# New accreditation activities, evaluation of conformity schemes and transitions to standards

**Implementer: General Directorate of Accreditation staff, technical working group members, accreditation board members.**

**Responsible for implementation: Director of Development Directorate.**

**Control: Quality Manager**

**Ardita MELE**

**Approved: General Director**

**Pranvera FAGU**

## 1 Purpose.

This document sets out the General Directorate of Accreditation (GDA) procedure for adding activities, evaluating conformity assessment schemes and managing the transition to the new standards / documents. The procedure is intended to facilitate a harmonized approach within GDA, accreditation organizations, owners of conformity assessment schemes and stakeholders.

## 2 Scope of application.

Procedure DA-PM-008 implements in cases of extension of new accreditation activities of the General Directorate of Accreditation (hereinafter: GDA), new conformity assessment schemes (hereinafter: CAS) and in cases of transitions to standards/new documents. This procedure does not apply for evaluating of CAS in cases where all requirements for this CAS are documented in a single standard published by an international, regional or national standardization body.

## 3 Responsibilities.

This procedure is implemented by General Directorate of Accreditation staff, technical working group members, accreditation board members. It is the responsibility of the Director of Development to implement this procedure.

## 4 References.

This procedure refers to:

- Standard S SH ISO 17011:2017 "requirements for accreditation bodies that accredit conformity assessment bodies", paragraph 4.6,

- Standard ISO 17000:2020 "Assessment of conformity - Vocabulary and general principles"

- GDA policy on the expansion of activity DA-PO-004,

- Law no. 116, dated 11.09.2014 “On Accreditation of Conformity Assessment Bodies in the Republic of Albania”, amended with Law 92/2023;

- GDA quality manual, DA-MC-001

- Procedure DA-PT-001 ‘Procedure of accreditation, supervision and renewal’,

- Evaluation Policy DA-PO-002,

- DA-FO-079 Form of application for conformity assessment scheme,

- DA-FO-080 Check-list for evaluating a conformity assessment scheme,

- IAF MD 25:2023 ‘*Criteria for evaluation of conformity assessment schemes*’,

-EA-1/22 A-AB:2023 '*EA procedure and criteria for the evaluation of conformity assessment schemes by EA accreditation body members'.*

## 5 Definitions.

The definitions that are the subject of this procedure, that are not included in annex 1 of GDA quality manual, DA-MC-001, have the following meanings:

**New accreditation activity** means the addition of a new accreditation scheme and/or the addition of a new conformity assessment scheme.

**Scheme Owner (SO)**

SO is an organization responsible for developing and maintaining a CAS. SO can be:

- The standardization body,
- Conformity Assessment Bodies - (CAB)
- Organizations using the services provided by CAB,
- Organizations that buy or sell conformity assessment activities;
- Manufacturers or associations that have developed their own conformity assessment scheme
- Organizations set up specifically for that purpose; and
- Governmental Authorities including regulators and other governmental bodies.
- Accreditation bodies can't be SO.

**Conformity Assessment Scheme (CAS)**

The conformity assessment scheme is a documented and publicly available set of requirements which establishes the following:

a. The object of conformity assessment, e.g., product, process, service, system, person;
b. The requirements against which conformity is to be assessed;
c. The mechanism by which conformity is determined, e.g., testing, inspection, verification, validation or auditing and any other supporting activities to ensure conformity;
d. Any requirements placed on CABs by the SO, and any specific applications or interpretations thereof, if applicable;
e. Any specific applications or interpretations of ISO/IEC 17011, if applicable.

For the purposes of this document, an international CAS is one where CABs legally established in more than one EA member country are involved and more than one NAB is requested to provide accreditation for the CAS in question.

It should be noted that being an international CAS does not depend on the locations where the object of the conformity assessment is utilised.

**Specific scheme requirements for accreditation bodies**

The specific requirements of the scheme for the accreditation bodies are specific requirements described by SO and must be filled for the accrediting bodies to carry out the accreditation activity in relation to the CAS. These requirements are additional to the requirements of the IAF, ILAC and EA as well as of ISO/IEC 17011 and cannot conflict with them. These requirements will result in additional efforts for the NABs with regard to resources, specific procedures, time spent on assessments, reporting, training and competence of assessors, keeping records, collecting data etc.

**Specific scheme requirements for CABs**

This refers to specific requirements for the CAB prescribed by the SO for operating under its CAS, in addition to the AB's rules and the applicable IAF Level 3, International Standard.

**SO Authorization of a CAB**

SO authorization means that the SO accepts certificates, reports, statements or attestations issued by a CAB for the purposes of confirming that the object of the conformity assessment meets the requirements of its CAS.

*Note: SOs may use different wording to denote/state/describe authorization, such as listing, approval, recognition, designation, etc.*

**Regulator**

Governmental entity implementing legislation

**Home Accreditation Body (hAB)**

The NAB which takes the lead for evaluating an international CAS operated in more than one EA member country. The hAB will normally but not necessarily be the NAB from the country where the SO is legally established. The hAB must be, in those cases where the CAS is to be implemented in several countries, a signatory to an EA MLA Accreditation Activity appropriate to the CAS.

**Acceptance of a CAS (by an EA member)**

Confirmation by a NAB of the suitability of the standard to be used to accredit CABs participating in the CAS and fulfilment of the requirements for SO and evaluating of CAS.

**Acceptance of an international CAS (by EA)**

Confirmation of the satisfactory evaluation of the CAS by the hAB and publication on EA intranet.

*Note: EA acceptance of a given CAS does not mean a judgment on the market value or usefulness of the technical requirements of the CAS.*

Transition of a standard to another standard does not make a new CAS. In this cases GDA has the responsibility to draft documents for transition that are based in competence evaluating, procedures and criteria according to the new standard.

# 6 Description of the procedure of extending new accreditation activities.

## 6.1 Identification of a new activity

The need to launch a new accreditation activity may arise when:

1. Legal acts (national and/or European), require accredited status for a conformity assessment activity;

2. Introduce a new conformity assessment standard;

3. In specific areas of expertise, conformity assessment activity is referred in the specific standards (e.g. ISO 50001, EN 9104, ISO /IEC 22003);

4. A new conformity assessment scheme is developed and is applied for accreditation in name of SO;

5. Introduce new conformity assessment schemes by conformity assessment bodies (such as product certification bodies etc.).

## 6.2 Analysis of new activity

Identification of new accreditation activity by legislation and new standards/documents will be carried out by the Director of the Directorate of Development.

Identification of new accreditation activity from CAB applications will be performed by the Director of Testing, Calibration, Medical laboratories Directory/ Director of Certification and Inspection Bodies Directory. Within five days of identification, the Director of Testing, Calibration, Medical laboratories Directory or Director of Certification and Inspection Bodies Directory notifies the General Director and the Director of Development Directory.

Within 10 days of receiving the notification, the Director of the Development Directorate makes an analysis of the market need for the new activity and the type of conformity assessment, which he presents to the General Director. It is the General Director who decides whether GDA will start preparations for setting up the new activity or not within three weeks. In cases where the identification of the activity starts from the application of a CAB and if the General Director decides not to start the preparation for the new activity, then the applicant is notified.

If the General Director decides to start preparations for the provision of the new activity, within five days, by order of the General Director, a working group is formed to analyze the necessary resources. The working group consists of at least: the general director, the directors of the GDA directories, the quality manager, and the head of the finance and services sector. GDA specialists or external competent persons may also be included in the working group. The analysis of resources is carried out according to the point 7 of this procedure.

In cases where there are changes in the criteria for accreditation, the transition is followed according to the guidelines issued by European and international accreditation bodies, if any. Based on these instructions, the Director of the Development Directorate, the Director of the relevant directorate covering the changed scheme and the quality manager perform the resource analysis according to points 7.2; 7.3 and 7.5 of this procedure.

If there are no guidelines issued by international accreditation bodies, the Director of the Development Directorate, the Director of the relevant directorate covering the changed scheme and the quality manager draw up the GDA guidelines and perform the resource analysis according to points 7.2; 7.3 and 7.5 of this procedure.

Based on the modified requirements and international guidelines, the GDA defines the steps and deadlines for the accredited bodies, to ensure time for safe preparation and assessment of the fulfillment of the requirements.

The Director of the Development Directorate informs accredited bodies and applicants about changes in requirements on the GDA website.

The GDA calls on the accredited bodies through a communication that they must prepare and submit their plans for the transition period within the specified deadline.

The Development Directorate organizes the necessary training courses for the proper preparation of internal staff and external assessors.

The GDA after evaluating and collecting the transition plans, prepares its own transition plan as part of the audit plan.

In case the requirements are changed, the European and international accreditation organizations define a transition period. After the end of the transition period, accreditation for accredited bodies that do not meet the new requirements is revoked by the GDA, or revocation can be requested voluntarily.

## 7. Resource analysis

The working group shall, within a period of not more than one month, carry out the analysis of the following sources:

### 7.1 Conformity Assessment Analysis

The working group evaluates the type of conformity assessment (Level 2) and determines the standard (Level 3) according to EA 1/06 classification. The working group may also determine the methods or standards for carrying out the conformity assessment (Level 4 and 5).

### 7.2 Human Resources Analysis

The working group determines the need for human resources in field required for accreditation. For this reason, the working group:

- –Analyzes the competence of GDA, if the extension of accreditation activity can be implemented, taking into account existing resources for reviewing the application, making the evaluation, recommendation and taking the decision,
- –Evaluates and receives expertise from other external sources (experts, technical assessors, technical working groups and the accreditation board),

- –Studies the level of staff training in this field as well as the opportunities and needs for technical assessors from list of GDA assessors,
- –Looks at opportunities for training staff and technical assessors abroad as well as training organization internal using lecturers from internal staff or external lecturers from home or foreign staff.
- –Receives new members for technical working groups (if necessary) for new accreditation activity.

When human resources for personnel that is included in evaluation are insufficient, the Director of Development Directory search assessors for the relevant field within the country. Information about recruiting new assessors and the criteria they must meet is disseminated to various scientific institutions, accredited bodies, technical working groups, the accreditation board, etc. Information on new appraisers is also provided on the GDA's Website. Selection of candidates for assessor is carried out according to procedure DA-PM-002.

If no local assessors are found, then DA-PO-003 policy, paragraph 4.3 applies to finding foreign assessors or applies procedure DA-PM-013 for subcontract of evaluating.

If the competence of the decision makers is not ensured, then the recommendation from the relevant technical team is required. If the competence in taking the decisions is not ensured, the General Director automatically takes the decision for not starting offering the new accreditation activity.

**7.3 Drafting of procedures and inclusion in management system documents**

The working group assesses the need for implementation documents or guidance. The GDA, as appropriate, adopts implementation documents or guidelines and / or participates in their preparation. The Working Group shall ensure in advance that such documents are formulated by committees or persons possessing the necessary competence and involvement of stakeholders. GDA uses international implementation documents or guidance when available.

GDA also uses national or international guidelines for CAB operation. The criteria for the CAB evaluation are set out in `` Evaluation Policy` 'DA-PO-002, point 3.

The working group drafts the necessary procedures and after approval by the General Director, the Quality Manager incorporates them into management system documents.

**7.4 Analysis of financial resources**

The working group also determines the financial needs related to the new field of accreditation in which GDA wants to expand its activity and if necessary establish new tariffs.

**7.5 Decision on the new activity**

After conducting the analysis and after fulfilling / not fulfilling the requirements for offering a new activity, the Director of Development Directory proposes to the General Director:

a) Starting of new activity
b) Not starting new activity

c) Starting of new activity using subcontracting of the evaluation.

a) If the decision is to start the new activity, then the Testing, Calibration, Medical laboratories Directory/ Certification and Inspection Bodies Directory based on the sources provided follows the accreditation procedure according to DA-PT-001. Within 7 (seven) The Development Department publishes on the GDA's official website the launch of service provision and related requirements.
b) If the decision is not starting the GDA notifies the client or interested parties of the reasons for not starting this activity.
c) If the General Director decides to start the new activity through subcontract the evaluation, then Testing, Calibration, Medical laboratories Directory/ Certification and Inspection Bodies Directory must be implement the DA-PO-006 policy. In this case the competence of the persons involved in decision-making must be confirmed.

## 8. Acceptance of a CAS from an accreditation body

Acceptance of a CAS by an accreditation body requires:

- identification of the most appropriate conformity assessment standard that will be used to assess the competence of the CAB(s) participating in the CAS. This will be determined taking into account the nature of the conformity assessment activities and the content of the declaration of conformity. Consequently, that standard will be the one used as a reference for the accreditation of the CAB(s).

*Note: The CAS may need to be modified in some elements in order to enable the CAB(s) to meet all the requirements of the selected standard.*

- CAS and SO meet the requirements defined in this document. Acceptance by an accreditation body of a particular CAS does not imply a judgment on the market value or usefulness of the CAS. The responsibility for the technical viability and market acceptance of the CAS rests entirely with the SO.
- However, it is the responsibility of the accreditation body to ensure that the process undertaken to ensure the technical viability and market acceptability of the CAS by SO was appropriate and complete.
- If a signatory accreditation body of MLA has decided, based on a positive assessment carried out, that an CAS is considered suitable as an MLA EA Level 4 and accredits the CAB(s) for that CAS, the accreditation body is declaring that CAS is covered by MLA.

## 9. Assessing new conformity assessment schemes.

GDA follows the following procedure for assessing the suitability of conformity assessment schemes:

1. The applicant must submit to GDA the application form for the conformity assessment scheme according to form DA-FO-079 as well as all the information and documents necessary for the assessment of the new conformity assessment scheme according to form DA-FO-080.

2. After submitting to the GDA secretariat the two forms DA-FO-079 and DA-FO-080, the applicant must appear in the Finance and Services Sector for the conclusion of the contract with the GDA according to the DA-FO-092 form, which is defined clearly the relationship and conditions of cooperation between SO and GDA, the fee which includes the phases of application, review and final result (positive/negative). We emphasize that this fee will be paid by the applicant regardless of the final result that will be issued by the GDA.

3. The initial evaluation of the application is done by the Development Directorate specialist within 1 month from the submission of all relevant documentation.

4. After the completion of this evaluation, the specialist of the Development Directorate submits a memo of the evaluation carried out together with the relevant documentation to the Director of the Development Directorate, who takes measures within 15 days to notify the relevant technical work group(s), stakeholders and government authorities for organizing the meeting for the analysis and evaluation of the scheme. The Development Directorate specialist in charge of analyzing the schemes distributes all the necessary documentation to members of technical working groups.

If the technical working group, the interested parties and the government authorities recommend not accepting the scheme, within 10 days the Director of Development notifies the General Director, who within 10 days sends the applicant the decision of not accepting the scheme and the reasons for taking this decision.

If the technical working group, the interested parties and the government authorities have remarks regarding the fulfillment of the requirements of the scheme, within 10 days the Director of Development notifies the General Director, who within 10 days sends the remarks to the applicant regarding the non-fulfillment of the requirements of the scheme. The applicant has the right to send the revised scheme no later than 6 months. Otherwise, he must apply again.

5. If the technical working group, interested parties and government authorities have no objections regarding the fulfillment of the requirements, the entire documentation will be passed for review to the Accreditation Board, which gives the final recommendation on the suitability of the scheme. The meeting of the Accreditation Board is organized in accordance with the regulation of the Accreditation Board.

6. The final decision for the suitability of the conformity assessment scheme is taken by the General Director of GDA within three weeks of receiving the Board's recommendation.

7. The decision taken by the General Director is communicated to the applicant within 10 days. The Director of the Development Directorate publishes the decision on the new scheme on the GDA website within 10 days.

## 10. Suspension or termination of an accreditation scheme

When, due to changes in the legislation or the lack of market interest, it is necessary to take a decision on the suspension or termination of an accreditation scheme. This decision is taken by the General Director at the proposal of the Director of the Directorate of Development. The Director of the Development Directorate bases his recommendation on the following analysis:

a) The opinion of the interested parties on the relevant scheme,

b) Review of the fulfillment of contracts with SO/CAB (termination),

c) Informing interested parties in a communique on its official website,

d) Following external communication,

e) Providing the statement on the validity of the issued accreditations,

f) If a new CAS is presented to replace the previous ones, the transition rules are published. The Director of the Development Directorate draws up a process verbal on the consultation and its results with the interested parties and the fulfillment of contracts with SO/CAB.

## 11 Requirements for the SO

GDA shall ensure that the following conditions are met before cooperating with an SO, unless any of the conditions are not applicable to a specific CAS:

**11.1** The SO shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its activities.

**11.2** The SO has the authority to establish and change the requirements of the CAS.

**11.3** The SO should determine the authorised person to cooperate with the GDA.

**11.4** The SO should maintain sufficient evidence and justification that the conformity assessment activity and the standard selected for the accreditation of the CABs is appropriate.

**11.5** The SO shall make a general description of the CAS publicly available without request. The scheme documents, including the criteria and process to be used in assessing conformity shall be publicly available.

**11.6** The SO should demonstrate that the CAS has been validated. The validation should be documented and include the following aspects:

i) A description of the purpose of the CAS;

ii) A description of the requirements of the CAS;

iii) An analysis of the appropriateness of the established requirements for fulfilling the defined purpose of the CAS;

iv) A description of the methods to be used for determining fulfilment of the requirements;

v) An analysis showing that the described methods to be used for determining fulfilment of the requirements are appropriate;

vi) The decision on the conformity assessment activity to be used (including identification of the applicable conformity assessment standard); and

vii) An analysis showing that the selected conformity assessment activity is appropriate.

viii) The identification of applicable requirements from other relevant standards used for conformity assessment.

*Note: The validation can be in terms of pilot audits or by demonstrating that the scheme is based on available international or national standards.*

**11.7** In case the SO provides any clarification on the CAS to any interested party, this information shall also be available to the GDA and CABs within the CAS.

**11.8** The SO shall have a legally enforceable agreement with CABs it authorizes which, as a minimum, shall ensure that the CABs use the CAS as published by the SO, without any additions or reductions, and comply with SO rules for applying the symbol/statement/mark, as applicable. A transition arrangement should clarify how the transition from non-accredited conformity assessment will be managed and how new CABs may start using the CAS.

**11.9** The SO shall have a procedure for dealing with complaints relating to the CAS, ensuring that complaints processes of CABs' clients, CABs and GDA are not affected. Investigation and decision on complaints shall not result in any discriminatory actions.

*Note 1: A description of the complaints handling process can be publicly available with or without request.*
*Note 2: Guidance on the complaints handling process is available in ISO 10002.*

**11.10** The SO shall have a mechanism to provide for feedback from the GDA on the operation of the CAS. The monitoring of CABs by the SO does not exempt the SO from the above obligation. If the SO monitors the CABs, it should consider cooperation with the ABs and have a feedback mechanism to provide information on the performance of the CABs to the GDA.

**11.11** The SO should have a process for a periodic review of the CAS taking into account the experience gained and the feedback received from parties interested in the CAS.

**11.12** The SO shall be responsible for keeping the hAB and CABs informed of any relevant information and developments relating to the CAS, including in particular any proposed change in requirements.

**11.13** The SO should monitor the development and review of the standards and other normative documents, whether its own or external, which define the specified requirements used in the scheme. Where changes in the normative documents of the CAS occur, the SO should have a process for making the necessary changes in the CAS, and for managing the implementation of the changes (e.g. transition period) by the Conformity Assessment Bodies clients and, where necessary, other parties interested in the CAS.

**11.14** Changes to the CAS that affect the output of the CAS, should be validated.

**11.15** The SO shall be able to demonstrate that there is a need and support in the market for the CAS. This may include demonstration of added value, the involvement of interested parties, government initiatives or

regulatory needs. The SO shall be able to provide evidence of market need and support for the CAS coming from relevant interested parties.

*Note: GDA acknowledges that the number and nature of these "relevant interested parties" may be different for different CASs. Of particular relevance and importance in the demonstration of market need is the viewpoint of interested parties representing the CAS end-users (e.g. consumers or industry).*

**11.16** The SO shall commit to accept results from CABs accredited by any EA MLA signatory (for the relevant scope) which follows the requirements laid down in the CAS.

**11.17** The SO shall be prepared to pay for the costs of the evaluation of its CAS by the GDA.

**11.18** The SO shall commit in writing to comply with the evaluation procedure.

## 12 Requirements for CAS

**12.1** The conformity assessment process described or chosen by the SO shall fall within the scope of one of the EA MLA Level 3 standards (see EA-1/06).

**12.2** Scheme specific requirements placed on CABs by the SO shall not contradict, or exclude, any of the requirements included in the standard referred to in 12.1.

**12.3** If a CAS places scheme specific requirements on GDA, they shall not contradict or exclude any of the requirements in ISO/IEC 17011, EU Regulation (EC) 765/2008 and, where applicable, EA mandatory documents and IAF or ILAC documents endorsed by EA as mandatory. Any requirements for accreditation body must be included in the CAS, not in contractual agreements between GDA and SO.

Scheme specific requirements for accreditation body for international CASs require specific endorsement by the EA HHC. If a national CAS intends to expand to become international, then any agreement with the accreditation body on additional requirements to ISO/IEC 17011 will be considered as specific requirements to NABs and will not automatically be binding on other accreditation bodies. These specific requirements will first need to be accepted and endorsed by the EA HHC.

**12.4** CASs in the voluntary sector shall neither contradict, nor simply be the fulfilment of, applicable legal requirements, unless it has been accepted by the competent authority(ies) and it does not create any confusion between the CAS and the duties of the competent authority(ies) (e.g. monitoring mechanism) or between the role of the CABs and that of the said authority(ies).

**12.5** The CAS should cover the following elements:

i) Selection of the object(s) of conformity assessment, including selecting specified requirements to be assessed and planning information collection and sampling activities;

ii) Determination, including the use of one or more determination methods (e.g. test, audit and/or examination) to develop complete information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample;

iii) Review, decision and attestation, including the review of evidence from the determination stage. Conclusion based on the results of the review as to whether fulfilment of specified requirements has been demonstrated and a subsequent attestation that the object of conformity assessment has been reliably demonstrated to fulfil the specified requirements, and any subsequent marking or licensing and their related controls, where applicable; and

iv) Surveillance and recertification, as applicable, systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.

**12.6** A CAS shall include the following:

i) The objectives of the scheme for the specific industry or user group;

ii) The object of conformity assessment, e.g. product or process or person or claim;

iii) The requirements against which conformity is to be assessed;

iv) The conformity assessment process used in order to determine conformity of the object. This process shall fall under the scope of one of the IAF MLA Level 3 standards without any contradictions or exclusions;

v) Any specific applications or explanations of ISO/IEC 17011 (e.g. specific competence criteria for assessors/technical experts/assessment teams, assessment criteria, specific details in the assessment reports), if applicable; and

vi) Any specific application or explanation of accreditation standard at Level 3, e.g. ISO/IEC 17021-1, ISO/IEC 17065, ISO/IEC 17024/ ISO/IEC 17029 (e.g. specific competence criteria for auditors/ evaluators/ inspectors/ technical experts/ audit teams, audit/ evaluation/ inspection criteria, specific details in the audit/ evaluation/ inspection reports), if applicable.

**12.7** Where applicable, the requirements in the CAS should be written in terms of results or outcomes, together with limiting values and tolerances.

**12.8** The requirements in the CAS should be stated unambiguously using wording that is objective, logical, valid and specific and enable consistent application by organizations as well as evaluation across CABs.

**12.9** Where the CAS includes legal requirements, these shall be formulated in such a way that compliance is a condition for outcome of conformity assessment.

**12.10** The CAS should describe the method used to monitor that the certificate or attestation or statement holder continues to comply with the requirements, if applicable.

**12.11** Where the SO authorisation is given before accreditation, which implies that the CAB can perform conformity assessment activities covered by the CAS and may have the right to use the SO's mark, the CAS shall require the CABs to be accredited in a defined period of time.

**12.12** The CAS shall specify the statement of conformity which appears on the conformity assessment documents.

**12.13** Where the CAS provides for the use of certificates, marks or other statements of conformity, there should be a license and/or rules or another form of enforceable agreement to control such use. Licenses can include provisions relating to the use of the certificate, mark or other statement of conformity in communications about the object of conformity assessment, and requirements to be fulfilled when the certification is no longer valid.

**12.14** The CAS may specify a manner by which the SO monitors CABs, beyond requiring that the CABs are accredited to the CAS requirements.

## 13 The proccess of evaluating international CAS

Before evaluating a CAS for the purposes of accrediting the CAB(s) working within the CAS, the GDA must ensure that the EA has not already appointed a hAB for that CAS (information on nominated hABs is available on the EA intranet). If a hAB has already been appointed, then the GDA does not undertake any assessment, but follows the instructions given by the hAB.

If no hAB has been appointed by the EA, before the assessment of an CAS begins, the SO informs the GDA, in writing, if it intends to operate the CAS in more than one EA country and therefore agrees to follow the assessment procedure described in point 13 of this procedure.

If no hAB is appointed, the GDA uses forms DA-FO-079 and DA-FO-080. The accreditation body will notify the SO-applicant of the estimated time period needed for evaluation. Records of the assessment will be kept, including the basis on which the admission decision was made. The accreditation body will use the report template available on the EA intranet.

If the SO of an CAS operating in several countries chooses not to follow the procedure described in point 13 of this procedure, the GDA will inform the SO in writing that there will be no hAB and other EA accreditation bodies will not be forced to follow one approach and therefore it will have to deal with each accreditation body where it operates separately, and therefore accept any change in approach from them.

If the initial intention is to operate the CAS in only one country, GDA will inform the SO that the CAS will only be assessed at the national level and if the situation changes in the future, and the SO wishes to have a common approach in all countries of EA, the evaluation process described in point 13 of this procedure will have to be applied. In this case, the decisions of the GDA that evaluated the CAS may change for this CAS.

*13.1 Steps of evaluation of new international CAS from GDA*

*Step 1*: SO's agreement and choice of hAB

Before starting an evaluation of an international CAS, GDA must receive notification from the SO in writing:

- that it is aware of the fact that the GDA will be the hAB for that CAS and it will work with the hAB without contact with other EA NABs about the particular CAS until the evaluation is finished.
- whether the CAS includes additional requirements to ISO/IEC 17011, Regulation (EC) 765/2008 and/or, where applicable, EA mandatory documents and IAF or ILAC documents endorsed by EA as mandatory. If it does, then written confirmation is also required that the SO is aware of the fact that those additional requirements will need to be endorsed by EA before the evaluation process by the GDA starts; that such endorsement by EA is not a guaranteed outcome; and that the endorsement process may affect the timing of the evaluation process.
- that it agrees to follow the evaluation procedure described in 11 of this document.

*Step 2*: EA registration of CAS in process

Once this notification has been received, the concerned GDA shall inform the EA Secretariat that it has been approached by the SO and intends to perform the initial evaluation. GDA shall commit to be the hAB.

*Step 3*: Analysis by hAB

The EA Secretariat will inform all EA members that a new CAS is under evaluation and will identify the hAB (GDA). Records of this will be kept in the EA intranet. During this step, the hAB (GDA) and other acccreditation bodies shall not offer accreditation to CABs in relation to this CAS.

Once the hAB (GDA) has performed the initial evaluation of a CAS to be operated in several EA member countries, it will report the outcome of the evaluation to the EA Secretariat. This outcome must include:

- A report giving evidence on the elements in form DA-FO-080, supporting why the GDA deems the scheme as compliant with the requirements of this document.
- In case SO has established scheme specific requirements for other accreditation bodies (point 4.11 of form DA-FO-080), the report shall include an explicit reference to them and rationale used by the hAB to decide that they are acceptable based on the justification made by the SO.
- Confirmation of the standard to be used to accredit CABs, including a justification for why the standard has been chosen.
- Expression of the scope of accreditation including the documents to be quoted and the extent of possible flexibility, as defined by the hAB(GDA) and agreed with the SO. This expression of scope shall be the one used by all NABs offering accreditation of CABs in relation to this CAS.
- The documentation (or a link to the documentation) of the CAS (in English)

*Step 4*: EA Consultation

The EA Secretariat shall circulate the CAS documents and hAB(GDA) evaluation report to other NABs for a 30-day comment period. In case SO has established Scheme specific requirements for NABs (see ii above) the EA Secretariat will ask the EA members for 2 separate set of comment (in the same period) for this issue: one for the comments on the results of the evaluation of the CAS by the hAB(GDA) , and one dedicated to comments on the scheme specific requirements placed on NABs.

Until the commenting stage has been finalised, it is recommended that the hAB(GDA) and other NABs do not start assessment activities related to the CAS under evaluation unless the need to start the assessment before the end of the commenting period can be fully justified. In such cases, the hAB and other NABs shall make the SO and the CABs it intends to assess explicitly aware that its conclusions may be challenged by other NAB members and that this may result in changes to the assessment approach and or the CAS requirements. However, where assessment work does commence before the commenting stage is finalised, accreditation cannot be granted before the CAS has been accepted.

*Step 5*: EA Conclusion and registration on the list of CAS Accepted

Once the comment period has finished, if no negative comments have been received, then the hAB conclusions are confirmed and the Secretariat shall inform all NABs of the conclusions and all NABs may operate the scheme.

After the successful evaluation of the CAS, the name of the CAS, including version number and/or date and the conformity assessment standard used for accreditation, will be published within the Members-Only area of the EA Intranet where a list is maintained by the EA Secretariat of CAS evaluated according to EA-1/22 and the hAB holding the responsibility as contact point for the CAS.

Where not all modules were part of the evaluation, only the evaluated modules will be identified in the list. The list will include the scope of accreditation expressed as defined in step 3 as well as the start date of the transition and, where applicable, also the end date.

*Step 6*: Process for dealing with negative comments

If any negative comments have been received then the EA Secretariat shall report these to the hAB(GDA) for resolution in the first instance. The hAB (GDA) shall get in touch with commenting NABs to reach a consensus. If consensus is not reached the matter shall be escalated to the EA HHC for discussion and decision involving, if and when necessary, a task force comprising the hAB, NABs having provided the comments, other NABs volunteering and the SO. As the last possibility to reach a decision, the HHC chair may decide to ballot.

If the negative comments relate only to scheme specific requirements placed on NABs, not contradicting or excluding any of the requirements in ISO/IEC 17011, the standard used for accreditation, EU Regulation (EC) 765/2008 and, where applicable, EA mandatory documents and IAF or ILAC documents endorsed by EA as mandatory, a NAB may decide to start to operate the scheme, before the end of the process.

If after the process, the scheme is not accepted at EA level, it is the responsibility of each individual NAB to decide to operate the scheme on a bilateral relationship with the SO, but only if the conditions in the preceding sentence are fully met.

In the case where the requirements (including, if relevant, scheme specific requirements for NABs) are not accepted, the scheme will not be included in the list. The hAB (GDA) approach is stopped and the SO will be informed by the EA Secretariat of the outcome and reasoning.

The SO will receive the documents of the evaluation which will allow the SO to use the documentation in eventual applications of the SO to individual NAB.

**Changes of an international CAS**

The SO shall inform the hAB as soon as possible of any proposed revision for all or for part of the CAS. This information shall identify all the changes in the CAS and will provide a documented evaluation of their impact on the initial validation of the CAS. Where applicable, the SO shall also include information on the transition requirements (e.g. deadline and arrangements for CABs and for clients of CABs).

The hAB (GDA) informs the active NABs and the EA secretariat that it has received a request to evaluate a revision of the CAS and that further communication will follow from the hAB (GDA).

The hAB (GDA) will evaluate the impact on the accreditation process and on the validation of the CAS. If the conformity assessment standard was to change then this would require a full evaluation of the CAS as described in point 13. The same applies in case there are additional requirements to NAB's.

Evaluation of proposed changes to the CAS shall be led by the hAB involving all active NABs.

The hAB (GDA) shall keep records of the communication with SO, other active NABs and of the conclusions and decisions.

The hAB will send the results of the evaluation and documentation to the other NAB's for a commenting period. This period will normally be not less than 30 days although the hAB (GDA) could increase it if the volume or importance of the changes recommends a longer period.

In case of comments, the SO shall be informed by the hAB (GDA). The SO shall take appropriate actions to the given comments which do not contradict the transition period.

After completion of the evaluation process of the new version of the CAS, the EA secretariat will update the EA list of CAS evaluated according to EA-1/22 with revision date and or number of the CAS and will inform all NABs accordingly.

**Acceptance of a CAS evaluated by other NABs**

*1. If the hAB is a member of the EA and the scheme is accepted by the EA.*

In cases where the GDA will receive an application for the evaluation of a CAS which results that this CAS has been evaluated by a hAB that is a member of the EA and the scheme has been published on the EA intranet, GDA will inform the hAB and in accordance with EA-1/06 5 (p), will make it publicly accessible on the website, that the GDA is now offering accreditation to this CAS.

Any questions that the GDA will have for the SO regarding the CAS will be raised through the hAB

*2. If a CAS has been evaluated by a hAB that is a member of the EA but the scheme is not recognized by EA.*

In cases where an application for the evaluation of a CAS will come to the GDA, which results that this CAS has been evaluated by a hAB that is a member of the EA and the scheme is not recognized by the EA, the GDA will follow the evaluation procedure of conformity assessment scheme. In this case, GDA can request the documentation of the hAB assessment.

*3. If a national CAS intends to develop into an international CAS*

If a national CAS intends to develop into an international CAS, in this case the accreditation body that has accredited CABs according to this CAS will be appointed as hAB for this scheme and the process will be developed according to point 13 of this procedure.

## 14. Changes in Accreditation Requirements.

In case the accreditation requirements change, GDA always follows the instructions of international organizations.
Based on the guidelines of international organizations, GDA prepares the plan for the transition period for the introduction of the modified requirements system. The plan contains the tasks of GDA and accredited bodies, also specifying deadlines.

**GDA tasks for the transition period.**

Based on the modified requirements and international guidelines, GDA sets out the steps and deadlines for accredited bodies to ensure time for safe preparation and evaluation of compliance.

GDA informs accredited bodies and applicants about changes to requirements on its website.

GDA invites accredited bodies through a communication that they must prepare and submit their plans for the transition period within the deadline.

GDA organizes the training courses necessary for the proper preparation of internal staff and external evaluators.

After GDA assesses and collects transition plans, prepares its transition plan as part of the audit plan.

If the requirements change, European and international accreditation organizations set a transition period. After the transition period expires, accreditation for accredited bodies that do not meet the new requirements is revoked by the GDA, or revocation may be requested voluntarily.

During the transition period, the accredited body shall take into account the date of issue of the relevant standard when determining the expiry date of the certificates issued under the relevant standard. Therefore, the expiration date cannot be later than the end of the transition period and the certificates granted by invalid standards become invalid.

GDA confirms the conformity of the accreditation bodies' certification activity under the accreditation procedure and annual supervision procedure and / or emergency supervision procedure. The accredited body can issue new certification to the new standards only after successfully transitioning.

**Duties of accredited bodies for the transition period.**

In order for GDA to plan the transition accreditation program to the new standard, accredited bodies must submit to the GDA Secretariat the transition period plan for transition to accreditation under the new standards within the deadline sets by GDA.

When preparing a transition plan, the following should be considered:

a) Training of internal staff, auditors, evaluation of competencies;

b) Informing existing and prospective clients of the transition period and requirements;

c) Review of the audit and certification plan;

d) Reviewing the certification period and the transition cycle;

e) The time needed to make certification decisions for updating certificates.

## 15. Registrations

| Document title | Who completes it | When you complete it | Who guards it |
|---|---|---|---|
| DA-FO-079 | Applicant | When applying for conformity assessment scheme evaluation | Director of Development Directory |
| DA-FO-080 | Working group | At the conclusion of the scheme evaluation | Director of Development Directory |

## 16 History

| Date of rework | Revision number | Prepared | Description of changes |
|---|---|---|---|
| 30.10.2006 | 0 | Aleks Cuni | Initial version |
| 30.10.2009 | 1 | Ermira Fyshku<br><br>Besnik Pani | Changes to clause 4 references, GDA logo and spelling correction. A paragraph is added to clause 7.1.1 regarding staff training |
| 20.05.2010 | 2 | Ermira Fyshku | Changes in clauses 3 and 6.1.3 regarding the responsibility of the development director.<br><br>Amendments to point 7.1.1 with respect to paragraph 4.6.3 of ISO / IEC 17011 standard and to point 7.2 with respect to paragraph 4.6.2; 4.6.3 c of ISO / IEC 17011 standard |
| 22.12.2014 | 3 | Ermira Fyshku | Header changes and new legislation |
| 20.05.2019 | 4 | Suela Kromidha | Implementation of ISO / IEC 17011: 2017 standard |
| 10.09.2019 | 5 | Suela Kromidha | Changes in point 7, 8 and 9 |
| 31.03.2021 | 6 | Suela Kromidha | Changes in point 7 ; 9 ; 11 |
| 14.11.2024 | 7 | Suela Kromidha<br><br>Emiliana Muca | Changes in paragraphs 5,6,7,8,9,10,11,12, 13 and 14 |