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POLICY ON ASSESSMENT

DAK-PO-02

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CONTENTS

1. SCOPE

This document describes the assessment policy of the Kosovo General Accreditation Directorate (DAK) regarding the assessment of Conformity Assessment Bodies (CABs), such as testing, calibration, medical laboratories, and certification bodies for the certification of products, processes and services (product certification bodies).

2. REFERENCES

Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.

3. RESPONSIBILITIES

This policy applies to internal and external personnel of DAK involved in accreditation (assessors and experts of PC/AC/TC) and DAK clients (CABs accredited or seeking accreditation from DAK).

4. GLOSSARY AND ABBREVIATIONS

4.1. Glossary

For the purpose of this Policy, the terms and definitions given in ISO/IEC 17011:2017 standard apply.

Finding: result of the evaluation of evidence collected against accreditation criteria. A finding may indicate conformity or non-conformity.

Evidence: records, statements of fact, or other information, which are relevant to the criteria and verifiable.

Conformity: fulfilment of a requirement.

Non-conformity: non-fulfilment of a requirement.

Witnessing: observation by DAK of a CAB performing conformity assessment activities within the scope of accreditation.

4.2. Abbreviations

A	Assessor
CAB	Conformity Assessment Body
DAK	Kosovo General Accreditation Directorate
PC	Professional Council
AC	Accreditation Council
TC	Technical Committee
LA	Lead Assessor
TA	Technical Assessor
PCB	Product Certification Body

5. DESCRIPTION OF THE POLICY

When, during the assessment of the technical competence of a conformity assessment body, it is found that one or more accreditation criteria are not fulfilled, DAK formulates one or more non-conformities. The absence of documented procedures, or failure of the CAB to carry out processes in accordance with its own defined procedures, will also be considered a non-conformity. A non-conformity may also be identified when the CAB does not comply with rules established by DAK. Non-conformities may be identified as a result of:

- CAB documentation not in compliance with the requirements of the standard.
- CAB personnel not following documented procedures.
- CAB personnel demonstrating lack of competence for the work they perform or are authorised to perform.
- Operational procedures such as measurement and testing methods, measurement traceability, method validity, etc., showing deficiencies in technical validity.
- Non-functioning of the CAB's management system.
- CAB not complying with rules established by DAK.

Comments are findings formulated by DAK on opportunities for improvement of conformity assessment activities carried out by the Conformity Assessment Body within the accreditation programme.

Actions taken by DAK as a result of non-conformities: If the file manager or assessment team identifies non-conformities during document review, they are formulated in the appropriate forms. If the assessment team identifies non-conformities during assessment visits or pre-assessment visits, they must be formulated at the closing meeting of the visit (on-site or remote) according to form PT-01-F09 and presented to the Conformity Assessment Body. A copy of the non-conformities is

handed to the assessed CAB. If the non-conformity is formulated after the visit, it must be written in the assessment report. Form PT-01-F09 (Part a) for non-conformities formulated after the closing meeting is sent to the CAB together with the assessment report and the relevant explanation. If the CAB refuses to sign the non-conformity identified by the assessment team during the assessment or pre-assessment visit, the Director of Accreditation and Development Directorate (DADD) decides whether the finding is a non-conformity or not, or determines the correct formulation of the finding. For each non-conformity identified during the assessment visit or recorded in the report, the CAB must carry out a thorough root cause analysis, extended analysis and impact assessment of the non-conformity, the actions (correction, corrective action) taken or planned to resolve the non-conformity, and the timeframe for implementation. The assessment team analyses the root cause analysis, extended analysis and impact assessment, and the actions proposed by the CAB. If the analyses and proposed actions are not sufficient or appropriate, the assessment team requires the CAB to re-perform the root cause analysis, extended analysis and impact assessment, and propose appropriate actions based on the new analysis. The CAB is obliged to send all records of actions taken to DAK. The adequacy and sufficiency of the actions taken by the CAB will be evaluated by the assessment team either through review of records or during an assessment visit, or through a combination of both. Before issuing a recommendation for accreditation in the case of initial accreditation or extension, or a recommendation for maintenance of accreditation, all identified non-conformities must be resolved. Failure to resolve non-conformities in initial accreditation or extension leads to rejection of the accreditation application or non-extension of the accreditation programme. Failure to resolve non-conformities identified in surveillance visits (planned or unplanned) leads to reduction, suspension or withdrawal of accreditation.

The assessment team may also formulate comments in areas of possible improvement, which must be delivered to the Conformity Assessment Body either at the closing meeting or written in the assessment report. In formulating comments, the assessment team must be careful not to provide recommendations for specific solutions. Regarding comments formulated, DAK does not expect the CAB to submit records of actions, but they will be evaluated in future visits as opportunities for improvement.

5.2 Assessment Techniques

To carry out its assessment activities, DAK may use the following assessment techniques:

a) document review

b) file review

c) witnessing

d) interviewing

e) review of performance in proficiency testing and other interlaboratory comparisons.

5.2.1. Document Review

The assessment team reviews the documentation (e.g. quality manual, procedures, policies, etc.) submitted by the CAB and evaluates its compliance with accreditation requirements.

5.2.2. File Review

The assessment team reviews the current files of the CAB related to conformity assessment activities to be accredited or already accredited (e.g. records, data analysis, reports) in order to verify the effective implementation of requirements for the CAB's work.

5.2.3 Interviewing

An interview is essentially a structured conversation in which the assessment team member asks questions regarding the CAB's performance within its scope of accreditation, and the CAB staff provide answers.

Interviews are usually conducted face-to-face during the on-site assessment, but may also be organized by telephone or video conference.

5.2.4 Witnessing

During witnessing, the assessment team observes the CAB performing conformity assessment activities within its scope of accreditation.

The objectives of witnessing during the assessment of a CAB are:

- verification of the implementation of CAB procedures and forms;
- verification of the effectiveness of CAB procedures;
- verification that conformity assessment activities undertaken by the CAB are effective, taking into account accreditation criteria and requirements;
- contributing to obtaining a representative sample for the assessment of CAB competence; and
- supporting a recommendation for granting, maintaining, suspending or withdrawing accreditation.

When planning the witnessing of personnel performing conformity assessment activities, it is necessary to take into account the complexity and risk level of different types of conformity assessment activities, as well as the frequency with which they are performed, the required competence level of personnel performing testing, calibration or inspection, the total number of employees and newly hired personnel, the CAB's training system, and the effectiveness of the CAB's internal staff monitoring programme.

Conformity assessment activities are usually witnessed at the CAB during on-site assessment. Where witnessing is conducted separately from the on-site assessment, the CAB must agree the witnessing

date with DAK at least one month in advance, to allow DAK to secure the necessary resources for conducting the witnessing.

The decision on which conformity assessment activities and CAB staff are to be witnessed during the assessment is made by the Lead Assessor in consultation with the relevant member of the assessment team (technical assessor, technical expert). In cases where the CAB does not agree to make the witnessing possible (including when the CAB's client refuses to permit witnessing), DAK will not be able to accredit the CAB for the specific conformity assessment activity.

5.2.4.1 Witnessing of Testing and Calibration Laboratories

During the 4-year accreditation cycle, all test/examination/calibration methods within the scope of accreditation will be witnessed in a representative manner (the principle of the selected method or groups of methods is a key indicator for choosing the representative method for witnessing, see below).

During accreditation and re-accreditation, the entire scope of accreditation (requested or accredited) is assessed (in combination of file review and witnessing), and for each surveillance, 1/4 (one-quarter) of the scope of accreditation is assessed (including witnessing).

If the CAB requests re-accreditation, the last surveillance becomes a re-assessment and the entire scope will be assessed: with witnessing assessments (covering the remaining 1/4 [one-quarter] of methods from the last surveillance) and file review.

The selection of tests, calibrations and inspections to be witnessed is made by the Lead Assessor in cooperation with technical assessors/technical experts. Criteria for selecting witnessing include at least:

- importance and complexity of tests/calibrations;
- competence of authorised persons to perform them;
- environmental conditions and methods chosen to perform the tests, calibrations, and inspections;
- unsuccessful participation in interlaboratory comparisons;
- changes in staff, methods and environmental conditions;
- non-conformities raised during previous assessments.

At least one methodology for each measurement principle in the scope of accreditation must be included in a laboratory.

DAK has the right to increase the number of tests/examinations or calibrations to be witnessed if there is evidence at any time indicating that the laboratory may not be competent to perform its technical activities.

5.2.4.2 Witnessing of Inspection Bodies

The selection of inspections to be witnessed depends on the following criteria:

- experience and qualification of the inspector
- geographical locations
- required extent of technical judgement
- previous witnessing inspections
- on-site assessment results
- any complaint received
- scheme requirements.

For accreditation and re-accreditation, the entire scope is assessed (by file review and/or witnessing). All accredited inspections must be witnessed within one accreditation cycle.

The number of inspections to be witnessed is determined by DAK based on:

- fields and types of inspection
- main locations of the inspection body
- required extent of technical judgement
- number of inspectors
- frequency of inspections
- required competence of inspectors (e.g. professional certification).

DAK has the right to increase the number of inspections to be witnessed if there is evidence at any time indicating that the inspection body may not be competent to perform its activities.

In the case of inspection, at least one witnessing must be carried out for each inspection area included in the CAB's scope of application.

5.2.4.3 Witnessing of Product Certification Bodies

Witnessing of PCB activities may be carried out on dates separate from the on-site assessment, depending on the availability of the PCB's client and the planned activities related to certification.

In PCB, witnessing focuses on activities of product, process and service evaluation. These may be performed as audits, inspections or testing. From the witnessing, a separate report is prepared (PT-01-F10-4-1).

5.2.4.3.1

During witnessing of system audits, the main attention should be directed to the applicable parts of ISO/IEC 17021-1:2015 standard, namely:

a) Preparation for evaluation of product processes and services (determining audit duration, sampling from multiple sites, planning evaluation activities, distribution of tasks within the evaluation/audit team, communication with clients, suitability of evaluation/audit with procedures, forms, necessary information from previous evaluations/audit activities);

b) Conducting evaluations/audits (opening of the evaluation/audit, audit performance, compliance with documented procedures/standards for conducting evaluation/audit activities, personal conduct, record keeping, handling of previous findings, closing of evaluation/audit activities, reporting);

During witnessing of inspection activities, the relevant requirements of ISO/IEC 17020:2012 standard must be taken into account, including competence of persons performing inspections, preparation for inspection, covering necessary information for certification purposes, conducting the inspection and reporting, etc.

During witnessing of testing activities, the relevant requirements of ISO/IEC 17025:2017 standard must be taken into account, including competence of persons performing testing, sampling, metrological traceability, ensuring validity of results, reporting, etc.

5.2.4.3.2

During initial assessment, one witnessing is carried out for the relevant certification scheme/module/system identified in the requested scope of accreditation. During re-assessment, witnessing is carried out for at least one certification scheme/module/system, other than those witnessed during the previous assessment. During extension of the scope of accreditation, witnessing is carried out for each relevant certification scheme in the field of activities subject to extension. During surveillance(s), witnessing is carried out for each relevant certification scheme.

The relevant certification scheme is the one that includes evaluation activities performed by PCB personnel at the product manufacturer. In the case of different certification schemes that include the same evaluation activities, witnessing is carried out only for one selected scheme.

5.2.4.3.3

Evidence within sector-specific certification schemes:

- GLOBALG.A.P. - witnessing is carried out in accordance with Art. 2.3 Integrated Farm Assurance Standards, General Regulations, Part III,

- Organic production according to EA-3/12 - witnessing is carried out according to the requirements of EA-3/12 M policy.

For other schemes/modules/systems, there are no specific requirements.

5.3 Accreditation of Opinions and Interpretations

DAK does not accredit opinions and interpretations related to testing, calibration or inspection.

In case the CAB's test report includes opinions and interpretations, they shall be clearly marked as not covered by accreditation.

For medical laboratories, opinions and interpretations related to examinations and examination results are considered an integral part of demonstrating their competence.

5.4 Accreditation for a Flexible Scope

DAK does not offer accreditation with a flexible scope.

5.5 Number of Assessment Days

5.5.1 General Rules

The number of assessment days for a given type of accreditation (i.e. initial accreditation, extension of the scope of accreditation, surveillance, re-accreditation) depends on the scope of accreditation, number of locations and size of the CAB.

Assessment days cover different types of assessment techniques (e.g. on-site assessment, remote assessment, witnessing, document review, file review, audits, performance review in proficiency testing, interviewing, unannounced visits).

An integral part of assessment for granting or maintaining accreditation is observing (or witnessing) of CAB performance to obtain objective evidence that it is competent to perform conformity assessment activities. The number of witnessing must be representative of the requested or granted scope of accreditation. Criteria for determining the number of days for witnessing conformity assessment activities may include the following:

- complexity of conformity assessment activities;
- conformity assessment activities with potential to pose risks;
- relationship between standard and non-standard testing/calibration methods (e.g. user specifications, internal methods developed by the CAB for testing/calibration) or inspection methods;
- relationship between observing of conformity assessment activities and checking of reports/certificates and validation of records, quality control records and/or inspection of testing equipment;
- frequency of conformity assessment activities performed;
- complaints lodged against the CAB's work for specific conformity assessment activities.

If testing, calibration or inspection in the requested/granted scope of accreditation is performed at multiple locations, all locations where key activities are carried out (e.g. policy formulation, method and/or procedure development, contract review, planning of conformity assessment activity, performance of conformity assessment activity, review and approval of results, decision-making on results of conformity assessment) must be assessed during initial accreditation. During the accreditation cycle, all locations belonging to testing, calibration or inspection where key activities are carried out must be assessed at least once. Selection of locations to be assessed depends on results of previous assessments.

In addition to the number of assessment days, assessment team members are reimbursed for pre- and post-assessment activities, such as:

- pre-assessment activities: preparation for assessment, including review of applicant documentation and preparation of the assessment plan,
- post-assessment activities: reporting on assessment results, updating the assessment programme, evaluation of applicant corrective actions, preparation of documentation for decision-making.

The number of assessment days takes into account the assessment days of all members of the assessment team, i.e. Lead Assessor (team leader), technical assessor(s), assessor(s) and technical expert(s) assigned to the assessment team. Technical experts appointed to the assessment team may work only under supervision during assessment, and therefore, for this activity DAK appoints additional assessors to the team. Assessment days of supervising assessors are additional to the number of assessment days defined below.

Administrative Instruction (MTI) No. 01/2021 on Setting Up Tariffs and Fees for Accreditation regulates the assessment fee per hour. DAK usually calculates that

1 assessment day is equal to 6 hours.

This DAK practice is taken into account for determining the assessment days below.

5.5.2 Number of Assessment Days for Testing Laboratories, Medical Laboratories, Calibration Laboratories, and Inspection Bodies.

The number of assessment days for testing, medical, calibration laboratories and inspection bodies is calculated based on the number of test/examination/calibration methods/techniques and the number of technical areas/sub-areas defined in PO-03 Annex 1 Accreditation Criteria and Activities.

The table below provides the required number of evaluation days for initial accreditation, extension of the scope of accreditation, and surveillance assessment.

Table 1 - Number of Assessment Days

	On-site visit	Audit with evidence	Selection methods
Management system assessment	Initial assessment/reassessment At least two days Surveillance: At least one day Extension: At least 1.5 days	N/A	N/A
Technical assessment	Initial assessment/reassessment At least one day per assessor	At least one day or more depending on the complexity of the method/procedure/scheme	Initial, extension and reassessment: each grouping/material/certification scheme will be assessed

	Surveillance: At least one day per assessor Extension: At least one day per assessor		During the accreditation cycle, each technical field/each technique/each inspection object/each certification scheme will be assessed at least once For CABs with multiple locations Initial/extension/reassessment: all sites where key activities are performed and locations

5.5.4 Number of Assessment Days for Product Certification Bodies

The number of assessment days for product certification bodies is calculated based on the number of product/process/service groups to be certified, as defined in PO-03 Annex 1 Activities and Accreditation Criteria.

Table 4 provides the necessary number of assessment days for initial accreditation, extension of the scope of accreditation, re-accreditation, and for surveillance assessment.

When extension of the scope of accreditation is carried out during surveillance assessment, a minimum of 50% of the assessment days calculated according to Table 4 for extension of the scope of accreditation are added to the number of surveillance assessment days.

Table 2 – Number of Assessment Days

	Initial Accreditation & Extension of the Scope of Accreditation	**Surveillance Assessment**	**Re-accreditation**
Number of Assessment Days	2,5 days + 0,5-1 for each product/process/service group	1,5 days + 0,5-1 for each product/process/service group	1-2 days + 0,5-1 for each product/process/service group

When the product certification body has multiple office locations, the base number of assessment days for the planned sites to be assessed will be increased by DAK.

For witnessing, at least one day is planned separately from the on-site assessment (the number of days depends on the range of necessary assessment activities).

Considering the factors listed in point 5.5.1, a deviation of ±20% from the number of assessment days presented in the table may be determined by DAK.

5.5.5 Number of Assessment Days for Pre- and Post-Assessment Activities

For pre- and post-assessment activities of assessment team members, the following days are added to the number of assessment days defined above:

Type of Assessment	Number of Days for Pre- and Post-Assessment Activities			
	Lead Assessor	**Technical Assessor**	**Assessor**	**Technical Expert**
• **Initial Accreditation** • **Extension of the Scope of Accreditation** • **Re-accreditation**	0,5 day (6 hours)	0.5 day (3 hours)	0.3 day (2 hours)	0.5 day (3 hours)
Surveillance Assessment	0.5 day (4 hours)	0.3 day (2 hours)	0.2 day (1 hour)	0.3 day (2 hours)

6. Risk Analysis

DAK will take into account risks related to activities, locations and persons when planning assessments, surveillances and re-accreditations of CABs. Risk analysis is recorded according to forms: DAK-PT-01-F18 for testing laboratories and DAK-PT-01-F19 for inspection bodies.
Risks related to assessment include:

1) Risks related to activities included in the scope of accreditation:
Complexity of CAB activities and their management system (suitability and effectiveness of the management system)
Nature of the accreditation scope in different technical fields (e.g. matrix/product/testing technique/medical examination/calibration, certification schemes and inspection fields). Activities assessed must be within the scope of accreditation.
Technological and legislative changes affecting selection during assessment
External services (subcontracting) for some activities included in the scope of accreditation.

- For laboratories: Impact resulting from the use of test/examination/calibration results, including health and environmental risks; metrological traceability including the lack of certified reference materials and internal calibrations; and participation in proficiency testing/external quality assurance schemes for results.

- For certification bodies: Risks related to impartiality and conflicts of interest such as organization of training and consultancy by the certification body.

- For inspection bodies: risks related to impartiality and independence of the inspection body, competence of personnel for specific inspection activities, complexity of inspection methods and facilities, use and traceability of inspection equipment, and impact of inspection results on safety, health, property and environment, subcontracting of inspection activities, and consistency in implementation of procedures and reporting of results.

2) Risks related to locations covered by the scope of accreditation, such as:
- Size and number of locations, locations outside the territory of Kosovo,
- Activities from the scope at each location such as different testing/calibration/certification/ inspection fields, total number of activities, high volume of activities, low frequency of conformity assessment activities.
- Number of new locations compared to old ones.
- Cross-border activities

3) Risks related to CAB personnel
- Experience and knowledge of technical staff;
- Turnover and changes of technical staff;
- Sufficient number of staff;
- Legal requirements regarding staff.

4) Results from previous assessments and status of effectiveness of corrective actions (if applicable)

5) Sector-specific aspects: e.g. legal requirements included in the certification scheme, mandatory documents (decisions, etc.)

6) Other aspects include:
- Number of complaints regarding CAB activity;
- Requirements of standards, mandatory documents (EA, ILAC and IAF documents) and decisions;
- Availability of competent and impartial assessors;
- Results of findings from previous assessments with evidence and vertical audits.

7. ANNEXES

Not applicable

8. RECORDS

Not applicable

9. HISTORY

Date of Edition	Prepared by	Description of Changes Applied
02.12.2015	Ibush Luzha	New document
11.03.2016	Ibush Luzha	Articles 3.1.1; 3.1.2; 3.1.3
15.11.2019	Valmira Sejdiu	Full revision to align with ISO/IEC 17011:2017 and DAK-PM-01
19.05.2021	Valmira Sejdiu	Revision to align withISO/IEC 17011:2017 and DAK-PM-01
25.02.2026	Valmira Sejdiu	Revision in accordance with ISO/IEC 17011:2017 and DAK-PM-01, addition of point 6