

<b>Title</b>	<b><i>Directives for accreditation with flexible scope, Certification and Inspection Bodies Department</i></b>
<b>Reference</b>	<b>RT-37</b>
<b>Revision</b>	<b>01</b>
<b>Date</b>	<b>28-05-2020</b>

<b>Preparation</b>	<b>Approval</b>	<b>Authorization</b>	<b>Application date</b>
The Director Certification and Inspection Department	The Directive Council	The President	15-06-2020

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## 1. INTRODUCTION

The description of the competences of an accredited CAB (certification/inspection/verification or validation body) 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.

This description of the scope of accreditation, however, presents some limitations, because if any changes or extensions to the scope are necessary, the CAB shall make a specific application to ACCREDIA-DC, with subsequent evaluation and approval.

The introduction of the flexible scope of accreditation (see definition below) enables the CAB, within the defined field of accreditation already obtained, to respond to the requests of clients and authorities, and to extend its application to new technical standards for products, personnel or inspection procedures, as long as they belong to the same category or typology regarding the requirements for competences and resources used in conformity assessment activities.

## 2. SCOPE AND FIELD OF APPLICATION

The present Technical Regulation defines the requirements for the application of the flexible scope of accreditation in accordance with the requirements of the standard UNI CEI EN ISO/IEC 17011 § 7.8.4: *"When the accreditation body uses a flexible scope of accreditation, it shall have documented procedures on how it addresses and manages flexible scopes. The procedure shall include how the accreditation body addresses 7.8.3 bullets a) to h), including specifying how the information required for bullets a) to h) shall be maintained and made available on request"*.

The flexible scope of accreditation may be applied for CABs of management systems, product, persons, inspection, verification or validation.

Regarding CABs operating in the mandatory/regulated area, the same as those operating in verification and validation activities, the fixed scope of accreditation is maintained, unless it is possible to apply the flexible scope of accreditation, upon specific request from the competent authority.

The requirements contained in this Technical Regulation constitute the criteria adopted by ACCREDIA-DC in conformity with the requirements of the point referred to above of the standard UNI CEI EN ISO/IEC 17011 for the management of flexible scopes of accreditation if requested and adopted by the CAB.

These requirements are applicable in the assessment and approval of the flexibility of the scopes of accreditation of each CAB.

### **3. REFERENCES**

#### **3.1. NORMATIVE REFERENCES**

The normative documents applicable to the flexible scope, in the 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 14065 Greenhouse gases — Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition.

#### **3.2. EA DOCUMENTS**

- EA-2/15M:2018 EA Requirements for the accreditation of flexible scopes.

#### **3.3. ACCREDITATION REGULATIONS**

The Accreditation Regulations applicable to the flexible scope, in the current version, are given below:

- RG-01 Regulation for the accreditation of Certification, Inspection, Verification and Validating Bodies – General Requirements;
- RG-01-01 Regulation for the accreditation Management Systems Certification Bodies;
- RG-01-02 Regulation for the accreditation of Personnel Certification Bodies;
- RG-01-03 Regulation for the accreditation of Product/Service Certification Bodies;
- RG-01-04 Regulation for the accreditation of Inspection Bodies;
- RG-01-05 Regulation for the accreditation of Verification Bodies verifying and validating GHG (greenhousegas) emissions.

## 4. TERMS AND DEFINITIONS

**Scope of accreditation:** specific conformity assessment activities for which accreditation is required or has been granted. (standard UNI ISO/IEC 17011 § 3.17).

**Fixed scope accreditation:** description of the scope of accreditation which details fully the standards, specifics and product schemes, inspection standards and procedures and the standards, procedures and schemes for the certification of persons.

**Flexible scope of accreditation:** more generic description of the scope of accreditation, regarding management of systems, products, persons, inspection activities, admitting the possibility that the CAB may, on the basis of its competences, which have already been assessed with positive outcome, to modify and/or increase the scope of application, use new revisions of standards, procedures and schemes, or it may add new products, persons or inspections.

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 Persons Certification Bodies (ISO/IEC 17024): the addition of sector professionals profiles requiring the competences of examiners and decision maker which are similar as those for professionals profiles already covered by accreditation;
- for product certification bodies (UNI CEI EN ISO/IEC 17065): the addition of new products (and the relative applicable standards) in cases where the technical competences regarding the product of the auditor 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 state the year or revision of issue.

## 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 in showing that its operative modalities used for the scope have been designed and developed competently and coherently (see EA -2/15M § 4.1 and § 4.2).

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 responsibility to determine exactly the limits of the flexibility in terms of the homogeneity of the necessary competences and resources, i.e. the person who, on an internal level, establishes the typology / product family / inspection activities / professional profiles within which the CAB intends to apply the flexible scope;
- the operative modalities adopted for the assessment of conformity of the object of the flexible scope and the correct application and management of the related 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 the elements covered by the flexible scope and how the list is made available to ACCREDIA-DC (it shall be published on ACCREDIA's website) and also to the public.

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.

## 5.2. APPLICATION FOR THE FLEXIBLE SCOPE OF ACCREDITATION

The application for **flexible scope accreditation** is to be considered an extension as it can be requested only if the CAB already has fixed scope accreditation for a 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 manage in a correct way a flexible scope.

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.

The application for the extension for the flexible scope shall describe the scope of application (typology/product category, inspections, personnel) 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 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 § 6.3.2 of EA-2/15M (degree of preparation / understanding of the CAB of the rules and procedures for the implementation and management of a flexible scope, performance and stability of the CAB management system with particular reference to the previous two years of accreditation required by ACCREDIA in the fixed scope, complexity of the conformity activities for which the flexible scope is requested, degree of extension of the flexibility, reputational risks for ACCREDIA, for the CAB and for the market according to the flexibility required, expectations of the interested parties,

extension of the controls proposed by the CAB for the management of a flexible field, any risks resulting from the applicant CAB's operative location from a geographical point of view etc.), etc.

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

### **5.3. EXECUTION OF THE ASSESSMENTS AND DECISIONS CONCERNING FLEXIBLE SCOPE ACCREDITATION**

The evaluation of the flexible scope of accreditation requires to pay particular attention to the following factors:

- 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, modalities for entering, modifying and/or cancelling of certified or inspected elements, the date of certification, accessibility for ACCREDIA-DC and for the public etc.).

If the result of the above assessments set out in the technical 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 decides regarding a CAB's flexible scope for a certain typology or family of products, personnel or inspection activity, the accreditation certificate is duly modified.

Corresponding to each typology or family which is the object of the flexible scope the list of elements present is eliminated and the following wording is entered:

***"For this typology the CAB has been granted flexible scope accreditation. For details concerning the scope refer directly to the accredited CAB."***

If ACCREDIA-DC is asked to confirm the details of a flexible certificate, ACCREDIA-DC shall send the request to the CAB in question which has the responsibility of keeping the document updated and of providing explanations to ACCREDIA-DC, to the authorities, and to the market regarding management of the scope (correct list, competences, activities undertaken etc.).

## **5.4. MAINTENANCE OF THE FLEXIBLE SCOPE OF ACCREDITATION**

During the preparation of the surveillance and/or renewal assessment of the CAB which has obtained use of the flexible scope, ACCREDIA-DC requires the assessment team to check the CAB's Controlled List to analyze the elements included in the flexible scope in order to select the files most important for the evaluation to be done during the office assessment .

These elements are reviewed during the assessment with the objective of ascertaining:

- that the elements contained in the CAB's controlled list are indeed congruent with what the CAB made available and was approved by ACCREDIA-DC relating to the flexible scope and that, therefore, elements were not included which do not belong to the approved category/typology with respect to the homogeneity of the necessary competences and resources (usually these are the competences of auditors/inspectors, 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 which has effectively been included in the flexible scope and did not require an extension to the accreditation.

The planning of the assessment as above will take into consideration the need to perform, when necessary, witness assessments of elements which the CAB has included in the flexible scope.

## **5.5. OBLIGATIONS OF THE CAB**

**5.5.1** The CAB shall have an internal procedure identifying the responsibilities and operative modalities followed for the inclusion of each new element in the flexible scope. The CAB shall show that it possesses and applies a "design process" of its flexible scope to including new products/services, professional profiles, inspection activities within the flexible scope of accreditation.

These procedures shall consider also cases where the CAB receives a request for certification or inspection activities which could be included in the flexible scope but which have not yet been performed by the CAB and are therefore not yet in the list.

In this case the CAB shall inform the client that the relative certificate or report cannot be issued under accreditation until the CAB has obtained extension of its accreditation to the flexible scope for the requested object area.

**5.5.2** 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 person, inspection area;
- the certification or inspection standard with the code of identification, the year and the revision;
- the document containing the rules for the issuance of certification of the product or persons with the code of identification, the year and the revision;



- the date of inclusion by the CAB of the element in question in the flexible scope.

## **6. MANAGEMENT OF NONCONFORMITIES AND SANCTIONS IMPOSED BY ACCREDIA-DC**

In addition to the motivations normally contained in the Accreditation Regulations in force, any failures in the flexible scope may lead to the presentation of sanctions by ACCREDIA-DC to the sector accreditation committee for imposition commensurate with the failure in question; this may consist of the return to the fixed scope, the reduction of the scope and/or the suspension of accreditation.