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Procedure of suspension, withdrawal, reduction and extension of accreditation

DA - PT - 006

Revision no.8
Dt: 05.10.2023

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Procedure of suspension, withdrawal, reduction and extension of accreditation

Implemented by: General Director, Directorate for accreditation of testing, calibration and medical laboratories, Directorate for accreditation of certification and inspection bodies, Development Department, Secretariat, lead assessor, assessors and technical experts

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

Controlled by: Ardita MELE
Quality manager

Approved by: Pranvera FAGU
General Director



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1. PURPOSE

This procedure specifies the conditions for suspension, withdrawal, reduction and extension of accreditation and actions to be taken in such cases.

2. SCOPE OF APPLICATIONS


This procedure is implemented in all the cases of suspension, withdrawal, reduction and extension of accreditation of conformity assessment bodies (CAB) accredited by DPA upon request of the accredited CAB or upon DPA decision.

3. RESPONSIBILITIES

This procedure is implemented by the General Director, Directorate for accreditation of testing, calibration and medical laboratories, Directorate for accreditation of certification and inspection bodies, Development Department, DPA Secretariat, lead assessors, assessors and technical experts. The Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies is responsible for checking the implementation of this procedure.

4. REFERENCES

- ISO/IEC 17011:2017 ‘‘Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies’’, paragraph 7.10; 7.11.
- Law Nr. 116, date 11.09.2014, ‘‘On the accreditation of conformity assessment bodies in the Republic of Albania’’.
- IAF MD 7:2023 Harmonization of Sanctions to be applied to Conformity Assessment Bodies.
- IAF MD 2:2007 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems
- Procedure for assessment visit (DA-PT-002)
- Procedure for appeals and complains (DA-PM-005)
- Form for assessment plan (DA-FO-002)
- Form for presenting the nonconformities (DA-FO-003)
- Form for presenting the corrective actions (DA-FO-011)

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- Form for assessment report of laboratories (DA-FO-001)
- Form for assessment report of personnel certification bodies (DA-FO-013)
- Form for assessment report of product certification bodies (DA-FO-049)
- Form for records of appeals and complains (DA-FO-024)

5. VOCABULARY AND ABBREVIATIONS

For the purpose of this document terms and definitions provided in ISO/IEC 17011:2017, ISO 9000:2015 and the DPA Quality Manual, are used.

6. SUSPENSION OF ACCREDITATION


Suspension of accreditation means that DPA puts temporary restriction of the accreditation status for full or part of the scope of accreditation. The accreditation status can be suspended on voluntary request by the accredited CAB or on request of DPA, when one or more of the conditions laid down in clause 6.3 are fulfilled. Suspension of accreditation was decided only for a part of the scope of accreditation when the conditions mentioned in clause 6.3 of this procedure are fulfilled for a part of scope of accreditation. In both cases, voluntary suspension or suspension requested by DPA, the following procedure applies.

6.1 Suspension of accreditation requested by CAB

The accredited CAB submits to DPA a written request for self-suspension of accreditation.

The Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies, or the relevant technical committee in case of related bodies, after evaluating the request, recommends a suspension period to the General Director. The General Director makes the decision on suspension. The period for self-suspension cannot be longer than 6 months. After that the accreditation is withdrawn as described in section 7 of this procedure.

The Development Directorate updates the list of accredited bodies in DPA website and indicates the suspension status. The suspension status is indicated by strikethrough and the suspended scope is invisible.

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6.2 Suspension of accreditation requested by DPA

When one or more of the conditions for suspension listed in clause 6.3 of this procedure is fulfilled, the Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies, or the relevant technical committee in case of related bodies, or the Head of Sector for Finance and Services, within 10 days, submits a recommendation for suspension to the General Director. The General Director can request more information about the suspension recommendation. Within 15 days having received all information the General Director makes decision on the suspension. He gives formal notice to the CAB on the decision on suspension including a clear explanation of reasons which resulted in suspension.

Within 10 days of receipt, the CAB has the right to appeal against this decision. The appeal is handled according to the procedure DA-PM-005. However, launching of an appeal does not lead to the suspension of the DPA decision on accreditation.


If the CAB doesn't launch any appeal within the specified period, DPA:

- Prepares the invoice for the tariff of assessment visit procedure which is to be paid by the accredited body within the deadline defined by DPA.
- Ensure the payment of the assessors.
- Publishes the suspension of accreditation in DPA website. The suspension status is indicated by strikethrough and the suspended scope is invisible.

6.3 Conditions for suspension of accreditation

The conditions upon which DPA decides on the suspension of accreditation are the following:

- a. There are findings against the activity of the accredited CAB, including the misuse of accreditation symbol, but the nature and the risk of such findings doesn't justify the withdrawal of accreditation.
- b. Failure to respect the deadlines defined in DPA's procedures.
- c. Failure to resolve nonconformities in accordance with DPA's procedures.
- d. Negative outcome of a complaint investigation.
- e. Non-payment of fees

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- f. CAB has not notified the occurred changes to DPA, according to time defined in contract, which affects the fulfilment of the accreditation requirements.
- g. The accredited CAB doesn't provide DPA access to personnel, documentation, location, equipment, information and records.
- h. The accredited CAB doesn't ensure the access to their client for witnessing when carrying out conformity assessment activities at the client's site.
- i. Absence of documentation requested to perform surveillance visits.
- j. The accredited CAB doesn't respect the accreditation programme.
- k. The accredited CABs has not performed any conformity assessment activity under the accreditation scope for more than one year.
- l. The accredited CAB doesn't accept the organization of the surveillance visit or the extraordinary visit.
- m. If accredited CAB provides certification to any standard used as a basis for the accreditation of conformity assessment bodies (e.g ISO/IEC 17025, ISO 15189)
- n. where the issuing accredited certification body does not cooperate with the accepting certification body or suspends the transferring client's certification without cause.

The Head of Sector for Finance and Services recommends the suspension only when the CAB refuses to pay the fees (clause 6.3 e).


The period of suspension of accreditation shall not exceed more than 6 months.

6.4. Lifting of suspension

When CAB considers that the reason(s) which resulted in the suspension of accreditation is/are resolved, it formally communicates to DPA its readiness to restart the activity, asks for lifting of suspension and sends the necessary documentation/evidences.

When the accreditation was suspended for financial reasons (6.3.e), the Head of Sector for Finance and Services verifies the payment and reports to General Director who, within 15 days, makes the decision on lifting the suspension.

When the accreditation was suspended for technical reasons (all other cases in 6.3 except e), the lead assessor reviews all the documentation/evidences submitted by the CAB and proposes to the Director of Directorate for Accreditation of testing, calibration and

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medical laboratories/Director of Directorate for accreditation of certification and inspection bodies one of the following actions:

- assessment of documentation/records by the assessment team,
- organization of an on-site assessment.

The Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies reviews all the documentation/evidences and proposal of lead assessor and decides which action will be taken. The lead assessor implements procedure DA-PT-001 for both actions. The decision on lifting of suspension is made by the General Director according to procedure DA-PT-001. If the decision is positive, i.e. to lift the suspension, the Development Department updates the list of accredited bodies. If the decision is negative, the withdrawal procedure starts. In both cases DPA informs the CAB on the decision. If the decision is negative, the CAB has the right to launch an appeal according to appeal procedure (DA-PM-005).



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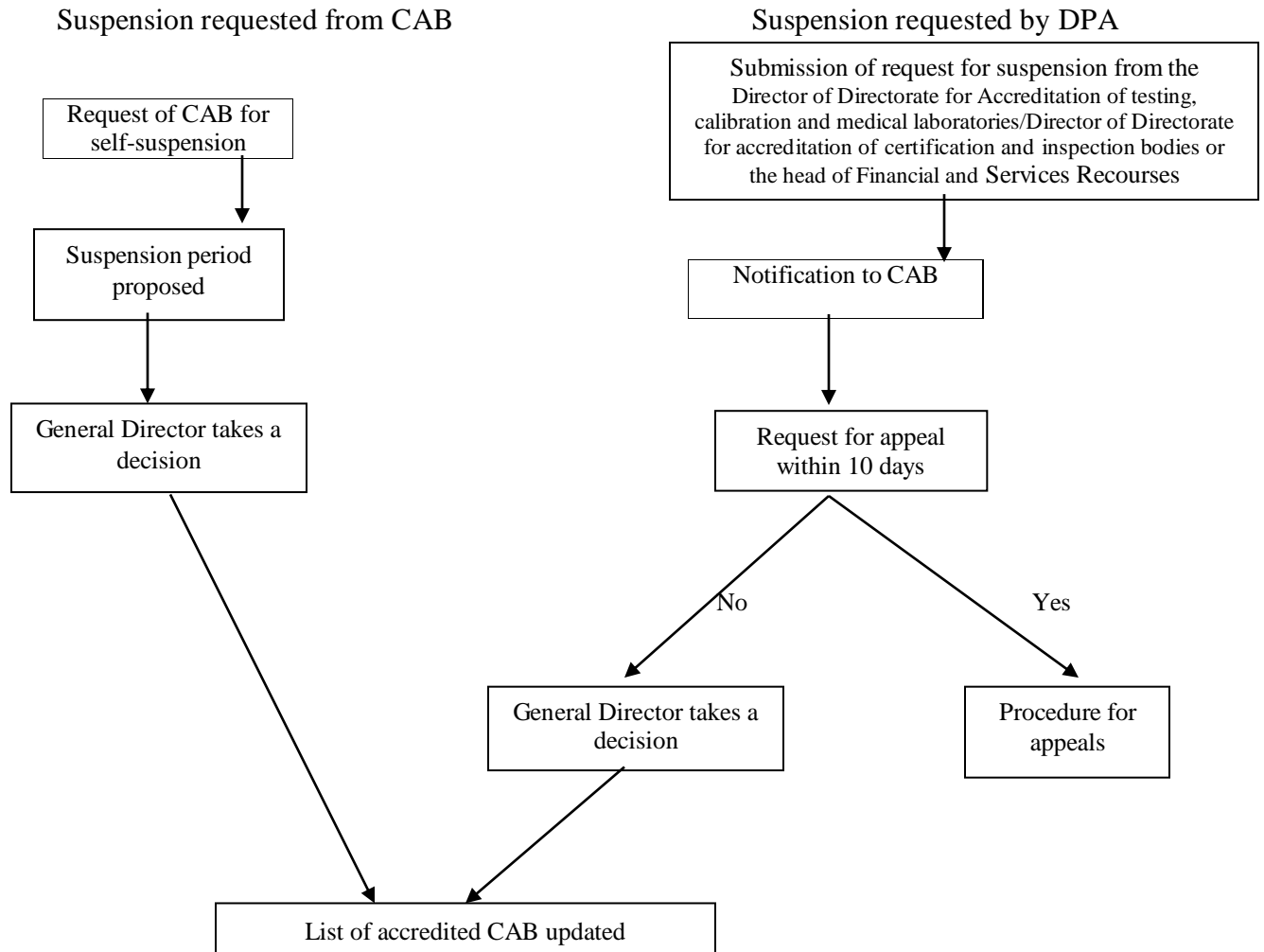
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6.5 Diagram of suspension



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7. WITHDRAWAL OF ACCREDITATION

The withdrawal of accreditation means the termination of the accreditation status for full scope of accreditation. Withdrawal can be requested by the accredited CAB or by DPA. In both cases, voluntary withdrawal or withdrawal requested by DPA, the following procedure applies.

In case of withdrawal of accreditation, the CAB can re-apply for accreditation only after 6 months.

7.1 Withdrawal of accreditation requested by the accredited CAB

The accredited CAB can submit to DPA a written request for withdrawal of accreditation.


After checking the request, the Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies, analyses the motives for which withdrawal is being requested and reports to the General Director. If it needed, the Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies can request opinion of lead assessor. Lead assessor review the request of the CAB and makes a note to the Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies.

Within 15 days, the General Director makes decision on withdrawal. DPA informs the CAB on the decision and requests to send back the accreditation certificate.

The Development Directorate updates the list of accredited bodies and list the CAB to the table of CABs which the accreditation status is withdrawn. The CAB will be in this table as far as the accreditation status would be valid.

7.2 Withdrawal of accreditation requested by DPA

The accreditation status is withdrawn by DPA when one or more of the conditions for withdrawal listed in clause 7.3 of this procedure is fulfilled. In case of clause 7.3 a) and f), the Head of Sector for Finance and Services makes the recommendation for withdrawal and submits it with evidences, within 10 days, to the General Director for decision-making. In all other cases listed in clause 7.3, the lead assessor makes recommendation for withdrawal and submits it to the Director of Directorate for

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Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies with all the evidences. In case of related bodies, the Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies submits the lead assessor’s recommendation with all the evidences to the relevant technical committee.

Having analyzed all evidences, Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies or the relevant technical committee in case of related bodies, within 10 days, submits a recommendation for withdrawal to the General Director. The General Director can request more information about the withdrawal recommendation. Within 15 days having received all information, the General Director makes decision on withdrawal. He gives formal notice to the CAB on the decision on withdrawal including a clear explanation of reasons which resulted in the withdrawal. If the decision is to withdraw accreditation, DPA requests the CAB to send back the accreditation certificate and accreditation program.


The Development Directorate updates the list of accredited bodies and list the CAB to the table of CABs which the accreditation status is withdrawn. The CAB will be in this table as far as the accreditation status would be valid.

Within 10 days of receipt, the CAB has the right to appeal against this decision. The appeal is handled according to the procedure DA-PM-005. However, launching of an appeal does not lead to the suspension of the DPA decision on withdrawal of accreditation.

7.3 Conditions for withdrawal of accreditation

The conditions upon which DPA decides on the withdrawal of accreditation are the following:

- a) The CAB or the legal entity it is bankrupted.
- b) The CAB fails to meet the requirements for accreditation when the suspension deadline is over.
- c) The CAB fails to meet the deadline defined in suspension decision and no information was submitted by CAB.
- d) There are nonconformities against the activity of the accredited body, including the misuse of accreditation symbol/accreditation certificate, which presents high risk and impact.

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- e) If there is objective evidence of fraud in OVK's conformity assessment activities and/or if it is determined that OVK issues false registrations/reports/certificates,
- f) If CAB deliberately misinforms DPA, deliberately conceals information or provides false records and/or evidences to DPA.
- g) If CAB makes wrong reference to accreditation against to DPA policy, DA-PO-005, in accreditation scheme or conformity assessment activities for which it is not accredited.
- h) Existence of objective situations which impede the fulfillment of the accreditation agreement between DPA and the CAB (contract).
- i) The deadline for payment defined in suspension decision is over.
- j) Failure to close the complaint against the CAB.
- k) If CAB is involved in declarations and behaviors that damage the prestige and reputation of its accreditation or DPA
- l) where the issuing accredited certification body continues to refuse the cooperation with the accepting certification body or withdraws the transferring client's certification without cause.

7.4 Information to IAF

In case of sanctions for OVK, whose accreditation is completely withdrawn due to one of the reasons defined in 7.3 (e), (f), (g), or suspended due to the reason defined in 6.3 (m) and is active in accreditation programs under the IAF MLA, the development directorate specialist notifies the IAF secretariat at the end of the appeal period; or after the appeal is concluded. The DPA notice will be in the format:

"[DPA] [suspended/withdrawn] [OVK status accreditation] on [date] due to [identified non-conformity]".



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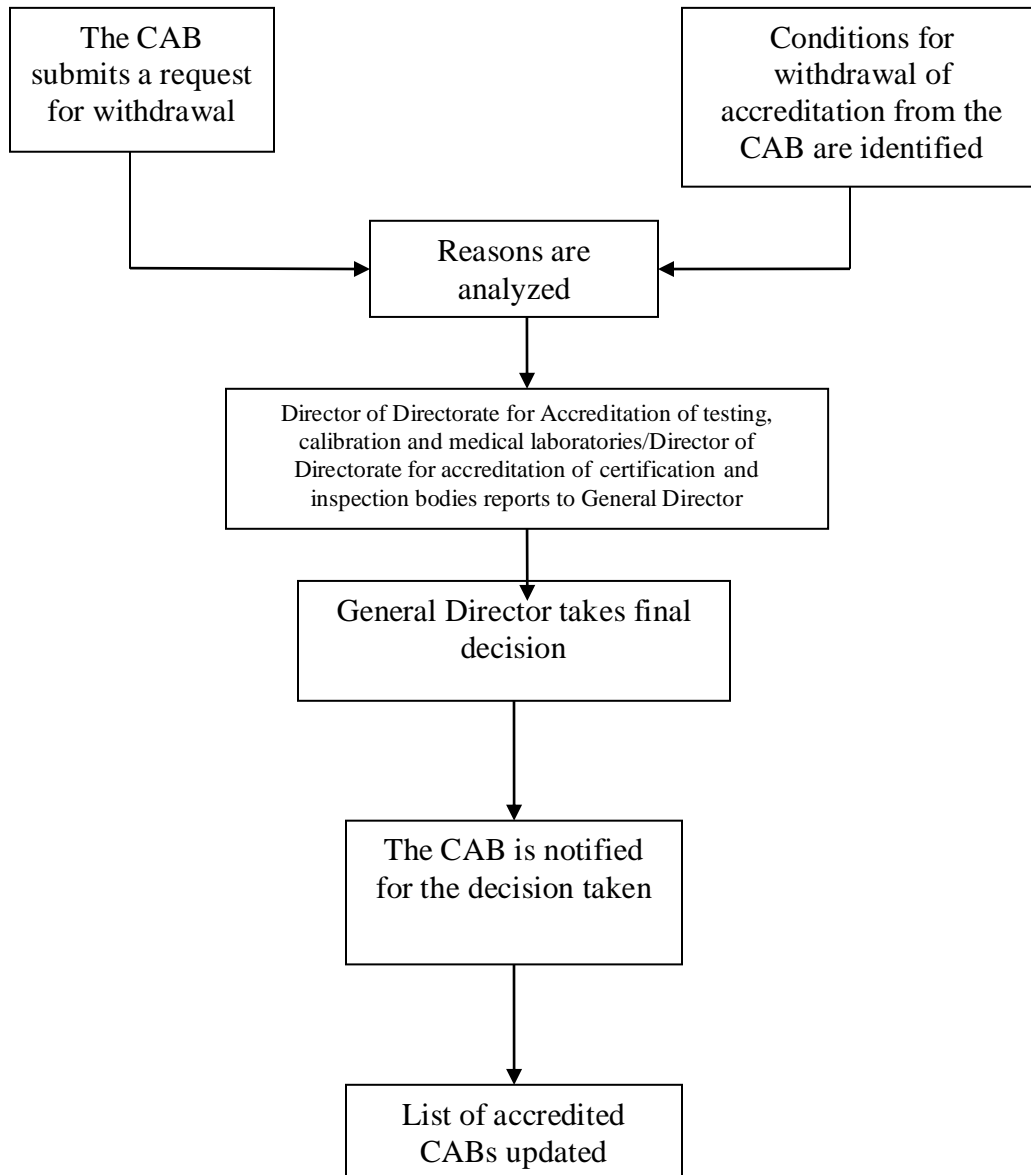
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7.5 Diagram of withdrawal



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8. EXTENSION OF ACCREDITATION

With the extension of accreditation, we will understand the increase in the number of internal analyses/services in the program for which OVK is already accredited, the increase in the number of locations where the conformity assessment activity is carried out within the same accreditation scheme as well as the request for accreditation for a new activity or conformity assessment scheme within the same accreditation scheme .

The CABs which has the status of initial accreditation can apply for extension of the accreditation after having the first surveillance visit been successfully completed.

The accredited CABs can apply for extension of accreditation after it has received the decision on the maintenance of accreditation in any surveillance visit.

If the accredited CAB would like DPA to manage the extension of accreditation during the next surveillance visit, it must apply for extension at least two months before the surveillance visit.

When accredited CAB requests the extension of accreditation, it must fulfill the relevant application form and submit it with the associated documents to DPA. Within 10 days of receipt, the Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies analyzes the application and proposes to the General Director to start the assessment procedure for extension. The General Director takes the decision on starting the procedure.

When the accredited CAB applies for extension of accreditation within the scope in which is already accredited, with the recommendation of technical assessor/expert the extension can be done in administrative way. The recommendation of technical assessor/expert and Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies is referred to General Director who takes the decision on extension of accreditation.

When the extension cannot be done in administrative way or CAB applies for extension in a new scope, DPA follows the procedure DA-PT-001.

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When the CAB requests to have the assessment for extension before the next surveillance visit, DPA organizes the assessment visit. The assessment includes only assessment of technical part.

When the CAB applies for extension of accreditation after the initial accreditation is granted, DPA reviews the assessment programme and planning of the subsequent assessment.

9. REDUCTION ACCREDITATION

The reduction of accreditation means that DPA cancels part of the scope of accreditation. Reduction of accreditation can be voluntarily requested by the accredited CAB or requested by DPA when one or more of the conditions laid down in clause 9.3 are fulfilled. In both cases, the following procedure applies.


9.1 Reduction of accreditation requested by the CAB

Reduction of accreditation can be requested by the accredited CAB e.g. because of technical, personnel or financial problems. The CAB has to submit the request for reduction of accreditation to DPA. The Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies, having after received the opinion of lead assessor, checks the request and recommends to the General Director the reduction of the accreditation scope. The General Director makes the decision on reduction. For the right formulation of the reduced scope of accreditation, DPA asks for the opinion of technical assessor/expert.

The reduced scope of accreditation is issued to the CAB. The Development Directorate publishes the reduced scope of accreditation on DPA website.

9.2 Reduction of accreditation requested by DPA

The scope of accreditation is reduced by DPA when at least one of the conditions for withdrawal listed in clause 9.3 of this procedure is fulfilled. The lead assessor, based on the opinion of technical assessor/expert, elaborates the reduced scope of accreditation and submits it with all evidences to the Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies. In case of related bodies, the Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate

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for accreditation of certification and inspection bodies submits the reduced scope of accreditation with all evidences to the relevant technical committee.

Having analyzed all evidences, Director of Directorate for Accreditation of testing, calibration and medical laboratories/Director of Directorate for accreditation of certification and inspection bodies or the relevant technical committee in case of related bodies, within 10 days, submits a recommendation for reduction of scope of accreditation to the General Director. The General Director can request more information about the reduction recommendation. Within 15 days having received all information, the General Director makes decision on reduction. He gives formal notice to the CAB on the decision on reduction including a clear explanation of reasons which resulted in the reduction and the reduced scope of accreditation.

The Development Department published the reduced scope of accreditation on DPA website.

Within 10 days of receipt, the CAB has the right to appeal against this decision. The appeal is handled according to the procedure DA-PM-005. However, launching of an appeal does not lead to the suspension of the DPA decision on reduction of the scope of accreditation.

9.3 Conditions for reduction the scope of accreditation

The conditions upon which DPA decides on the reduction of the scope of accreditation are the following:

- a) The CAB fails to meet certain technical requirements for accreditation.
- b) OVK has not taken effective corrective actions for non-conformities related to technical issues found during the surveillance visit.
- c) There are significant changes in the operational conditions of CAB relating to technical issues which have significant impact on the compliance with the accreditation requirements.



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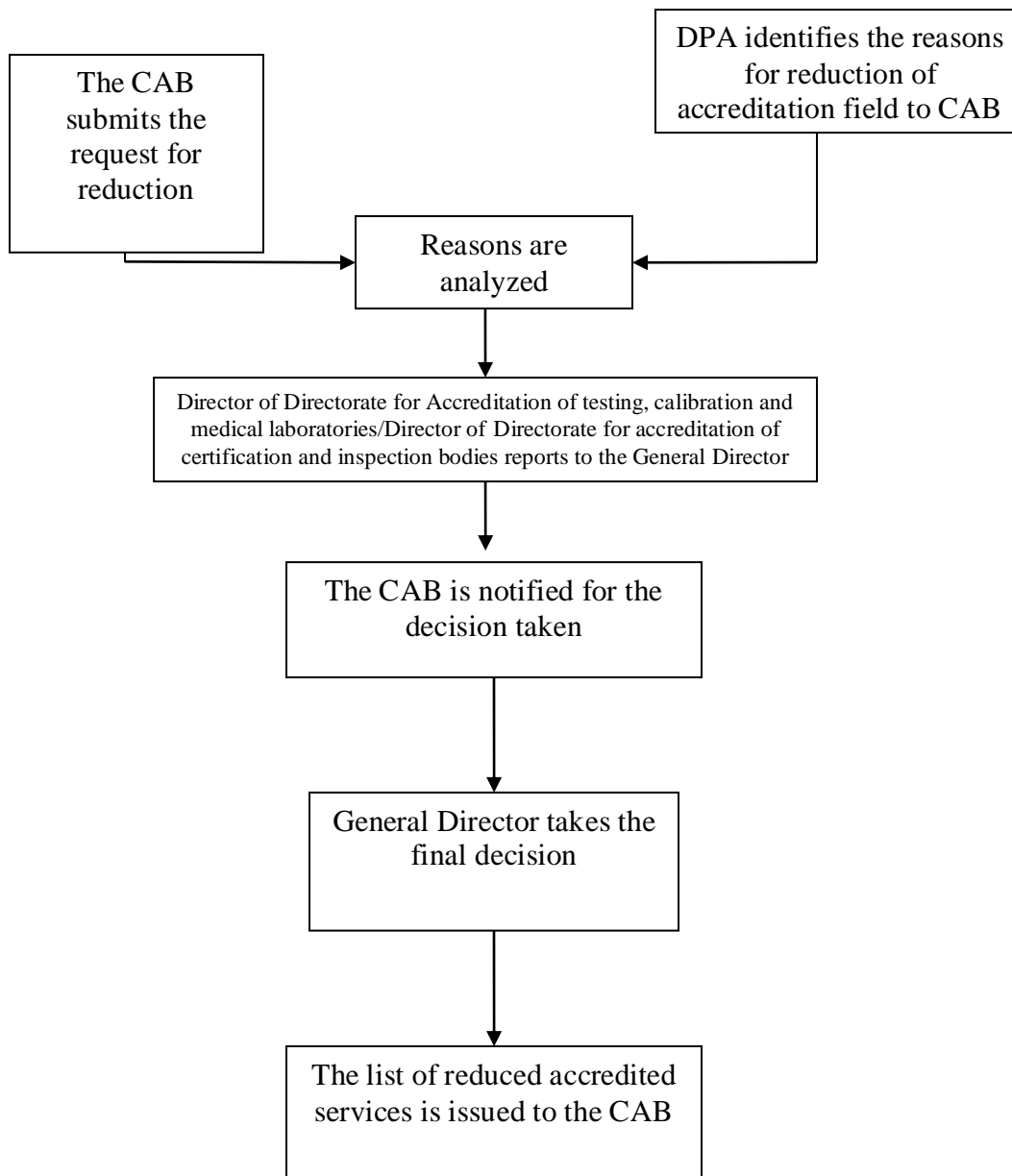
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9.4 Diagram of reduction of scope of accreditation



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10. REGISTRATIONS FROM THIS PROCEDURE

Title of document	Who fills it in	When	Who maintains
List of accredited CABs	Secretariat	When accreditation is suspended, withdrawn, extended or reduced	Development Department
Data base for conformity assessment bodies	Specialist of Directorate of Development	When accreditation is suspended, withdrawn, extended or reduced	Development Department
Form for assessment report according to ISO 17025	Assessment team	When accreditation is extended and reduced	Secretariat
Form of presenting the non conformities	Assessment team	When accreditation is extended and reduced	Secretariat
Form of notification of assessment date and its approval	Specialist of the sector	When accreditation is extended and reduced	Secretariat
Form for assessment plan	Specialist of the sector	When accreditation is extended and reduced	Secretariat
Form for assessment of technical procedures	Technical assessor	When accreditation is extended and reduced	Secretariat
Form for presenting the corrective actions	Assessment team	When accreditation is extended and reduced	Secretariat
Form for notification of team members and its approval	Specialist of the sector	When accreditation is extended and reduced	Secretariat
Form for assessment report for personnel certification bodies	Assessment team	When accreditation is extended and reduced	Secretariat
Form of reporting to the General Director	Director of Directorate for Accreditation of testing, calibration, medical laboratories/Director Directorate for accreditation of certification and inspection bodies	When accreditation is extended and reduced	Secretariat
Form for registration of appeals and complains	Quality Manager	When accreditation is suspended and withdrawn	Quality Manager
Form for accreditation decision	General Director	When accreditation is extended and reduced	Secretariat
Contract template for assessors	Financial sector	When accreditation is extended and reduced	Secretariat

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Contract template for conformity assessment bodies	Director of Directorate for Accreditation of testing, calibration medical laboratories/Director Directorate for accreditation of certification and inspection bodies	When accreditation is extended and reduced	Secretariat
Reporting form for assessment of product certification bodies	Assessment team	When the accreditation scope is reduced or extended	Secretariat
Reporting form for assessment of management system certification bodies	Assessment team	When the accreditation scope is reduced or extended	Secretariat
Reporting form for assessment of inspection bodies	Assessment team	When the accreditation scope is reduced or extended	Secretariat

11. HISTORY

Date of review	Number of review	Prepared by	Description of changes
30.10.2006	0	Briseida Xhafa	Initial version
30.10.2008	1	Briseida Xhafa	Approval of the procedure based to the law no. 9824 1.11.2007 and paragraph 8 related to extension.
23.10.2009	2	Ermira Fyshku & Besnik Pani	Paragraph 6.1.4 in relation to the payment in case of suspension. paragraph 6.3.5 Suspension or reduction of accreditation of a organism with many locations.
21.07.2011	3	Ardita Fuga	In paragraph 6.3.1 and 6.3.2 concerning the conditions of accreditation by DPA; In 6.4.3 regarding the resumption of activity after suspension; In paragraph 8 with respect to deadlines submission of documentation for the extension of accreditation. In paragraph 9 reflection of updates according to DA-PT-014.
22.12.2014	4	Briseida XHAFa	There have been changes to the document head of page about numbers telephone and email address



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			In paragraph 4 is amended number of Law
20.05.2019	5	Vilma Mara	Changes according to the Standard ISO/IEC 17011: 2017.
31.01.2021	6	Ardita Mele	Changes in point 6.1; 6.2; 7.1 and 7.2 about the presentation of CAB which are suspended or withdraw.
26.04.2021	7	Ardita Mele	Revised based on the new organization chart of DPA and it is added the point 6.3 (n) based on IAF MD 2 point 2.4.4
05.10.2023	8	Ardita Mele	Revision of paragraph 8 regarding the extension and the manner who to inform the IAF