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

Implementer: Quality Manager, Department Directors, Personnel Leader, General Manager, specialists.


Responsible for implementation: Director of Development Directorate.

Control: Quality Manager

Ardita MELE

Approved: General Manager

Armond HALEBI

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1 Purpose.

Procedure DA-PM-008 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 term of accreditation can be extended when there are new requirements and when the accreditation requirements are changed. 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 regulates the extension of the scope of accreditation of the General Directorate of Accreditation (hereinafter: GDA) while adding new accreditation activity and conformity assessment scheme (hereinafter: CAS). Current rules of procedure also contain the steps and actions to be taken when changing requirements that serve as the basis of accreditation (transition to standards). This procedure can also be applied by accreditation bodies, accredited bodies as well as the scheme owners (hereinafter: SP) / scheme managers who wish to use accredited conformity assessment bodies to carry out their activities. conformity assessment.


3 Responsibilities.

This procedure is implemented by the Head of Personnel and Financial Resources Division, Heads of Departments, General Manager, specialists and Quality Manager. It is the responsibility of the Director of Development to implement this procedure.

4 References.

This procedure refers to:

- SSH ISO 17011, SSH ISO 19011 Standards,
- GDA policy on expanding DA-PO-004 activity,
- Law no. 116, dated 11.09.2014 “On Accreditation of Conformity Assessment Bodies in the Republic of Albania”,
- GDA Quality Manual,
- Procedure DA-PT-001 `` Accreditation, surveillance and renewal procedure``,
- Evaluation Policy DA-PO-002,

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- Evaluation subcontracting policy DA-PO-006.

- DA-FO-079 Conformity Assessment Scheme Application Form

- DA-FO-080 Checklist for the Evaluation of a Conformity Assessment Scheme

- Procedure EA-1/22 A: 2016 “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 are published in ISO 17011.

Accreditation Activity - Accreditation Schemes

Scheme Owner (SO)

SP is an identified organization that has developed the CAS (Conformity Assessment Scheme) and is responsible for planning and improving the scheme.

Examples of potential scheme owners:

- a) The standardization body,
- b) Conformity Assessment Bodies - (CAB)
- c) Organizations using the services provided by CAB,
- d) Organizations that buy or sell conformity assessment activities;
- e) Manufacturers or associations that have developed their own conformity assessment scheme


Conformity Assessment Scheme (CAS)

The conformity assessment scheme is a document that contains publicly accessible requirements and must contain the following components:

- a) Subject of conformity assessment, eg, product, process, services, system, personnel,
- b) conformity assessment requirements,

c) the method by which conformity is determined, e.g. testing, inspection or any activity that ensures conformity,

d) any claim specified by the SP to the CAB and any particular claim or interpretation / explanation, if

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applicable, concerned, by the EA General Assembly.

e) any particular application or interpretation / interpretation of ISO / IEC 17011, if applicable.

Specific scheme requirements for accreditation bodies

Additional applications of any requirement of ISO / IEC 17011 to a conformity assessment scheme established by the SP (eg specific competence criteria for the assessor, assessment criteria, particulars in the assessment report, etc.). They shall not contravene or exclude the requirements contained in ISO / IEC 17011, EU Regulation No. 765/2008 and mandatory EA / ILAC / IAF documents. The final decision on the adoption of these requirements will be made nationally by the DA, and in cases where more countries are

Specific scheme requirements for CABs

Special requirements for CABs set by SO. They may not contradict each other and may not exclude the requirements contained in the accreditation standards.

SO recognition of CAB

Recognition by the SO means that the SO receives the certificates and reports issued by the CAB confirming that the test or calibration result, product, process, service, system or person complies with the requirements of the conformity assessment scheme. As a result, the CAB is able to carry out the conformity assessment activity covered by the SVK or may have the right to use the SO brand.

CAB self-assessment


CAB compliance assessment with SO or CAB accreditation requirements.

6 Description of the procedure.

Expanding the GDA's activity or expanding the scope of accreditation with new accreditation activities is becoming increasingly important, enabling GDA to support the introduction of any application that has been accepted by the economy or other stakeholders. By adding new accreditation activities and conformity


assessment schemes GDA aims to strengthen confidence in accreditation to the general public. In this respect, GDA defines the following aspects:

1. GDA essentially accredits conformity assessment bodies to the harmonized standards. DA offers a new accreditation activity, for which an appropriate harmonized standard has been developed, in the DA's accreditation activity program.
2. GDA launches a new accreditation activity or conformity assessment scheme only if the requirement and

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need for the scheme or activity is justified and secured.

3. GDA supports standardization by launching a new accreditation activity or conformity assessment scheme to ensure that stakeholders are involved as widely as possible.
4. Until the decision to launch a new accreditation activity or conformity assessment scheme, GDA shall continue its activity in an impartial and unaffected manner.
5. In order to facilitate the free movement of goods within the EU and around the world, GDA supports the launch of new national or international conformity assessment schemes.
6. GDA assesses and introduces these new accreditation activities and conformity assessment schemes in a transparent and effective manner.
7. GDA starts new accreditation activity or conformity assessment scheme, namely expansion of accreditation field, based on exchange of information with other European accreditation bodies and EA, and in accordance with applicable EA rules.
8. GDA performs its activity in accordance with the applicable requirements of ISO / IEC 17011.

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The need to launch a new accreditation activity or conformity assessment scheme may arise where:

1. Legal (national and / or European) acts require accredited status for an activity that did not require prior accreditation,
2. Introduce a new conformity assessment standard (eg ISO 14065, ISO 45001, EN ISO 17034),
3. In specific areas of expertise, conformity assessment activity is specified in the standards (eg ISO 50001, EN 9104, ISO / TS 22003),
4. The need to add a new conformity assessment scheme on behalf of the owners of accreditation programs / schemes,
5. Introduce new conformity assessment schemes by conformity assessment bodies (such as product certification bodies etc.).

7 Identifying new activity.

The identification of the new activity can come from:

- a) legislation
- b) new standards and documents
- c) application by CAB

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

Identification of new activity from CAB applications will be performed by the Director of Accreditation Directorate. Upon identification, the Director of the Accreditation Directorate notifies the Director General and the Director of Development Directorate.

Upon identification of the new activity, the Director of Development Directorate, within five days, conducts an analysis of the market need for the new activity and the type of conformity assessment it submits to the Director General. It is the Director General who decides whether GDA will be involved in this new activity or not. If the Director General decides not to start preparing for the new activity then the applicant or the interested party shall be notified. If the Director General decides to begin preparations for the delivery of the new activity, the Director of the Development Department shall, within five days of making the decision, establish a working group consisting of at least the Quality Manager, Departmental Directors and the Personnel Sector and financial resources for reviewing and analyzing resources to start a new GDA activity. The working group may also include GDA specialists or other competent persons. The General Director may

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also decide to subcontract evaluation under policy DA-PO-006. In this case, a resource analysis is carried out for the persons involved in decision making.

8. Resource analysis

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

8.1 Conformity Assessment Analysis


The working group evaluates the type of conformity assessment and determines the level of standards according to EA 1/06 classification. The working group may also determine the methods or standards for carrying out the conformity assessment.

8.2 Human Resources Analysis.

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

- Analyzes the competence of GDA, if the extension of accreditation activity can be implemented, taking into account existing sources for reviewing the application and making the decision
- Evaluates and receives expertise from other external sources (experts, technical evaluators, technical committees 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 are insufficient, the Director of Development Directorate seeks assessors for the relevant field within the country. Information on the search for new appraisers, the criteria they must meet is disseminated to various scientific institutions, accredited bodies, technical committees, the accreditation board, etc. Information on new appraisers is also provided on the GDA's Website. Selection of candidates for evaluation 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. If the competence of the decision makers is not ensured, then the recommendation from the relevant technical team is required

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8.3 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 Party 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 Director General, the Manager of Quality incorporates them into management system documents.

8.4 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.

8.5 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 Department proposes to the General Director:

- a) The start of new service delivery
- b) Not to start new service
- c) Subcontracting of the evaluation.


a) If the decision is to start the service delivery, then the Accreditation Directorate based on the sources provided follows the accreditation procedure according to DA-PT-001. The Development Department publishes on the GDA's official website the launch of service provision and related requirements.

b) If the decision is not to provide service, GDA notifies the client or interested parties of the reasons for not starting this activity.

c) If the General Director decides to subcontract the evaluation, then must be implemented DA-PO-006 policy. In this case the competence of the persons involved in decision-making must be confirmed.

9 Adding a new conformity assessment scheme.

By submitting a request for the application of a new conformity assessment scheme as per DA-FO-79 "Conformity Assessment Scheme Application Form", GDA will carry out the evaluation of the scheme as per DA-FO-080 "Check list for evaluation of a conformity assessment scheme ",

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New CASs created by the legislator after being evaluated by DA will be included in its accreditation activities. New CASs that are evaluated by EA, IAF, ILAC or any other accreditation body (MLA) will not be re-evaluated by GDA, but GDA will recognize the results of the evaluation carried out and decide on its addition.

New conformity assessment schemes made by associations, certification bodies, manufacturers or other interest groups, so-called "private interest" conformity assessment schemes, will be reviewed by GDA if they can be added to accreditation. The body should apply for the addition of the conformity assessment of "private interest". GDA should draw the attention of the owners of the conformity assessment scheme to the requirements of the EA-1/22 A: 2016 procedure.

New stakeholder accreditation requirements may occur in the following ways for the introduction of a new CAS:

- a) New laws have been introduced by government authorities in the legally regulated field with regard to the approval of products (including services) in the fields of safety, health protection, environmental protection and to prevent fraud and ensure fairness. market competition;
- b) Market-based requirements that are not legally regulated, where some industries may submit - partly within designated entities and partly across the sector - conformity assessments and approval schemes aimed at achieving a minimum standard technician, under the same conditions of competition.


The requirements applicable to conformity assessment schemes are based on accreditation standards and applicable EA, IAF and ILAC guidelines as well as GDA procedures. Procedure EA-1/22 A: 2016 provides guidance on conformity assessment schemes. It is generally recommended that scheme owners should use the guidance in ISO / CASCO conformity assessment instrument documents when planning a conformity assessment scheme.

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9.1 The process of adding a new conformity assessment scheme.

The addition of the new conformity assessment scheme is carried out as follows:

1. Application by the owner of the scheme to evaluate the new accreditation conformity assessment scheme under forms DA-FO-079.
 2. The applicant shall provide the GDA with all information and documents necessary for the evaluation of the new scheme under DA-FO-080.
 3. Information to be provided by scheme owners must be submitted in accordance with the requirements of procedure EA-1/22 A: 2016.
 4. Conditions and requirements for scheme owners are included in EA-1/22 A: 2016 procedure.
 5. GDA may involve technical working groups, the Accreditation Board, government authorities and other stakeholders in the analysis and evaluation of the scheme.
 6. GDA should consult with representatives of interested parties before accepting the request.
 7. GDA examines whether human resources (vt, et, vs) are available.
 8. The documentation for the new conformity assessment scheme is submitted to the Accreditation Board for review, which at the end of the meeting will come up with relevant suggestions.
- The final decision on the acceptance of the new conformity assessment scheme is taken by the Director General of GDA.
9. The applicant's notification of the decision and the publication of the decision shall be made available on the DA website.
 10. If necessary, GDA should also cooperate with technical working groups to develop uniform rules and applicable technology and accreditation requirements.
 11. If necessary, GDA should also cooperate with national and / or international bodies regarding the mission of the new scheme.
 12. GDA takes measures to expand the evaluation team with experts, evaluators under the new scheme.
 13. Training of GDA staff and external assessors of GDA.
 14. GDA should take measures to include new members in the technical working groups and in the Accreditation Board.

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15. Adding new scheme among GDA accreditation activities.

16. GDA maintains stakeholder registrations in the various CASs and their changes.

Where, due to changes in legislation or a lack of market interest, GDA decides to suspend or terminate accreditation under a particular CAS, and shall:

- a) seek the opinion of interested parties,
- b) consider the fulfillment of contracts with SP (termination),
- c) informs interested parties in a communiqué on its official website,
- d) to follow external communication,
- e) give a statement on the validity of the accreditations issued,
- f) if a new CAS is introduced to replace the previous ones, the transition rules shall be published.

GDA should draft minutes on consultation and its results with stakeholders.

9.2 Applicable requirements for CAS

9.2.1 Competence and impartiality

- a) Each CAS will be compiled by persons who demonstrate that they are capable of performing this task.
- b) This competence includes knowledge of the technical field and the conformity assessment procedure.
- c) Determine the competencies required for persons performing the conformity assessment activity of a CAS.

9.2.2 Market support

Evidence of market acceptance of the scheme should be provided. The SO should be able to present evidence of CAS market support received from relevant stakeholders - especially end users (eg consumers and industry). Stakeholders should be consulted and evidence of this consultation should be provided.


9.2.3 CAS Validity

The owner of the scheme must certify the validity of the CAS before submitting it to GDA. A requirement for the validity of the scheme is that the scheme must have a successful audit period indicating that the

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scheme can be implemented and is in line with the goals and expectations of the scheme owners. The document for evaluating an CAS should contain:

- a) description of the scheme objective;
- b) a description of the scheme requirements;
- c) the analysis of the compliance of the requirements set for the fulfillment of the objectives of the scheme;
- (d) a description of the methods to be used in determining compliance;
- e) the decision on the conformity assessment activity (including the identification of the conformity assessment standard to be applied);
- f) the suitability analysis of the selected conformity assessment activity

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9.2.4 Evaluation of conformity assessment schemes.

Two options can be followed for evaluating conformity assessment schemes:

1. The scheme is owned by a body that has applied to be accredited or an accredited body (OWC),
2. The scheme is owned by an organization (the owner of the scheme) who applies for acceptance of its scheme.

Option 1: CAB Owned Schemes.


The scheme is assessed by GDA in the initial evaluation or extension of the accredited field. Before conducting such an assessment, which most of the time also includes evidence of conformity assessment activity, the applicant must submit application DA-FO-079 and DA-FO-080 together with the documentation of the scheme.

We emphasize that the EA 1/22 procedure is not mandatory to apply if the owner of the scheme is an OWC that requires accreditation for an SVC for internal use. However, even in these cases, it is recommended that the evaluation of such CASs follow the process described in Annex 1 to EA 1/22.

Option 2: Application submitted by SP for acceptance of scheme.

The SP may submit a request for acceptance of their CAS. Evaluating a scheme prepared by an SP consists of the following steps:

1. The owner of the scheme shall submit the scheme documentation (including DA-FO-079 and DA-FO-080 forms) to the GDA.
2. At least one CAB has requested the DA to be accredited in accordance with the requirements of the CAS.
3. The GDA then reviews the application for scheme evaluation, determines and prepares the cost estimate to be submitted to the SP.
4. After approving the relevant budget, GDA carries out the evaluation and sends its results to the SP (applicant). After resolving the non-conformities, a positive decision can be taken to approve the scheme. Based on CAS, CAB accreditation may continue.
5. In the CAB's assessment of a new accreditation, discrepancies may arise with respect to the CAB, which are left unnoticed in the initial CAB assessment. The discrepancies identified in the observed activity are corrected by CABs, which are expected to be in line with the needs of the SP.

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9.3 Cooperation with EA and other international accreditation bodies.

GDA assesses and decides on adding conformity assessment schemes of national (internal) application only to accreditation activities. In the case of such schemes, GDA does not include EAs or other accreditation bodies.

In the case of internationally applied schemes, GDA identifies the national accreditation body, the so-called "home accreditation body", which has carried out the first evaluation and monitored possible changes to the scheme. Only the accreditation body cooperates with the owner of the scheme.

Cooperation of GDA with EA is carried out according to procedure EA-1/22 A: 2016. Procedure EA-1/22 A: 2016 outlines further requirements for international extension and mutual recognition for the SP.

9.4 Changes in Accreditation Requirements.

If the accreditation requirements change, GDA always follows the guidelines of international organizations.

Based on the guidance of international organizations, GDA prepares the transition period plan for the introduction of the modified claims system. The plan contains the duties of the GDA and of the accredited bodies, also specifying the deadlines.

9.4.1. DPA 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.

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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.

9.4.2. 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.

10 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 Directorate
DA-FO-080	Work group	At the conclusion of the scheme evaluation	Director of Development Directorate

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11 HISTORY

Date of rework	Revision number	Prepared	Description of changes
30.10.2006	0	Aleks Cuni	Initial version
30.10.2009	1	Ermira Fyshku 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. 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