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Assessment procedure

Implemented by: Lead assessor, assessors, experts, Accreditation Department

Responsible for implementation: Director of Accreditation Department

Controlled by: Ardita MELE
Director of Accreditation Department

Approved by: Armond HALEBI
General Director

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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 Accreditation Department staff. The Director of Accreditation Department is 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
- Form of nonconformities settlement plan DA-FO-032

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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.

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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

6.1.1.3 Meeting 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
- h) Presents the witness activities which will be carried out according to the assessment plan

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- 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
- l) 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, measurements 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 visit may be interrupted due to conditions including but not limited to the followings:

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

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- 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.

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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.

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 DPA's Director of Accreditation Department.


6.1.1.4 Closing meeting

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

The authorized person of the CAB is asked to put his/her signature that she/he accepts the nonconformities and suggestions by the assessment team. Where CAB refrains from signing the nonconformities and the suggestions of the assessment team, explanation is given that DPA will decide about the issue. CAB can apply for explanation to DPA.

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.

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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 explanation 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.

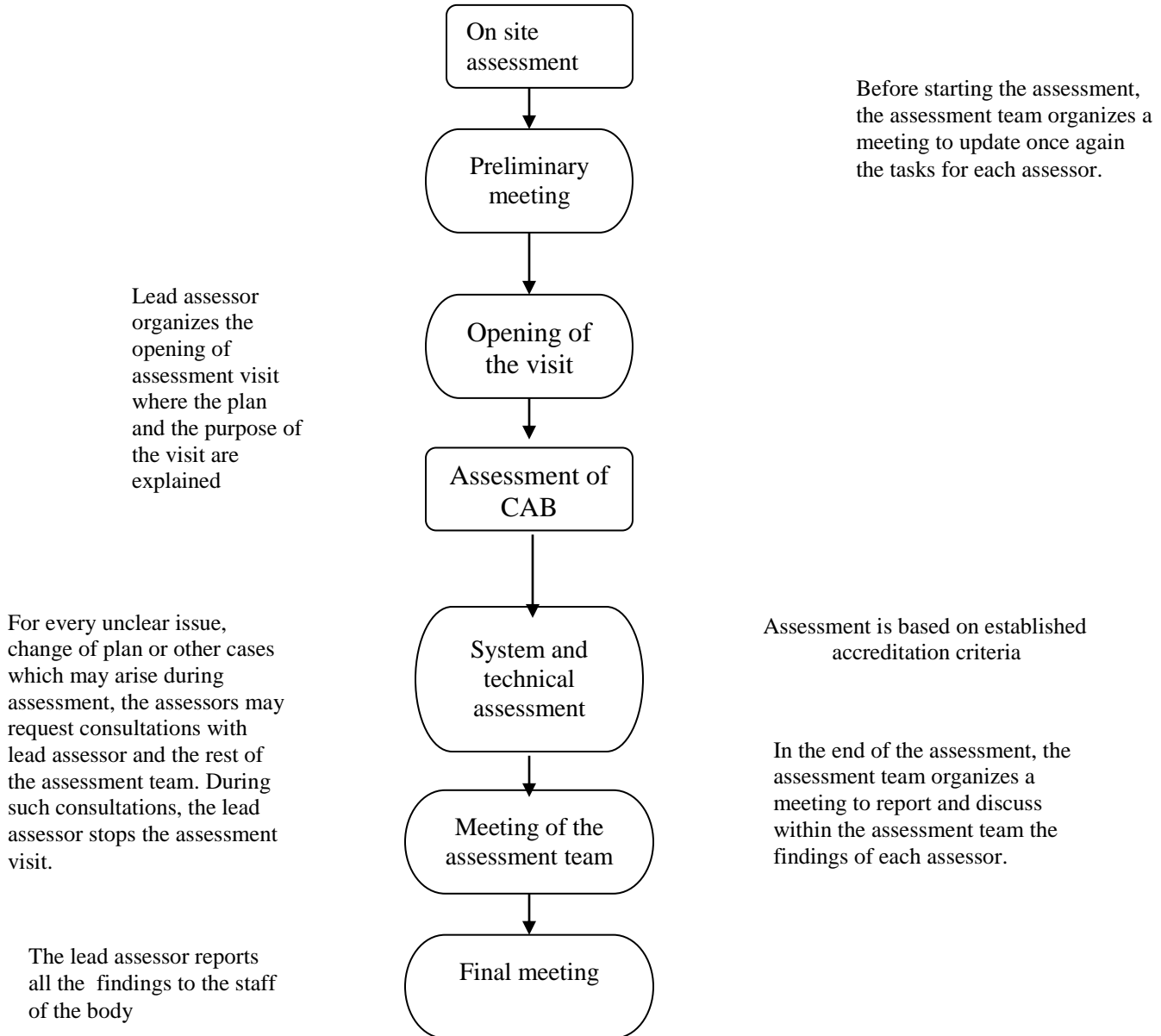
In case of initial accreditation/extension and reaccreditation, the assessed CAB shall provide DPA with the evidences of the corrective actions and improvements no later than five months. In case of surveillance, the deadline for providing the corrective actions and improvements is two months.

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 Accreditation Department 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 Accreditation Department can approve this extension or not. The extension cannot last more than one month if it is justified.

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7. DIAGRAMME



8. REGISTRATIONS

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Title of document	Who fills it in	When	Who maintains
Forms of assessment DA-FO-001, DA-FO-013 DA-FO-003 DA-FO-004, DA-FO-013, DA-FO-048, DA-FO-049 DA- FO – 063	Lead assessor	After the assessment	Director of Accreditation Department

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 in 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 approval	3	B. Pani	Paragraph 6.5 on assessment visit to bodies established in many locations
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.
20.05.2019	5	B.Xhafa	Changes are based on the new standard ISO 17011:2017.