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0.1 SCOPE AND FIELD OF APPLICATION

The present Regulation is applicable to the accreditation of Bodies providing certification of product/service (hereafter referred to as CBs), setting out the conditions and procedures for the issue, 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 guidances, 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 in the version in force of the ACCREDIA LS-03 document: *"Reference standards and documents for the accreditation of inspection 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.

The application of the provisions of the individual technical RT/DT documents and technical circulars for inspection activities carried out abroad is to be considered optional unless otherwise specified in such documents.

0.3 TERMS

The terms and definitions of the General Regulation RG-01 are applicable.

0.4 ACRONYMS

ACCREDIA-DC: ACCREDIA Department of Certification and Inspection Bodies.

CSA: Sector Accreditation Committee.

DDC: Director of the Dept. of Certification and Inspection.

FT: Technical Officer.

PART 1 – GENERAL REQUIREMENTS REGARDING THE ACCREDITATION PROCESS

1. REQUIREMENTS AND INFORMATION FOR ACCREDITATION

1.1. GENERAL INFORMATION

1.1.1 Accreditation and subsequent listing on the Register are granted to IBs that perform inspection activities in accordance with the standards and reference documents applicable to them and detailed in the ACCREDIA document LS-03.

Accreditation for inspection activities is issued, in the ambit of the INSP scheme, for each specific sector with respect to which the IB has shown that it possesses competence and experience.

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

1.1.2 The required conditions enabling an IB to be accredited are as follows:

- the IB fulfills the requirements of General Regulation RG-01;
- at the initial assessment at its head office it shall be operative and have issued inspection reports for at least 12 months (this is not applicable to IBs already accredited in other schemes);
- it has issued at least 3 inspection reports for each sector applied for.

For applications for accreditation regarding inspection activities in the mandatory areas, and for which accreditation is a legal requirement the provisions of specific regulations and technical documents are applicable.

1.1.3 The IB shall send annually to ACCREDIA (by mid-year), using the appropriate module which is available in the reserved area for bodies in ACCREDIA's website, the following data concerning activities conducted under accreditation:

- annual revenue (including non-accredited activities);
- annual revenue for inspection activities;
- n° of internal staff involved in inspection activities;
- n° of inspection reports.

The elements and data concerning the calculation of the above parameters shall be kept available to ACCREDIA-DC and/or its assessors.

If such data is not received within the specific timeframe, ACCREDIA-DC may impose sanctions on the IB in question.

1.1.4 The IB shall demonstrate, through the presentation of the appropriate accounts documents, (balance sheet or equivalent, with additional notes and management report), that it possesses, or can obtain, the necessary financial resources to carry out inspection activities at least for the next accreditation period. Financial sources which do not come from inspection activities shall be signaled and must not compromise the independence and impartiality of the body for type A and type C bodies. Where this cannot be directly deduced from the data of the balance sheet, this information shall be provided through specific documents (e.g. additional notes and other documents requested by ACCREDIA or by ACCREDIA-DC assessors).

ACCREDIA-DC reserves the right to examine the minutes of the assembly of members of the IB, where such exist.

Type A and type C bodies shall include, in such documentation, revenue from all activities which are different from those which are the object of the accreditation.

1.1.5 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).

If a breach of the above rules is proven, sanctions may be imposed in accordance with § 1.8.

1.1.6 If an IB outsources one or more activities regarding the accredited or applicant sector to an external juridical person/body, 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 performs 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. PRESENTATION AND EXPLANATIONS REGARDING THE APPLICATION FOR ACCREDITATION

1.2.1 General Regulation RG-01 is applicable for the application to be presented to ACCREDIA-DC using the modules DA and DA-03 which are available on ACCREDIA's website, together with any 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. ACCREDITATION PROCESS

1.3.1 Document Review

The provisions of General Regulation RG-01 are applicable.

The IB shall propose the formulation of the scope of accreditation for the inspection activities in question. ACCREDIA-DC, starting from the phase of acceptance of the application, evaluates the completeness of the scope. The definitive version will be established during the phase of issue of the accreditation, undertaken by the relevant CSA.

The completeness of the documentation describing all the features of the scheme (technical requirements and inspection rules), is fundamental. The documentation depends not only on the organizational complexity of the IB but especially on the number and typology of the items to be inspected.

The cost of the first review is met by ACCREDIA-DC and the cost of all subsequent document reviews is met by the IB.

1.3.2 Assessments

1.3.2.1 General Regulation RG-01 is applicable, with the specification that the duration of the on-site assessment (*) depends on the specifics of the scheme (such as the number and criticalities of the typologies of inspection activities required, the number and criticality of the typologies of inspection activities in question,, whether the IB operates in the voluntary or mandatory/regulated area), and other factors such as the number of findings raised during the document review, language, transfer times etc.

Note *: if the accreditation assessment is conducted in jointly with another scheme, ACCREDIA-DC shall assess taking into consideration the above critical factors, reducing, where possible, the total time necessary for the assessment.

The objective of the on-site assessment is to verify whether the operative practices adopted by the IB regarding the activities performed are in conformity with the present regulation and all other reference standards, general and sector legislation, as well as the IB's own procedures and regulations as formalized in its management system documentation (QM, regulations, procedures, instructions, control plan, personnel qualifications etc.). Previous inspection reports already issued by the IB are also reviewed.

1.3.2.2 The accreditation process continues with the performance of one or more witness assessments unless such activities are inapplicable for reasons such as 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.

If a witness assessment is not applicable to the scheme, the assessment times at the IB's office 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.

Usually, at least one witness assessment is performed for each sector of the scope of accreditation (categories of project, product, service, plants etc.), except for the application of criteria for sampling depending on the number of sectors and their similarity.

Witness assessments involve observing the behavior of the CB's audit team during the conduct of the inspection in question.

Witness assessments have the following objectives:

- to assess the effectiveness of the IB's procedures, especially the use of auditors, who possess the necessary experience and competences;
- to observe the behavior of the auditors (capacities of professional judgment) and the conformity of their behavior with the IB's procedures and with every other reference applicable to the inspection.

The witness assessment permits an evaluation of whether the IB is able to formulate correct and competent judgment regarding the conformity to the applicable specific or generic requirements of the item/s for inspection.

The duration of the witness assessment depends on the type of inspection activity to be assessed.

Witness assessments are performed by at least one qualified ACCREDIA-DC assessor.

If, for accreditation sectors for which there is not an ACCREDIA-DC assessor with the necessary competences available, a technical expert takes part alongside the assessor, chosen from the list.

1.4. DECISION-MAKING PROCESS AND GRANTING OF ACCREDITATION

General Regulation RG-01 is applicable with the specification that at the time of the issue of accreditation, ACCREDIA-DC sets out the scope of accreditation and, for some mandatory/regulated areas, it may be obligatory to send a communication describing its decisions to the competent authorities (e.g. the ministries), for subsequent deliberation.

1.5. SURVEILLANCE AND RENEWAL OF ACCREDITATION

1.5.1 Surveillance of accreditation

1.5.1.1 General

General Regulation RG-01 is applicable with the following specifications:

- for the surveillance assessment, all the locations of the IB and of the laboratories used in the ambit of the inspection schemes covered by the accreditation, shall be made accessible to the ACCREDIA-DC assessment team.

1.5.1.2 Programmed surveillance of accreditation

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

- in exceptional cases the DDC may request that the first surveillance activity takes place at 12 months if the IB operates in only one mandatory field (e.g. project audit for validation....) and has not obtained any new clients;
- the on-site and witness assessments are planned in such a way as to permit a meaningful sampling of the scope of accreditation, during the entire cycle of accreditation;
- in order to determine the number of man-days for the on-site surveillance assessment and the more specific surveillance assessment modalities, ACCREDIA-DC conducts periodical risk analyses, on the basis of the parameters defined in collaboration with ACCREDIA's Committee of Control and Guarantee which approved them, including factors such as: the number and criticality of the professionals to assess, the number of locations to assess, whether the IB operates in the voluntary or regulated area, the volume and complexity of the IB's inspection activities, the outcomes of previous assessments, any sanctions which were imposed on the IB, the annual performance of all assessments of maintenance in compliance with the technical estimate etc.. Such parameters are made publicly available in the reserved area for Bodies in ACCREDIA's website;
- more precise modalities for the surveillance witness assessment may be established for critical sectors (e.g. inspection activities in regulated and/or mandatory sectors).

Note *: if the on-site surveillance takes place jointly with another scheme, ACCREDIA-DC will decide if it is possible (bearing in mind the critical factors as mentioned above) to reduce the total time.

A surveillance assessment at an IB includes direct interviews with a meaningful sampling of auditors.

1.5.1.3 Non-programmed accreditation surveillance

The provisions of General Regulation RG-01 are applicable.

1.5.1.4 Decision-making process and granting of maintenance of accreditation

The provisions of General Regulation RG-01 are applicable.

1.5.1.5 Changes to the field of accreditation and to the accreditation standards

The provisions of General Regulation RG-01 are applicable with the specification that at the time of the change to the field of accreditation, ACCREDIA-DC – for some mandatory/regulated areas – may be obliged to send a communication describing its decisions to the competent authorities (e.g. the ministries), for their deliberation.

1.5.1.6 Transfer of accreditation between Accreditation Bodies

The provisions of General Regulation RG-01 are applicable with the specification that at the time of the transfer of accreditation, ACCREDIA-DC – for some mandatory/regulated areas - may be obliged to send a communication describing its decisions to the competent authorities (e.g. the ministries), for their deliberation.

1.5.1.7 Transfer of ownership of accreditation

The provisions of General Regulation RG-01 are applicable with the specification that at the time of the transfer of ownership of accreditation, For ACCREDIA – for some mandatory/regulated areas – it may be obligatory to send a communication describing its decisions to the competent authorities (e.g. the ministries), for their deliberation.

1.5.2 Renewal of accreditation

1.5.2.1 Process of renewal of accreditation

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

- the document review for renewal of the scheme takes into consideration any such re-examinations carried out during the year in other schemes for which the IB is accredited,. ACCREDIA may decide whether to undertake the document review for renewal during the on-site assessment;
- in order to determine the number of man-days for the on-site surveillance assessment and the more specific surveillance assessment modalities, ACCREDIA-DC conducts periodical risk analyses, on the basis of the parameters defined in collaboration with ACCREDIA's Committee of Control and Guarantee which approved them, including factors such as: the number and criticality of the professionals to assess, the number of locations to assess, whether the IB operates in the voluntary or regulated area, the volume and complexity of the IB's inspection activities, the outcomes of previous assessments, any sanctions which were imposed on the IB, the annual performance of all assessments of maintenance in compliance with the technical estimate etc.. Such parameters are made publicly available in the reserved area for Bodies in ACCREDIA's website.

Note *: if the on-site renewal assessment takes place jointly with another scheme, ACCREDIA will decide if it is possible (bearing in mind the critical factors as mentioned above) to reduce the total time.

1.5.2.2 Decision-making process and granting of renewal of accreditation

The provisions of General Regulation RG-01 are applicable with the specification that at the time of the renewal of accreditation, ACCREDIA confirms the scope of accreditation and – for some mandatory/regulated areas - .may be obliged to send a communication describing its decisions to the competent authorities (e.g. the ministries), for their deliberation.

1.6. EXTENSION OF ACCREDITATION

1.6.1 General information

In cases of an application for the extension of accreditation to new sectors (e.g. new types of project, products, plants etc.), within the ISP scheme already under accreditation, the IB is obliged to have issued at least one inspection report for each sector applied for and it shall also satisfy the requirements of RG-01, except in cases of different specifications given in the specific regulations and technical documents (RT and DT), and technical circulars,

For IBs operating in the mandatory/regulated area the provisions of the specific regulations and technical documents are applicable.

1.6.2 Presentation and explanation of the application for extension

1.6.2.1 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 and DA-03 (section for extension), 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, see § 1.8.

1.6.2.2 Flexible Scope

In line with § 1.5.1.5.2 of Regulation RG-01, the following shall be considered:

The first application with flexible scope shall be considered an extension in that it can only be sought if the IB has obtained accreditation with fixed scope, for a specific accreditation standard since at least 2 years before.

Unless specifically authorized by the competent administration authorities, accreditation with flexible scope is not applicable in regulated areas, where the ACCREDIA-DC certificates cite the Directive, the regulation or standard under the pertinent national law.

By adopting the flexible scope of accreditation the IB may add inspection procedures in cases where the technical competence and professional capacities of the auditors and of the technical manager and any testing requirements are the same as other inspection activities (and relative applicable standards / specifics) already covered by the accreditation.

In cases where the IB operates on "client specifications", it is exempted from maintaining the controlled list of inspection activities which are the object of the flexible scope of accreditation, but it shall have available the list of client specifics which shall be made available to ACCREDIA-DC, but it is not necessary for it to be made publicly available.

In all cases, the adoption of the flexible scope by a CAB is subject to the authorization of ACCREDIA-DC, granted in compliance with the requirements contained in Technical Regulation RT-37.

1.6.3 Document Review

The provisions of General Regulation RG-01 are applicable; with the specification that the examination takes into account any previous ones carried out during the year in typologies of inspection activity for which the IB already has accreditation.

1.6.4 Assessments

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

- following the positive outcome of the document review as set out above, the process of extension continues with the performance of on-site or witness assessments, depending on the typology of the inspection activities which are the object of the application for extension.

In exceptional cases, justified by objective difficulties in the organization of witnesses (e.g. a high number of inspections in the extension sector), the DDC may authorize such assessments before the document review has been completed.

In these cases the process of extension is suspended until the document review has been concluded.

The application for extension cannot be submitted if a sanction blocking extension is in place, see § 1.8.

1.6.4.2 The criteria regarding the composition of the assessment team for extensions shall be the same as those for initial accreditation assessments.

1.6.4.3 If any NCs are raised during a witness assessment the process of extension is suspended until the resulting CAs are closed and shown to be effective and verified to be resolved by means of supplementary assessments undertaken by ACCREDIA-DC. The time limit for the implementation of CAs is usually not more than two months. Supplementary assessments may also be necessary after the granting of extension if a significant number of Concerns has been raised.

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 that if, during the assessments carried out for extension, any situation whatsoever of inadequacy, in any way or for any reason emerges, not directly related to the object of the extension but related to the INSP scheme or other scheme/s covered by the accreditation, action is taken in the form of surveillance activities.

For some mandatory/regulated areas, ACCREDIA-DC must transmit, where applicable, a descriptive communication of resolutions to the competent Authorities (e.g. Ministries), for the consequent determinations.

1.8. SUSPENSION, WITHDRAWAL AND REDUCTION OF ACCREDITATION

1.8.1 Minor sanctions measures

The provisions of General Regulation RG-01 are applicable.

In the mandatory/regulated area, where necessary, ACCREDIA-DC informs the competent authorities (e.g. ministries) regarding the minor sanctions provisions imposed on accredited IBs, in particular the increase of assessment activities.

1.8.2 Major sanctions measures (Suspension, Reduction, Withdrawal)

The provisions of General Regulation RG-01 are applicable.

For IBs operating in the mandatory/regulated area, the decisions of the CSA, where applicable, shall be sent in copy to the competent authorities (e.g. ministries) for their deliberation.

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, with the specification that, for IBs operating in the mandatory/regulated area, the decisions of the CSA regarding a reduction/renunciation of accreditation, where necessary, shall be sent in copy to the competent authorities (e.g. ministries) for their deliberations.

1.8.5 Resumption of accreditation

The provisions of General Regulation RG-01 are applicable with the specification that: for IBs operating in the mandatory/regulated area, decisions taken by the CSA concerning the resumption of accreditation shall, where necessary, be sent in copy to the competent authorities (e.g. ministries) for their deliberations.

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, with the specification that ACCREDIA-DC commits to notify, where necessary, the competent authorities of any appeals received by accredited or applicant IBs operating in the mandatory/regulated area.

1.10. OBLIGATIONS OF THE CAB

The provisions of General Regulation RG-01 are applicable.

1.11. OBLIGATIONS OF ACCREDIA

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, with which the Bodies are under obligation to conform in the framework of conformity to the applicable normative references.

2.1. COLLABORATION WITH ACCREDIA

2.1.1 As already partially specified, the Inspection Body shall allow ACCREDIA to select the audit group set up by the IB, and/or the objects in question for the performance of the witness assessments. For this purpose the IB shall send to ACCREDIA-DC, in timely fashion, the program related to its audit activities and all other necessary information for ACCREDIA-DC to perform assessments, in good time for the relative planning.

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 carry out 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.

2.1.2 At the request of ACCREDIA-DC, whose assessors are required to report also the IB's positive aspects, the IB shall also signal and document the strong points of its organization.

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

2.1.4 All information relating in any way to the relationships between ACCREDIA-DC and the accredited or applicant IBs or to the relationships between the IBs and their clients or to the object of the inspection shall remain confidential and ACCREDIA-DC shall not communicate to third parties unless:

- publication is foreseen by the accreditation or certification rules;
- communication is foreseen in compliance with the present Regulation or is deemed necessary by ACCREDIA-DC to effectively perform its tasks though it shall remain limited only to those who receive it;
- otherwise established by law or provided for by the Legal Authorities;
- the request, with justification, comes from another AB signatory to the EA MLA or ILAC MRA agreements;
- disclosure is made with the explicit and unanimous consent of all the parties involved.

Failure to observe the above rules may lead to the imposition of sanctions in accordance with § 1.8.

2.2. ORGANIZATION AND PROCEDURES OF THE IB

2.2.1 Administrative requirements

2.2.1.1 The statute, or equivalent document of the IB, shall specifically provide for the performance of inspection activities as the purpose of its activities.

2.2.1.2 As required by the reference standard UNI CEI EN ISO/IEC 17020, § 5.1.4, the IB shall be adequately covered (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 (contract auditors).

2.2.1.3 The Body 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. Such 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 Impartiality, independence and integrity

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

2.2.3 Organization and management aspects

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

2.3. MANAGEMENT SYSTEM

The requirements of standard UNI CEI EN ISO/IEC 17020 § 5.8 are applicable.

2.4. IB PERSONNEL

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

2.5. PERSONNEL AND EQUIPMENT OF THE IB

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

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 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 measurement 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:

- 1) analyze 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 standard UNI EN ISO 10012 and ISO/IEC 14253 part II);
- 2) as part of the above analysis, to 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 bearing 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 § 6 of ILAC P-10).

This is true 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);

- 3) ensure traceability to recognized national samples by means of an uninterrupted chain of traceability (see Note below), following the indications in points 1) and 2) in ILAC P-10 for all remaining measurements in which the uncertainty is a determining factor regarding the reliability of the inspection report;
- 4) 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 analyzed 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 ILAC P-10.

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 centers 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 avail itself of laboratories which are accredited for specific measurements and tests in the relevant measurement field.

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

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 it shall verify it for adequacy for specific uses.

2.6. INSPECTION METHODS AND PROCEDURES

The standard UNI CEI EN ISO/IEC 17020 § 7.1 is 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 plants).

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 met;
- 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 done;
- list of important activities in order of logic and time, with the identification of any possible critical phases;
- particular elements or aspects to watch out for carefully 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), drawn up specifically for the inspection In question.

2.7. HANDLING INSPECTION ITEMS AND SAMPLES

The standard UNI CEI EN ISO/IEC 17020 § 7.2 is applicable.

2.8. RECORDS

The standard UNI CEI EN ISO/IEC 17020 § 7.3 is applicable, with the following specifications:

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

2.9. INSPECTION REPORTS

The standard UNI CEI EN ISO/IEC 17020 § 7.4 is applicable, with the following specifications:

The final inspection report – the final product of inspection activity – is generally signed by the person who wrote it and by the Technical Manager by way of approval.

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 he is qualified and explicitly authorized.

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.

2.10. SUB-CONTRACTING

The standard UNI CEI EN ISO/IEC 17020 § 6.3 is applicable.

2.11. COMPLAINTS AND APPEALS

The standard UNI CEI EN ISO/IEC 17020 § 7.5 is applicable.

2.12. PUBLICITY OF ACCREDITATION

The Body 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 shall entail the imposition of the sanction measures outlined in § 1.8 of RG-01.