings of these meetings are in conformity with the applicable dispositions.

The composition and rules for the proceedings of the bodies referred to of the CB shall be in conformity with the standard UNI CEI EN ISO/IEC 17065).

2.1.1.1. Mechanism for the safeguarding of impartiality

The provisions of the standard UNI CEI EN ISO/IEC 17065 § 5.2 are applicable.

2.1.1.2. Technical staff for decisions regarding certification:

§ 7.6 of the standard UNI CEI EN ISO/IEC 17065 is applicable, with the addition of any specific rules defined by the scheme/reference technical circulars.

2.2. Performance of certification activities

The documents or parts of the documents specifying the rights and tasks of the CB and of the client organization shall be made available to the client before or concurrently with the signature of the formal certification application.

The CB shall make available general information concerning the pricelist applied to the applicant and the clients as set out in the standard UNI CEI EN ISO/IEC 17065, § 4.6 b).

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 (e.g. insurance or risk funds) to cover professional risks of internal staff and collaborators (e.g. auditors, decision-taking committees) deriving from its activities, also with regard 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 must be agreed with the cleint, specified contractually and if possible reported on the audit plan/program, indicating at least: the sampling performed (processes, locations, etc.), the possible intervention period and organizational 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 carried out by parties (individuals and legal entities) in any way connected to it. This separation shall be guaranteed concerning every aspect and moment of the activities carried out by the CB, starting from the definition of policies and guidelines, through the development of the entire certification process, up to the issuance, maintenance and renewal of certifications.

In order to do this the CB shall conduct an appropriate analysis of the associated risks in order to issue certifications ensuring the principles of competence, consistency 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 auditors also working as consultants.

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

In order to do this a useful guide is represented by the Recommendations made by ACCREDIA's Steering and Guarantee Committee relating to the definition of homogeneous criteria for the verification of some

requirements of the standard UNI CEI EN 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. The ascertained violation of the above provisions entails the imposition of the sanctions set out in § 1.8.

3. Part 3 – Provisions relating to Product/Service/Process Certification Systems/Schemes

3.1. Provisions for Product/Service/Process Certification Systems/Schemes

In the area of the certification scheme the CB shall retain all the records available for ACCREDIA-DC relating to the activities performed, including outsourced activities (e.g. to laboratories, auditing/inspection companies etc.) with particular reference to the following aspects: performance times, characteristics of the samples taken, acceptance criteria adopted, accreditation status or the qualification results of the accredited laboratories used, etc. (apart from laboratories accredited by ACCREDIA.) etc.

The CB shall also have available for ACCREDIA-DC the documentation regarding the results of verifications of conformity to the standard UNI CEI EN ISO/IEC 17025, performed in non-accredited laboratories used in the certification scheme and give evidence of the competence of the personnel used for these audits.

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 shall be sent in advance also to the laboratory so that it can evaluate its use for its own internal audits.

The CB shall also promote, for laboratories which are not yet accredited for the tests in which the CB is interested, a program of awareness in accreditation, starting with laboratories which carry out tests related to matters of health, safety and environmental protection.

If the CB offers, to the producer of goods or to the supplier of services, the use of its conformity mark, it shall make sure that the mark is clearly and unambiguously related to the qualitative characteristics of the object of the certification, as well as, (where applicable) the procedures of certification (e.g. marks related to surveillance).

With regard to the expertise of the certification activities personnel (internal staff managing files and auditors), the CB shall ensure, by means of the definition of the requirements and evidence of conformity, that:

- the personnel has the necessary expertise and/or experience, where required by the legal requirements in force;
- the personnel has adequate knowledge of the audited products, including, if applicable, any criticalities related to their use, if there is awareness of this situation;
- the personnel has 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 CB's personnel and for audit personnel.

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