

Certification and Inspection Department

Directives for accreditation with flexible scope, Certification and Inspection Bodies Department

RT-37

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TITLE **Directives for accreditation with flexible scope,
Certification and Inspection Bodies Department**

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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. To identify the revised parts reference must be made to the Italian version only.*

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1. Introduction

The description of the competences of a CAB (certification/inspection/verification and validation body), as attested by accreditation, is reported in the scope of accreditation, which shall be kept available for the clients, for other interested parties and for the market in general. The scope of accreditation shall be defined precisely and unambiguously so as to identify the activities covered by accreditation.

The fixed scope of accreditation (see definition below) is set out by ACCREDIA's Department of Certification and Inspection (ACCREDIA-DC) in the document attached to the certificate, which is named according to the relevant Sector Accreditation Committee.

This description of the scope of accreditation, however, presents some limitations, as any required variation or extension must be submitted by the CAB to ACCREDIA-DC through a specific application, followed by evaluation and approval.

The introduction of the flexible scope of accreditation (see definition below) enables the CABs, within a well-defined area of the already granted accreditation, to respond to requests made by clients and authorities, and to extend applicability to new technical standards for products, personnel, or inspection procedures, as long as they belong to the same category/homogeneous typology in terms of the requirements for competence and resources used in conformity assessment activities.

2. Scope and field of application

This Technical Regulation aims to define the requirements for the application of the flexible scope of accreditation in accordance with the requirements of the standard ISO/IEC 17011 § 7.8.4¹ and with reference to the scope of accreditation, as defined in EN ISO/IEC 17011 § 7.8.3. However, it does not apply to any other accreditation-related information provided for in ISO/IEC 17011 § 7.8.1.

The flexible scope of accreditation may be applied in the case of Certification Bodies of systems, product, persons, inspection, verification and validation. It may also be applied in the case of proprietary conformity assessment schemes, where expressly permitted by the Scheme Owner.

Bodies operating in mandatory/regulated areas, as well as those performing validation and verification activities, retain a fixed scope of accreditation, unless the application of a flexible scope is expressly requested by the competent authorities.

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¹ If the accreditation body uses flexible scopes of accreditation, it shall have documented procedures on how these are managed. The procedure shall include how the accreditation body addresses § 7.8.3, from items a) to h), including specifications on how the information required under points a) to h) will be maintained and made available upon request.

The requirements set out in this Technical Regulation constitute the criteria adopted by ACCREDIA-DC, in accordance with the provisions of the aforementioned clause of the EN ISO/IEC 17011 standard, for the management of flexible scopes of accreditation, where requested and adopted by CABs.

These criteria are applied in the verification and approval of the flexibility of the scopes of accreditation for each CAB.

3. References

3.1. Normative references

The normative documents applicable to the flexible scope, in their current version, are given below:

- ISO/IEC 17011 Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies;
- ISO/IEC 17020 Conformity assessment – Requirements for the operation of various types of bodies performing inspection;
- ISO/IEC 17021-1 Conformity assessment - Requirements for bodies providing audit and certification of management systems. Part 1: Requirements;
- ISO/IEC 17024 Conformity assessment — General requirements for bodies operating certification of persons;
- ISO/IEC 17065 Conformity assessment — Requirements for bodies certifying products, processes and services;
- ISO/IEC 17029 Conformity Assessment - General principles and requirements for validation and verification bodies.

3.2. EA Documents

- EA-2/15 “EA Requirements for the accreditation of flexible scopes” in the current revision.

3.3. Accreditation regulations

The general and technical ACCREDIA Regulations issued for the accreditation of Certification, Inspection, and Validation and Verification Bodies shall apply. For each of the referenced documents, the latest revision in force shall apply. ACCREDIA documents are freely available for download from the documents section of the ACCREDIA website.

4. Terms and definitions

Scope of accreditation: specific conformity assessment activities for which accreditation is required or has been granted. (standard ISO/IEC 17011 § 3.6)².

Fixed scope accreditation: a detailed, unambiguous, and clearly defined description of the scope of accreditation for each element (descriptor) within the accreditation scope. For example, this may include the year and reference of standards, specifications, and product schemes; standards and procedures for inspection; and standards, procedures, and schemes for certification of persons.

Flexible scope of accreditation: more generic description of the scope of accreditation, regarding management systems, products, persons, inspection activities, admitting the possibility that the CAB may, on the basis of its competences, which have already been assessed, to modify and/or increase the scope of application, use new revisions of standards, procedures and schemes, or it may add new products, professional profiles, or inspections, provided that the conformity assessment activities require the same competencies and resources as those already accredited.

For example:

- for Inspection Bodies (ISO/IEC 17020): the addition of inspection procedures in cases where the technical competences and professional capabilities of the assessors and the Technical Manager and other possible testing requirements are the same as for other inspection activities (and relative standards/applicable specifications) already covered by accreditation;
- for Bodies operating certification of persons (ISO/IEC 17024): the addition of sector professional profiles that require the same level of competence from Examiners and decision-makers as those already covered under the existing accreditation;
- for product certification bodies (ISO/IEC 17065): the addition of new products (and the relative applicable standards) in cases where the technical competences regarding the product of the assessment personnel and of the decision makers, as well as the requirements for performing tests, are the same as for other products (and the relative applicable standards/specifications) already covered by accreditation.

The scope of accreditation can also be “mixed” – partly fixed and partly flexible.

Note: the flexible scope of accreditation is also applied in cases where the accreditation certificate alongside the standards/specifications, rules of certification and inspection do not indicate the year or revision of issue.

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² In the text of this document, it is also referred to, with the same meaning, as ‘accreditation field’ or ‘accreditation application scope’

5. Requirements for accreditation with flexible scope of accreditation

5.1. General

Accreditation with flexible scope requires greater responsibility on the part of the CAB to demonstrate that it has competently and consistently designed and developed suitable operational procedures (see EA -2/15M § 6.1).

In particular, the CAB shall demonstrate that it has defined and applied a process of **design** for the flexible scope and it shall provide evidence of application of specific procedures for the management of the flexible accreditation scope that include at least:

- the methods by which it determines the requirements;
- the definition of the limits of the flexibility in terms of the homogeneity of the necessary competences and resources, including the person who, internally, manages the typology / product category / inspection activities / professional profiles within which the CAB intends to apply the flexible scope;
- the operative modalities adopted (including validation activities) for the assessment of conformity of the object of the flexible scope and the correct application and management of the related scope;
- the necessity that, in the contract review process, it is confirmed and communicated to the client that the request falls within the limits of their flexible scope;
- the responsibility to communicate to ACCREDIA-DC any significant modification or variation regarding the area of the flexible scope for which the extension of accreditation is requested, with particular, but not exclusive reference to, staff competences who is responsible for the management of the scheme and to any testing or measuring equipment;
- the responsibility and operative modalities for the management of the **Controlled list** of all elements included in the flexible scope, as well as how this List is made available to ACCREDIA-DC (it shall be published on ACCREDIA's website) and to the public³.

In cases where the IB operates on “client specifications”, the same is considered equivalent to the flexible scope and therefore must comply with the requirements of this regulation.

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³ The scope may not be made available to the public if there are specific impediments in this regard (e.g., regulatory requirements).

5.2. Obligations for the CAB

In addition to what has already been stated in the previous point 5.1.

In the event that the CAB receives a request for certification/inspection activities that could fall within the flexible scope but have not yet been performed by the CAB and therefore are not yet included in the List, the CAB shall:

- inform the Client that the related Certificate / Report cannot be issued under accreditation until the CAB itself has obtained the extension of its accreditation to the flexible scope for the area covered by the request;
- inform the client of the related implications (e.g., request processing times, costs, etc.);
- ensure that the necessary resources and any other means required to complete the specific requested activity are available;
- have adequately qualified personnel for the completion of the specific validation or verification activity within the scope covered by the request;
- have conducted the necessary validation or verification;
- update the list only after the related technical activities have been correctly performed in accordance with the design and implementation process and duly authorized by the CAB;
- inform ACCREDIA of all CAB sites involved in the additional or modified conformity assessment activity. It should be noted that an additional or modified conformity assessment activity must not be included in the List if it involves new CAB sites until these have been positively evaluated by ACCREDIA and are included among the accreditation information as required by § 7.8.1 of the ISO/IEC 17011 standard.

5.2.1 The CAB shall keep and make publicly available on its website an updated and controlled List of the elements managed in the flexible scope.

This list shall contain at least, the following:

- typology/category of product, personnel, inspection activity;
- product (service), professional profile, inspection area;
- the certification/inspection standard with the code of identification, the year/revision;
- the document containing the rules for the issuance of certification of the product or personnel with the code of identification, the year/revision;
- the date of inclusion by the CAB of the element in question in the flexible scope.

5.3. Obligations for ACCREDIA

5.3.1. Risk-Based Approach

As indicated in document EA-2/15, ACCREDIA adopts a risk-based approach during the acceptance of the application for flexible accreditation and in the subsequent processes of planning, assessment, granting, and maintenance of accreditation with a flexible scope for a CAB. This approach takes into account, in particular, the following aspects:

- the CAB's knowledge of the accreditation requirements and its level of conformity;
- the extension of the flexibility requested by the Body;
- the robustness of the process (including the level of control measures in place) defined by the CAB for managing the flexible accreditation;
- the stability of the CAB's management system and of the personnel involved in managing the flexible scope;
- the type, complexity, and familiarity of the conformity assessment activities for ACCREDIA (with particular attention to new and emerging activities, for which competence and requirements may not be fully known);
- the CAB's ability to demonstrate that its way of operating is appropriate, valid, and carried out in an impartial, competent, and consistent manner;
- expectations of stakeholders and the Competent Authority;
- risks related to the reputation of ACCREDIA, the CAB, or the market itself;
- the geographical area in which the applicant CAB operates.

5.4. Application for the flexible scope of accreditation

The application for **flexible scope accreditation** is to be considered an extension as it may only be submitted if the CAB has held accreditation with a fixed scope for the specific accreditation standard for at least two years. This time period of fixed scope accreditation enables ACCREDIA-DC to evaluate the grade of competence and reliability of the CAB to properly manage a flexible scope⁴.

The application for the extension for the flexible scope shall be presented by the CAB to ACCREDIA-DC filling the module DA-10 which is available on ACCREDIA's website, together with all the necessary documentation.

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⁴ CAB operations under another accreditation (either directly or as a branch office, in the case of multinational CABs) may also be considered as compensation for the two-year period indicated. In such cases, ACCREDIA-DC must review the outcomes of the assessments carried out by the relevant NAB to determine whether the conditions are met to proceed with the subsequent steps outlined in this regulation. Furthermore, any reductions to the two-year period may be evaluated based on the level of complexity and criticality of the product macro-category, professional profile, inspection type, etc., for which the flexible scope is being requested.

In particular, the extension application for the flexible scope of accreditation must describe the scope of application itself (typology/category of product, inspections, persons) and it shall include:

- the motivations and evidence ensuring the homogeneity of the elements contained in the flexible scope for each typology/category identified;
- the procedure prepared and made available by the CAB for the complete management of the flexible scope.

The application for the extension for the flexible accreditation scope is evaluated by ACCREDIA-DC which, before accepting it and issuing a technical financial quotation including the details of the necessary assessment activities, shall conduct a risk analysis of the CAB in accordance with all the requirements as set out in § 6.2.3 of EA-2/15M (refer to § 5.2.1 above).

Following the risk analysis result, ACCREDIA-DC proceeds to the acceptance of the application and the issuance of the technical and financial quotation, evaluating whether it is sufficient to perform only a document review of the duration of 0.5 man-day for each conformity assessment scheme for which the flexible scope has been requested, or if it is necessary to perform an office assessment at the CAB's location or a witness assessment.

If the result of the risk analysis reveals that the CAB does not possess sufficient competence to manage the flexible scope of accreditation or if the complexity of the scope does not permit the management of the requested flexibility, ACCREDIA-DC will reject the application for the extension to the flexible scope.

5.5. Execution of the assessments and decisions concerning flexible scope accreditation

The evaluation of the "flexible scope of accreditation" demands particular consideration of the following elements:

- competence and responsibility of staff involved in the management of conformity assessment activities included in flexible scope;
- conduct of the process of design and management of the flexible scope, of the Controlled List of the flexible scope (responsibilities, entry procedures, modifying and/or cancelling of certified/inspected elements, certification date, accessibility for ACCREDIA-DC and for the public etc.).

If the result of the above assessments set out in the technical/financial quotation is positive ACCREDIA-DC will present to the relevant Sector Accreditation Committee the extension of the flexible scope of accreditation.

When the Sector Accreditation Committee approves the flexible scope of a CAB for a specific type/category of products, personnel, or inspection activities, the accreditation certificate is amended accordingly.

Specifically, for each typology/category subject to the flexible scope, the list of included elements is removed and replaced with the following statement:

"For this typology the Body has been accredited with a flexible scope; for detailed information on the scope, please refer directly to the list published by the accredited Body."

If ACCREDIA-DC is asked to confirm the details of a scope of a flexible certificate, ACCREDIA-DC shall refer the applicant to the relevant CAB, which is responsible for maintaining the document up to date and for providing justifications to ACCREDIA-DC, the authorities, and the market in general regarding the management of the flexible scope (correct list, competencies, activities performed, etc.).

5.6. Maintenance of the flexible scope of accreditation

For the purposes of maintaining and renewing accreditation, in developing and confirming its assessment programme, ACCREDIA-DC shall take into account the following factors:

- results of previous assessments and degree of conformity with accreditation requirements;
- robustness of the process (including the level and extent of controls implemented) defined by the CAB for managing the flexible accreditation and its limitations;
- the CAB's understanding of the requirements and procedures for managing flexible accreditation;
- the frequency defined by the CAB for using flexible accreditation, i.e., how often it intends to update the lists;
- the extension of flexibility granted to the CAB.

During the preparation of the surveillance and/or renewal assessment of the CAB which has obtained use of the flexible scope, ACCREDIA-DC appoints the assessment team to check the CAB's Controlled List in order to analyze the elements included in the flexible scope, with the aim of selecting the files considered most significant for the examination during the office assessment.

These elements are reviewed during the assessment to ensure:

- that the elements contained in the CAB's controlled list are actually consistent with what has been prepared by the CAB and approved by ACCREDIA-DC in relation to the flexible scope and that, therefore, no elements have been included that fall outside the approved category/typology with respect to the homogeneity of the necessary competences and resources (usually these are the competences of assessors, the methodology for testing/measuring and the equipment and instruments used);
- the responsibilities and modalities for the effective controlled management of the List and its public availability;
- the completeness and accuracy of the records regarding the investigation performed by the CAB to establish that the new element of certification/inspection could indeed be included within the flexible scope and did not instead require an accreditation extension.

The planning of the above-mentioned assessment will take into account the possible need to conduct witness assessments related to elements included by the CAB within the flexible scope.

6. Management of non-conformities and sanctions issued by ACCREDIA-DC

In addition to the motivations normally provided for by the current Accreditation Regulations, it should be noted that deficiencies within the flexible scope of accreditation may lead ACCREDIA-DC to submit to the relevant Sector Accreditation Committees sanctioning measures depending on the severity of the case, such as: reverting to a fixed scope, reducing the scope itself, and/or suspension of accreditation.

In the event that the CAB submits a withdrawal of the flexible scope of accreditation and requests to revert to a fixed scope, ACCREDIA-DC may carry out a 0.5-day document review to assess how the Body manages the transition to the fixed scope.

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