

Assessment procedure

Implemented by: Lead assessor, assessors, experts, Directorate for testing, calibration and medical laboratories and Directorate for certification and inspection bodies

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

Controled by: Ardita MELE Quality manager Approved by: Pranvera FAGU General Director

Review no 8 Dt: 28.06.2024

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

1. PURPOSE

The purpose of this procedure is to determine the rules and steps how DPA performs the assessment of the competence of conformity assessment bodies.

2. SCOPE OF APPLICATIONS

This procedure is implemented during the assessment of conformity assessment bodies whether performed on-site or remotely. The procedure is implemented in the process of initial accreditation, extension, , surveillance, extraordinary visits and reassessment. The same rules and procedure DPA also applies during pre assessment visits.

3. RESPONSIBILITES

The procedure is implemented by the technical assessors, lead assessors, experts and Directorate for testing, calibration and medical laboratories and Directorate for certification and inspection bodies staff. The Director of Directorate for testing, calibration and medical laboratories and Director of Directorate for certification and inspection bodies responsible for checking the implementation of this procedure.

4. REFERENCES

Standard S SH EN ISO/IEC 17011:2017 "Conformity assessment- Requirements for accreditation bodies accrediting conformity assessment bodies", clause 7.6

Law Nr. 116, date 11. 09.2014, "On the accreditation of conformity assessment bodies in the Republic of Albania "

- Quality Manual DA-MC-001.
- Assessment report of testing and calibration laboratories according to ISO 17025 DA-FO-001
- Assessment report of medical laboratories according to DA-FO-063
- Assessment report of Certification Bodies for person according to DA-FO-013
- Assessment report of Certification bodies for management systems according to DA-FO-004
- Assessment report of Certification bodies for products according to DA-FO-049
- Assessment report of Inspection Bodies according to DA-FO-048
- Nonconformities Submission Form DA-FO-003
- Form for submission of corrective action DA-FO-011



Review no 8 Dt: 28.06.2024

Page 3 from 17

- Form of nonconformities settlement plan DA-FO-032

5. VOCABULARY AND ABBREVIATIONS

For the purpose of this document terms and definitions provided in S SH EN ISO/IEC 17011:2017 and DPA Quality Manual annex are used.

6. PROCEDURE

6.1 Assessment

Assessment is a very important step of the procedure of accreditation of conformity assessment bodies aiming at to evaluate whether the accreditation requirements are being met.

The assessment is carried out by the assessment team. The assessment team is composed by the lead assessor, and technical assessors and experts, as necessary. The number of technical assessors is determined depending on the number of technical fields to be assessed as well as the number of services for which accreditation is being sought. Experts are used for very specific/narrow fields of assessment based on their technical competence, but they don't perform any assessment alone. Observers authorized by DPA may be included in the assessment team. The number of observers should not exceed two.

DPA can perform the assessment of conformity assessment bodies on-site or remotely. The assessment team conducts the assessment according to the assessment plan, whether performed on-site or remotely. DPA can use remote assessment only when DPA and CAB has the appropriate recourses for it.

DPA uses the following techniques to assess the CAB's competence:

- On-site assessment
- Remote assessment
- Witnessing
- Document review
- File review
- Measurement audits
- Review of performance in proficiency testing and other interlaboratory comparisons
- Validation audits
- Unannounced visits
- Interviewing

The assessment team selects one technique or combination of them to assess the competence of CAB.



Fax : + 355 4 2 269325

E-Mail: info@dpa.gov.al

For initial assessment, DPA:

- a) Never uses the remote assessment.
- b) Uses on-site assessment in combination with other techniques based on risk associated to the activities, locations and personnel of the CAB.

For surveillance visits during an accreditation cycle, the assessment technique(s) used are defined by assessment team based on risk associated to CAB's management system, activities and performance. The selection of assessment techniques is fully documented and justified in terms of its effectiveness.

6.1.1 Stages of the assessment visit

The stages of the assessment visit are the followings:

- 6.1.1.1 Opening meeting
- 6.1.1.2 Assessment of the management system and technical competence
- 6.1.1.3Meeting of the assessment team for preparation of final meeting
- 6.1.1.4 Final meeting (closing meeting)

6.1.1.1 Opening meeting

For an assessment whether performed on-site or remotely, the assessment team commences the assessment with an opening meeting. The opening meeting is held with CAB management and personnel who will be assessed.

The opening meeting is chaired by lead assessor who

- a) Introduces the assessment team
- b) Explains the objectives of the assessment, the procedures that will be followed, and the task of each team member
- c) Presents the assessment plan, and the criteria based on which the assessment will be performed
- d) Redefines the scope of accreditation
- e) Explains the assessment techniques
- f) Confirm practical arrangements (language used during the assessment, room available to the assessment team for meetings, hours of work, meal breaks etc.)
- g) Requests the participation of the CAB management in the closing meeting



Tel: + 355 4 2 269097

Review no 8 Dt: 28.06.2024

- h) Presents the witness activities which will be carried out according to the assessment plan
- i) Presents matters relating to confidentiality, information security and health and safety
- j) Conditions under which the assessment can be terminated.
- k) Presents documentation that the assessment team will use
- 1) Confirms that a representative of the CAB has been appointed to accompany each assessor throughout the visit.

During the opening meeting the CAB management

- a) has the right to ask questions about the assessment plan,
- b) presents all the changes which have happened since the application or between the two surveillance visits.

If it is needed, the modification of assessment plan can be done.

6.1.1.2 Assessment of management system and technical competence

The assessment visit is planned to assess the implementation of management system and to assess the technical competence of CAB. The assessment of the management system is made by the lead assessor whereas the technical competence is assessed by the technical assessor(s) and/or expert(s) accompanied by assessor(s) according to the assessment plan. The assessment team uses the combination of the assessment techniques (such as interview, file/records review, document review, meaurements audit, validation audits, witness and records of participation in PT or ILC schemes) as necessary to assess the CAB performance according to the assessment plan.

The assessor(s) record each findings, and for each nonconformity the form DA-FO-003 is filled out.

When it is necessary, the assessors, could request to have a intermediary meeting of assessment team regarding:

a) the exchange of information useful for continuation of visit

b) the determination of possible modifications of assessment plan based on upcoming facts.

For the time of the intermediary meeting takes place, the lead assessor temporarily interrupts the assessment visit. If the assessment plan was necessary to be modified in the intermediary meeting, the team leader immediately communicates the modification to the CAB's authorized person.

The assessment visitmay be interrupted due to conditions including but not limited to the followings:



Review no 8 Dt: 28.06.2024

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

a) Assessment conditions adversely affect the health or jeopardize the safety of the assessment team,

b) Significant environmental or safety risks arise depending on the nonconformity identified,

c) It is determined that CAB is not ready for the assessment visit in terms of infrastructure, personnel or documentation although it has declared its readiness,

d) Adequate records of implementation are not available in areas for which accreditation is requested and/or CAB precludes access to records and/or conditions are not present for the assessment team to collect objective evidence,

e) CAB has failed to organizational preparations including logistics etc. to proceed with the assessment;

f) It is determined that records reviewed at the on-site assessment are substantially false or records are created partially or fully in a misleading manner deliberately or incorrect information or documents or records are deliberately presented;

g) CAB prevents access to records;

h) CAB makes proposals of financial benefits to the assessment team members,

i) If during the initial assessment or surveillance visits, assessment team finds evidences of fraudulent behavior by the conformity assessment body that intentionally provides false information or if the conformity assessment body conceals information.

The reason for interrupting the assessment shall be captured in an incident report by the assessment team and CAB's management.

If the assessment is interrupted due to any reason not arising from the client, the assessment is realized/completed on an appropriate date without charging any additional fees to CAB. However, if the assessment is interrupted due to any reason such as CAB not completing its preparations, not making its key personnel available during the assessment and/or their other deficiencies, misconduct or negligence; pursuant to the assessment plan, it is considered that the assessment is executed completely and the fee is invoiced fully to CAB; and the assessment is finalized as unsuccessful.

If the interrupted assessment is an initial accreditation assessment, a new assessment shall be scheduled within one year from the application date unless the CAB decides not to request accreditation. The duration/scope of the newly scheduled assessment may be reduced considering the successful parts of the interrupted assessment.

If the interrupted assessment is a surveillance assessment, a new surveillance assessment shall be scheduled within 30 days. The duration/scope of the newly scheduled assessment may be reduced considering the successful parts of the interrupted assessment. If the time limit specified for surveillance assessment is exceeded, suspension/withdrawal procedures shall be executed. If the interrupted assessment is a re-assessment, a new re-assessment shall be scheduled within 4 years from the date of accreditation decision. The duration/scope of the newly scheduled assessment may be reduced considering the successful parts of the interrupted assessment may be reduced considering the successful parts of the interrupted assessment may be reduced considering the successful parts of the interrupted assessment.

Review no 8 Dt: 28.06.2024

Tel: + 355 4 2 269097 Fax : + 355 4 2 269325

E-Mail: info@dpa.gov.al

If the assessment is interrupted due to the condition of point (i), DPA makes the decision to terminate the assessment process or to withdraw accreditation.

Witness Assessment

Laboratories for testing, calibration and medical

During initial/extension assessment, each material will be assessed during on-site assessment and with witness assessment. During an accreditation cycle, each property measured/measurant is assessed at least once (ideally twice) with witness/vertical audit. All technical areas and measurement technique must be assessed with witness at least once per accreditation cycle. If possible, all methods should be assessed at least once per accreditation cycle.

Sampling activities, where applicable, are assessed at initial and extension assessments, and at least one surveillance assessment per accreditation cycle.

Sample collection activities are assessed on the field if they are under the scope of accreditation. If the sampling activities are not covered by the accreditation, the assessment team will have to check the acceptance criteria of the samples as part of the assessment.

Sample collection centers for medical biology laboratories: At each assessment, sampling activities are assessed. Each sampling center should be assessed at least once per accreditation cycle. This assessment is performed by a technical assessor.

Metrological traceability is checked during each assessment. If the laboratory performs in-house calibrations, the assessment team assesses in detail the records concerning the validation/verification of the calibration method, metodology used, the procedure for estimating uncertainties and the competence of those performing calibrations once for initial/extension assessment and at least once per accreditation cycle.If it is necessary a technical expert for calibration can be involved in the assessment team.

The selection of witness activities (including number of witness assessments and which measurement techniques) s for initial assessment, surveillanceor extension of accreditation scope for for testing, calibration and medical laboratories depends on risk assessment.

- 1. The risk assessment includes at least: Measurement techniques
- 2. Equipment
- 3. Competence of persons authorized to perform the test/calibration



Assessment procedure

Code: DA-PT-002

Tel: + 355 4 2 269097 Fax : + 355 4 2 269325 E-Mail: info@dpa.gov.al *Review no 8 Dt: 28.06.2024*

Page 8 from 17

- 4. Location (inside or outside) where the test/calibration will be performed, environemental conditions.
- 5. Results from participation in PT / ILC
- 6. Changes in personnel of laboratories, equipment and measurement techniques.
- 7. Grouping of analyses
- 8. Importance and complexity of service
- 9. History of laboratory (accreditation cycle, changes in years, etc)

8.2 Inspection bodies

Office assessment: During initial /extension assessment, each group of products/service (e.g pressure equipment, eletrcial equipment, etc) is assessed. During the an accreditation cycle, each product/service is assessed at least once (ideally twice). If possible, all "inspection objects" or "products or groups of materials" should be assessed at least once per accreditation cycle.

Assessment with witness: During initial /extension assessment, each group of products/service (e.g pressure equipment, eletrcial equipment, etc) is assessed with witness. During the accreditation cycle, each type and range of inspection per each product/service shall be assessed with witness. At each assessment, at least one witness assessment is organized in parallel. They are carried out, either at the same time as the office assessment, or offset according to the availability of the objects to be inspected, or the sites / assessments available. The period of their organization can be spread more or less 3 months around the date of the assessment office.

If applicable, metrological traceability is checked during each assessment. If an inspection body performs internal calibrations, the assessment team assesses in detail the records concerning the validation / verification of the calibration method, methodology used, the procedure for the estimation of uncertainties and the competence of the calibrators in initial/extesnion assessement and at least once per accreditation cycle. If it is neccesary a technical expert on metrology can be used in order to assess the competence for carring out internal calibrations.

The selection number of witness assessments and of type of inspection (e.g full examination, periodical inspection, initial inspection) from product/service or from the group of products/services shall be based on risk assessment which takes into account the following factors:

- a) number of certificates/reports issued;
- b) number and competence of inspectors
- c) whether inspectors are internal staff or external resource and its changes;
- d) type and range of inspection;
- e) importance and complexicity of service (complex clients)
- f) countries where conformity assessment avtivity are performed;



Assessment procedure

Code: DA-PT-002

Review no 8 Dt: 28.06.2024

Page 9 from 17

- Tel: + 355 4 2 269097 Fax : + 355 4 2 269325 E-Mail: info@dpa.gov.al
 - g) result of previous witnessing activities;
 - h) complaints, customer surveys;
 - i) interested parties and regulators requests;
 - j) History of inspection body (accreditation cycle, changes, etc)
 - 8. 3. Management system certification bodies

Office assessment: During initial / extension assessment, each certification scheme is assessed. During the surveillance visits of an accreditation cycle, each scheme is assessed at least once (ideally twice).

Assessment with witness: For management system certification bodies which certify according to ISO 9001, ISO 14001, ISO 45001, the selection of witness assessments shall be based on IAF MD 17. During the accreditation cycle, number and technical fields for witness assessemnt shall be based on IAF MD 17. Anyway, DPA can decide to designate different critical codes within each technical cluster, according to national regulations, local market conditions and effective use. The technical justification for these modifications shall be recorded.

For management system certification bodies which certify according to ISO 27001, ISO 39001, ISO 37001, ISO 20000-1, at least one witness (includes phase 1 and phase 2 of audit) in initial/extension assessment shall be assessed. During the accreditation cycle, at least one witness assessment (including phase 1 and phase 2 audit) for each certification scheme shall be performed. The selection of witness activity will be based on risk assessment.

At each office assessment, at least one witness assessment is organized in parallel. For management system certification bodies which certify according to ISO 22301, DPA shall be based on DA-IN-006.

For certification bodies that certify under the ISO 22301 certification scheme, DA-IN-006 applies.

DA-IN-026 applies to certification bodies that certify under the ISO 27701 certification scheme.

For certification bodies that certify under the certification scheme according to ISO 27001 and the two guidelines ISO 27017 and ISO 27018, DA-IN-027 applies.

DA-IN-028 applies to certification bodies that certify under the ISO 20121 certification scheme.

DA-IN-029 applies to certification bodies that certify under the ISO 28001 certification scheme.

For management system certification bodies which certify according to certification scheme ISO 50001, at least one witness (includes phase 1 and phase 2 of audit) per



Review no 8 Dt: 28.06.2024

Page 10 from 17

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

technical area in initial/extension assessment shall be assessed. During the accreditation cycle, at least one witness assessment (including phase 1 and phase 2 audit) for each technical area shall be performed. The selection of witness assessment(s) will be based on risk assessment.

In case of management system certification bodies which certify according to ISO 13485:

Office assessment: During the initial/extension assessment and accreditation cycle on-site assessment shall be performed every year. During the initial/extension assessment each main technical area will be assessed. During the accreditation cycle each technical area is assessed at least once (ideally twice).

Witness assessement: during the initial/extension assessment and during the accreditation cycle one witness activity shall be performed. In case of initial/extention assessment, the selection of witness acitvities shall include minimum an audit with high risk of technical field for each main technical area (refer to B3 of this procedure) which are under the accreditation scope. Taking in consideration international and national classification of risk and/or complexicity of process (e.g. sterilization, parts and services). The assessment programe with witness shall include a minimum one audit per each main technical area (refer to B3 of this procedure) under the scope of accreditation during an accreditation cycle. DPA shall avoid the assessment with witness of the same client of the certification body in replicate way. When DPA prepares the assessment program, it shall take in consideration the results of witness acitvities performed in previous assessment visits.In case of certification bodies verifying food safety management systems (FSMS):

Office assessment: During the initial/extension assessment each category shall be assessed. During the accreditation cycle in each surveillance visits, each category shall be assessed at least once (ideally twice). If it is possible each subcategory is assessed during one accreditation cycle.

Assessment with witness shall be determined according to IAF MD 16. DPA shall not grant accreditation for a given food chain category without at least one witness assessment performed in the cluster. This criteria is also applicable to extension of scopes. For extensions inside a cluster, witnessing is not mandatory. Witnessing is mandatory for extensions to categories in a new cluster

Assessments with witness during the surveillance visits in an accreditation cycle shall be performed in accordance with the requirements of the existing and valid IAF MD 16 mandatory document. The assessment with witness during an accreditation cycle shall be planned to allow the presentation of witnessed visits in high risk food safety sectors. If the body is accredited for the cluster "processed food for humans and animals", at least one audit for this cluster will be evaluated in each surveillance visit. At least one audit for



Tel: + 355 4 2 269097 Fax : + 355 4 2 269325

E-Mail: info@dpa.gov.al

each of the other clusters will be evaluated more closely during the accreditation cycle. In the accreditation cycle, the entire scope/programme of accreditation will be covered.

For food safety management system certification bodies according to certification schemes FSSC 22000, they can apply for accreditation /extension according to FSSC 22000 for the categories in which they have already been accredited according to ISO 22000 and after the licence by Food Safety certification Foundation (FSSC).

Office assessment: for initial/extension assessment at least one full certification process (since application to decision-making) shall be assessed. During the accreditation cycle, each category will be assessed at least once. (ideally twice).

Witness assessment: for initial/extension assessment at least one witness activity shall be performed for each category. This witness shall include one full, audit (phase 1 and phase 2) and all scheme requirements FSSC 22000 and standard requirements ISO 22000 per category.

Witness activities during the accreditation cycle shall be selected based on IAF MD 16. The witness assessment can include all type of audits, surveillance, transfer, recertification, special, extension, integrated audit.

Note: As office assessment and witness assessment for scheme FSSC 22000 include all requirements of ISO 22000 standards, these assessments can be accepted for meeting the requirements of ISO 22000 standard. E.g. when one witness assessment was performed for category C of certification scheme FSSC 22000, this assessment presumes and the assessment according to ISO 22000 standards per category C. The visa-versa is not valid.

For all the management system certification: not the same CAB clients and the same audit team shall be witnessed in two consecutive visits, if possible.

The accredited management system certification bodies are obliged to provide DPA with all the information requested by guide DA-IN-009.

The following additional factors shall be taken into account to risk assessment and to selecting witness activities:

- a) number of certificates issued;
- a) number of auditors;
- b) whether auditors are internal staff or external resource;
- c) different audits, initial audit (stage 1/stage 2), surveillance and recertification;
- d) complex clients, combined and/or integrated audits, multi-site audits;
- e) countries where audits in the certification process are performed;
- f) result of previous witnessing activities;
- g) complaints, customer surveys;
- h) interested parties and regulators requests;
- i) previous history of the CB's ability to manage its operations;
- j) level of controls exercised by a CB over its critical activities;
- k) specific scheme requirements; and



Review no 8 Dt: 28.06.2024

Page 12 from 17

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

l) national agreements with clients.

8.4 Certification bodies of persons

Office assessment: During initial /extension assessment, each group of persons (e.g auditors, lead auditors, etc) which are under the application scope shall be assessed. During the surveillance visits in an accreditation cycle, each group of persons shall be assessed at least once (ideally twice).

Assessment with witness: The same rule as for the organization office assessment is applicable. At each office assessment, at least one witness assessment is organized in parallel. The witness assessment in initial/extension assessment includes all phases of certification process . The witness assessment during the accreditation cycle can include a phase of certification process.

The following factors shall be taken into account to risk assessment select witnessing activities:

- a. number of certificates issued;
- b. number and competence of examinaters;
- c. whether examiners are internal staff or external resource;
- d. field of certification;
- e. complex clients;
- f. countries where such conformity assessment process are performed;
- g. result of previous witnessing activities;
- h. complaints, customer surveys;
- i. interested parties and regulators requests;
- j. previous history of the CAB's ability to manage its operations;
- k. specific scheme requirements; and
- l. national agreements with clients.

8.5 Product certification bodies

Office assessment: During initial /extension assessment, each products/service under the application scopeshall be assessed. During the an accreditation cycle, each product/service under the accreditation scope shall be assessed at least once (ideally twice).

Assessment with witness: The same rule as for the organization of assessment in office is applicable. At each office assessment, at least one witness assessment is organized in parallel. They are carried out, either at the same time as the office assessment, or offset





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

according to the availability of the objects to be certified. The period of their organization can be spread more or less 3 months around the date of the office assessment.

If applicable, metrological traceability is one of the points to check during each assessment. If internal calibrations are done, the assessment team is requested to check in detail the records concerning the validation / verification of the calibration method, methodology used, the procedure for the estimation of uncertainties and the competence of the calibrators in initial /extension assessment and at least once per accreditation cycle. If it is neccesary a technical expert on metrology can be used in order to assess the competence for carring out internal calibrations.

During the surveillance visits, the selection of product from product/service or from the group of products/services shall be based on the risk assessment taken into account the following factors:

- a) number of products certified;
- b) number and competence of experts
- c) whether experts are internal staff or external resource;
- d) type of product certified;
- e) complex clients;
- f) countries where such conformity assessment process are performed;
- g) result of previous witnessing activities;
- h) complaints, customer surveys;
- i) interested parties and regulators requests.

6.1.1.3 Meeting of assessment team

The assessment team meets prior to the closing meeting in order to:

a) review the assessment findings and any other appropriate information collected during the assessment against the assessment objectives;

- b) agree on the assessment conclusions,
- c) discuss the follow-up of the assessment
- d) record each nonconformity on form DA-FO-003.

In case of diverging opinions between the assessment team members with respect to the formulation and classification of finding(s) proposed by the concerned assessor, the lead assessor may feel necessary to make a comment in his/her report, to the attention of the Director of Directorate for testing, calibration and medical laboratories and Director of Directorate for certification and inspection bodies.

6.1.1.4 Closing meeting

Review no 8 Dt: 28.06.2024

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

> For an assessment, whether performed on-site or remotely, a closing meeting takes place between the assessment team and the CAB. At this meeting, the team members, CAB management and staff who are assessed take part. The closing meeting is chaired by lead assessor. He/she makes a summary of the assessment, reports on the findings identified during the assessment and explains other steps which will be followed

> If the authorized person of the CAB does not sign, the nonconformities and suggestions shall be reported by signatures of the assessment team.

The assessment team leaves a copy of each nonconformity recorded on form DA-FO-003 with the CAB so that the corrective actions can be performed, the root-cause analysis, the extent of nonconformity (spread to other areas) and the completion dates can be written on it.

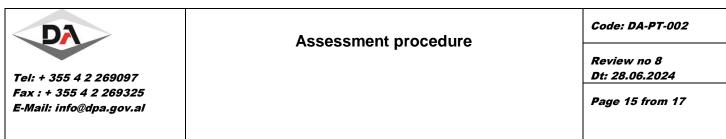
6.1.2 Reporting

The assessment team reports on the outcome of the assessment, including the nonconformities and areas for possible improvements, to DPA no later than one month from the last assessment day. The assessment team reports on the form according to the type of CAB, (DA- FO – 001, DA- FO – 004, DA- FO – 013, DA- FO – 048, DA- FO – 049 and DA- FO – 063) and the witness/vertical audits reports. If the report on the outcome of the assessment differs from the outcome delivered in the closing meeting of the assessment, DPA provides a written explaination to CAB.

DPA is responsible for the content of the assessment report. The assessed CAB can request explanation for assessment report no later than 15 working days. DPA provides explanation to CAB no later than 15 working days.

If nonconformities are found during the assessment, the CAB shall make a root-cause analysis and proposes the plan for solving the nonconformities, according to the form DA-FO-032, no later than 15 working days from the last assessment day. If the assessment team concludes that the root-cause analysis is not appropriate and/or the actions proposed by CAB are not appropriate or sufficient, DPA requests to CAB to make an extended analysis and to propose other actions.

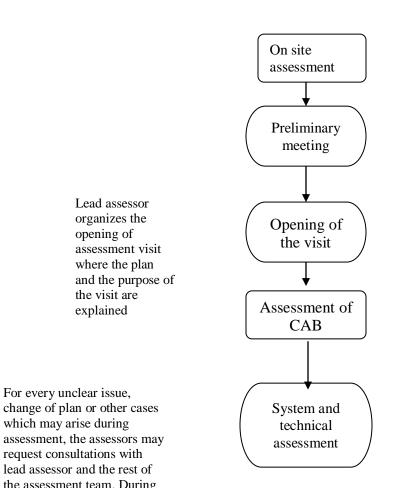
In case of initial accreditation/extension and reaccreditation, the assessed CAB shall provide DPA with the evidences of the corrective actions and improvements no later than five months. In case of surveillance, the deadline for providing the corrective actions and improvements is two months.



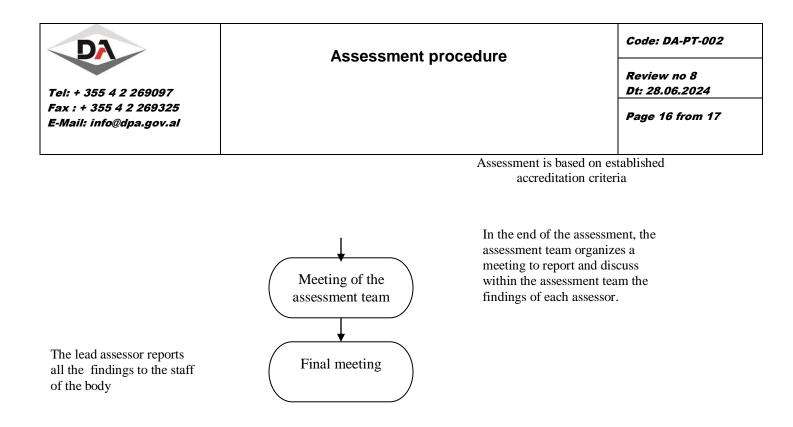
Within the determined time frame, the assessed CAB shall send the evidences of corrective actions and improvements and form DA-FO-011 to DPA. The assessment team assesses the efficiency and efficacy of the undertaken actions. The assessment team can request to CAB other information or if it is necessary the organization of another assessment visit for evaluation of solving nonconformities. The results of verification are shown in a report included in the form DA-FO-011. The process for verification of corrective actions lasts no more than 15 days. If the CAB doesn't solve the nonconformities on time, the lead assessor requests the start of the procedure for refusal/suspension of accreditation. If CAB has solved the nonconformities, lead assessor reports in writing to Director of Directorate for testing, calibration and medical laboratories/Director of Directorate for certification and inspection bodies about the status of nonconformities.

CAB can request, only once, the extension of the deadline for carrying out the corrective actions. The extension must be requested in writing. The Director of Directorate for testing, calibration and medical laboratories and Director of Directorate for certification and inspection bodies can approve this extension or not. The extension cannot last more than one month if it is justified.

7.DIAGRAMME



Before starting the assessment, the assessment team organizes a meeting to update once again the tasks for each assessor.



8. REGISTRATIONS

| Title of document | Who fills it in | When | | Who maintains |
|---------------------|-----------------|------------|-----|--------------------------|
| Forms of assessment | Lead assessor | After | the | Director of Directorate |
| DA-FO-001, | | assessment | | for testing, calibration |
| DA-FO-013 | | | | and medical laboratories |
| DA-FO-003 | | | | and Director of |
| DA-FO-004, | | | | Directorate for |
| DA-FO-013, | | | | certification and |
| DA-FO-048, | | | | inspection bodies |
| DA-FO-049 | | | | _ |
| DA- FO – 063 | | | | |

9. HISTORY

| Date of Review | Number of Revision | Author | Description of changes | |
|-------------------|--------------------------|---------|--|--|
| 30.10.2006 | 0 | B. Pani | Original document | |
| | 1 | B. Pani | Approval of this procedure accordance with law no. 9824 dated on 1.11.2007 | |
| 22.10.2009 | 2 | B. Pani | Paragraph 6.5 on assessment visit to bodies established in many locations | |
| For | 3 | B. Pani | Paragraph 6.5 on assessment visit to bodies | |



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

Assessment procedure

Code: DA-PT-002

Review no 8 Dt: 28.06.2024

Page 17 from 17

| 8 | approval | | | established in many locations | |
|---|------------|---|---------|--|--|
| 2 | 22.12.2014 | 4 | B.Xhafa | There have been changes to the document head of page about phone numbers and email address of DPA. The first page also been renamed the Ministry. In paragraph 4 is amended to add the reference to the law. | |
| 2 | 20.05.2019 | 5 | B.Xhafa | Changes are based on the new standard ISO 17011:2017. | |
| 2 | 25.05.2021 | 6 | A.Mele | The witness acitities are added and new organization chart of DPA is reflected | |
| (|)5.10.2023 | 7 | A.Mele | Addition to paragraph 6.1.1.2 regarding the evaluation method of the new conformity assessment schemes. | |
| 2 | 28.06.2024 | 8 | A.Mele | A.Mele Witness assessment according to procedure DA PT-003 | |