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Certification and Inspection Department

Regulation for the accreditation of Inspection Bodies

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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 Inspection Bodies (hereafter referred to as IBs), 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 IB 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 current version of the ACCREDIA document LS-03: *"Reference standards and documents for the accreditation of inspection Bodies."*

It follows that – in the framework of a given scheme/inspection activity, 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 inspection scheme/activity specific definitions are applicable:

- **Type of inspection:** as defined in § 4.1.6 and in Annex A of the standard UNI CEI EN ISO/IEC 17020:2012 (referred to as "level of independence");
- **Inspection category** - the inspection category refers to the nature of the inspected element, as reported in the definition of inspection referred to in the standard UNI CEI EN ISO/IEC 17020 in the current revision, i.e. product, process, service or facility;
- **Inspection field** - a large area of activity in which inspection is used. The fields of inspection can be divided into **subfields**, where appropriate;
- **Range of inspection** - limits to inspection work within an inspection field or subfield delimited by appropriate textual or numerical parameters (see table 1 of the document ILAC G28 in the current revision for examples). If an Inspection Body has demonstrated competence to inspect all the elements included in the listed fields and subfields, it is not necessary to mention a range;
- **Stage of inspection** – the point in the life cycle of a product, process, service or facility at which the inspection is carried out;

- **Inspection requirements** - the criteria on the basis of which conformity is assessed by means of inspection.

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 IBs that perform inspection activities in accordance with the standards and reference documents applicable to them and detailed/referred to in the ACCREDIA document LS-03.

Accreditation for inspection activities is issued, as part of the INSP scheme, for each specific inspection activity, with respect to which the IB has demonstrated its competence and experience.

Within the ambit of these sectors ACCREDIA-DC may define appropriate homogeneous families of accreditation.

In general, the IB seeking accreditation in accordance with the standard UNI CEI EN ISO/IEC 17020 may operate as a type A, type B or type C inspection body. However, for some schemes it is possible that not all the above typologies are applicable.

With reference to the requirements of § 1.1.5 of the General Part of Regulation RG-01, ACCREDIA-DC reserves the right to examine the minutes of the IB's Members' Assembly, if they exist.

IBs shall identify and make available upon request, revenue from all activities which are different from those which are the object of the accreditation.

The IB commits to respect the conditions of independence, impartiality and integrity in accordance with Part 2 depending upon their various typologies (A, B or C).

The ascertained violation of the above provisions entails the adoption of the sanctions set out in § 1.8.

If an IB outsources one or more activities regarding the accredited or applicant sector to an external legal party, the provisions of General Regulation RG-01 are applicable.

The names of any such persons/bodies shall be communicated beforehand to ACCREDA-DC as a part of the application.

The IB is responsible, with respect to ACCREDIA, for the qualifications of persons in cases of outsourcing as described above, and shall provide evidence of such by means of adequate management procedure and contractual documents.

ACCREDIA-DC may perform assessments together with the IB, at the premises of such persons/bodies in order to ascertain their effective levels of competence. Accreditation recognized at EA (European Co-operation for Accreditation) and/or ILAC (International Laboratory Accreditation Cooperation) level is sufficient to ensure conformity with the applicable standards.

1.2. Presesentation and submission regarding the application for accreditation

General Regulation RG-01 is applicable for the application to be presented by an IB to ACCREDIA-DC using the modules DA-00 and DA-03 which are available on ACCREDIA's website, together with all other necessary documents.

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

1.3. Process of accreditation

1.3.1. Document review

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

- The IB shall propose the formulation of the scope of accreditation, for the inspection activities for which it requests to be accredited, according to the ILAC G28 document "Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies" in the current version.

ACCREDIA-DC assesses the correctness and completeness of this scope right from the application acceptance stage. The definitive formulation will be established during the accreditation phase, by the relevant CSA.

The completeness of the documentation describing all the features of the scheme (technical requirements and inspection rules) is fundamental.

1.3.2. Assessments

The provisions of General Regulation RG-01 are applicable.

The accreditation process continues, unless otherwise provided for, with the performance of one or more witness assessments (WA) unless such activities are inapplicable (for example for the inspections of projects).

For the accreditation of IBs operating in regulated/mandatory areas, the modalities and times for the conduct of witness visits follow the requirements contained in the specific regulations/technical documents in question.

In specific cases (e.g., notifications, inspection activities pursuant to legal provisions, etc.), witness assessments may be carried out following the granting of accreditation and the corresponding Ministerial authorization. In such cases, the Inspection Body 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).

If a witness assessment (WA) is not applicable to the scheme, the assessment times at the IB's premises are increased in order to permit an effective sampling of the records of the inspection activities conducted by the IB (e.g. documentation concerning the assessment of projects); in such cases direct interviews shall be conducted with the IB's auditors, where possible.

Usually, at least one witness assessment (WA) is performed for each inspection activity included in the scope of accreditation, except for the application of criteria for sampling depending on the number of activities.

1.4. Decision-making process and the granting of accreditation

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

- for some specific fields, a general accreditation scope can be issued which will be subsequently detailed, after carrying out the specific witness assessment with decision by 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 specifications:

- 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;
- more precise modalities for the surveillance witness assessment (WA) may be established for critical sectors (e.g. inspection activities in regulated and/or mandatory sectors.
- a surveillance assessment at an IB includes direct interviews with a representative sampling of auditors.

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 remotely

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. Variation of the field of accreditation and of 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. 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 submission of the application for extension

The provisions of General Regulation RG-01 are applicable, with the specification that the application for extension of accreditation of an IB shall be presented to ACCREDIA-DC, using the modules DA-00 and DA-03 available on ACCREDIA's website, together with all the necessary documents.

For an application for extension of accreditation of an accredited IB 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, available on ACCREDIA's website.

The application for extension cannot be submitted if a sanction blocking extension is in place, as defined in § 1.8 of the General Regulation RG-01.

1.6.2.1. Flexible scope

For the extension of accreditation to the flexible scope, the requirements set out in the General Regulation RG-01 and in the Technical Regulation RT-37 are applicable.

1.6.3. Document review

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

1.6.4. Assessments

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

- in some cases it is possible that the application for extension is evaluated only on a documental basis, without carrying out the assessment at the IB or witness activities, where this possibility has been expressly provided for by ACCREDIA-DC.

In specific cases (e.g., notifications, inspection activities pursuant to legal provisions, 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 fields, a general accreditation scope can be issued which will be subsequently detailed, after carrying out the specific witness assessment (WA) and following a decision by 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.

1.8. 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, witdrawal)

The provisions of General Regulation RG-01 are applicable.

In cases where the Inspection 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 among those provided for during the first assessment activity performed by the Body.

This witness assessment 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 conformity assessment activity shall be revoked (or first suspended, 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 normal accreditation procedure shall be followed, including the execution of the witness activity (obviously simulated) prior to the accreditation/extension decision.

The above-mentioned provisions are intended to apply to all regulated areas unless different indications/timings are provided by the relevant Authority.

1.8.3. Suspension requested by the IB

The provisions of General Regulation RG-01 are applicable.

1.8.4. Procedural 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 IB

The provisions of General Regulation RG-01 are applicable.

1.11. Obligations of ACCREDIA-DC

The provisions of General Regulation RG-01 are applicable.

2. Part 2 – Requirements for Inspection Bodies

Part 2 contains a series of requirements regarding the organization and operation of IBs, which the Bodies are under obligation to conform with in the context of conformity to the applicable normative references.

2.1. Collaboration with ACCREDIA

In cases of significant situations when a supplementary assessment becomes necessary (e.g. following a market feedback or remark from an authority) the IB shall collaborate with ACCREDIA-DC to make it possible to conduct tests and controls on items inspected by the IB. Such tests may be undertaken by a laboratory chosen by the IB, provided it is accredited or with the agreement of ACCREDIA-DC if it is not accredited. The cost of these tests is met by the IB if the result is negative and/or they reveal unsuitability of the product; otherwise the costs are met by ACCREDIA-DC.

When an assessment is conducted at the IB's location, the IB shall organize, if requested, an interview between the ACCREDIA-DC assessors and an agreed sample of its auditors to enable ACCREDIA-DC to carry out the necessary in-depth appraisals.

2.2. Organization and procedures of the Inspection Body

2.2.1. Administrative requirements

As required by the reference standard UNI CEI EN ISO/IEC 17020, § 5.1.4, the IB shall be adequately covered by resources (e.g. with insurance or financial reserves) to cover all responsibilities deriving from its activities undertaken by both internal staff (personnel and dependent auditors) and external employees and collaborators (contracted auditors).

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 defined by these.

The IB shall possess a contractual document (UNI CEI EN ISO/IEC 17020 § 5.1.5) to attach to the contract (such as a regulation or equivalent document) describing the rights and tasks of the client as well as those of the IB. This document shall be sent to the client before issuance of the order for inspection services. If the client (e.g. public) asks for the application of one of its requirements, the IB is not obliged to send the contract as above, accepting, de facto, the client's conditions. The IB shall, however, verify consistency with its own internal procedures, commenting on the output and informing the client.

2.2.2. Independence, impartiality and integrity

The requirements of UNI CEI EN ISO/IEC 17020 § 4.1 and of Annex A are applicable.

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

For this, a useful guide is provided by the Recommendations made by the ACCREDIA 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 17020 during the assessment and surveillance of the accredited IB.

It is therefore 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 adoption of the sanctions set out in § 1.8.

2.2.3. Organizational and management aspects

The requirements of § 5.2 of the standard UNI CEI EN ISO/IEC 17020 are applicable.

2.2.4. Management System

The requirements of § 8 of the standard UNI CEI EN ISO/IEC 17020 are applicable.

2.2.5. Inspection Body personnel

The requirements of § 6.1 of the standard UNI CEI EN ISO/IEC 17020 are applicable.

2.3. Facilities and equipment of the IB

The requirements of § 6.2 of the standard UNI CEI EN ISO/IEC 17020 are applicable with the following specifications in accordance with the document ILAC P-10.

The IB, using tools, equipment and testing and measuring devices for inspection services, shall show and guarantee their conformity with the metrological requirements (in terms of accuracy, calibrations, traceability, metrological confirmation), even if it does not own the equipment it uses.

The IB shall ensure that all equipment is properly maintained, in conformity with the documented procedures and instructions.

The IB shall also ensure, where applicable, that the equipment has been calibrated before being put into service and, subsequently, in compliance with an established program.

The general calibration program of the equipment shall be planned and implemented in such a way that any measuring activity carried out by the IB can be traceable to national and international measurement samplings, where such are available.

If traceability by national and international sampling is not possible, the IB shall provide evidence of the correspondence or accuracy of the inspection results.

In order to write inspection reports which are reliable and in conformity, the IB shall:

- analyse all the types of measurement to carry out during accredited inspection activities; define what uncertainties are required for the report to be reliable, in order to choose the instruments which are most

suitable for the scope (a useful guide for understanding the process of measurement-uncertainty-instrument is the standards UNI EN ISO 10012 and ISO/IEC 14253 part II);

- as part of the above analysis, identify those measurements for which the calibration is not a dominant factor in the result of the inspection or test. In these cases the IB shall provide quantitative written evidence to show that the calibration does not have a significant influence on the result of the associated measurement and uncertainty regarding the reliability of the inspection report and that it is therefore not necessary to demonstrate traceability (see § 2 of ILAC P-10). This is the case for IBs which have to carry out indicative measurements, where the maximum admitted instrument error (as declared by the manufacturer) is significantly less than the required accuracy for the measurement and where the modalities for the performance of the measurement by the operator may have a much greater influence on tool error (For example: a linear measurement on a construction site with measurement tape: if the measurement is not carried out carefully following the straight line which unites the two points, the mistake made may be appreciably greater than the error declared by the manufacturer of the measurement tape itself);
- ensure traceability to recognized national samples by means of an uninterrupted chain of traceability (see the Note below), following the indications in points 1) and 2) of the document ILAC P-10 for all remaining measurements in which the uncertainty is a determining factor regarding the reliability of the inspection report;
- submit for evaluation by ACCREDIA-DC the criteria that it intends to apply to ensure traceability, as required by the accreditation standard and in conformity with Annex A of ILAC P-10 in cases where the IB, having analysed the measurement typologies of interest, for certain particular measurements, ascertains the impossibility of using an uninterrupted traceability chain, as indicated in points 1) and 2) of § 2 of ILAC P-10.

For further details see the indications in the document ILAC P10 in the current version.

Note: an uninterrupted traceability chain requires that all the “transfers of traceability” take place at accredited locations because only in this way is it possible to be sure of the correct procedure and the competences used for the transfer of traceability.

If the IB carries out the calibrations internally, it shall possess primary calibrated samples at accredited centres possessing all the necessary competences. These aspects will be assessed during the accreditation assessments.

If the IB sub-contracts testing activities to an organization without specific accreditation, it shall take full responsibility to ensure the above elements, exactly as if it conducted the calibration internally.

In all other cases the IB shall use laboratories which are accredited for specific measurements/tests in the relevant measurement field.

The above is applicable except in cases of more stringent legal requirements certain areas.

An inter-laboratory comparison – proficiency testing – is advisable between laboratories and IBs, aiming at an objective and independent evaluation of the quality of analytical measurements carried out by the analysis laboratories.

IBs which use software for inspection activities such as calculation programs, data acquisition systems etc., shall use software of proven validity and recognized to be suitable for such use, and for the confirmation of its adequacy for specific uses.

2.4. Inspection methods and procedures

The requirements of § 7.1 of UNI CEI EN ISO/IEC 17020 are applicable, with the following specifications.

Inspection/control plans are required when the inspection concerns long-term activities and/or activities which require the coordination of specialists (as in the case, for example, of inspections for project audits or inspections regarding construction works or facilities).

The specific inspection/control plan, either directly or by means of reference documents, shall cover, at least, the following factors:

- description of the item for inspection and commercial references (client, order, delivery times etc.);
- basic data and requirements/aims to be fulfilled;
- any criticalities identified during the performance of the tasks assigned;
- necessary technical competences to perform the activities;
- composition of the inspection group with description of role and specialization of each member;
- timeframe necessary for each member of the inspection group;
- tests and controls to be conducted;
- list of important activities in order of logic and time, with the identification of any possible critical phases;
- particular elements or aspects to take into consideration during the inspection;
- sampling procedure used with statistical validity regarding the inspection.

The IB shall operate with control lists or equivalent documents (e.g. modules or technical guides developed internally by the IB), prepared specifically for the inspection in question.

2.5. Handling of samples and items submitted for Inspection

The requirements of § 7.2 of UNI CEI EN ISO/IEC 17020 are applicable.

2.6. Records

The requirements of § 7.3 of UNI CEI EN ISO/IEC 17020 are applicable, with the following specification:

- The records regarding the IB's inspection activities shall be kept safely for a period of time established by the IB, possibly in agreement with the client, which is not less than the end-date of the guarantee

period requested by the client, established by the law or defined by the standards regulating inspection activities.

2.7. Inspection reports

The requirements of § 7.4 of UNI CEI EN ISO/IEC 17020 are applicable, with the following specifications:

The final inspection report – the final product of inspection activity – is generally signed, or otherwise acknowledged, by the inspector (for preparation) and by the Technical Manager as authorized personnel.

If it is not possible to do this, and only in cases where long-term inspection activities are not expected with the use of many inspectors (e.g. in the case of reports issued directly at the client's location immediately after the inspection), the report may be signed only by the inspector, as long as s/he is qualified and explicitly authorized for the task.

If there is agreement between the interested parties, ACCREDIA-DC may define cases and typologies of inspection in which the Technical Manager reviews the inspection report on the basis of statistically valid sampling. The IB shall keep the appropriate records regarding the choice and the relevant explanations.

2.8. Sub-contracting

The requirements of § 6.3 of UNI CEI EN ISO/IEC 17020 are applicable.

2.9. Complaints and appeals

The requirements of § 7.5 of UNI CEI EN ISO/IEC 17020 are applicable.

2.10. Publicity of accreditation

The IB shall comply with the requirements detailed in the Regulation for the use of the ACCREDIA accreditation mark (RG-09) when publicizing or in any way communicating to the market the accreditation that it possesses.

An accredited IB shall not issue inspection reports without the ACCREDIA mark (see § 5.2.1 of RG-09).

Breach of the obligations detailed in the Regulation entails the imposition of the sanction measures set out in § 1.8.

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