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ENTE ITALIANO DI ACCREDITAMENTO

Certification and Inspection Department

Regulation for the accreditation of Inspection Bodies

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TITLE **Regulation for the accreditation of Inspection Bodies**

REFERENCE **RG-01-04**

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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 Inspection Bodies (hereafter referred to as IBs), 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 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 normative references 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 of the General Regulation RG-01, the applicable standards, and the specific definitions set out in ILAC G28 (current version) shall apply:

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 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 ISP scheme, for each specific inspection activity, with respect to which the IB has demonstrated its competence and experience.

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

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, where applicable.

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

In the event of an established breach of the above requirements, the sanctioning measures set out in § 1.8 of General Regulation RG-01 shall apply.

Where the IB outsources one or more parts of inspection activities falling within the accredited or applied-for scope to an external legal entity, the provisions of General Regulation RG-01 shall apply.

The names of such entities shall be communicated to ACCREDIA-DC in advance, at the time of application.

The IB is responsible to ACCREDIA-DC for the qualification of the above-mentioned assignees and shall provide evidence thereof through appropriate management procedures and contractual documents.

ACCREDIA-DC shall have the right to carry out inspections, alongside the IB, at the above-mentioned assignees, in order to verify their actual competence. Accreditation recognised at EA (European Co-operation for Accreditation) and/or Global- ACI (Global Accreditation Cooperation Incorporated) level shall constitute presumption of conformity with the applicable standard.

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 an IB must be submitted to ACCREDIA-DC using the relevant forms DA-00 and DA-03, available on the ACCREDIA website, together with all the documentation required therein. Where the IB 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 IB shall propose the formulation of the accreditation scope for the inspection activities for which accreditation is requested, taking into account the guidance provided in ILAC G28 “Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies”, current version.

From the application acceptance stage onwards, ACCREDIA-DC shall assess the accuracy and completeness of such scope. The final formulation shall be determined at the time of granting accreditation by the relevant CSA.

The correctness and completeness of the documentation describing all scheme characteristics (technical requirements and inspection rules) is essential.

The application for 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 form DA-00 and DA-04, available on the ACCREDIA website, together with all the documentation required therein.

It is ACCREDIA-DC policy not to accept accreditation applications from Inspection Bodies carrying out “stand-alone” sampling activities, to which accreditation under ISO/IEC 17025 applies.

1.3. Process of accreditation

1.3.1. Document review

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

1.3.2. Assessments

The provisions of General Regulation RG-01 shall apply.

The accreditation process shall then proceed, unless otherwise specified, through the conduct of one or more witnessed assessments, including simulated assessments, where permitted by the specific inspection scheme, except in cases where such a verification method is substantially not applicable (for example, in the case of design-related inspections).

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

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 IB shall be required to inform ACCREDIA-DC well in advance 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.

As a rule, one witness assessment shall be carried out for each inspection activity included within the accreditation scope, where applicable.

1.4. Decision-making process and the granting 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.

1.5. 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 the General Regulation RG-01 shall apply, with the following clarification:

- the office and witness assessments are planned as to permit a representative sampling of the scope of accreditation, during the entire cycle of accreditation;

1.5.1.3 Unscheduled surveillance of accreditation

The provisions of General Regulation RG-01 shall apply.

1.5.1.4. Scheduled and unscheduled remote surveillance

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

1.5.1.6. Variation of the accreditation scope and of 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. 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, as well as those of Technical Document DT-01-DC, in its current revision, shall apply to 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

The provisions of General Regulation RG-01 shall apply, with the clarification that an application for extension of an IB's accreditation must be submitted to ACCREDIA-DC using the relevant forms DA-00 and DA-03, available on the ACCREDIA website, together with all the documentation required therein.

The application shall be completed carefully, clearly and comprehensively, providing all required information and data, and justifying any non-applicable sections in the event of incomplete responses, failing which the

application itself may not be accepted. Given the specific nature of this accreditation scheme, ACCREDIA-DC reserves the right to request any additional documentation necessary for the processing of the extension application.

Where the IB 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.

In the case of an application for extension of accreditation submitted by an already accredited IB, 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, the application shall be submitted to ACCREDIA-DC using forms DA-00 and DA-04, available on the ACCREDIA website.

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 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.

1.6.4. Assessments

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

- 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 extension and the corresponding Ministerial authorization. In such cases, the IB shall be required to inform ACCREDIA-DC sufficiently in advance 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 extension. 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 extension 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.

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 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 sanctions measures (suspension, reduction, withdrawal)

The provisions of General Regulation RG-01 shall apply.

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. 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.

Once the accreditation has been revoked, the CAB may submit a new application. With regard to fields for notification purposes, the option of being accredited with deferred witness assessment activities (i.e. after having received the first requests from clients) shall 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.

It is specified that the market effects of a suspension/withdrawal of accreditation do not depend on ACCREDIA-DC, but on the competent Authorities when they use such accreditation for notification or authorisation purposes.

1.9.3. Suspension requested by the IB

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/reports

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 IB

The provisions of General Regulation RG-01 shall apply.

1.12. Obligations of ACCREDIA-DC

The provisions of General Regulation RG-01 shall apply.

2. Part 2 – Requirements for Inspection Bodies

Part 2 sets out a series of requirements concerning the organisation and operation of Inspection Bodies, with which IBs are required to comply in order to ensure conformity with 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.

2.2. Organization and operation of the Inspection Body

2.2.1. Administrative requirements

The IB, as required by the reference standard ISO/IEC 17020, shall have adequate resources (e.g. insurance or financial reserves) to cover liabilities arising from its activities, both in relation to its internal personnel (organisation and employed inspectors) and external personnel (contracted inspectors).

For mandatory/regulatory areas where the stipulation of insurance coverage is required by regulations/laws, reference shall be made to the requirements defined therein.

The IB shall have a contractual document (ISO/IEC 17020) to be annexed to the contract (e.g. rules or equivalent document) describing the rights and obligations of the client and those of the IB. Such document shall be transmitted to, or made available to the client prior to the issuance of the purchase order for the inspection service. Where the client (e.g. public) requires the application of its own set of rules, the IB shall not be required to transmit the above-mentioned contractual document, thereby accepting the conditions submitted by the client; however, the IB shall verify their consistency with its internal procedures, document the outcome, and inform the client accordingly.

2.2.2. Independence, impartiality and integrity

The requirements of ISO/IEC 17020 and of Annex A shall apply.

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

To this end, a useful guide is provided by the Recommendations made by the ACCREDIA Steering and Guarantee Committee(CIG) relating to the definition of homogeneous criteria for the verification of some requirements of the standard ISO/IEC 17020 during the assessment and surveillance of the accredited IBs.

It is therefore required 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.

2.2.3. Inspection Body personnel

The requirements of the standard ISO/IEC 17020 shall apply.

The IB shall define the competence criteria for inspection personnel in relation to its inspection areas of operation, taking into account the specificities associated with fields, ranges and requirements.

2.3. Facilities and equipment of the IB

The requirements of ISO/IEC 17020 shall apply, with the following clarifications arising from the Global- ACI documents.

The IB, using tools, equipment and testing and measuring devices for inspection services, shall demonstrate 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 programme 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 standards, where such are available.

Where traceability to national or international standards is not possible, the IB shall provide satisfactory evidence of the correlation or accuracy of the inspection results.

In order to issue compliant Inspection Reports, the IB shall:

- analyse all types of measurements to be performed during accredited inspection activities, define the uncertainties required to ensure the reliability of the results reported in the Inspection Report, and select the appropriate equipment for the intended purpose;
- as part of the above analysis, identify those measurements for which the calibration is not a dominant factor in the result of the inspection/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 results reported in 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 required to perform indicative measurements, where the maximum permissible error of the instrument (as declared by the manufacturer) is significantly lower than the accuracy required for the measurement, and where the manner in which the measurement is carried out by the operator may have a substantially

greater influence than the instrument's error itself (for example: linear measurement on a construction site using a measuring tape; if the measurement is not taken exactly along the straight line between the two points, the resulting error may be significantly greater than the error declared by the manufacturer of the tape itself);

- ensure traceability to recognized National Standards 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 results reported in the Inspection Report;
- submit for evaluation by ACCREDIA-DC the criteria that it intends to apply to ensure traceability, as required by the accreditation standards 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.

Where the IB performs internal calibrations, the requirements of ILAC P9 shall apply.

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 shall apply, unless otherwise specified by more stringent legal requirements in particular areas.

The IB that uses software for inspection operational activities (calculation programmes, data acquisition systems, etc.) shall ensure its validation, in order to confirm its suitability for the intended specific use.

2.4. Inspection methods and procedures

The requirements of ISO/IEC 17020 shall apply, with the following clarifications.

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 work implementation).

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. Inspection reports

The requirements of ISO/IEC 17020 shall apply, with the following clarifications.

Inspection reports shall bear the signature or other identification of the inspector(s) and of the Technical Manager as authorised personnel (for approval).

Where this is not practically feasible, and only in cases where no prolonged inspection activity involving multiple inspectors is foreseen (e.g. when reports are issued directly at the client's premises immediately following the inspection), the report may be signed solely by the inspector, provided that the inspector is qualified and explicitly authorised for this purpose. The inspection report shall, in any case, be subsequently reviewed and approved by the Technical Manager.

2.6. Certification of Inspection Bodies according to ISO 9001

The management system of an Inspection Body may be certified in accordance with ISO 9001 by a Certification Body. However, inspection activities cannot be certified as a service, as recognition of competence in conformity assessment activities is achieved through accreditation.

It is not permitted to certify the conformity of an Inspection Body operating in accordance with ISO/IEC 17020, as this falls within the scope of accreditation.

See also the provisions of RG-01 General Part.

2.7. Remote assessment activities

Inspection activities shall be carried out on-site, except where otherwise provided for by ACCREDIA circulars, the Scheme Owner, system documents, normative documents, or relevant Authority requirements.

In such exceptional cases, the IB shall conduct a suitably structured risk analysis to determine the feasibility of performing the inspection 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-ACI documents shall also apply as exceptions. In applying such derogations, the IB is responsible for maintaining appropriate evidence and records and making them available to ACCREDIA upon request.

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