

**TITLE** **PROCEDURE FOR SETTING UP NEW ACCREDITATION SCHEMES**

**REFERENCE** **PG-13**

**REVISION** **03**

**CONFIDENTIALITY** **06**

**DATE** **11-02-2021**

**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.*

**PREPARATION**  
**THE QUALITY MANAGER**

**APPROVAL**  
**THE DIRECTIVE COUNCIL**

**AUTHORIZATION**  
**THE GENERAL DIRECTOR**

**APPLICATION DATE**  
**18-02-2021**

## CONTENTS

<b>1. SCOPE AND FIELD OF APPLICATION .....</b>	<b>3</b>
<b>2. REFERENCE DOCUMENTS AND ABBREVIATIONS .....</b>	<b>3</b>
2.1 NORMATIVE DOCUMENTS .....	3
2.2 INTERNAL DOCUMENTS .....	3
2.3 ABBREVIATIONS .....	3
<b>3. DEFINITIONS.....</b>	<b>4</b>
<b>4. INTRODUCTION OF A NEW ACCREDITATION SCHEME .....</b>	<b>4</b>
4.1 IDENTIFICATION AND EVALUATION OF NEEDS FOR A NEW SCHEME.....	4

## 1. SCOPE AND FIELD OF APPLICATION

The present procedure defines the criteria, the modalities and responsibilities related to setting up new accreditation schemes and to changes in existing schemes regarding Level 2, Level 3 and Level 4 accreditation standards as classified by EA and given in Table A attached. For clarification some schemes of this typology are referred to which are already in use: ISO 15189, ISO 14065, ISO/IEC 17043 etc.

The present procedure does not regard evaluation modalities for the assessment of new conformity assessment schemes referring to standards of Levels 5 in Table A. these modalities are described in the ACCREDIA procedure PG-13-01.

## 2. REFERENCE DOCUMENTS AND ABBREVIATIONS

### 2.1 NORMATIVE DOCUMENTS

- UNI CEI EN ISO/IEC 17011:2017 Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies (Par. 4.6);
- EA 1/06 A AB:2020 rev.09 EA Multilateral Agreement Criteria for signing. Policy and procedures for development;
- Regulation (CE) N. 765/08 setting out the standards regarding accreditation and market surveillance for the marketing of products.

### 2.2 INTERNAL DOCUMENTS

- MQ: ACCREDIA management manual;
- ST: ACCREDIA Statute;
- ST-01 Regulation for the application of the Statute;
- RG 04 Regulation for the proceedings of the Committee for Accreditation Activities.

### 2.3 ABBREVIATIONS

The following abbreviations used in this document:

- CAB** Conformity Assessment Body;
- CD** Directive Council;
- CdA** Committee for Accreditation Activities;
- CSA** Sector Accreditation Committee;
- DG** General Director;
- DDD** Director of Department;
- WG** Working group.

### 3. DEFINITIONS

**Accreditation scheme:** the rules and procedures regarding the accreditation of CABs for which the same requirements are applied (§ 3.8 of the standard UNI CEI EN ISO/IEC 17011:2018<sup>1</sup>).

The accreditation scheme can be developed by an AB, by associations of ABs and by standardization bodies.

### 4. INTRODUCTION OF A NEW ACCREDITATION SCHEME

#### 4.1 IDENTIFICATION AND EVALUATION OF NEEDS FOR A NEW SCHEME

The introduction of new accreditation schemes – and the improvement of existing ones – are complex matters for an AB as the technical requirements for the scheme have to be identified, interpreted and satisfied. They also have to be contractually defined to be operatively effective and consistent with the scheme and they must be able to guarantee impartiality through an adequate involvement of the interested parties<sup>2</sup>.

The need to introduce new accreditation schemes regarding Level 3 standards may derive from:

- the development of new international schemes;
- requests coming from the reference socio-economic area from economic operators and social representatives;
- the need to meet conformity assessment elements in the mandatory area.

The scheme shall be based on harmonized accreditation standards and shall not contradict or exclude any of the requirements of the standards or of other normative documents (e.g., UNI CEI EN ISO/IEC 17011, Reg. (EC) 765/08 etc.).

In particular, ACCREDIA shall verify the conformity of the new scheme against national and international decisions concerning what can be accredited and what does not have to be accredited.

The necessities for a new accreditation scheme are gathered by the DDD or the DG for analysis who analyzes and formalizes the following aspects:

- a) the opportunity and feasibility of developing or extending an accreditation scheme;
- b) consultation to obtain the opinion of the interested parties;
- c) the definition of the competence criteria of internal and external staff: assessors/technical experts and members of the CSAs involved in the management and performance of the assessments and other activities relating to the process of accreditation of a new scheme;

---

<sup>1</sup> The requirements of the accreditation scheme include but are not limited to UNI CEI EN ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17025, ISO/IEC 17024, ISO/IEC 17029, ISO 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189 and ISO 14065.

<sup>2</sup> An "interested party" is a person or organization with direct or indirect interests in accreditation (§3.33 of UNI CEI EN ISO/IEC 17011:2018). The interested parties include the AB, the CABs, CAB associations and their clients, industrial services, commercial associations, scheme owners, government regulatory bodies, other governmental or non-governmental organizations, and consumers associations.

- d) the assessment of the availability of the competences and resources deemed necessary (competent department, assessors/experts, competent CSAs);
- e) the decision to access and use the unavailable resources and competences;
- f) the evaluation of the need to draw up new ACCREDIA guidelines or documents applicable to the scheme (e.g., new regulations, technical documents, procedures or instructions) including the competence criteria which are then entered in the department's procedures/instructions;
- g) staff training (internal and external: assessors/experts, members of the CSAs) involved in the assessments and other activities relating to the process of accreditation of the new scheme;
- h) the introduction and implementation of rules for the management of the period of transition.

During such analysis ACCREDIA, if necessary, shall consult technical experts, EA experts or experts from other ABs signatory to the MLA EA / IAF / MRA ILAC agreements.

## **4.2 PROCESS OF APPROVAL**

### a) Directive Council

Following the analysis as described in § 4.1, the DG sends the results to the Directive Council for approval to start the scheme.

The Directive Council deliberates regarding the possibility for ACCREDIA to start the new accreditation scheme, including the identification of the applicable standards, the relevant department and any needs for new resources/personnel or training as well as the need to define the criteria for transition.

### b) Committee for Accreditation Activities

Following approval by the CD, according to the proposal of the ACCREDIA Director, the CdA evaluates the potential need for competence requirements among assessors and/or the relevant CSA.

### c) Sector Accreditation Committee

The CSA is informed by the department director of the start of the new scheme after approval by the DC.

### d) Setting up a WG for preparing a regulation/procedure/instruction

If ACCREDIA decides on the necessity for a specific regulation/procedure/instruction it performs the task of creating it, setting up a WG if necessary and following the process of approval as defined in the internal procedures.

## **4.3 START OF THE SCHEME**

Following the decision to introduce the scheme, the department director informs the accredited/applicant bodies either by means of a circular or by means of the ACCREDIA website.

#### **4.4 MODIFICATIONS TO, OR TERMINATION OF, EXISTING ACCREDITATION SCHEMES**

In cases of modification of an existing accreditation scheme, ACCREDIA shall:

- carry out a full assessment based on the applicable points of the method set out in § 3.1 4.1;
- decide whether any actions are to be taken such as the modification of accreditation regulations or whether to issue new technical documents, if it's necessary, a dedicated working group and following the approval process required by internal procedures.

#### **4.5 TERMINATION OF EXISTING ACCREDITATION SCHEMES**

In cases of termination of an accreditation scheme the department directors, in agreement with the DG, analyze the reasons (internal or external), taking into account:

- the views of interested parties;
- the contractual obligations;
- the requirements for transition;
- communication with CABs and eventually their clients.

The termination of an accreditation scheme shall be made publicly available on ACCREDIA's website.

#### **4.6 INFORMATION TO ACCREDITATION BODIES CONCERNING EA, IAF, ILAC MATTERS**

It is the responsibility of all ACCREDIA's personnel taking part in meetings and in EA, IAF and ILAC working groups to present the content of new regulations prepared by ACCREDIA concerning the start of a new scheme so that the contents are discussed and adopted also within the applicative guides produced by EA, IAF and ILAC.

**TABLE A ref. § 9. Appendix 2 THE EA MLA EA 1/06 A AB:2020 rev.09**

