



**Tel: + 355 4 2 269097**  
**Fax : + 355 4 2 269325**  
**E-Mail: info@dpa.gov.al**

**The procedure of accreditation, surveillance  
and renewal of accreditation**

**Code: DA - PT - 001**

**Review no. 8**  
**Dt: 20.05.2019**

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**The procedure of accreditation, surveillance and  
renewal of accreditation**

**Implemented by:** Director General, Director of Accreditation Department, DPA  
Secretariat, lead assessors, technical assessors and experts

**Responsible for implementation:** Director of Accreditation Department.

**Controlled by: Ardita MELE**  
**Accreditation Director**

**Approved by: Armond HALEBI**  
**Director General**



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## The procedure of accreditation, surveillance and renewal of accreditation

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### 1. PURPOSE

This procedure specifies in detail all the accreditation, surveillance and reaccreditation processes, the persons, their responsibilities and authorities since application for accreditation till re-accreditation decision.

### 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 re-accreditation by conformity assessment bodies (CABs) as well as in cases of surveillance of accredited CABs.

### 3. RESPONSIBILITIES

The Director of Accreditation Department is 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”
  - 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



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- 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 non conformities 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 plan of witnessing and vertical audit DA-FO-069
- 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 quality manual DA - FO- 006
- Form for assessment of technical procedures DA -FO -007
- Forma for assessment of management procedures DA- FO- 008
- 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 DA'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 knowing the procedure**

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



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After receiving the request, DPA secretariat 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](http://www.dpa.gov.al).

During the preliminary meeting, DPA secretariat requests information relating to the CAB, accreditation scope, number of employees in CAB, number of location and addresses of CAB and authorized representative and his/her contact details. DPA secretariat provides this information to Director of Accreditation Department who uses it for analyzing the resources.

### **6.2 Application for accreditation**

The CAB can apply online for accreditation through DPA website. After the notification of application, DPA and the CAB sign the contract (accreditation agreement). When the contract is signed, the CAB has the right to upload the application form and other documentations to the relevant part of DPA website.

Having the CAB uploaded the completed application form for accreditation, the completed check-list and all the necessary documentation/information 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 upload the documents within 10 days from signing the contract. The CAB has also to upload the bank confirmation for payment of application and administrative fees.

At any point in the application or initial assessment process, if there is evidence of fraudulent behavior, if the CAB intentionally provides false information or if the CAB conceals information, DPA reject the application or terminate the assessment process.

### **6.3 Resource review**

After having received the application, based on the uploaded documents and the information provided by DPA secretariat, the Director of Accreditation Department analysis DPA resources for offering accreditation for the requested scheme and scope. The analysis consists of at least:

- a) the analysis of 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.



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- 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 Accreditation Department informs the General Director for making decisions such as: recruitment and/or training of lead assessor/assessors/experts, using 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. In lack of competence of decision-makers, DPA will asks for the recommendation 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.
- 6.3c) The analysis of the relevant procedures includes the criteria and procedures for the evaluation process. When these resources are not sufficient, the Director of Accreditation Department informs the General Director who decides on starting of the procedure of establishment of accreditation scheme, DA-PM-008. If DPA decided not to offer accreditation for the new scheme, DPA informs, with undue delay, the CAB.
- 6.3d) If DPA has not ability to respect the deadlines for carrying out the initial assessment, the Director of Accreditation Department informs the General Director and the CAB on commencing with the initial accreditation process.
- 6.3e) If the validation/verification of the scheme is necessary, Director of Accreditation Department 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, the Director of Accreditation Department appoints a file manager from DPA internal staff to review the application within 15 days.

When major nonconformities are found in application review, the file manager proposes to Director of Accreditation Department not to proceed with the accreditation process. All nonconformities are reported by file manager and the Director of Accreditation Department to General Director. DPA reports, in writing, on the nonconformities to CAB. DPA asks the CAB to close all the nonconformities and to upload the documentation of the undertaken corrective actions. CAB has the right to respond within maximum 6 months from the DPA reporting date. If the CAB doesn't respect this deadline, DPA informs the CAB that the application was refused. The CAB has to apply for accreditation again. When there are not major nonconformities, the file manager reports to Director of Accreditation Department to proceed with the accreditation process.



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When the scope of accreditation in the application is not defined properly, the file manager can request, with the agreement of the CAB, conducting of a pre-assessment visit. DPA can conduct a pre-assessment visit on the request of the CAB. The pre-assessment visit will be performed in the CAB head office. It can last no more than one day. The Director of Accreditation Department appoints a lead assessor and asks for his/her approval by the CAB. DPA confirms with CAB the date and plan of visit. The lead assessor performs the visit in accordance with the assessment visit procedure DA-PT-002. If major nonconformities are found during the pre-assessment visit, the CAB must undertake corrective actions for resolving them. All the nonconformities must be reported in the pre-assessment report on form DA-FO-043. The maximum time for resolving the nonconformities is 6 months.

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

### **6.4 Preparation for assessment**

The Director of Accreditation Department, within 10 days from the recommendation by file manager for continuation of accreditation process, appoints, in cooperation with the file manager, the technical assessors and or technical experts (called, together with the lead assessor as team leader, assessment team,) based on the analysis of recourses. The assessment team is composed according to DPA policy on assessment teams DA-PO-003.

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

The CAB has the right to object against one or more members of the assessment team. When the CAB lodges an objection against the appointment of any member(s) or observers or entire team, DPA proceeds according to DA-PO-003. If CAB disagrees the team for three consecutive terms, DPA rejects the application for accreditation.

### **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 documentation to review it. Within 15 days, each team member has to provide information on nonconformities according to forms DA-FO-006, DA-FO-007 and DA-FO-008.

If major nonconformities are found, DPA decides not to proceed with further assessment and reports it in writing to CAB. The CAB has the right to respond to the nonconformities within 6 months. If CAB doesn't respect the deadline, 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.



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If major nonconformities are not found, the assessment team develop an assessment plan covering the activities to be assessed, the locations at which activities will be assessed, the personnel to be assessed where applicable and the assessment techniques to be utilized including the witnessing where appropriate or applicable, and the date of assessment. The assessment plan is compiled based on risks associated with activities, locations, personnel and scope of accreditation.

DPA proposes to the CAB the date of assessment (DA-FO-005) and the assessment plan (DA-FO-002). The date of assessment proposed cannot be earlier than 10 working days from notification. The CAB is requested to approve the date and plan of 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, within 5 working days, the Director of Accreditation Department calculates the assessment fee. The CAB must pay all the cost of the assessment fee at least two days before the realization of the assessment visit. If the CAB doesn't pay in advance, DPA doesn't 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 team leader provides to Director of Accreditation Department 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, the Director of Accreditation Department, within three days, submits the accreditation file, including all the information mentioned above,





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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 according to the form DA-FO-016. Technical Committee functions according to its internal regulation (scheme 1). The report also includes the scope for which the accreditation is to be granted.

If the legal entity is a not related body, the Director of Accreditation Department reviews the accreditation file and formulates its recommendation for accreditation. The Director of Accreditation Department has the right to ask for additional information from the lead assessor or the CAB before formulation of his/her recommendation. The Director of Accreditation Department, within 20 days, reports on the accreditation processes and the recommendation to the General Director according to the form DA-FO-016 (scheme 2). The report also includes the scope for which the accreditation is to be granted.

The General Director reviews the received information and makes decision on according to the form DA-FO-031. The General Director has the right to request additional information from the Director of Accreditation Department or from the relevant technical committee. The maximum deadline for making the decision is 30 days. The General Director cannot make other decision than recommended by the Director of Accreditation Department or by the technical committee.

### **6.7 Accreditation information**

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

The General Director sends, within 10 days from accreditation decision, the following documents to the accredited CAB,

- Certificate of Accreditation,
- Rights and obligations of CAB procedure, DA- PM – 011
- Copy of the assessment report (if it is different from the report sent in clause 6.5)
- Procedure for using the accreditation symbol DA-PM-004.

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

If the decision is negative, General Director provides in writing the assessed CAB 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 secretariat together with the payment for appeal, DPA procedure on appeals, DA-PM-005 is being followed.





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All accreditation file, regardless of the decision, is submitted to the Director of Accreditation Department, who checks the inventory of all documentation according to DA-PM-059 before forwarding the file to DPA secretariat for archiving according to the procedure of records control , DA-PM-009.

The Development Department 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 initial accreditation decision. The duration of the accreditation cycle and the validity period of the certificate is 4 years (48 months) from the date of initial accreditation provided that the surveillance assessment and re-assessment are successful. In accreditation renewals, the validity period of the new cycle and certificate is always determined by adding 4 years (48-months) period to the validity date of the initial accreditation. Effective date of re-accreditation decisions taken inside the accreditation cycle period is the next day from the validity date of the certificate. If re-accreditation decision is received within 3 months after the expiration of the certificate's validity period (accreditation is not valid within this period), the effective date of the certificate becomes the date on which the decision is taken. Similarly, the validity period of the new cycle and the certificate is determined by adding 4 years (48-months) period to the validity date of the initial accreditation. File is closed if a decision cannot be taken within 3 months due to reasons originating from CAB. CAB makes an initial accreditation application if it wants to be re-accredited. The validity date of the reformulated accreditation certificate does not change except for reaccreditation.

An accreditation cycle program is prepared for each CAB that will enable assessment in related locations in a way to represent all activities in the scope of accreditation (scope in the annex to the accreditation certificate) together with the management system throughout the cycle. The accreditation cycle program is established after the initial accreditation decision by the assessment team according to form DA-FO-069. The accreditation program is based on the risk-based analysis. The assessment program is subject of alterations prior to and after each assessment and in case of the CAB changes 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. The CAB has to provide the DPA with all information about the change in staff, equipment, apparatus, locations, conformity assessment methods/procedures, etc. Based on information received, DPA performs the risk analysis and decides which on the next step, duration of assessment and the appropriate assessment techniques. Based on risk analysis, extraordinary assessment visit can also be organized.

Within the framework of the initial accreditation cycle program, the 1<sup>st</sup> surveillance assessment of CAB shall be carried out at the 6 months from the start date of the cycle.



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The 2<sup>nd</sup> surveillance shall be conducted 12 months after the 1<sup>st</sup> surveillance. The 3<sup>rd</sup> surveillance shall be conducted 12 months after the 2<sup>nd</sup> surveillance. A maximum deviation of 2 months can be allowed in the 2<sup>nd</sup> and 3<sup>rd</sup> surveillance.

Within the framework of accreditation cycle program the 1<sup>st</sup> surveillance assessment of the accredited organization shall be carried out at the 12<sup>th</sup> months from the start date of the cycle. The 2<sup>nd</sup> and 3<sup>rd</sup> surveillance assessment is conducted 12 months after respectively the 1<sup>st</sup> and 2<sup>nd</sup> surveillance assessment. A maximum deviation of 2 months can be allowed in routine assessments.

DPA requests accredited CABs to submit the amended/updated documentation 30 days before carrying out each surveillance visit. For the surveillance visit, DPA follows this procedure from clause 6.3.

For reasonable conditions (request for scope extension, complaint, changes in regulations and standards of CAB's activity area, changes in CAB's structure, suspension of accreditation etc.), an additional 2 months deviation may be allowed in assessments; however, the time between sequential surveillance/re-assessments shall not exceed 24 months under any circumstances. While 2 routine surveillance assessments are contemplated for an accreditation cycle, this number may be increased for reasons mentioned below:

- \* 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 routine surveillance and re-assessments. However, in cases where the witness assessment cannot be carried out together with the surveillance and renewal assessment within 3 months period, independent witness assessments can be performed before or after the related assessment in accordance with the accreditation cycle program.

### **8 Extraordinary assessment visits**

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 of the extraordinary assessment and techniques are decided based on risk analysis. 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**



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In case, the accredited CAB requests the renewal of the Accreditation Certificate, it applies to DPA in written form at least 9 months before the end of the validity of its accreditation certificate. Re-assessment is normally carried out at the 41st month of the cycle. If the re-accreditation application has been made late or if the re-assessment could not be done in time due to reasons arising from CAB, then the responsibility lies with the CAB of not conducting of re-assessment before the cycle ends and consequently the loss of its accreditation status at the end of the cycle. If re-assessment is not performed before the end of the cycle, the accreditation status is lost and the file is closed. CAB makes an initial accreditation application if it wants to be re-accredited.

Re-assessment is planned, performed and reported similar to the initial accreditation assessment. The re-assessment shall be carried out to confirm CAB's competency and to cover all requirements of the standard for which the conformity assessment body has been accredited. When planning reassessment to confirm CAB's competency, information on the personnel and other resources for CAB's entire scope is evaluated, the assessment team is formed in a way to include expertise for the scopes needed for review. Within this framework, scopes and all locations where key activities are carried out that were not assessed in previous assessments in the cycle, and other activities and locations determined by a sampling method within the framework of a risk based approach by taking into account previous assessments and the issues defined in relevant

If the CAB does not request for re-accreditation, the file manager shall confirm that CAB has no re-accreditation request two months prior to the expiry of the 4 years (48-months) period and starts the process to Director of accreditation Department and then to General Director for closing the file; the file shall be closed upon the expiry of the period.

By the end of the accreditation period, the name of CAB is deleted from DPA website.

### **10. Internal information/communication**

For each decision on accreditation is made by the General Director. DPA secretary officially announces the Director of Accreditation Department, the Director of Development Department and the Head of Sector for Finance and Secrices. The Development Department updates the records on the CAB on DPA website.



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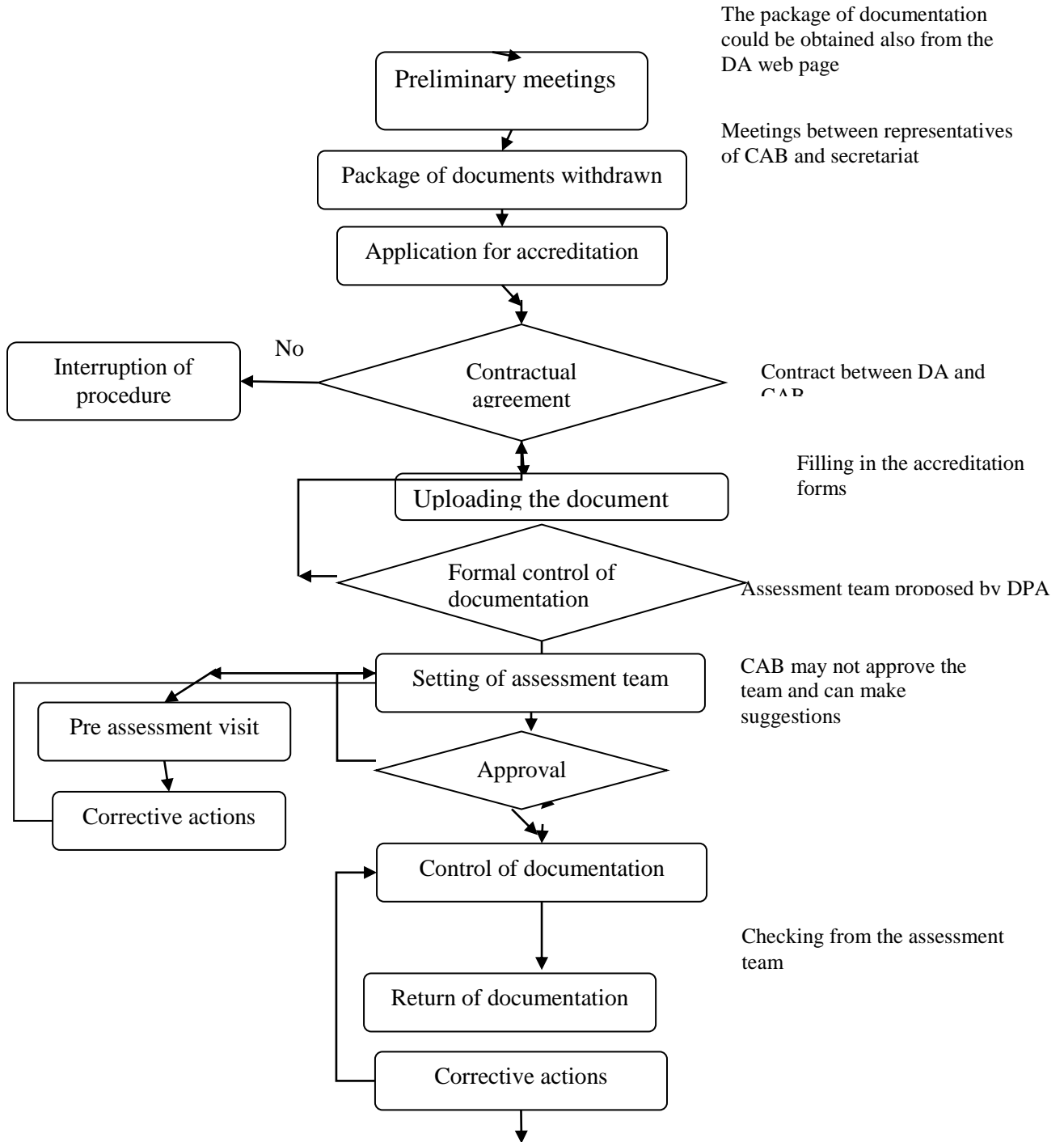
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Request for accreditation

9.

### DIAGRAM





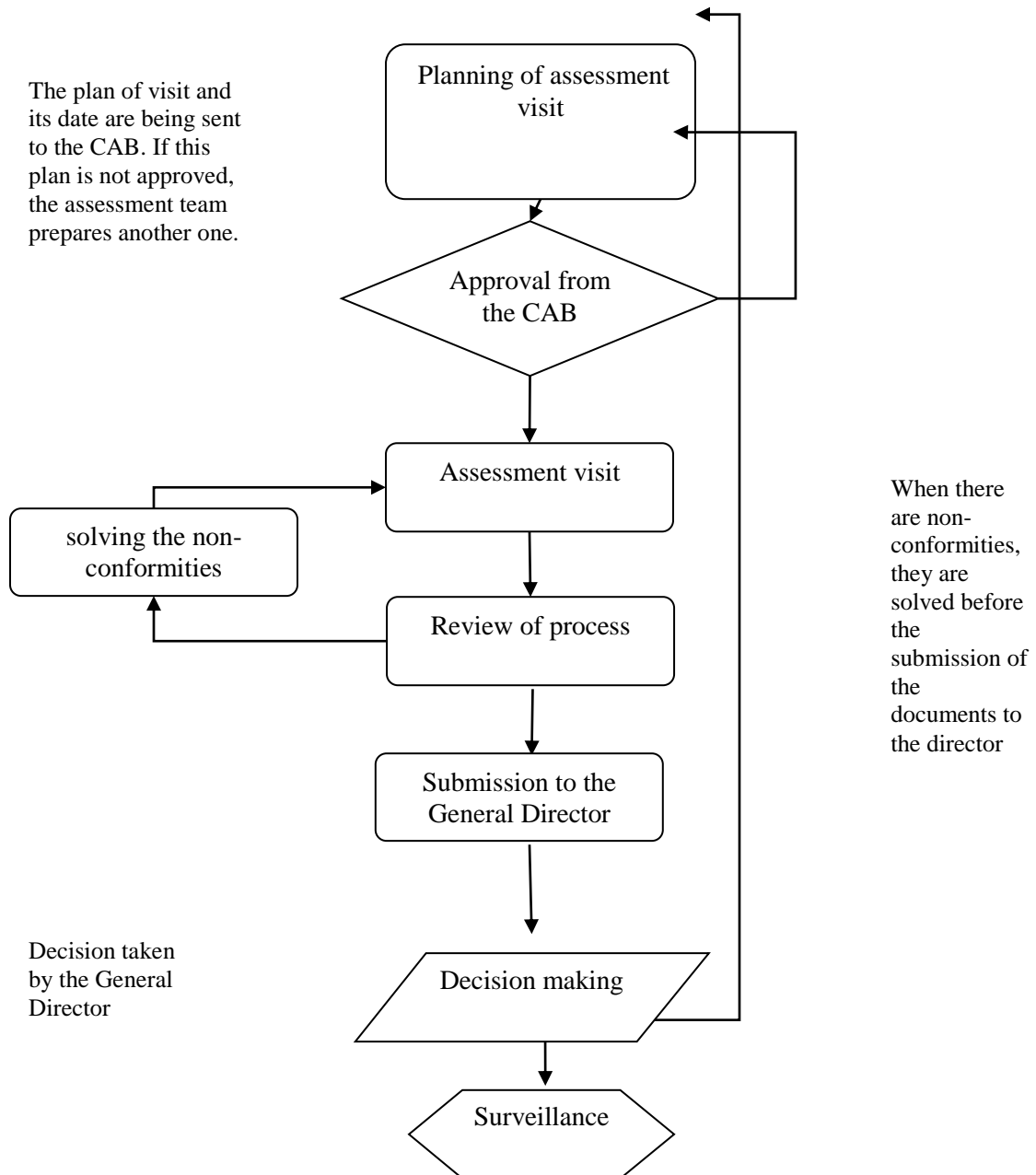
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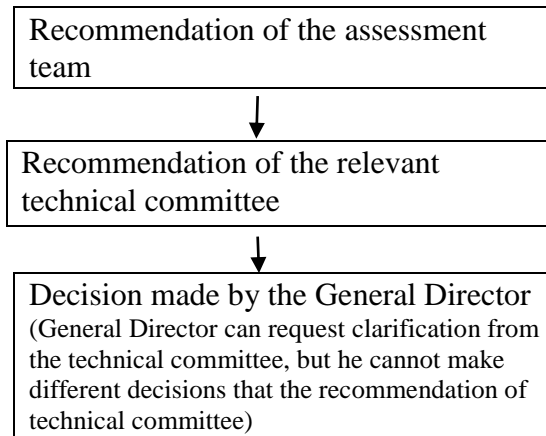
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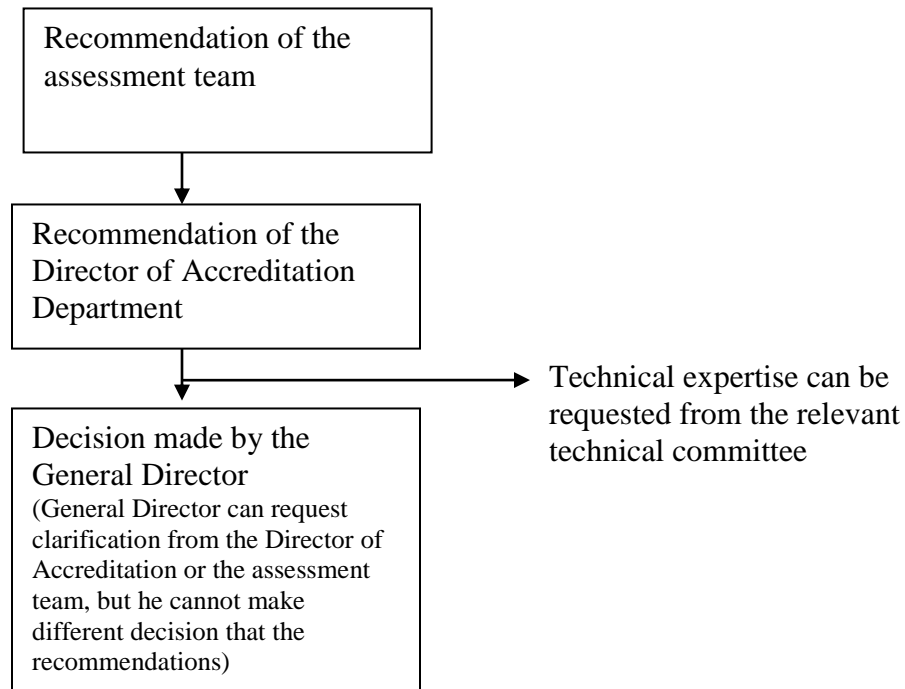
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### Scheme 1: Decision-making on related bodies



### Scheme 2: Decision-making on non-related bodies





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### 10. REGISTRATIONS FROM THIS PROCEDURE

<b>Title of the document</b>	<b>Who fills it in</b>	<b>When</b>	<b>Who maintains</b>
Check list	Assessment team	When checking the documentation	Secretariat
Form for assessment of quality manual DA – FO- 006	Lead assessor	When checking the documentation	Secretariat
Form for assessment of technical procedures DA –FO – 007	Technical assessor	When checking the documentation	Secretariat
Form for assessment of management procedures DA-FO-008	Lead assessor	When checking the documentation	Secretariat
Form of presenting corrective actions DA-FO-011	Assessment team	After assessment	Secretariat
Form for notification of assessment date and its approval DA-FO-005	Specialist of sector	After checking the documentation	Secretariat
Form of assessment team DA-FO-70	Lead assessor	After the meeting	Secretariat
Form for annual plan for witnessing DA-FO-069	Assessment team	After granting the accreditation	Secretariat
Plan of assessment visit	Specialist of sector	Before assessment visit	Secretariat
Form for notification of team members and its approval DA-FO-012	Specialist of sector	Before assessment visit	Secretariat
Form of reporting the laboratory assessment according to ISO/IEC 17025 DA-FO-001	Assessment team	After assessment visit	Secretariat
Form of reporting of assessment according to ISO/IEC 17024 DA-FO-013	Assessment team	After assessment visit	Secretariat
Form of reporting of assessment according to ISO/IEC 17065 DA-FO-049	Assessment team	After assessment visit	Secretariat
Form of reporting the assessment according to ISO/IEC 17021-1 DA-FO-004	Assessment team	After assessment visit	Secretariat
Form of reporting to general Director DA-FO-016.	Head of sector	After assessment	Secretariat
Form of presenting the non	Assessment team	After assessment	Secretariat





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conformities DA-FO-003		visit	
Preparation of certificate	Secretariat	When the document issued or change	Secretariat
Pre-assessment report DA-FO-043	Assessment team	After the pre-assessment visit	Secretariat

**11. 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 new 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 part of 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 implementation 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; 6.2.6; 7.2; 8, 9, Also in the diagram. Deadlines are reduced in the accreditation procedure and placed in the way internal information regarding Decision of the Director General.
04.06.2013	4	Ardita Fuga	Such changes were reflected in the below paragraphs on paragraph 6.5 and 6.6 the decision-making process in cases to be related CAB.



**Tel: + 355 4 2 269097**  
**Fax : + 355 4 2 269325**  
**E-Mail: info@dpa.gov.al**

## The procedure of accreditation, surveillance and renewal of accreditation

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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 meeting plan for witnessing
20.05.2019	8	Briseida Xhafa	Changes of procedure according to ISO/IEC 17011:2017