

Title	Application of the acceptance for a new Conformity Assessment Scheme (CAS), different from certification of persons (ISO/IEC 17024), to be submitted for accreditation
Reference	DR-02
Revision	04
Date	11-02-2021

NOTE: This document is the English version of 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 version in Italian.

Preparation	Approval	Authorization	Application date
The Director of Department	The General Director	The General Director	18-02-2021

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NOTES FOR COMPLETING

The application for acceptance of a new Conformity Assessment Scheme (CAS) to be submitted to ACCREDIA for accreditation, has two Annexes: Annex 1 General Part and Annex 2 Specific Part (from the document EA-1/22 A:2020).

When to fill in Annex 1

The Organization which defined the scheme (Scheme Owner - SO) shall mandatorily fill in Annex 1 General Part for verification by ACCREDIA and submission to the Committee for Accreditation Activities and to the ACCREDIA Directive Council.

The evaluation process of a new Conformity Assessment Scheme proceeds as follows:

1. a preliminary analysis by ACCREDIA and, if the outcome is positive;
2. a subsequent evaluation of the acceptability of the CAS by the Committee for Accreditation Activities and the ACCREDIA Directive Council and, if the outcome is positive,
3. a detailed technical analysis of the CAS carried out by ACCREDIA assessors.

If it is a UNI PdR only for the questions referred to the point B of Annex 1, it will be sufficient to refer to the UNI PdR where it contains such information (or to any other adequate and detailed documentation produced by UNI).

Annex 1 General Part must be fill in by the Scheme Owner and sent to ACCREDIA together with the document that describes the characteristics of the scheme being assessed (containing rules and requirements) and the evidences of the opinion of the interested parties regarding the scheme and the validation of the scheme.

The questions were grouped into some macro themes: generalities, market elements, competences and experiences, transparency and "procedural" elements.

When to fill in Annex 2

Annex 2 Specific part shall be fill in by the SO only following positive evaluation by the Accreditation Activities Committee and the ACCREDIA Directive Council, in order to be able to start the detailed technical analysis of the scheme. It is therefore not necessary to complete this form in the initial stage.

The information required in the Specific Part covers the requirements of Document EA-1/22 (refer to Annex 1 of PG-13-01 published on the ACCREDIA website which is the translation of the EA document by ACCREDIA).

For some questions, if the SO has no information to add, he can refer to the sections already completed in Annex 1 General Part.

The Specific Part of the application must be completed in English to allow evaluation by EA if the scheme is for international application.

When to fill in Annex 3

It is not necessary to fill in either the general part (Annex 1) or the specific part (Annex 2), but it is necessary to attach the report of the presentation of the scheme (Annex 3) 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, a UNI Publicly Available Specification, a PAS of BSI, CWA of CEN);
- the CAS is applied internationally and it is based on an official standard (UNI, ISO, BSI..);
- it is a mandatory scheme in accordance with national or EU laws;
- the scheme has already been evaluated positively by EA members in accordance with EA document 1/22.

ANNEX 1 GENERAL PART

Note: the answers provided must be concise and clear and must not refer to other documents (unless requested) that will eventually be provided and examined in subsequent stages, if this application is accepted by ACCREDIA.

A) General information regarding the SO and description of the proposed Scheme

N.	REQUIRED EVIDENCE	TO BE COMPLETED BY THE APPLICANT FOR THE SCHEME ASSESSMENT
1	Who is the developer of the scheme (name, legal status, partners, business purpose, year of establishment...). Specify if it is an accredited CAB.	
2	Specify if the developer of the scheme is also the party submitting the scheme to ACCREDIA for evaluation. Specify if it is an accredited CAB.	
3	Which economic and/or professional sector might the scheme impact (e.g. medical, agriculture, automotive, tourism...)?	
4	Summarize in one sentence the main object of the scheme.	
5	Describe the scheme to be submitted to ACCREDIA for assessment.	
6	What is the accreditation standard applicable (MS, product, person, verification, inspection) with explanations where necessary.	
7	Are the requirements for assessment clearly identified in the scheme? Examples:	

N.	REQUIRED EVIDENCE	TO BE COMPLETED BY THE APPLICANT FOR THE SCHEME ASSESSMENT
8	<p>For MS certification schemes: is the extent of the system clearly defined? Are there references to other systems (e.g. quality, environment, safety etc.)?</p> <p>For Product schemes: are the requirements of the product to be certified described?</p>	
9	<p>Are the modalities (rules) for this assessment and periodic re-assessment correctly identified in the scheme? (audits, inspections, tests, testing methods...)</p>	
10	<p>Are the competences and characteristics correctly identified regarding the:</p> <ul style="list-style-type: none"> - Auditors (for MS) - Inspectors (for Product, Inspection) - Persons responsible for conducting the review (for Product and Verification/Validation) - Persons responsible for granting certification (the decision) - Experts (where required) 	

B) Aspects relating to the reference market

N.	REQUIRED EVIDENCE	EXPLANATION: what can be expected of those making the proposal to ACCREDIA. Required evidence	TO BE COMPLETED BY THE APPLICANT FOR SCHEME ASSESSMENT
1.	<p>Has any institution or other representative body of general or sector specific interests expressed a favorable opinion on the creation and development of this scheme?</p>	<p>It is necessary to produce evidences showing explicit interest of the authorities or other interested parties in the scheme.</p> <p>The "significance" means the importance regarding the socio-economic plan of the scheme or its</p>	

N.	REQUIRED EVIDENCE	EXPLANATION: what can be expected of those making the proposal to ACCREDIA. Required evidence	TO BE COMPLETED BY THE APPLICANT FOR SCHEME ASSESSMENT
	Do such persons represent a significant segment of the market (or the role of a regulatory authority) in the area in which the certification scheme should operate?	importance (not only quantitative) in an identifiable product and/or service area. If the representative party is a minority party or sector, it is necessary to specify why the scheme is considered to be of general interest.	
2.	Does the System, Product / Process / Service covered by the certification scheme have any relevance to Systems, Products already governed in the mandatory / regulated area? If so, were the competent authorities involved?	In cases where mandatory factors are involved, it is necessary to have a favorable opinion from a competent regulatory authority.	
3.	Do other similar certification schemes exist, either nationally or internationally, with or without accreditation, based on a standard or guidelines or owner schemes?	The existence of other schemes on the market covering the same topic is not in itself an obstacle to the approval of a new scheme (ACCREDIA is neutral and impartial in the decision to accredit a new scheme, also considering its situation of monopoly and the role of the public interest in accreditation), but if it is, the reason for justifying a new scheme shall be clarified. If a scheme is based on a guideline, note that accreditation shall only be granted for schemes that contain requirements (shall and not should).	
4.	Analysis of the usefulness and/or opportunities of this new scheme and potential overlapping or conflicts with other existing certification models	<i>By "opportunity" we mean the overt need and / or expectation of rules in a specific area / sector / domain, for example on the recommendation of a competent authority.</i> The aim is to understand whether the scheme brings an element of novelty to the market or that it has already been dealt with by normative documents or owner schemes or if there may be a potential overlapping with qualifications already required by the law.	

N.	REQUIRED EVIDENCE	EXPLANATION: what can be expected of those making the proposal to ACCREDIA. Required evidence	TO BE COMPLETED BY THE APPLICANT FOR SCHEME ASSESSMENT
5	Has the certification potential of the scheme been considered?	A rough estimate is necessary regarding the potential market for this certification in terms of numbers and/or market share. A low number of certifiable parties is not in itself an obstacle to the approval of a new scheme. It is necessary to evaluate on a scheme-by-scheme basis.	

C) Competences and experiences

N.	REQUIRED EVIDENCE	EXPLANATION: what can be expected of those making the proposal to ACCREDIA? Required evidence	TO BE COMPLETED BY THE APPLICANT FOR SCHEME ASSESSMENT
1.	What is the competence (both technical and certification) on the topic covered by the scheme, of the people who developed the scheme?	It is necessary to be sure that the requirements of the scheme are technically correct.	
2.	Describe the first experiences/history of the scheme.	It is necessary to show that the scheme has already been validated/used and that it has achieved the expected targets.	

D) Transparency and procedural aspects

N.	REQUIRED EVIDENCE	EXPLANATION: what can be expected of persons/bodies making the proposal to ACCREDIA? Required evidence	TO BE COMPLETED BY THE APPLICANT FOR SCHEME ASSESSMENT
1.	Explain the reasons for which it was decided not to develop a PdR in UNI or for which a normative process was not attempted.	It is possible to accredit an owner scheme but it is recommended to use normative tools.	
2.	Who will be able to certify against this scheme? Only the owner of the scheme (w which therefore coincides with the certification body) or a limited number of CABs, or any CAB?	The closure of the scheme is possible (certifiable only by one CAB or by a small number of CABs).	
3.	Will the certification scheme (the requirements and modalities for evaluating them) be publicly available? If it will be, is it free of charge or at a cost?	It is not mandatory for all the information on the scheme to be available to the public (e.g. checklists, guidelines, details of assessment methods), but it is mandatory that the requirements used to perform the conformity assessment are publicly available.	
4.	Does the scheme involve royalty payments by the CAB using it or by the certified companies? Will there be mandatory courses, paid for by the companies, by the CAB or by ACCREDIA? Are there other costs to be met by other parties?	It is not forbidden the SO requires costs for the CAB, certified company or others, but these costs must be fair and transparent.	
5.	Is it mandatory for the CAB or certified parties to use a mark?	The SO or standardization body can require use of a mark associated with the issue of a certification.	

DATE:	DD/MM/YYYY
FULL NAME OF THE REFERENCE OF THE SCHEME OWNER	FULL NAME
POSITION	POSITION
SIGNATURE	FULL NAME

ANNEX 2 SPECIFIC PART

This annex is the transposition of Annex 1 of document EA-1/22. It's Scheme Owner 's responsibility the compilation, and it must be done only after the favorable opinion issued by the ACCREDIA Committee for Accreditation Activity and Directive Council. Some questions are similar to the sections already filled in Annex 1 General Part.

If the owner of the scheme has no other information to add, he can refer to the completed General Section.

This attachment does not need to be filled if the scheme has already been positively assessed by EA. The form must be filled in English in case it is expected that the scheme can also be accredited by other accreditation bodies in Europe, and it is intended to proceed with the evaluation by EA.

ACRONYM AND COMPANY NAME OF THE OWNER OF THE SCHEME

1) Is the SO willing to use ACCREDIA as the unique contact point for evaluation of the CAS?

To be completed by the SO
ACCREDIA comments and evaluations

2) Is the CAS currently being used by CABs under accreditation from any of the EA members?

- If YES, please identify the EA member;
- If NO but it has previously been reviewed by an NAB, please provide details and outcome of the evaluation.

To be completed by the SO
ACCREDIA comments and evaluations

3) Provide a complete description of the SO including the following information:

N.	DATA AND DESCRIPTION	TO BE COMPLETED BY THE SO
a)	Name and acronym:	
b)	Type of legal entity:	
c)	Address and website address:	
d)	Members (if relevant) and membership	
e)	Brief history	
f)	Any other activities performed (if relevant)	
g)	Relations to or links with other organizations and the authorities, both at international and national levels, if any	
h)	Technical area of activity, for example aerospace, electrical testing, food safety, etc.	
i)	Is the CAS intended to be used only at a national level? If no, please specify geographical area of acceptance, for example a few European countries, all of Europe or global.	

ACCREDIA comments and evaluations

4) Under which conformity assessment standard(s) does the scheme operate? (For example product certification, testing, etc.) Include the rationale for your choice and identify the scheme document where it is specified.

To be completed by the SO
ACCREDIA comments and evaluations

5) Has the SO established CAS specific requirements for the operation of CABs wishing to operate within the CAS?

If yes, please describe the specific CAS requirements and identify the CAS documents where these are described. State also how such requirements are made publicly available.

To be completed by the SO
ACCREDIA comments and evaluations

6) Does the SO (by itself or through another organization) perform any kind of assessment of the CAB?

If YES, refer to the CAS document where it is described.

Does the SO perform any other kind of activity to confirm recognition of CABs which wish to work within the scope of the CAS, beyond requiring that they are accredited to the CAS requirements? If so, describe the activity and identify the CAS document(s) where this is stated.

To be completed by the SO
ACCREDIA comments and evaluations

7) If the answer to the first question under 6 is yes, does the SO request the NABs to accept or take into account such an assessment during the accreditation process?

If yes, please identify the CAS document where this is described.

To be completed by the SO
ACCREDIA comments and evaluations

8) Does the CAS request EA or EA members to cooperate with the SO on issues other than accreditation of CABs?

If yes, specify the areas of cooperation required and refer to the CAS document where these are described.

To be completed by the SO
ACCREDIA comments and evaluations

9) Has the SO established CAS specific requirements for the operation of NABs?

If "yes", please identify the CAS document where these requirements are described.

To be completed by the SO
ACCREDIA comments and evaluations

10) What is the object of conformity assessment? Please state as specifically as possible and submit a copy of the certificate containing the specific attestation.

The objects of conformity assessment may be products, services, materials, installations, processes, systems, persons or bodies.

To be completed by the SO
ACCREDIA comments and evaluations

11) What are the specific requirements relating to the characteristics of the object of conformity assessment? Please identify the CAS documents where these are stated.

Requirements shall be written in a clear, direct and precise manner and that they shall result in accurate and uniform interpretation, so that parties making use of the CAS normative document are able to derive from the contents of the normative document have a common understanding of its meaning and intent.

- Requirements shall be written in terms of results or outcomes, together with limiting values and tolerances, where pertinent.
- Requirements shall be stated unambiguously using wording that is objective, , valid and specific.

To be completed by the SO
ACCREDIA comments and evaluations

12) Are all measurement values expressed in SI units (International System of Units)?

To be completed by the SO
ACCREDIA comments and evaluations

13) Does the CAS cover the following typical elements of a conformity assessment scheme?

N.	DATA AND DESCRIPTION	TO BE COMPLETED BY THE SO
a)	Selection of the object/s of conformity assessment, including selecting specified requirements to be assessed and planning information collection and sampling activities.	
b)	Determination , including the use of one or more determination methods (e.g. test, audit and/or examination) to develop complete information regarding fulfillment of the specified requirements by the object of conformity assessment or its sample.	
c)	Review and attestation , including the review of evidence from the determination stage, and a subsequent attestation that the object of conformity assessment has been reliably demonstrated to fulfill the specified requirements, and any subsequent marking or licensing and their related controls, where applicable.	

N.	DATA AND DESCRIPTION	TO BE COMPLETED BY THE SO
d)	Surveillance (where applicable), including the frequency and extent of surveillance activities and reassessments to ensure the object of conformity assessment continues to fulfill the specified requirements.	

ACCREDIA comments and evaluations

14) If the CAS involves sampling, which procedures are required for sampling?

To gain consistent and reproducible results, sampling methods should be based, whenever possible, on statistical methods provided in International Standards.

To be completed by the SO

ACCREDIA comments and evaluations

15) Are there test methods or inspection procedures involved in the CAS? Where are these described?

To be completed by the SO

ACCREDIA comments and evaluations

16) Does the CAS consider the use of marks of conformity?

If yes, the SO shall provide evidence to demonstrate how it has protected those marks and laid down rules for their use in accordance with the requirements of the conformity assessment standard chosen.

To be completed by the SO
ACCREDIA comments and evaluations

17) Provide evidence that the CAS was designed by persons demonstrably competent in that capacity. The competence shall cover both the technical field of expertise and the conformity assessment procedure used

Note: CABs may be involved in the development process of CASs within the limitations given in the standards used for their accreditation.

To be completed by the SO
ACCREDIA comments and evaluations

18) Provide evidence that the interested parties for the CAS were analysed, identified and consulted, and that any issue has been solved".

To be completed by the SO
ACCREDIA comments and evaluations

19) Provide evidence that the CAS is validated, considering the details given in clause 3.1.6 of the EA document A/22.

As a minimum validation must demonstrate that the CAS has successfully completed a test period, demonstrating that it is 'fit for purpose' (i.e. capable of consistently achieving its stated objectives). As a minimum the validation should demonstrate that:

- the conformity assessment, as described, is practicable?
- the determination activities as described quantify or in other ways identify and confirm the characteristics which the SO intends and expects to identify and which constitute the basis for conformity assessment?
- the requirements are specified in a way that ensures reproducibility and reliability of results?

To be completed by the SO
ACCREDIA comments and evaluations

20) For the evaluation of existing CASs the SO shall identify all the EA NABs implementing the CAS and demonstrate to hAB what measures have been taken so that the NABs currently accrediting CABs for the CAS perform the accreditation in a harmonized way.

To be completed by the SO
ACCREDIA comments and evaluations

DATE:	DD/MM/YYYY
FULL NAME OF THE REFERENCE OF THE SCHEME OWNER:	FULL NAME
POSITION:	POSITION
SIGNATURE:	FULL NAME

ANNEX 3

FAC SIMILAR REPORT FOR THE PRESENTATION OF THE CONFORMITY ASSESSMENT SCHEME¹

Presentation of the scheme/system and characteristics

Requirements of the scheme/system

The general reference framework and normative context

The national framework

The European and international framework

The added value of the certification

Rules regarding the certification process

¹ It is necessary to send the report only if 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 a standardization body (e.g. IWA of ISO, PdR of UNI, PAS of BSI, CWA of CEN) or if the CAS is internationally applicable and based on an official standard (UNI, ISO, BSI..).