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**Proçedure cross frontier
accreditation**

Code: DA - PT - 012

Rieview no. 4
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**Proçedure
``cross frontier accreditation``**

Implemented by: General Director, the Director of the Directorate of testing, calibration and medical laboratories and the Director of the Directorate of certification and inspection bodies, lead assessors, technical assessors and experts


Responsible for implementation: Director of the Directorate of testing, calibration and medical laboratories/ Director of the Directorate of certification and inspection bodies

Controlled by: Quality manager

Ardita MELE

Approved by: Director General

Pranvera FAGU

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1. PURPOSE

The purpose of this document is to define the process that DPA follows in the accreditation procedures of conformity assessment bodies registered outside Albania, conformity assessment bodies registered in Albania with locations in other countries or performing conformity assessment activities in other places. In addition, this procedure also provides details about following the accreditation procedure of an CAB accredited by an accreditation body of another country and that offers activities or is located in Albania.

2. SCOPE OF APPLICATIONS


This procedure is applied in all cases when DPA accredits a conformity assessment body in another country, when it accredits a branch or critical location of a conformity assessment body registered in Albania, or when a conformity assessment body registered in Albania carries out conformity assessment activities outside the territory of Albania under DPA accreditation.

3. RESPONSIBILITIES

This procedure is implemented by the General Director, the Director of the Directorate of testing, calibration and medical laboratories and the Director of the Directorate of certification and inspection bodies, lead assessors, technical assessors and experts. Responsible for controlling the implementation of this procedure is the Director of the Directorate of Testing, Calibration and Medical Laboratories/Director of the Directorate of Certification and Inspection Bodies

4. REFERENCES

ISO/IEC 17011:2017 “Conformity assessment-Requirements for accreditation bodies accrediting conformity assessment bodies”
Law no. 116/2014 "On the accreditation of conformity assessment bodies in the Republic of Albania", amended
Quality Manual DA-MC-001
Accreditation policy DA-PO-002
DPA policy for cross-border accreditation DA-PO-012
Accreditation, surveillance and renewal procedure DA-PT-001
Assessment visit procedure DA-PT-002

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5. VOCABULARY AND ABBREVIATIONS

For the purposes of this document, the terms and definitions given in the S SH ISO 17011:2017, S SH ISO 9000:2015 and the DPA Quality Manual were used. For the purposes of this procedure, the terms and explanations given in document EA 2/13 are also used.

OVK – Conformity Assessment Organization.


6. DESCRIPTION OF PROCEDURE.

6.1. Accreditation of conformity assessment bodies that are not registered as legal entities in Albania.

When an OVK that is not registered in Albania applies for accreditation, the Director of the Directorate of Testing, Calibration and Medical Laboratories / the Director of the Directorate of Certification and Inspection Bodies verifies if are met the criteria according to Article 8 of Law no. 116/2014 "On the accreditation of conformity assessment bodies in the Republic of Albania", amended. If the criteria are not met, the Director of the Directorate of testing, calibration and medical laboratories / the Director of the Directorate of certification and inspection bodies informs CAB that the request for accreditation will be refused. If these criteria are met, the Director of the Directorate of testing, calibration and medical laboratories/ Director of the Directorate of certification and inspection bodies

- Informs CAB about the existence of the local accreditation body in its country. (where applicable)
- Informs CAB if the local accreditation body is a signatory of multilateral recognition agreements between EA, IAF and ILAC for the relevant conformity assessment activity.
- Informs CAB that obtaining accreditation from a local accreditation body is often less expensive.
- Informs CAB that the accreditation issued by the local accreditation body signatory to multilateral recognition agreements is equivalent to that issued by the DPA.

If, regardless of this information, CAB still wants to use the services of DPA, according to the criteria defined in point 8 of Law 116/2014, the Director of the Directorate of testing, calibration and medical laboratories/ the Director of the Directorate of certification and inspection bodies informs the local accreditation body for the request received from CAB and the reasons for this request. Only after the information, the DPA follows the application according to procedure DA-PT-001. When reviewing resources and preparing for assessment under DA-PT-001, DPA requests information from the

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local accreditation body (where applicable) regarding the existence of legislation/regulations in force, knowledge of the local market, volume of work carried out by CAB, the impact of CAB activities carried out under DPA accreditation on the local market, the history of the assessment results of the conformity assessment activity. If necessary, the DPA asks the local accreditation body to have assessors in the DPA assessment group or at least to participate as an observer. DPA proposes to the local accreditation body to carry out joint assessment, but only when CAB agrees.

If CAB chooses the services of the DPA and the local body at the same time, the DPA undertakes to fulfill the following steps:


- Obtain written authorization from the CAB that the data collected during the assessment process are allowed to be shared with the local accreditation body.
- Take into account the assessment results of the local accreditation body when planning the CAB assessment program

The DPA provides the necessary competence to carry out assessments taking into account factors such as language, national legislation and regulations, culture, etc. When the DPA engages assessors from the local accreditation body, the DPA takes all measures and information necessary to perform the work under optimal conditions. In this case, the assessors will be considered DPA assessors and will be engaged according to DPA regulations and procedures.

6.2 Accreditation of locations in other countries of conformity assessment bodies that are registered in Albania,

When conformity assessment bodies accredited by DPA request the accreditation of branches, representative offices or have subcontracted entities that perform or manage conformity assessment activities on behalf of the body accredited by DPA, DPA subcontracts the local accreditation body for their assessment, including witnessing that are carried out in the other country in case when the local accreditation body is a signatory of the EA MLA, ILAC MRA or IAF MLA for the respective conformity assessment activity. Subcontracting may not apply even if the local accreditation body refuses to perform the assessment on behalf of the DPA. In cases of subcontracting, the DPA will apply the subcontracting procedure.

When the assessment is carried out by the local accreditation body, in the stage of preparation of the assessment DPA cooperates with the local accreditation body to determine the techniques, the way of assessment of the CAB and announces at an early stage any difficulties it anticipates. For existing accredited activities, the DPA sends sufficient information to the local accreditation body regarding anticipated assessment

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requirements during the accreditation cycle. DPA announces also the local accreditation body for its needs in the next calendar year no later than three months before the beginning of the calendar year. The scope of the assessment will be reported to the local accreditation body no later than three months before the scheduled date of the assessment. For additional requests, e.g. extraordinary assessments or extensions of the assessment scope, the DPA notifies the local accreditation body as soon as it is aware of the request.


Before each assessment, the DPA provides the local accreditation body with at least the following:

- the detailed scope of the assessment required in order to minimize the risk of misunderstanding;
- all the information necessary to ensure an effective assessment as agreed under the signed agreement;
- The report of the last assessment of the location identified as maintenance and management control; including details of non-conformances and resulting actions;
- Updated information about the CAB including details of how it is organized and managed and how conformity assessment activities are carried out at/from that location;
- Any additional specific requirements or activities to be specifically evaluated by the local accreditation body;
- Any requests from regulators that may have an impact on the activities of location when accreditation is granted for notification purposes;
 - The full scope of activities that can be carried out from the local location under CAB accreditation;
- Detailed description of the field to be assessed, including any sectoral scheme;
- The evaluation plan, including evaluations with evidence for the location during the full accreditation cycle;
 - Assessment program for all CAB activities, including witnessing, if necessary;

The DPA requires the local accreditation body to at least:

- Assessment results in accordance with the deadlines defined in the agreement between two accrediting bodies
- The assessment report defined in the agreement between the accreditation bodies
- Statement on recommendations regarding the closure of any findings if they are to be evaluated by the local accreditation body.

Making the decision always remains the responsibility of the DPA according to paragraph 6.7 of procedure DA-PT-001. Every decision taken by the DPA, the director of the directorate of testing, calibration and medical laboratories/the director of the

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directorate of certification and inspection bodies notifies the local accreditation body within 10 days of taking the decision.

In the event that the local accreditation body does not agree to carry out the assessment or when it is not a member of the EA MLA, ILAC MRA or IAF MLA, the DPA will not subcontract the local accreditation body, but will require representatives of this body to participate at least observer.

6.3 Accreditation of conformity assessment bodies registered in Albania, which do not have other locations but perform conformity assessment activities in another country.

When the conformity assessment bodies accredited by the DPA perform conformity assessment activities outside the territory of Albania the accreditation issued by the DPA, DPA subcontracts the local accreditation body for their assessment, including the witnessing that are carried out in the other country in if the local accreditation body is a signatory of the EA MLA, ILAC MRA or IAF MLA for the relevant conformity assessment activity. DPA implements all steps as in point 6.2 of this procedure.

In the case where the local accreditation body does not agree to perform the assessment (subcontracting), DPA will include assessors of the local accreditation body for the relevant assessment. When the local accreditation body does not agree to be included in the assessment or when it is not a member of the EA MLA, ILAC MRA or IAF MLA, the DPA will request that representatives of this body to participate at least as observers.

7. REGISTRATIONS FROM THIS PROCEDURE

Title of the document	Who fills it in	When	Who maintains
Check list	Assessment team	When checking the documentation	Archive
Form for assessment of quality manual DA – FO- 006	Lead assessor	When checking the documentation	Archive
Form for assessment of technical procedures DA –FO – 007	Technical assessor	When checking the documentation	Archive
Form for assessment of management procedures DA-FO-	Lead assessor	When checking the documentation	Archive



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Form of presenting corrective actions DA-FO-011	Assessment team	After assessment	Archive
Form for notification of assessment date and its approval DA-FO-005	Specialist of sector	After checking the documentation	Archive
Plan of assessment visit	Specialist of sector	Before assessment visit	Archive
Form for notification of team members and its approval DA-FO-012	Specialist of sector	Before assessment visit	Archive
Form of reporting the laboratory assessment according to ISO 17025 DA-FO-001	Assessment team	After assessment visit	Archive
Form of reporting of assessment according to ISO 17024 DA-FO-013	Assessment team	After assessment visit	Archive
Form of reporting of assessment according to EN 45011 DA-FO-049	Assessment team	After assessment visit	Archive
Form of reporting the assessment according to ISO 17021 DA-FO-004	Assessment team	After assessment visit	Archive
Form of reporting to general Director DA-FO-016.	Head of sector	After assessment	Archive
Form of presenting the non conformities DA-FO-003	Assessment team	After assessment visit	Archive
Preparation of certificate	Archive	When the document issued or change	Archive
Pre-assessment report DA-FO-043	Assessment team	After the pre-assessment visit	Archive
Assessment program for testing laboratories	Assessment team	After the decision is taken	Archive
Assessment program for calibration laboratories	Assessment team	After the decision is taken	Archive

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Assessment program for medical laboratories	Assessment team	After the decision is taken	Archive
Assessment program for management system certification bodies	Assessment team	After the decision is taken	Archive
Assessment program for certification bodies of persons	Assessment team	After the decision is taken	Archive
Assessment program for inspection bodies	Assessment team	After the decision is taken	Archive

8. HISTORY

Date of review	Number of review	Prepared by	Description of changes
20.11.2009	0	Ermira Fyshku	First version
22.12.2014	1	B.XHAFA	There have been changes to the document head of page about phone numbers and email address of DPA. In paragraph 4 is amended to add the reference to the law.
7.06.2019	2	Ardita Mele	Changes in paragraph 6
08.06.2022	3	Ardita Mele	Changes in paragraph 6
14.11.2024	4	Ardita Mele	Changes in paragraph 4 « References »