TITLE **PROCEDURE FOR SETTING UP THE ACCREDITATION OF NEW CONFORMITY ASSESSMENT SCHEMES**

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REVISION **03**

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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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AUTHORIZATION
THE GENERAL DIRECTOR

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0. INTRODUCTION

Market necessities lead to requests to start up new certification activities requiring accreditation. Applications for the accreditation of a conformity assessment scheme must be carefully evaluated by ACCREDIA owing to the fact that not all of them are acceptable for reasons as described in the present document and which derive from an assessment of the conformity of the scheme against all the requirements of the international accreditation standards of the ISO/IEC 17000 series, as well as other reference documents which are mandatory in accordance with ACCREDIA's signatory status of the MLA EA, IAF and MRA ILAC multilateral agreements. Also applicable are the provisions contained in the ministerial decree of 22.12.2009 for the designation of ACCREDIA.

1. SCOPE OF APPLICATION

The present document has been drawn up in order to clarify the modalities of approval and accreditation of new conformity assessment schemes (CAS) by ACCREDIA regarding Level 5 of Table A (given below).

With regard to inspection, testing and calibration schemes, the present procedure is applicable for every new scheme with international validity.

For schemes valid at the national level, the procedure is applicable when the new scheme is presented by a scheme owner.

Note: the evaluation modalities of new accreditation schemes referring to level 3 and 4 standards of Table A are described in the procedure PG-13.

2. REFERENCE DOCUMENTS AND ABBREVIATIONS

2.1. APPLICABLE STANDARDS AND EA/IAF/ILAC GUIDELINES

- UNI CEI EN ISO IEC 17000 "Conformity assessment – vocabulary and general principles" in the current version;
- UNI CEI EN ISO/IEC 17011: "Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies" (Par. 4.6.3);
- UNI CEI EN ISO/IEC 17020 "Conformity assessment — Requirements for the operation of various types of bodies performing inspection" in the current version;
- UNI CEI EN ISO/IEC 17021-1 "Requirements for bodies performing audits and certifications of management systems" in the current version;
- UNI CEI EN ISO IEC 17024 "Conformity assessment – requirements for bodies operating certification of persons" in the current version;
- UNI CEI EN ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories";
- UNI CEI EN ISO/IEC 17029 "Conformity assessment - General principles and requirements for validation and verification bodies";

- UNI CEI EN ISO 17034 "General requirements for the competence of reference material producers";
- UNI CEI EN ISO 17043 "Conformity assessment - General requirements for proficiency testing";
- UNI CEI EN ISO IEC 17065 "Conformity assessment – requirements for bodies certifying products, processes and services";
- ISO/IEC 17007 "Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment";
- ISO/IEC 17067 "Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes";
- UNI CEI 70099 "International metrology vocabulary – basic and general concepts and related terms (VIM)";
- UNI CEI EN 45020 "Standardization and related activities – general vocabulary";
- EA 1/06 A AB:2020 rev.09 "EA Multilateral Agreement Criteria for signing policy and procedures for development";
- EA-1/22 A-AB:2020 rev.04 "EA procedure and criteria for the evaluation of Conformity Assessment Schemes by EA Accreditation Body members";
- ILAC R6:05/2019 "Structure of the ILAC Mutual Recognition Arrangement and Procedure for Expansion of the Scope of the ILAC Arrangement".

All the above documents are applicable in their current version.

2.2. INTERNAL DOCUMENTS

- RG-19 "Regulation for Scheme Owners applying for acceptance for accreditation by ACCREDIA of new Conformity Assessment Schemes and their revision";
- MQ "ACCREDIA management manual";
- ST "ACCREDIA Statute";
- ST-01 "Regulation for the application of the Statute";
- RG 04 "Regulation for the procedures of the Accreditation Committee".

2.3. ABBREVIATIONS

The following abbreviations used in the original Italian version are retained in the English version:

hAB Home accreditation body;

CD Directive Council;

CdA Committee for Accreditation Activities;

CSA Sector Accreditation Committee;

SCSA Sector Accreditation Sub-committee;

DG General Director;

DDD Director of Department;

CAS Conformity assessment scheme (see below);

SO Scheme owner (owner of a conformity assessment scheme - see below);

CAB Conformity Assessment Body.

3. DEFINITIONS

The standard **UNI CEI EN ISO/IEC 17000** contains the definitions and general principles related to conformity assessment activities.

Below are the definitions related to the need to demonstrate that a product, process, person or organization is in conformity with the applicable requirements.

- Conformity assessment (4.1): showing that the specified requirements (5.1) have been fulfilled.
- Specified requirement (5.1): specified necessity or expectation.
- Object of the conformity assessment (4.2): entity to which specified requirements apply (5.1). Examples: product, process, service, system, installation, project, data, design, material, declaration (claim), person, body or organization or any combination of them.
- Product (3.3): result of a process (as defined in ISO/IEC 17065).
- Test (6.2): identification of one or more characteristics of the object of a conformity assessment (4.2), in accordance with the procedure (5.2).
- Inspection (6.3): examination of the object of a conformity assessment (4.2) and determination of its conformity with the specific requirements or, on the basis of a professional opinion, with general requirements.
- Audit (6.4): process for obtaining relevant information with regard to an object of conformity assessment (4.2) and the objective evaluation of such information to determine to what extent the specific requirements (5.1) have been fulfilled.

The results of the above activities may be included in a report or in a series of other documents. They shall be submitted for review (7.1) to verify conformity with the requirements. This review constitutes the basis for establishing conformity to requirements, and confirmation is formalized with the issue of the declaration (7.3) and, subsequently, the certification (7.6).

To ensure the continuity of conformity with the requirements, certain certification schemes provide for subsequent surveillance activities (8.1).

Consistent with the above, the following definitions are also considered:

Calibration: an operation performed in specific conditions. In the first phase a relation is established between the quantity values, with the respective measurement uncertainties provided by the measurement samples and the corresponding indications which include the associated measurement uncertainties. In the second phase this information is used to establish a relation whereby it is possible to obtain a measurement result starting from an indication.

NOTE: the Italian term "calibrazione" should not be used to mean calibration.

NOTE 1: A calibration may be expressed by means of a declaration, a function of calibration, a diagram of calibration, a curve of calibration or a table of calibration. In some cases, it may consist of a correction that is an addition or a multiplication, accompanied by the associated measurement uncertainty.

NOTE 2: The calibration should not be confused with the setting of a measurement system which, in certain sectors, is often wrongly called "self-calibration" and it should also not be confused with a verification of the status of calibration.

NOTE 3: Frequently, only the first phase referred to in the present definition is interpreted as a calibration.

Technical specification: a document setting out the technical requirements to be fulfilled by products, processes or services (a technical specification shall indicate, where necessary, the modalities with which it is possible to ascertain if the requirements have been fulfilled).

Accreditation scheme: the rules and processes regarding the accreditation of CABs for which the same requirements are applied (§ 3.8 of the standard UNI CEI ISO/IEC 17011:2018).

Note 1: the requirements of the certification scheme include, but are not limited to, the standards 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.

Standard: (UNI CEI EN 45020) a document created with consent and approved by a recognized body that provides, for common and repeated use, the rules, guidelines or characteristics regarding certain activities or the results of these activities in order to obtain the best order in a determined context.

Note: a standard should be based on proven scientific, technological and experimental results and have, as an objective, the promotion of benefits for the community.

Moreover, and not in conflict with the above definition, in compliance with Regulation EU 1025 of the European Parliament and of the Council of 2012-10-25 on European standardization, the term "standard" is used with the following meaning:
"*A specific technique used by a recognized standardization body, for repeated or continuous application, without obligatory compliance and belonging to one of the following categories*:

- *international standard: a standard adopted by an international standardization body;*
- *European standard: a standard adopted by a European standardization body;*
- *harmonized standard: a European standard adopted on the basis of a request by the Commission for the implementation of EC legislation on harmonization;*
- *national standard: a standard adopted by a national standardization body*".

Standards, therefore, are documents defining the characteristics (dimensions, performance, environmental, safety, organizational etc.) of a product, process or service, in accordance with the state of the art and they are the result of the work of national and international experts.

Publicly available specifications: documents introducing technical provisions and applicable sector models of technical standards, created on the basis of a rapid process of consultation limited to the authors under the operative leadership of the standardization body and drawn up

by it after verifying the absence of standards (or projects of standards) regarding the same matter, both nationally and internationally.

The main two definitions are set out in EA-1/22 A-AB rev. 04 and the others are contained in EA-1/22.

Conformity assessment scheme (CAS) § 2.1 EA-1/22: for the purposes of the present document, a CAS, as defined in UNI CEI EN ISO/IEC 17000, is a publicly available document containing the following requirements:

- The object of the conformity assessment (e.g. product, process, service, system or person);
- The requirements regarding the performance of the conformity assessment;
- The modalities used for determining conformity, e.g. tests, inspections, verifications, validations or audits, as well as all other activities carried out to ensure conformity;
- All requirements imposed by the scheme owner on the CAB and every specific request or interpretation, where applicable;
- Every required specification or interpretation of UNI CEI EN ISO/IEC 17011, where applicable.

Note (ACCREDIA):

- A CAS is defined as "mandatory" when it is required by law or by national or international regulations;
- A CAS is defined as "voluntary" when it is not required by law or by national or international regulations. A voluntary CAS shall take into consideration any mandatory factors related to the object of the certification.

Scheme Owner (SO) § 2.2 EA-1/22: the SO is the identifiable organization which has defined a CAS and is responsible for the design of the CAS. Some examples of a SO are given:

- a standardization body [1];
- a CAB;
- organizations using the services of a CAB;
- organizations buying or selling products submitted to conformity assessment;
- manufacturers or associations of manufacturers which have established their own CAS.

It is not possible for a NAB to be a scheme owner.

4. PROCESS OF APPROVAL OF A NEW CONFORMITY ASSESSMENT SCHEME AND START OF THE ACCREDITATION PROCESS

4.1. REVIEW OF THE APPLICATION FOR ACCEPTANCE OF A NEW CAS

The main reference document is EA-1/22.

[1] excluding cases where the scheme is entirely defined by the standards and the role of the standardization body is limited to the issue of the standard itself.

For this reason, the document in the original language and the Italian translation is available on ACCREDIA's website.

The Italian translation of EA-1/22 rev.02 is an annex to this procedure (Annex 1, PG-13-01) as is Annex 1 of EA-1/22 which is referred to in the application for the acceptance for a new CAS to be submitted for accreditation (DR-02 applicable to CASs that are different from the certification of persons ISO/IEC 17024 and DR-04), which must be completed by the SO for the review of the new CAS.

Below are some specifications regarding the applicability of EA-1/22 and of the requirements contained in Annex 1.

The procedure for the approval of a CAS (set out in EA-1/22), by ACCREDIA (hAB) and by the EA Secretariat and by other NABs signatory to the EA MLA agreements, with reference to § 4.2 of EA-1/22 (evaluation of a multi-national CAS) is applicable only when the following conditions are all fulfilled [2]:

1. The CAS refers to conformity assessment activities in the voluntary sector;
2. The CAS is not based on a normative document (e.g. ISO standards, ISO/PAS Publicly Available Specifications, ISO/TS Technical Specifications, ISO/TR Technical Reports) or other documents issued by standardization bodies (e.g. IWA of ISO, PdR UNI, PAS of BSI, CWA of CEN etc.);
3. The CAS is of international importance;
4. If the SO is also the CAB which is applying for accreditation for the CAS, the SO/CAB shall permit the use of the CAS by other CABs;
5. The SO shall show willingness to undergo evaluation in accordance with EA-1/22. It is not obligatory for a SO to submit a CAS to an EA evaluation, but if this is done, other European ABs can duplicate the assessment activities conducted by the hAB;
6. The scheme has not already been evaluated positively by EA or IAF/ILAC.

If the CAS is intended for the mandatory/regulated areas, or if the scheme is based on a normative document as per § 2, or the scheme has already been evaluated positively by all EA members in line with EA 1/22, or it already had IAF/ILAC recognition, it is necessary only to inform the CdA / CD using the appropriate informative document (Annex 3 of DR-02 or DR-04) also after the start of accreditation activities. If the scheme is not complete (to be complete a scheme shall contain the evaluation requirements and rules for evaluation), ACCREDIA may take part in the training of a working group with the involvement of all the interested parties (e.g. at UNI for the publication of a PdR, or with the publication of circulars) in order to define the missing rules.

Also in these cases ACCREDIA does not perform the tasks of the SO, but it coordinates or promotes the working group.

Also in cases where the CAS is intended for the mandatory/regulated areas, the requirements of EA-1/22 are applicable as a guideline for the technical analysis of the characteristics of the SO and of the CAS, as above. However, if any requirements are inapplicable, this shall be signaled

[2] national schemes already active before 21.05.2015 do not require an assessment in accordance with EA-1/22 if they are covered by national regulations.

and they shall be submitted to the attention of ACCREDIA's Committee for Accreditation Activities (see below).

ACCREDIA does not perform accreditations against draft standards.

4.2. REVIEW OF THE APPLICATION FOR ACCEPTANCE OF A NEW CAS BY THE DIRECTIVE COUNCIL (CD) AND THE COMMITTEE FOR ACCREDITATION ACTIVITIES (CDA)

The SO submits the application for acceptance of a new CAS for accreditation by means of the following modules:

- DR-02: for a new Conformity Assessment Scheme which is different from the certification of persons (ISO/IEC 17024);
- DR-04: for a new Conformity Assessment Scheme for the certification of persons (ISO/IEC 17024).

The modules DR-02 and DR-04 consist of three parts: Annexes 1, 2 and 3, which the SO shall complete as follows:

4.2.1.1. Completion of Annex 1 of DR-02 and DR-04

The organization that developed the scheme (Scheme Owner) must complete Annex 1 General Part which, once received, and checked by ACCREDIA, will be sent to the Committee for Accreditation Activities and to the ACCREDIA Directive Council.

In the case of a UNI PdR, only for the questions referred to in point B of Annex 1 of DR-02 / DR-04, it will be sufficient to refer to the UNI PdR where it contains such information (or any other adequate and detailed documentation produced by UNI). Point 3 does not apply to a UNI PdR.

Annex 1 of DR-02 / DR-04 "General Part" must be completed by the Scheme Owner (SO) and sent to ACCREDIA together with the document describing the characteristics of the scheme being evaluated (containing rules and requirements) and evidence of the opinion of the interested parties in the scheme and of the validation of the scheme.

The applications were grouped into some macro topics: general, market elements, skills and experience, transparency and "procedural" elements.

4.2.1.2. When to complete Annex 2 of DR-02 / DR-04

Annex 2 Specific Part must be completed by the SO only following the positive evaluation by the Committee for Accreditation Activities and the ACCREDIA Directive Council, in order to start the technical analysis of the scheme. It is therefore not necessary to complete this form during the initial stage.

The information requested in the Specific Part covers the requirements of EA-1/22 (see Annex 01 of PG-13-01 published on the ACCREDIA website, which is the version of the EA document curated by ACCREDIA)

For some applications, if the scheme owner has no information to add, reference can be made to the sections already completed in Annex 1 General Part.

The Specific Part of this application must be completed in English (to enable EA evaluation) if the scheme has international validity.

This phase is not applicable for UNI PdRs.

4.2.1.3. When to complete Annex 3 of DR-02 / DR-04

Neither the general part of DR-02 / DR-04 (Annex 1) nor the Specific Part (Annex 2) need to be completed, but only a report presenting the scheme (Annex 3) must be attached in cases where:

- the CAS is based on a normative document (e.g. ISO Standards, ISO/PAS Publicly Available Specifications, ISO/TS Technical Specifications, ISO/TR Technical Reports) or other documents issued by standardization bodies (e.g. IWA of ISO, PAS of the BSI, CWA of the CEN);
- the CAS applies internationally and is based on an official standard (UNI, ISO, BSI ..);
- it is a regulated scheme provided for by a national or European law;
- the scheme has already been positively evaluated by all EA members according to the EA 1/22 document, or by IAF/ILAC.

4.2.2. EVALUATION OF THE SCHEME

The evaluation process of a new Ownership Scheme includes:

1. a preliminary analysis by ACCREDIA and, in the event of a positive outcome
2. a subsequent formulation of opinion regarding the admissibility of the CAS by the Committee for Accreditation Activities and the ACCREDIA CD and, in the event of a positive outcome
3. a detailed technical analysis of the CAS, conducted by ACCREDIA assessors.

With regard to the evaluation by the CdA and the CD, in general three different situations will occur, as shown here, as examples, and subsequently in more detail.

a) Schemes based on standards: simple informative note presented to the CdA/CD (ref. Annex 3 DR-02 / DR-04)
b) Schemes based on a UNI PdR: evaluation by the CdA/CD (ref. Annex 1 DR-02 / DR- 04)
c) Owner schemes: evaluation by the CdA/CD and subsequent evaluation by an ACCREDIA assessment team (ref. Annexes 1 and 2 DR-02 / DR-04).

The Documentation is submitted to the CD and the CdA for review, regardless of a chronological order as they are separate and independent evaluations.

If the opinion of the CdA is not positive or the CD does not grant authorization to proceed, the decision is communicated by ACCREDIA to the SO, specifying the reasons. The proposing party may ask ACCREDIA to review its application, providing further elements for evaluation.

Before confirming to the SO the possibility of examining the scheme, ACCREDIA asks the CdA to give an opinion in cases where the CAS in question is not based on a normative document among those contained in § 4.1.2 and also it asks the SO to give reasons for not referring to the Standardization Body.

Following approval of the CdA and the authorization of the CD, ACCREDIA requests, in cases of where this is provided for, that the SO sends Annex 2 Specific part of DR-02 or DR-04 completed, in order to carry out the technical analysis of the scheme.

Following receipt of the Annex 2 Specific part, duly completed, ACCREDIA sends the technical-economic estimate to the SO on the basis of the current ACCREDIA pricelist, to the SO, the technical/cost estimate which quantifies the commitment necessary to carry out the detailed technical analysis of the new CAS, according to the typology of requests referred to in paragraph 4.1 above.

The review of this documentation is paid for by the applicant party, in accordance with the ACCREDIA pricelist TA-00.

Following acceptance of the estimate by the SO, ACCREDIA performs the detailed technical analysis on the basis of the contents of Annexes 1 and 2 of DR-02 and DR-04 and of any additional information requested from the SO.

ACCREDIA informs the SO of the result of the review.

In cases of the absence of the technical requirements, ACCREDIA informs the SO that the process cannot go ahead.

In cases of a negative result of the technical review ACCREDIA presents the evidence in question to the SO so that the SO can make the necessary modifications or additions within the agreed timeframe.

Following successful conclusion of the above review activities for both national and international CASs, ACCREDIA informs the SO that it can be accredited, and signs a contract with it that specifies the obligations of both ACCREDIA and the SO (CO-04).

If the result of the technical exam is positive:

- if § 4.2 of EA-1/22 is not applicable, ACCREDIA starts accreditation activities for each applicant CAB;
- if the process set out in § 4.2 of EA-1/22 is applicable ACCREDIA sends the documentation to EA for evaluation. The SO must send the English version of the applications for acceptance (DR-02 or DR-04) and fully comply with the requirements contained in EA-1/22. ACCREDIA will proceed to follow the provisions of § 4.2 of EA-1/22 and prepare all the documentation and complete the format provided by EA for sending all the documentation of the CAS, requesting where necessary additional information from the SO (e.g. evidence of the letters of adhesion to the scheme by foreign authorities). This activity may involve costs for the SO.

Note: the activities regarding the evaluation of the CAS are a different process with respect to the evaluation for the granting or extension of accreditation to an applicant CAB.

ACCREDIA checks the necessary competences within the CSA in question and communicates to the CSA the technical details of the new CAS, so as to make it aware of the contents when the first accreditation file will be presented to the CSA.

Note: also if the requirements and rules applicable for the new CAS are not considered adequate, these cannot be defined by ACCREDIA due to their being the responsibility of the SO.

4.3. PUBLICATION OF INFORMATION

On the ACCREDIA website, information relating to the start of accreditation activities concerning new CASs is made available to the public, also by issuing special Technical Circulars that define the operating procedures for the certification/accreditation process.

ACCREDIA also publishes on the website the list of CAS (LS-15) that have been positively evaluated by ACCREDIA, and against which it is possible to submit an application for accreditation or extension.

The list also shows the current version of the scheme.

4.4. REVISION OF THE CAS

The SO shall communicate to ACCREDIA as soon as possible any modification to the CAS in accordance with § 4 of Regulation RG-19.

Where applicable, the SO must also include information on transition requirements (e.g. agreements for CABs and for the CAB's clients).

For the management of minor modifications it is not necessary to repeat the process of obtaining the opinion by the CdA or the approval of the CD.

The cost of the analysis of the modifications to the scheme is met by the SO, in line with the current ACCREDIA TA-00 pricelist.

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