The procedure of accreditation, surveillance, and renewal of accreditation

Implemented by: DPA staff, lead assessors, technical assessors and experts, members of technical committees

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

Controlled by: Quality manager
Ardita MELE

Approved by: Director General
Pranvera FAGU

1. PURPOSE

This procedure specifies in detail all the accreditation, surveillance and renewal of accreditation (reaccreditation) processes, the persons involved in accreditation, their responsibilities and authorities from application for accreditation till re-accreditation decision and accreditation cycle.

2. SCOPE OF APPLICATIONS

This procedure is implemented by the internal and external staff of DPA and the technical committees involved in accreditation processes. This procedure is applied when there is a request for accreditation, and reaccreditation by conformity assessment bodies (CABs) as well as in cases of surveillance of accredited CABs.

3. RESPONSIBILITIES

The Director of Directorate for testing, calibration and medical laboratories and the Director of Directorate for certification and inspection bodies are responsible for checking the implementation of this procedure.

4. REFERENCES

- Standard ISO / IEC 17011:2017 “Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies” (Chapter 7)
- Law Nr. 116, date 11. 09.2014, “On the accreditation of conformity assessment bodies in the Republic of Albania", amended with the Law no. 92/2023

- Quality Manual of DPA	DA-MC-001
- Form of application for the labs	DA-FO-022
- Policy of assessment	DA-PO-002
- Policy regarding the assessment team	DA-PO-003
- Policy of classification of nonconformities	DA-PO-013
- Policy for scope of accreditation	DA-PO-015
- Form of application for CBs	DA-FO-023
- Form of application for Inspection bodies	DA-FO-018
- Procedure for assessment visit	DA-PT-002
- Check list for testing laboratories	DA-FO-020
- Check list for calibration laboratories	DA-FO–021

- Check list according to ISO 15189 DA-FO-064
- Check list according to ISO/IEC 17020 DA-FO-019
- Check list according to ISO 17024 DA-FO-025
- Check list according to ISO 17065 DA-FO-017
- Check list according to ISO/IEC 17021-1 DA-FO-035
- Form for assessment plan DA-FO-002
- Form for presenting the nonconformities DA-FO-003
- Form for notification of assessment date and its approval DA-FO-005
- Form of presenting the corrective actions DA-FO-011
- Database for accreditation tariffs DA –FT- 005
- Form for reporting the assessment according to ISO 17025 DA-FO-001
- Form for assessment team meeting DA-FO-070
- Form for assessment program for testing laboratories DA-FO-069
- Form for assessment program for calibration laboratories DA-FO-084
- Form for assessment program for medical laboratories DA-FO-085
- Form for assessment program for management system certification bodies DA-FO-086
- Form for assessment program for persons certification DA-FO-087
- Form for assessment program for inspection bodies DA-FO-088

- Form for reporting assessment according to ISO/IEC 17021-1 DA-FO-004
- Form for reporting assessment according to ISO 17065 DA-FO-049
- Form for reporting assessment according to ISO 17024 DA-FO-013
- Form for reporting assessment according to ISO 17020 DA-FO-048
- Form for reporting assessment according to ISO 15189 DA-FO-063
- Form for notification of names of assessment team and its approval DA-FO-012
- Form for assessment of management system documentation DA–FO-006
- Form for assessment of technical procedures DA–FO-007
- Form for reporting to General Director DA-FO-016.
- Control of registrations DA-PM-009
- Obligations of CABs DA-PM-011
- The procedure of management information of DPA's website and Intranet DA-PT-014
- Form for reporting pre-assessment visit DA-FO-043
- Procedure for management of risk on impartiality DA-PM-019

5. VOCABULARY AND ABBREVIATIONS

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

6. DESCRIPTION OF INITIAL ACCREDITATION PROCEDURE

6.1 Request for information about the procedure

Any CAB can submit a request (by fax/email/official letter) to DPA to get information about the accreditation procedures and the relevant documents necessary for accreditation.

After receiving the request, Director of Directorate for testing, calibration and medical laboratories/ Director of Directorate for certification and inspection bodies organizes a preliminary meeting with the CAB, during which DPA provides CAB with all information about the initial accreditation/surveillance/re-accreditation procedure, relevant policies and procedures, tariffs as well as clarifies each question of the CAB. This information is also available on DPA website, www.dpa.gov.al.

During the preliminary meeting, Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies requests information relating to the CAB, planned scope of application, number of employees in CAB, number of locations and addresses of the CAB and authorized representative and his/her contact details. Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies. use this information for resource review.

6.2 Application for accreditation

OVK makes an official request for accreditation. DPA and OVK sign the contract, according to form DA-FO-038. Within five days from the signing of the contract, the specialist authorized for the handling of contracts in DPA notifies the director of the relevant department by email. OVK is notified of the obligation to pay the application and administrative fee. OVK must submit the bank's confirmation for the demonstration of making the payment. When the payment has been successfully made, OVK has the right to submit the application form and other documents/records of the management system that demonstrate the fulfillment of the requirements for accreditation.

Having the CAB completed application form for accreditation, the completed checklist and all the necessary documentation/records demonstrating the compliance with the accreditation requirements, the CAB is called “applicant for accreditation”. The list of necessary documentation, but not limited to it, is described in the relevant application forms for accreditation. The CAB can submit the documentation within 10 days from the confirmation of the payment. At any point in the application or initial accreditation process, if there is evidence of fraudulent behavior, if the CAB intentionally provides false information or if the CAB conceals information, DPA rejects the application and terminates the assessment process. All the documentation submitted by OVK together with a copy of the contract goes to the Director of the relevant directorate.

6.3 Resource review

After having received the application, based on the submitted documents and the information provided during the preliminary meeting, the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies analyses DPA resources for conducting accreditation for the application scope. The analysis consists of at least:

a) the analysis of DPA's human resources
b) if CAB is a related body,
c) the analysis of relevant DPA procedures and
d) the analysis of DPA's ability to perform the initial assessment in a timely manner according to this procedure.
e) validation/verification of the requested accreditation scheme.

6.3a) The analysis of human resources consists of the existence of lead assessor, technical assessors and/or technical experts for the relevant scope of accreditation in DPA database of assessors and their competence to perform the assessment on behalf of DPA. The analysis of competence of decision-makers is also included. When these resources are not sufficient, the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies informs the General Director for making decisions such as: recruitment and/or training of lead assessor/assessors/experts, engagement of foreign assessors/experts or subcontracting another accreditation body for conducting the assessment. The use of foreign assessors/experts is effectuated by DPA only when there are no internal resources available or when the impartiality is not ensured. In lack of competence of decision-makers, or when the impartiality is not ensured , DPA will asks for the recommendation to be made by the relevant DPA technical committee.

6.3b) If the CAB is a related body, DPA registers it to the database of related bodies and conducts the assessment accordingly.

6.3c) The analysis of the relevant procedures includes the existence of accreditation criteria and procedures for the accreditation/conformity assessment scheme. When these resources are not sufficient, the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies informs the General Director who decides on starting the procedure of establishment of a new accreditation schemes, DA-PM-008. If DPA decided not to offer accreditation for the new scheme, DPA informs, with undue delay, the CAB. In such cases DPA has the right to refuse the application for accreditation.

6.3d) If DPA is not able to respect the deadlines for carrying out the initial accreditation process in a timely manner, the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies informs the General Director and the CAB when it can commence the initial accreditation process.

6.3e) If the validation/verification of the conformity assessment scheme the CAB would like to be accredited is necessary, the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies informs and requests the General Director to initiate the validation/verification of the scheme according to DA-PM-008. DPA informs the CAB that accreditation process will start only after the positive validation/verification of scheme.

If the result of the analysis is that DPA has all recourses to accredit for the requested accreditation scheme and scope, the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies appoints a file manager from DPA internal staff to review the application within 15 days.

When nonconformities are found in application review, the file manager proposes to Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies not to proceed with the accreditation process (forms DA-FO-006). All nonconformities are reported by file manager and the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies to General Director. DPA sends the forms DA-FO-006 to CAB where the nonconformities to the accreditation requirements are defined. DPA asks the CAB for closing all nonconformities and for submission of the documentation and for the undertaken corrective actions. CAB has the right to respond (close the nonconformities and submit the documentation of the corrective actions) within maximum 6 months from the date DPA reported on the nonconformities. If the CAB does not respect this deadline, DPA informs the CAB that the application was refused. The CAB has to apply for accreditation again.

When there is no nonconformity, the file manager reports to Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies and asks to proceed with the accreditation process.
DPA can conducts a pre-assessment visit on the request of the CAB or on decision of DPA when there are doubts that the CAB management system functions. When the pre assessment visit is decided by DPA, the CAB shall confirm it. The pre-assessment visit will be performed in the CAB's head office. It can last no more than one day. The Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies appoints a lead assessor and asks for his/her approval by the CAB. DPA confirms with CAB the date and plan of the pre-assessment visit. The lead assessor performs the pre-assessment visit in accordance with the assessment visit procedure (DA-PT-002). If nonconformities are found during the pre-assessment visit, they are reported according to the form DA-FO-003 and the CAB must undertake corrective actions for solving them. All the nonconformities must be reported in the pre-assessment report on form DA–FO–043. The maximum time for the CAB to solve the nonconformities is 6 months.

After implementing the corrective actions, the CAB informs DPA in writing about the solving of nonconformities and its readiness for the assessment visit.

6.4 Preparation for assessment

The Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies, within 10 days from the recommendation by file manager for continuation of accreditation process, approves the assessment team proposed by file manager based on the review of recourses and scope of accreditation. The assessment team is composed according to DPA policy on assessment team (DA-PO-003).

DPA informs the CAB about the composition of the assessment team including the observers too and asks the CAB for confirmation on form DA-FO-012.

The CAB has to opportunity to lodge an objection to the appointment of one or more members of the assessment team. When the CAB lodges an objection to the appointment of any member(s) or observers or entire team, DPA proceeds according to DA-PO-003.

6.5 Review of documented information

When the CAB agrees with the assigned assessment team, the file manager provides the assessment team with access to CAB's documentation to review it. Within 15 days, each team member has to provide information on nonconformities on forms DA-FO-006, DA-FO-007and DA-FO-008.

If nonconformities are found, DPA decides not to proceed further with assessment till the nonconformities are solved. DPA reports the nonconformities in writing to CAB according to forms DA-FO-006 and DA-FO-007. The CAB has the right to respond to the nonconformities within 6 months. If CAB does not respect the deadline or does not solve the nonconformities, DPA terminates the assessment process and sends the invoice to the CAB. In case of termination of the assessment process, the CAB has to apply again.

If nonconformities are not found, the assessment team carries out the risk assessment related to activities, locations, personnel and scope of accreditation. Based on the risk assessment, the team develops an assessment plan which covers all the activities, the locations and personnel that will be assessed, the assessment techniques to be utilized including the witnessing where appropriate or applicable. The assessment team also proposes the assessment date. The duration of assessment is based on risk assessment. DPA notifies to the CAB the assessment date (DA-FO-005) and the assessment plan (DA-FO-002). The proposed assessment date cannot be earlier than 10 working days from notification, except the cases when the CAB accepts to perform the assessment earlier. DPA shall confirm with CAB the date and the plan for the assessment. The CAB has the opportunity to lodge an objection on date and/or the plan of assessment. The

reason must be objective. In this case, DPA re-plan the visit. With the confirmation of the date and the plan of the assessment, the CAB is obliged to take all measures to ensure the organization of the assessment according to the plan.

Based on the assessment plan, the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies calculates the assessment fee. The CAB must pay at least 80% of the assessment fee at least two days before the realization of the assessment visit. If the CAB does not pay in advance, DPA does not proceed with the assessment visit.

6.6 Assessment

The assessment is performed according to DPA procedure of assessment visits (DA-PT-002). The purpose of the assessment visit is to determine the competence of the CAB, based on standards and/or other normative documents and for a defined scope of accreditation.

6.7 Accreditation decision-making

Having the assessment process completed, the lead assessor provides the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies at least with the following information:

- name of legal entity and the CAB assessed
- date(s) and type of assessment (initial/extension/surveillance/reaccreditation/extraordinary)
- composition of the assessment team
- identification of all locations assessed
- scope of accreditation assessed
- assessment report
- nonconformities and sufficient information to demonstrate the satisfactory response to all nonconformities
- reports on vertical audits and witnessing
- a statement on fulfillment of the requirements of standards and/or other documents related to the competence of CAB.
- Recommendation for accreditation to the decision-makers.

If the legal entity is a related body, (category 1 and category 2) the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies, within three days, submits the accreditation file, including all information mentioned above, to relevant technical committee. The relevant technical committee reviews the accreditation file and formulates its recommendation for accreditation. The technical committee has the right to ask for additional information from the lead assessor or the CAB before formulation of its recommendation. The Chairman of the technical committee reports, within 20 days, on the accreditation process and the recommendation of technical committee to the General Director on form DA-FO-

016. The technical committee functions according to its internal regulation (scheme 1). The report also includes the scope/program for which the accreditation is to be granted.

If the legal entity is a not related body, the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies reviews the accreditation file including all information mentioned above and formulates its recommendation for accreditation. The Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies has the right to ask for additional information from the lead assessor or the CAB before formulation of his/her recommendation. The Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies, within 20 days, reports on the accreditation processes and the recommendation to the General Director on form DA-FO-016 (scheme 2). The report also includes the scope/program for which the accreditation is to be granted. In the case when the competence and impartiality is not ensured the relevant technical committee formulates the recommendation for accreditation as in the case of related bodies.

The General Director reviews the received information and makes decision on accreditation on form DA-FO–031. The General Director has the right to request additional information from the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies or from the relevant technical committee according to the form DA-FO-090. The Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies or from the relevant technical committee gives the information according to the form DA-FO-090 within 5 days. The maximum deadline for making the decision is 30 days. In the case of related bodies. The General Director cannot make other decision than recommended by the relevant technical committee. When it is necessary the General Director can take opinions from relevant technical committee.

6.7 Accreditation information

If the decision on accreditation is positive, the procedure DA–PM–014 for preparation of accreditation certificate is followed including the information related to accreditation.

The General Director submits, within 7 days from accreditation decision, the following documents to the accredited CAB,

- Certificate of Accreditation including the accreditation programme,
- Accreditation symbol
- Copy of the assessment report (if it is different from the report mentioned in clause 6.6)

CAB is obliged to have knowledge of following documents which can find in DPA website:

- Policy for using the accreditation symbol (DA-PO-005).
- Procedure regarding the rights and obligations of CAB procedure (DA- PM – 011),

At the end of the process, DPA sends the final invoice to the CAB regarding what it owes to DPA (i.e. costs of certificate or other additional actions occurred during accreditation process).

If the decision is negative, within 7 days, General Director provides the assessed CAB in writing with the information on refusal of accreditation. The CAB has the right to appeal, within 4 weeks from date of decision, against the decision. When an appeal was submitted to DPA together with the payment for appeal, DPA procedure on appeals, DA-PM-005 is being followed.

All accreditation files, regardless of the decision, are submitted to the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies for checking the inventory of all documentation according to DA-PM-059 before forwarding the file to DPA's archive according to the procedure of records control, DA–PM–009.

The Development Directorate registers the accredited CAB in the relevant register and publishes it on DPA website.

7. Accreditation cycle

The first accreditation cycle begins on the date of decision on the initial accreditation. The duration of the accreditation cycle (consequently the validity of the accreditation certificate) is 4 years (48 months) from the date of initial accreditation with the condition that the surveillance assessments and re-assessment are successful.
In case of the renewal of accreditation, the validity period of the new accreditation cycle and certificate is always determined by adding 4 years (48-months) period to the validity date of the previous accreditation. Effective date of decisions on renewal taken within the accreditation cycle period is the next day from the end of the actual accreditation cycle (expiry date of certificate). The accredited CAB has the same identification number of accreditation for the next accreditation cycle too.

If the decision on renewal of accreditation is taken within 3 months after the expiry date of accreditation certificate (accreditation is not valid within this period), the effective date of the certificate becomes the date on which the decision was taken. Similarly, the new accreditation cycle and the validity of certificate is determined by adding 4 years (48-months) period to the expiry date of the previous accreditation. The accredited CAB has not the same identification number of accreditation for the next accreditation cycle too.

If the decision cannot be taken within 3 months from the expiry date of accreditation due to reasons originating from CAB, the effective date of certificate is the date when decision was taken. The four years' accreditation cycle starts on the date of decision, but it is called initial accreditation. The accredited CAB has not the same identification

number of accreditation for the next accreditation cycle too. The period between the expiry date of the previous accreditation and the new accreditation cycle is not covered by accreditation.

After the decision on the new accreditation cycle is taken, in order to ensure that the requirements for accreditation are met and that all accredited conformity assessment activities are covered during the four years' period, the assessment team develops the assessment program for all four years' accreditation cycle according to the relevant forms (DA-FO-069, DA-FO-084, DA-FO-085, DA-FO-086, DA-FO-087, DA-FO-088) in order to ensure that the requirements for accreditation are fulfilled and all the accredited conformity assessment activities is covered during the four years. DPA shall provide the assessment program to CAB not later than two months from the start of the new accreditation cycle.

The assessment program is based on risk assessment and is subject of changes prior to and after each assessment and as well as of the CAB's changes (e.g. the staff and/or location, the testing method/standards, the equipment and apparatus, there are non-conforming operations, non-satisfactory results in interlaboratory comparisons, complaints by clients, extension/reduction of accreditation). In case of CAB's changes, based on risk assessment, DPA can organize extraordinary assessment visits. DPA shall provide the revised assessment program to CAB.
The re-assessment is part of the accreditation cycle and shall be carry out before the accreditation cycle is over. Normally one accreditation cycle is composed by surveillance visits and a re-assessment visit.

During the first accreditation cycle, the 1st surveillance assessment to CAB shall be carried out 6 months from the effective date of accreditation. The 2nd surveillance assessment shall be conducted 12 months after the 1st surveillance. The 3rd surveillance assessment shall be conducted 12 months after the 2nd surveillance. A maximum deviation of 2 months can be allowed in case of the 2nd and 3rd surveillance assessment. The re-assessment or surveillance visit if the CAB has not applied for renewal of-accreditation, shall be conducted in the fourth year of accreditation cycle but at least 8 months before the accreditation cycle is over.

During any further accreditation cycle the 1st surveillance assessment of the accredited CAB shall be carried out at the 12th months from the first date of the cycle. The 2nd and 3rd surveillance assessment shall be conducted 12 months after respectively the 1st and 2nd surveillance assessment. A maximum deviation of 2 months can be allowed in routine assessments. The re-assessment or surveillance assessment if the CAB has not applied for renewal of accreditation, shall be conducted in the fourth year of accreditation cycle but at least 6 months before the accreditation cycle is over.

Based on the risk assessment, the surveillance assessment and re-assessment can be conducted through on-site assessment (location(s) of CAB) or remote assessment or blended assessment (a combination of on-site and remote assessments). The decision on

the assessment technique(s) to be used is taken by DPA. The time between two consecutive on-site assessments shall not exceed two years. A sample of the witness assessment defined based on the risk assessment shall be carried out at least every two years.

The accredited CAB shall provide DPA with all the information requested by the form DA-FO-083 at least 30 days before carrying out any surveillance assessment. For the surveillance assessment, DPA follows clause 6.3 of this procedure. The outcome of any surveillance assessment will be the decision on maintaining the accreditation status. This decision can be accompanied with extension or reduction of the scope of accreditation.

. The number of surveillance assessments defined in one accreditation cycle, can be increased for the following reasons:

- Request for scope extension, complaint, changes in regulations and standards of CAB's activity area, changes in CAB's structure, suspension of accreditation, etc.
- The requirements given in relevant accreditation program and accreditation cycle program,
- When witness assessments cannot be carried out in succession with office assessments.

Where possible, attention is paid to carry out witness assessments together with surveillance assessments and re-assessment. However, in cases where the witness assessments cannot be carried out together with the surveillance and re-assessment within 3-month period, independent witness assessments can be performed before or after the related assessment in accordance with the assessment program.

8 Extraordinary assessment

DPA organizes extraordinary assessment as a result of complaints or changes or other matters (reports of technical assessors) that may affect the ability of the CAB to fulfill the requirements for accreditation. The duration and the assessment techniques to be used during the extraordinary assessment are decided based on risk assessment. DPA performs the extraordinary assessments according to clauses from 6.3 to 7 of this procedure and procedure DA-PT-002.

9. Renewal of accreditation (re-assessment)

The accredited CAB shall apply for the renewal of accreditation, before the accreditation cycle is over. If the CAB applies, the reassessment shall be conducted in the fourth year of the accreditation cycle.

When the accredited CAB is in the first accreditation cycle, the re-assessment shall be conducted at least 8 months before the accreditation cycle is over. For further accreditation cycles, the re-assessment shall be conducted at least 6 months before the accreditation cycle is over.

Re-assessment is planned, performed and reported similar to the initial accreditation assessment based on chapter 6 of this procedure and procedure DA-PT-002. DPA and CAB have to sign the contract DA-FO-038 after the application for renewal of accreditation.

If the CAB applies for renewal of accreditation with the same scope of accreditation, the reassessment is undertaken to re-evaluate the competence and conformity of the CAB against the applicable accreditation criteria and other relevant requirements including assessment of a sample of the activities according to assessment program (ensuring that the full scope has been adequately covered during the four-year cycle, minimum once).

If the CAB applies for renewal of accreditation with extension/changes of accreditation scope, the reassessment is undertaken to re-evaluate the competence and conformity of the CAB against the applicable accreditation criteria and other relevant requirements, including assessment of a sample of activities according to assessment program (ensuring that the full scope has been adequately covered during the four-year cycle, as a minimum once), plus the sample of assessment activities representing the extension/changes of accreditation scope. The sample of assessment activities representing the extension/changes of accreditation scope will be based on risk assessment.

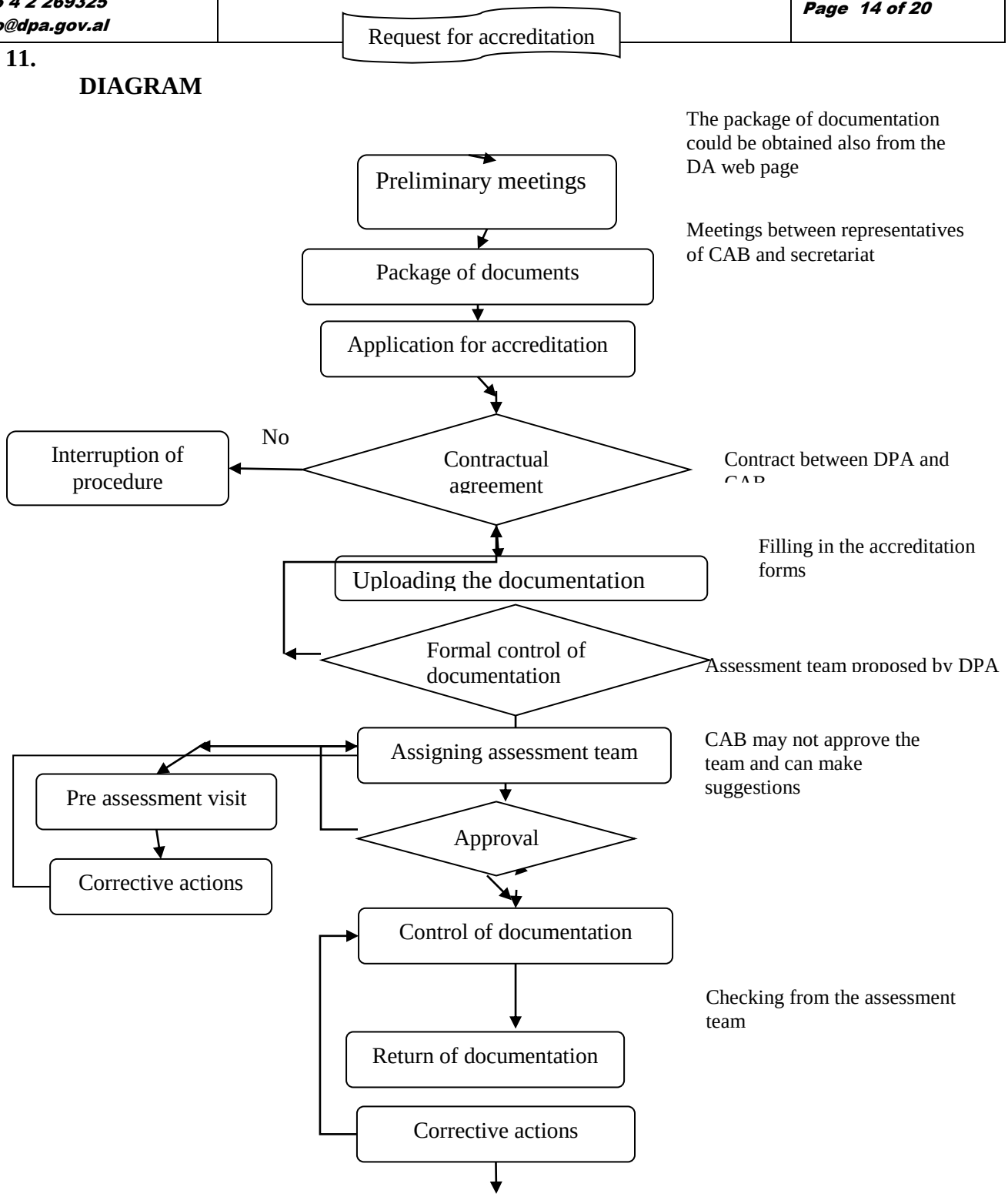
If the CAB applied for renewal of accreditation with delay or after the surveillance visit of the fourth year of accreditation cycle, or if the re-assessment could not be conducted within the accreditation cycle, due to reasons arising from the CAB, the accreditation status is lost and the file is closed when the accreditation cycle is over. The CAB has to apply for initial accreditation.

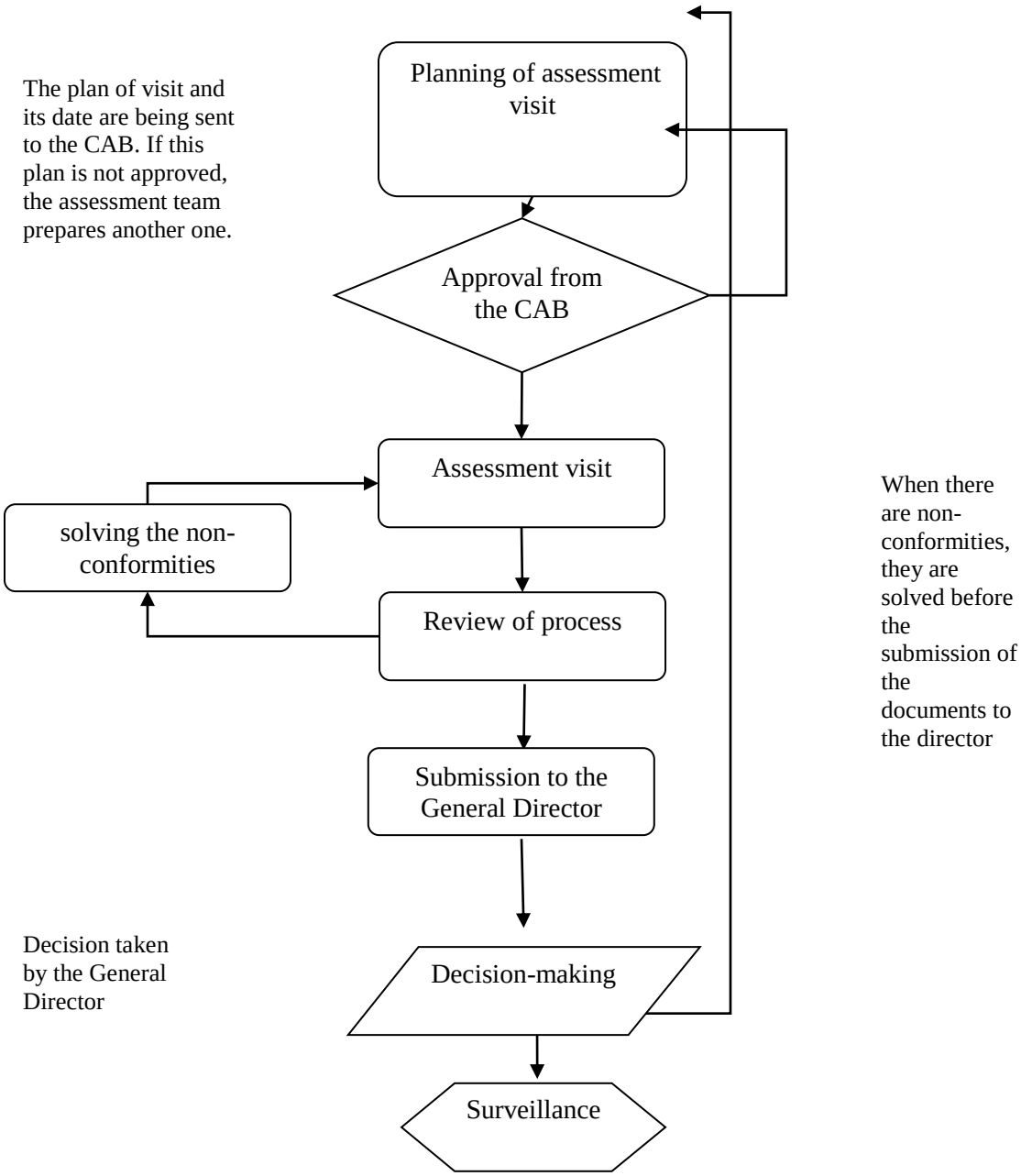
If the CAB does not apply for renewal of accreditation two months prior to the expiry date of accreditation, the file manager informs the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies
and then General Director for closing the file; the file shall be closed upon the expiry date of accreditation. When the accreditation status is over the name of CAB is deleted from the database on DPA website.

10. Internal information/communication

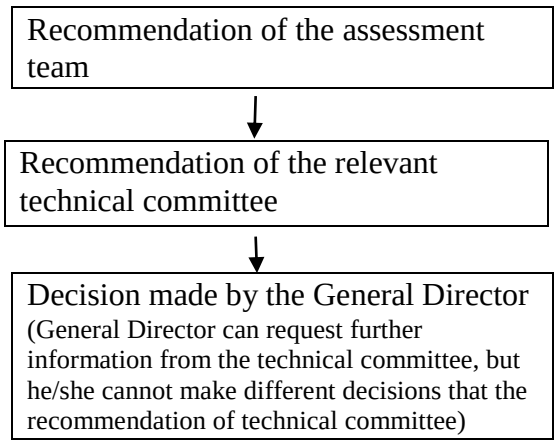
For any decision on accreditation made by the General Director, specialist of Sector for Finance and Services informs by email the decision within 5 days to the Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies, the Director of Development Directorate and the Head of Sector for Finance and Services. The Development Directorate updates the records on the CAB on DPA website.

11. DIAGRAM

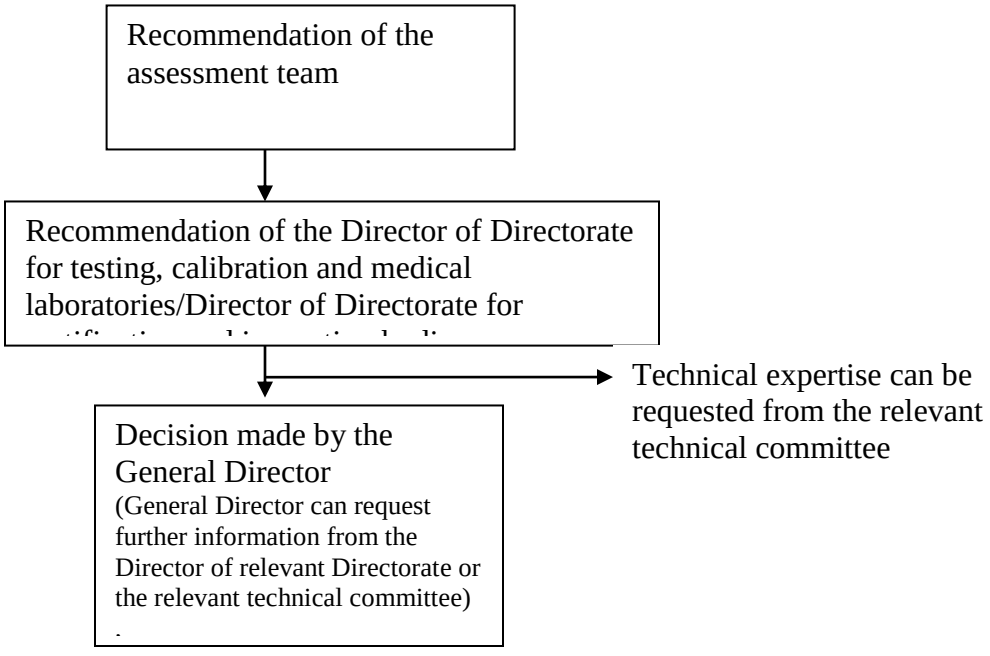

Request for accreditation
The package of documentation could be obtained also from the DA web page
Preliminary meetings
Meetings between representatives of CAB and secretariat
Package of documents
Application for accreditation
No
Interruption of procedure
Contractual agreement
Contract between DPA and
Filling in the accreditation forms
Uploading the documentation
Formal control of documentation
Assessment team proposed by DPA
Assigning assessment team
CAB may not approve the team and can make suggestions
Pre assessment visit
Approval
Corrective actions
Control of documentation
Checking from the assessment team
Return of documentation
Corrective actions


Planning of assessment visit
The plan of visit and its date are being sent to the CAB. If this plan is not approved, the assessment team prepares another one.
Approval from the CAB
Assessment visit
solving the non-conformities
Review of process
When there are non-conformities, they are solved before the submission of the documents to the director
Submission to the General Director
Decision taken by the General Director
Decision-making
Surveillance

Scheme 1: Decision-making on related bodies



Scheme 2: Decision-making on non-related bodies



12. 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 of presenting corrective actions DA-FO-011	Assessment team	After assessment	Archive
Form for notification of assessment date and its approval DA-FO-005	File manager	After checking the documentation	Archive
Form of assessment team DA-FO-70	Lead assessor	After the meeting	Archive
Assessment programme for testing laboratories (DA-FO-069),	Assessment team	After granting the accreditation	Archive
Plan of assessment visit DA-FO-002	File manager	Before assessment visit	Archive
Form for notification of team members and its approval DA-FO-012	File manager	Before assessment visit	Archive
Form of reporting the laboratory assessment according to ISO/IEC 17025 DA-FO-001	Assessment team	After assessment visit	Archive
Form of reporting of assessment according to ISO/IEC 17024 DA-FO-013	Assessment team	After assessment visit	Archive
Form of reporting of assessment according to ISO/IEC 17065 DA-FO-049	Assessment team	After assessment visit	Archive
Form of reporting the assessment according to ISO/IEC 17021-1 DA-FO-004	Assessment team	After assessment visit	Archive
Form of reporting the assessment according to ISO/IEC 17020 DA-FO-048	Assessment team	After assessment visit	Archive
Form of reporting to general Director DA-FO-016.	Director of Directorate for testing, calibration	After assessment	Archive

	and medical laboratories/Director of Directorate for certification and inspection bodies		
Form of presenting the non conformities DA-FO-003	Assessment team	After assessment visit	Archive
Preparation of certificate	Specialist of Finance and Service sector	When the document issued or change	Archive
Pre-assessment report DA-FO-043	Assessment team	After the pre-assessment visit	Archive
Assessment programme for calibration laboratories (DA-FO-084)	Assessment team	After granting the accreditation	Archive
Assessment programme for medical laboratories (DA-FO-085)	Assessment team	After granting the accreditation	Archive
Assessment programme for management system certification bodies (DA-FO-086)	Assessment team	After granting the accreditation	Archive
Assessment programme for persons certification bodies DA-FO-087)	Assessment team	After granting the accreditation	Archive
Assessment programme for inspection bodies (DA-FO-088)	Assessment team	After granting the accreditation	Archive
Form for further information on accreditation procedure, DA-FO-090	General Director/ Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies/ technical committee	Before granting the accreditation	Archive

13. HISTORY

Date of review	Number of review	Prepared by	Description of changes
30. 10. 2006	0	Briseida Xhafa	

05.11.2008	1	Briseida Xhafa	Changes were introduced based on the amendments in the ne accreditation Law No 9824 dated 06.03.2003 'On accreditation of conformity assessment bodies in Republic of Albania ", as well complying with all requirements of the standard ISO/IEC 17011. Such changes were reflected in the below pa the procedure: 4.6.1, 6.2.1, 6.2.2, 6.2.3, 6.2.5, 6.2.6, 6.3.2, 6.5, 6.6.1, 6.6.3 6.6.4, 7, 7.1, 7.1.2, 7.2, 7.3 and 8
30.10.2009	2	Ermira Fyshku Besnik Pani	Procedure has been completed in the points: 2, 4, 6.2.5 in order to reflect the assessment policy DA-PO-002 In the point 2 a note has been added regarding the field of im In the point 6.2.1 the note 1* on Application form has been added. In the point 6.2.5 Has been added the note 2*related to the assessment plan. In the point 7 "Surveillance", a note has been added related to the policy of DA in cases of changes of Manager or quality manager of CAB.
21.07.2011	3	Besnik Pani	Procedure has been completed in the points: 4; 6.2.2; 6.2.5; 6 7.2; 8, 9, Also in the diagram. Deadlines are reduced accreditation procedure and placed way internal information regarding Decision of the Director General.
04.06.2013	4	Ardita Fuga	Such changes were reflected in the below paragraphs on par and 6.6 the decision-making process in cases to related CAB.
22.12.2014	5	Briseida Xhafa	Such changes were reflected in the below paragraphs 6.2 for related bodies, Changes in the header and the reflection of the new law.
27.01.2017	6	Briseida Xhafa	Re-define the deadlines
20.06.2017	7	Briseida Xhafa	Changes to paragraph 6.2.6 about the assessment team meeti plan for witnessing
20.05.2019	8	Briseida Xhafa	Changes of procedure according to ISO/IEC 17011:2017
25.05.2021	9	Ardita Mele	Changes to paragraph 6; 7 and 9
08.06.2022	10	Ardita Mele	Changes to paragraphs 6.5; 7 and 12

04.01.2024	11	Ardita Mele	Changes to paragraphs 4; 6.2; 6.3; 6.7; 6.8 and 9
28.06.2024	12	Ardita Mele	Changes in paragraph 6.3 and 6.5 regarding the nonconformities