AKREDITIMI I KOSOVËS
ACCREDITATION OF KOSOVO

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PROCEDURE FOR ACCREDITATION

DAK-PT-001

APPROVED BY,
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CONTENTS

1. PURPOSE

This procedure describes the activities undertaken by DAK for carrying out the accreditation process.

2. SCOPE

This procedure is applied in all cases when there are requests for initial accreditation, surveillance, extension and renewal of accreditation by the Conformity Assessment Bodies (CAB) as well as in cases of withdrawal, suspension, reducing of accreditation.

Remark: DAK, in accordance with the European recommendations does not recognise and perform the accreditation of laboratories that only perform sampling or sample processing and not its testing.
The opinions and interpretations made by laboratories are not covered by accreditation and the laboratories shall mention that in the testing report.

3. REFERENCES

SK EN ISO/IEC 17011:2014- General requirements for the accreditation bodies that perform the accreditation of the conformity assessment bodies.

4. RESPONSIBILITIES

The responsibilities of the positions involved in the control of documents are those described in chapter 6 below.

5. GLOSSARY AND ABBREVIATIONS

For the purposes of this document the terms and definitions given in standard SK EN ISO/IEC 17011:2014, SK ISO 9004:2007.

The abbreviations used in this procedure are the following:
DAK – Directorate for Accreditation of Kosovo
GD – General Director of DAK
DADD – Director of Accreditation and Development Direction
LA – Lead Assessor
TA – Technical Assessor
As – Assessor
Ex - Technical Expert
DMF – Decision Making File

6. DESCRIPTION OF THE PROCEDURE

6.1 Application for accreditation

The application, form PT-001-F01 (PT-001-F01-1, for Testing Laboratories, PT-001-F01-2 for Calibration Laboratories and PT-001-F01-3 for Inspection Bodies), and the related records and documents submitted by CAB, is registered in the Protocol Book, form PT-001-F02, by the File Manager who checks if all the forms have been submitted and the application fee was paid, according to Administrative Instruction no. 04-2013 Accreditation fees.
The File Manager review for adequacy the information supplied by the CAB.

6.2 Application review

The File Manager reviews the application (using the part B of application) in order to check if DAK:

- is able to carry out the assessment of the applicant CAB, in terms of its own policy (is within its declared accreditation activities),
- has the necessary competence available (suitable assessors and experts),
- has the ability to carry out the initial assessment in a timely manner.

In case any of the above mentioned aspects are not fulfilled, File Manager addresses the issue in an e-mail to DADD requesting its involvement for solving the problem.

In case a qualified technical expert is not available, in exceptional circumstances, qualified technical experts from abroad will be considered.

In case is not possible to fulfil any of the aspects, DADD informs the File Manager by e-mail. File Manager informs e-mail the CAB that the application is not accepted and the reasons for not acceptance. File Manager sends to the CAB part B of the application.
If all the aspects are fulfilled the application is accepted and the accreditation process continues.

6.3 Cost estimates and Accreditation contract

6.3.1 The File Manager makes a cost estimate which includes: pre-assessment visits, assessment visits and issuance of certificates, in accordance with the fees foreseen in the Administrative Instruction no. 04/2013 and sends it to the CAB.

The deadline for the approval or disapproval of the cost estimate by the CAB is 15 working days. After this date, the accreditation process is stopped. In such case, the documentation of the CAB is archived according to the procedure DAK-PM-002.

If the CAB agrees with the cost estimate, the contract is signed by CAB and DAK, form PT-001-F03.

6.3.2 The accreditation contract, form PT-001-F03, contains the rights and obligations of DAK and CAB.

6.4 Appointment of Lead Assessor

The File Manager informs DADD by e-mail the name of the proposed Lead Assessor of the assessment team and awaits his approval.

File Manager informs the Lead Assessor on the appointment by e-mail.

6.4.1 Preliminary visit

Preliminary visit is carried out by the Lead Assessor who analyzes the documents and may decide if a preliminary visit is necessary in order to clarify some aspects that aren't clear or can't be assessed from documents. In this case LA sends an e-mail to CAB to request their agreement, specifying the date and the purpose of visit.
The preliminary visit is optional and the CAB has the right to decline the preliminary visit.
The purpose of this visit is to assess if the CAB is ready for the assessment by inspecting facilities and equipment and verifying that essential elements of the applicable accreditation standard(s) are in place.

6.4.2 LA reports on all the deficiencies found during the preliminary visit, if the case. The conclusions are notified by official letter to the CAB, using the form PT-001-F04 Notification of preliminary visit conclusions.

6.4.3 If during the preliminary visit major deficiencies in the system of the applicant CAB are identified, the LA may propose, in consultation with the DADD, to stop the accreditation process.
The decision to stop the accreditation process is taken by the Director General of DAK and CAB is informed by official letter about the decision by the File Manager.
If the found deficiencies are not major the accreditation process continue with document and records review.

6.5 Appointment of assessment team

6.5.1 The File Manager sends to DADD by e-mail, the proposed assessment team.
If DADD agrees with the team composition send his approval for the respective team by e-mail to File Manager.
If DADD does not agree with the team composition makes the necessary changes and sends it by e-mail to the File manager. The members of the assessment team are chosen by DADD from the List of DAK's assessment personnel, PM-003-F03.

6.5.2 File Manager, based on DADD approval, informs the CAB on the assessment team composition using form, PT-001-F05. The approval of the assessment team may be done by the CAB electronically.

If the CAB agrees with the team composition, the accreditation process continues.
In case CAB does not accept or partially accepts the assessment team it shall give the reasons which will be judged by the File Manager together with DADD. If the justification is accepted, other qualified assessor will be appointed.
The final decision on the assessment team composition is made by the DADD in case the CAB has not agreed with the assessment team composition the second time.

6.5.3 The assessment team declares if there are any conflicts of interest with the CAB under assessment and they shall sign the confidentiality agreement, impartiality and conflict of interest PM-003-F04.

6.6 Document and records review

6.6.1 The appointed assessment team assesses all documents and records submitted by the applicant. All the members of the assessment team shall provide their findings to the Lead Assessor.

In case there are any findings the assessment team reports those to the CAB as non-conformities without classifying them, using form PT-001-F06 Notification of document review conclusions.

6.6.2 CAB is requested to solve the non-conformities and to send to DAK the reviewed documentation within at maximum 15 working days months since the non-conformities were sent by DAK.
The accreditation process shall continue after the revised documentation is accepted by DAK as to fulfill the requirements of the applicable standard.

6.6.3 The Lead Assessor can propose not to continue with the accreditation process of the CAB based on the found non-conformities. The decision to stop the accreditation process is taken by the Director General of DAK and CAB is informed by official letter about the decision by the File Manager.

6.5.4 In case the CAB does not send the revised documentation within the deadline established by DAK, the accreditation process shall be stopped and CAB is informed. The decision to stop the accreditation process is taken by the Director General of DAK and CAB is informed by official letter about the decision by the File Manager. The process can be resumed only by a new application submitted by CAB.

6.7 Assessment

6.7.1 The File Manager sends the documentation of the CAB to the assessment team members prior to the date of the assessment.
The Lead Assessor prepares the assessment plan, form PT-001-F07, and establishes the tests/calibrations/inspections to be witnessed during the on-site assessment (carried out at office or at CAB's client) taking into account the Policy on assessment, code DAK-PO-002.
The assessment plan is sent to the CAB together with the Notification on the assessment team composition, form PT-001-F05 with 5 working days in advance of the date of assessment.
The purpose of the assessment visit is to assess whether the CAB meets the requirements of the respective standard(s) and that the CAB is competent to perform the activities included in the requested scope of accreditation.
During the assessment visit the laboratory competence is assessed taking into account DAK policies on traceability of measurements, PTs, use of accreditation symbols etc.

6.7.2 The assessment visit includes the following steps:

6.7.2.1 Initial meeting of the assessment team chaired by the Lead Assessor
The initial meeting is done to discuss the assessment visit details and to assign the duties amongst the assessment team members. The meeting is chaired by the Lead Assessor. During this meeting the duties of each assessor and any new information are explained.

6.7.2.2 Opening the meeting with the management of the CAB chaired by the Lead Assessor
The Lead Assessor is chairing the opening meeting, describing the way the assessment is going to be carried out and ensure the participants list is filled out in the opening meeting, PT-001-F08.

6.7.2.3 Assessment of the CAB's management system and technical competence
The assessment of the CAB's management system and technical competence against the applicable accreditation standard(s) will be performed by:

- Witnessing activities within the scope;
- Interviewing key personnel;

- Verifying quality records;
- Verifying technical records;
- Verifying personnel records.

The assessment of the CAB's management system and its implementation against the applicable accreditation standard(s) is performed by the Lead Assessor. Technical assessor(s) or experts perform the assessment of the activities within the requested scope of accreditation. Technical experts will always be accompanied by a qualified assessor.

The assessment team shall complete the applicable forms:
- Check list according to the respective standard;
- Assessment reports according to the standard requirements (form);
- Nonconformity form, form PT-001-F09.

6.7.2.4 Assessment team internal meetings chaired by the Lead Assessor
During the assessment, the assessment team will conduct internal meeting(s). An internal meeting is always conducted prior to the closing meeting. In addition, the assessment team may conduct a meeting (e.g. during lunch) to discuss the findings.

6.7.2.5 Closing meeting with the management of the CAB chaired by the Lead Assessor
The closing meeting is chaired by the Lead Assessor. The participants in the closing meeting are the DAK assessment team members and the management of the CAB.
Lead Assessor shall ensure that the participants list is filled out in the closing meeting, PT-001-F08.

During the on-site assessment there can be identified non-conformities. These are classified according to DAK Policy DAK-PO-008.

6.8 Reporting

6.8.1 Within two weeks from the assessment, the assessment team shall provide the File Manager with all the completed documents used for the assessment and the assessment report according to the CAB type:
- Assessment report for testing and calibration (PT-001-F10-1),
- Assessment report for inspection (PT-001-F10-2).

The File Manager sends the assessment report to the CAB.
The CAB has the right to send remarks and suggestions about the report within 5 working days. The Lead Assessor decides on whether to include the remarks and/or suggestions of the CAB in the report.

6.9 Follow up assessment

6.9.1 The deadline for the implementation of corrective actions in response of the non-conformities raised during the assessment is 3 (three) months from the date of the closing meeting.

6.9.2 CAB fills in the corrective actions in the non-conformity report, form PT-001-F09 and shall send it by e-mail together with the supporting evidences to the Lead Assessor.
The Lead Assessor, in cooperation with the assessment team members assesses if the CAB effectively implemented the corrective actions in order to close out the non-conformities (follow up assessment).

6.9.3 If the CAB is not able to submit the necessary evidences or the closing of the non-conformities is not adequate, the Lead Assessor proposes:

- the reducing of the scope affected by the non-conformities – for a CAB under initial accreditation;
- the suspension of the scope affected by the non-conformities – for an accredited CAB. In this case the process of accreditation can be resume by the accredited CAB by submitting a new application for extension of accreditation for the scopes that were reduced in case of an accredited body.

6.9.4 When all nonconformities are closed out, the Lead Assessor sends the corresponding records to the File Manager.
The File Manager, after receiving the records from the Led Assessor, prepares the decision making file (DMF) and fills in Summary of accreditation process, form PT-001-F11.

6.9.5 The DMF contains as a minimum the assessment report, assessment plan, assessment team composition, the accreditation application, the non-conformities and the results of the assessment that they are closed out. The DMF is send to the Accreditation Council. After reviewing the DMF, the Accreditation Council gives a positive or negative recommendation to the General Director using Accreditation Council Recommendation, form PT-001-F12.

6.10 Decision

6.10.1 The General Director, after having reviewed the DMF and based on the recommendation made by the Accreditation Council, takes the decision and fills in form PT-001-F12 to grant or not grant the accreditation of the CAB.
The General Director shall take a decision within 5 working days from the date the recommendation was made by the Accreditation Council.

6.10.2 The File Manager requests the CAB to make the final payments before the accreditation is granted.

6.10.3 If the **decision is positive,** instruction DAK–I-001 for compiling the certificate is carried out by File Manager.

6.10.4 The General Director sends the complete accreditation file to the File Manager who writes the official letter to inform CAB about the accreditation decision. General Director signs the Decision, form PT-001-F13 and Accreditation Certificate, form I-001-F01.
CAB is informed by about the decision by the File Manager.
The following documentation is sent to the CAB:

- The Accreditation Certificate, including the annex of the accreditation scope, the form I-001-F02;
- Accreditation symbol;
- Surveillance program, form PT-001-F14.

The accreditation is valid for a period of four years.

6.10.5 If **the decision is negative,** the CAB is informed of the rejection of accreditation and it is informed of its right to appeal the decision. .

6.10.6 File Manager sends the complete accreditation file, irrespective of the decision to the Quality Manager for archiving according to the procedure for record control DAK-PM-002.

6.10.7 The DAK publishes the accredited CAB in the list of accredited entities on the DAK's webpage.

6.11 Accreditation surveillance

6.11.1 During an accreditation cycle (4 years) DAK carries out 4 assessment surveillances. DAK will perform the first surveillance no later than 12 months after the initial accreditation was granted and the subsequent surveillances every year.
The last surveillance (S4) becomes reassessment in case the CAB submits the application for renewal of accreditation with 6 months in advance of the expiry date of the accreditation certificate.

6.11.2 The File Manager together with the Lead Assessor prepares the surveillance program of the CAB (PT-001-F15) for each calendar year from the time the CAB was accredited or re-accredited. The surveillance program includes the witness assessments that shall be undertaken by the accreditation body. In each accreditation cycle the full scope of the CAB will be assessed.

6.11.3 The Director of Accreditation and Development Direction appoints the assessment team that will conduct the surveillance assessment (usually the same assessment team is maintained during each accreditation cycle).

6.11.4 Before each surveillance visit DAK informs the CAB on the assessment plan and date of the visit, in order to receive its approval. At the same time, DAK sends to CAB its cost estimate.

6.11.5 The surveillance visit is conducted in a similar way as the initial assessment visit, but is less comprehensive.
During each surveillance visit, at least the following areas will be assessed:

- The effectiveness of the corrective actions taken in response of nonconformities raised during the last DAK visit
- Changes made to the management system
- Changes within the organization and/or, if applicable, the mother organization
- Changes of key personnel
- Participation in PT/ILC and the results obtained (for laboratories)
- Internal audits
- Management review
- Complaints and (if applicable) appeals
- Corrective action
- Quality control (for laboratories)
- Reporting
- Use of the DAK accreditation symbol

6.11.6 The reporting process for surveillance visit is the same as for initial assessment visits, see 6.8.

6.11.7 The corrective action process for surveillance visit is the same as for initial assessment visits, see 6.9, with the exception that for the corrective actions shall be implemented within 2 (two) months after the closing meeting.

6.11.8 The DAK General Director confirms the continuation of accreditation based on the documents provided by the assessment team, using form PT-001-F12. File Manager inform the CAB on the continuation of accreditation by e-mail.

6.12 Renewal of accreditation

No later than six months before the accreditation expires, the CAB shall file a request for renewal of accreditation to DAK if it wants to continue its accreditation. Upon receiving the request for renewal of accreditation (PT-001-F01), DAK initiates the process of renewal of accreditation which is a similar process as for the initial accreditation, with the exception that a preliminary visit is not conducted, as mentioned above.

6.13 Extending accreditation

6.13.1 The extending of accreditation is carried out similarly as the initial accreditation process.
Usually, the extension assessment is performed with the next planned surveillance visit.

6.13.2 The assessment for extending accreditation is not carried out unless the CAB is paying the invoice sent by DAK for the respective assessment.

6.13.3 The General Director may take the following decisions, based on the recommendation of the Accreditation Council:

- extending of accreditation;
- partially extending of accredited scope;
- not granting the extending of accreditation.

General Director informs the CAB on the decision, through the File Manager. In case of a negative decision the CAB shall be informed on the reasons that lead to the respective decision.

6.13.4 The extension of accreditation is granted within the same validity period of accreditation certificate issued initially.

6.14 Extraordinary visits

DAK may conduct extraordinary visits (unplanned) in cases when the continuity of the fulfilment of the requirements of the applicable accreditation standard(s) is suspected to be breached or at CAB request.
Extraordinary visits are carried out in the following situations: there are changes in the CAB's legal entity status, changes of the CAB's organizational structure or within its mother organization, changes in resources and premises, changes of the scope of accreditation, complaints from the clients or users, etc.
These additional visits are organised in the same manner as regular surveillance visits.

6.15 Suspending, withdrawing or reducing the accreditation

6.15.1 Suspending the accreditation

6.15.1.1 DAK suspends the accreditation of a CAB in the following situations:

a) at CAB's request due to temporary inability to carry out its activities under the accreditation - CAB may request to DAK to suspend totally or partially its accreditation, for a period of maximum 6 month.

In this case, the CAB requests the suspension in writing specifying:

- the scope of accreditation for which suspension is requested;
- the situations making the body to be unavailable which lead to failure in meeting the accreditation requirements;
- the necessary measures for improving the respective situation.
- date when the suspension requested by the CAB starts.

b) in the below mentioned situations, suspending a part or all the accreditation scope of an accredited CAB - for a period of maximum 6 months:

- not solving the non-conformities on time as foreseen in DAK's documents;
- following the research of a complaint;
- when the CAB does not agree with the surveillance/ extraordinary assessments, according to DAK 's established rules;
- incorrect reference to accredited status misuse of the symbol of accreditation or of the accredited status;
- the fees were not paid according to the contract.

6.15.1.2 The CAB is notified by General Director of DAK on the suspending decision. The official notification includes the accreditation scope for which the suspension was applied and the reasons for suspension, as well as the conditions for lifting the suspension.

6.15.1.3 CAB can appeal the decision on suspending the accreditation, according to DAK's Procedure on Appeals, code DAK-PM-006.

6.15.1.4 During the suspension period the CAB shall not issue any reports or certificates under accreditation and shall not make reference to its accreditation status or use the accreditation symbol for the scope for which it was suspended.

6.15.1.5 During the accreditation suspension period:

a) the expiry data of the accreditation certificate remains the same;
b) all the contractual obligations of the CAB remains in force;
c) the CAB is maintained in the list of accredited bodies which were suspended temporarily, on DAK's website, but marked as suspended;
d) the CAB shall inform its clients that the respective activities are no longer covered by accreditation.

6.15.1.6 DAK will proceed with the withdrawal of accreditation for any of the situations foreseen at 6.15.1.1 b), which were not solved within the established deadline and according to DAK's requirements.

6.15.1.7 The General Director takes the decision of suspending the CAB, on the recommendation of the Accreditation Council, based on the proposal of the LA.
General Director informs the CAB on the decision, through File Manager.

6.15.1.8. The person in charge with maintenance of DAK's website highlights in red the CAB suspension on DAK's website.

6.15.1.9. The accreditation suspension is lifted as soon as the CAB demonstrates the fulfillment of the accreditation requirements based on the evidences of solving the non-conformities which led to the decision of suspension.
The decision for lifting the suspension is made by General Director of DAK based on the recommendation of the Accreditation Council, based on the proposal of the LA.

6.15.1.10 The validity period of the certificate remains the same after the suspension is withdrawn.

6.15.2 Reducing/ withdrawing accreditation

6.15.2.1 DAK reduce or withdraw the accreditation of a CAB in the following situations:

a) at CAB's request, specifying:
   - the accreditation scope for which is requested the withdrawal /reducing of accreditation;
   - the situations leading to not meeting the accreditation requirements;
   - date when the reducing/withdrawal requested by the CAB starts.

b) in the below mentioned situations, reducing/withdrawing accreditation of an accredited CAB:
   - when the CAB does not fulfill, repeatedly, any of the accreditation requirements, as they are mentioned in the accreditation contract;
   - if the CAB could not demonstrate the solving of any situation for which was suspended;
   - in case DAK finds out that an accredited CAB provided intentionally false information or deliberately breached the accreditation rules.

6.15.2.2 The CAB is notified by General Director of DAK on the reducing/withdrawal of accreditation decision and the reasons behind the decision. The official notification includes the accreditation scope for which the reducing of accreditation was applied.

6.15.2.3 CAB can appeal the decision on suspending the accreditation, according to DAK's Procedure on Appeals, code DAK-PM-006.
Since the moment DAK took the reducing/ withdrawal decision, the CAB shall not issue any reports or certificates under accreditation and shall not make reference to its accreditation status or use the accreditation symbol for the scope for which it was reduced/ withdrawn.

6.15.2.4 The person in charge with maintenance of DAK's website:
   - publish the accreditation certificate following the reducing of accreditation;
   - withdraw from the website the accreditation certificate in case of withdrawal of accreditation.

7. ANNEXES

N/A

8. RECORDS

- PT-001-F01-Application form:
  - PT-001-F01-1 Application form for Testing Laboratories,
  - PT-001-F01-2 Application form for Calibration Laboratories and

- PT-001-F01-3 Application form for Inspection Bodies,
- PT-001-F02- Protocol Book
- PT-001-F03- Accreditation Contract
- PT-001-F04- Notification of preliminary visit conclusions
- PT-001-F05- Notification on team composition and assessment date
- PT-001-F06- Notification of document review conclusions
- PT-001-F07- Assessment plan
- PT-001-F08- Minute opening-closing meeting
- PT-001-F09- Nonconformity form
- PT-001-F10-1 Assessment report for testing and calibration laboratories
- PT-001-F10-2 Assessment report for inspection
- PT-001-F11- Summary of accreditation process
- PT-001-F12- Notification of document review conclusions
- PT-001-F13- Decision for accreditation
- PT-001-F14- Surveillance program

9. HISTORY

Date of Edition	Prepared by	Description of applied changes
3.06.2015	Banush Neziri	The entire document has been changed