National Accreditation Agency of Ukraine

Approved by NAAU Decree on № -Я

MANAGEMENT SYSTEM

Procedure "Performance of information review submitted by applicant and documents of laboratory"

1. Purpose

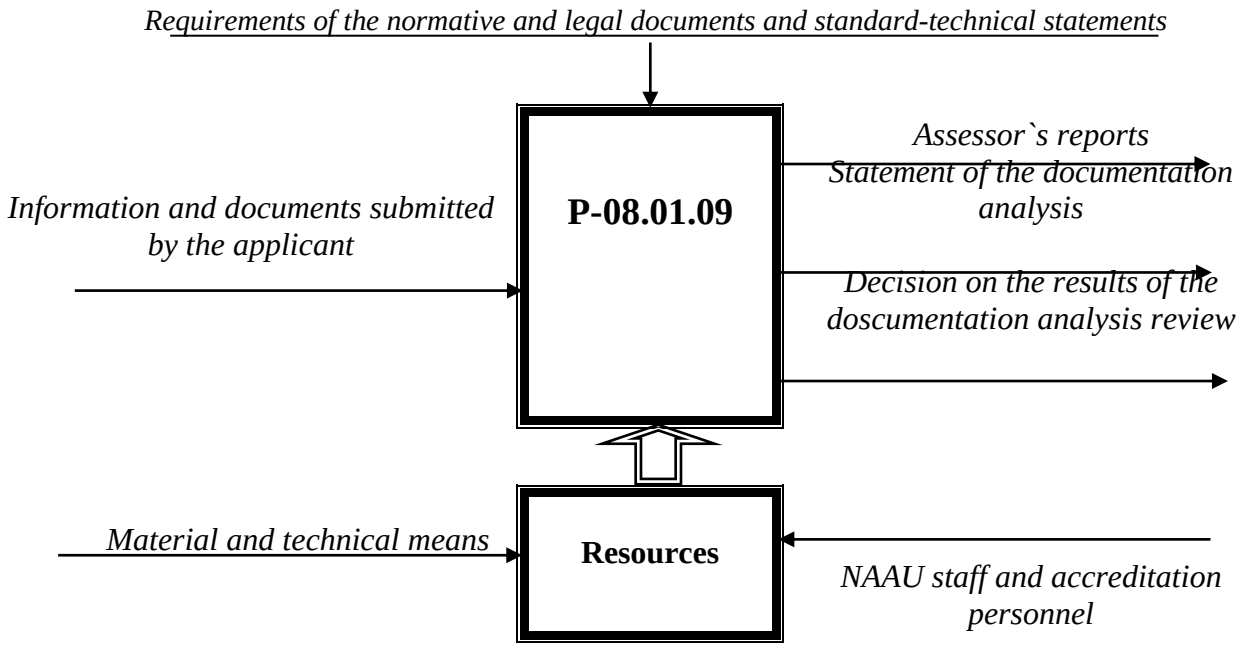
The procedure "Performance of information review submitted by applicant and documents of laboratory" (hereinafter – Procedure) is an integral part of the NAAU management system and describes the process of analyzing the documents and recorded data, which applicant submits to NAAU for accreditation, monitoring through re-evaluation, introducing changes to the accreditation provided or extension of the accreditation scope of of testing/calibration laboratory (hereinafter - the laboratory).

2. Scope

The procedure applies to the department for accreditation of conformity assessment bodies, the department for surveillance of accredited conformity assesment bodies, department of international cooperation and quality, as well as the testing laboratories accreditation personnel, involved to the CAB accreditation activities, monitoring by the means of re-evaluation, introducing changes for the granted scope of accreditation or extension of the accreditation scope of the laboratory.

3. Process description

3.1 Model of the process



3.2 General provisions

3.2.1 Flowchart of the process of the documents and information analysis (hereinafter – documents review) given in the Annex 1.

3.2.2 Main purpose of the review - enaluation of the documented laboratory management system on the compliance with the requirements of ДСТУ ISO/IEC 17025, taking into consideration requirements of international documents.

3.2.3 The review of documentation by applicant realizes by appointed assessors group on accreditation (hereinafter - the assessors group).

3.2.4 Based on the results of documents review the possibility of the furhter works is defined.

3.2.5 The following documents and registered data of the laboratory are subject to review:

- Application for accreditation;

- «Quality Manual» (hereinafter – QM) with the appropriate set of quality system documents;
- statutory documents of the applicant (Company Charter, Regulations on the TL, a copy of the certificate of the legal entity state registration and a copy of the certificate of registration as a payer of value added tax);
- laboratory passport;
- questionnaire;
- check-list;
- draft of the accreditation scope applied for;
- data validation methods;
- location data of the laboratory facilities (plan/extract/copy of the city plan);
- plan of the testing laboratory premises and adjacent spaces with a equipment;
- copies of certificates or other documents confirming leader qualification, his deputy and the person authorized to sign the protocols and signatures models;
- copies of original test reports for each of the activities.

3.2.6 During analysis conducting laboratory may asked for additional documents and information that are relevant to the CAB functioning and operating activities in accordance with its stated scope of accreditation, i.e. copies of the lease of equipment agreements,etc.

3.2.7 The process of document review conducted as follows:

- submitting documents for analysis to the team leader;
- distribution of documents among audit team members;
- verification the information about the status of laboratory-applicant;
- analysis of documents;
- drawing conclusions on the results of laboratory documents analysis;
- preparation of the decision;
- informing the applicant on the results of conducted activities.

3.2.8 The review and further storage of documents should be conducted with ensurance the protection of confidential information contained in the documents.

3.3 Receipt and transmission of documentation subject to review

3.3.1 Sector for Registry transmits the application with a set of the documents for review to the Head of department for accreditation of conformity assessment bodies aimed on laboratory documents review.

3.3.2 The responsible executor of the division on accreditation of laboratories submits the documents on a hard or electronic copy to the auditors team leader .

3.4 Distribution of documentation among the auditor team members

The assessment team leader distributes documentas with the purpose of review among the team members according to the allocation of responsibilities in the approved accreditation Program (F-08.0X.07) for the respective laboratory.

3.5 Review of the applicants data status

This review is carried out by analyzing the information contained in the statutory and other documents concerning the availability of the applicant's organizational structure and rights to manage of testing or calibration activities of the declared field of accreditation.

3.6 Documents review

3.6.1 Documents review includes: paper work review;

- documents content review
- documents technical analysis
- terminological documents analysis

3.6.2 Paper work review includes:
- review of the design of title-pages, titles, forms and columns headings of the documents;
- review of the availability of the required number of forms of documents;
- review of the availability of obligatory parts and information in the submitted documents.

3.6.3 Review of information that contains in testing laboratory documents is carried out by of representation in the documents:
- requirements of DSTU ISO/IEC 17025:2006
- general and special requirements to the accreditation of laboratories, set up by NAAU or documents of international and European organizations for accreditation.

3.6.3.1 During the review of the draft "Scope of accreditation" and "Descriptor of laboratory" the following works are carried out:
- checking the designation corectness and titles of normative documents (hereinafter – ND) on the production and testing methods/ ND on calibration methods upon the types of measurements;
- checking accuracy of description and titles of ND;
- checking the compatibility of the ND indicated in the tables of the Form 2 "Descriptor of TL" or the form 4 "Descriptor of CL" on the one hand and in the draft "Scope of accreditation" on the other;
- checking accuracy and completeness of the submitted information on the laboratories` capability to carry out testing according to the requirements of ND on production and methods of its testing/calibration MI in accordance with the procedures of calibration;
- checking level of provision the laboratory with testing facilities, measuring equipment, reference standards and industrial premises for carrying out of testings/calibration according to the "Scope of accreditation " draft;
- checking TL personnel capability to carry out testing on the basis of the data of the Form 7 "Descriptor of TL/calibration laboratory to carry out the calibration on the basis of Form 3 "Descriptor of CL";
- checking completeness and accuracy of putting down the necessary records to the appropriate forms of the submitted documents.

3.6.3.2 Review of the "Management Manual" and the check-list of the laboratory is conducted by the checking of the completeness of quality system documentation content in the extent required to the provision of quality of tests/calibrations results and compliance with the requirements of DSTU ISO/IEC 17025-2006, namely:
- It is determined on laboratory compliance with the requirements of DSTU ISO/IEC 17025-2006 (clause by clause);
- It is determined completeness and compliance of the processes description by the appropriate procedures.

3.6.3.3 During the data analysis on laboratory personnel is evaluated the adequacy of personnel with the necessary education, training, technical knowledge and experience of the functions of tests / calibrations in the declared scope of accreditation.

3.6.3.4 Review of the questionnaire is conducted in order to get the additional records about laboratory:
- Declared status;
- Form of ownership and management body;
- Availability of an own technical base and usage of leased technical basis for tests/calibrations;

- Internal structure;
- Application of the proper technical base for testing/calibration;
- Records on subcontractors;
- Work in other accreditation systems;
- Number of carried out works related with testings/calibrations during the last year.

3.6.4 Terminological analysis of documentation

3.6.4.1 Basic objects of the terminological analysis are:

- Names of products (object, material, matter etc);
- Names of testing/calibrations and characteristics (parameters) determined;
- Names and indication of physical units
- Technical terms;.

3.6.4.2 Terminological checking of documents is conducted by means of comparative analysis of objects stated in clause 3.7.1 of the given procedure and used in the submitted documents and, if necessary, in the standards on the scientific and technical terms, requirements and provisions of the laboratory accreditation documents.

3.7 Drawing up of the conclusions according to the results of documentation review

3.7.1 Decision on analysis results and possibility of accreditation extension should be based on the laboratory assessment of the following main issues:

- Status of laboratory;
- The appropriateness of the laboratory accreditation scope choice;
- Availability of personnel,
- Availability of documented procedures for testing / calibration,
- Material and technical support of testing / calibration activities.

On the basis of the abovementioned review the person who carried out review of submitted documents fills the left column of the "Cheklist" (F-08.0X.10) (in case of using) and draws up

3.7.2.3 Given mentioned above and based on the data obtained during documents reviewprocess every team member, except team leader draws up "The assessor report on review of submitted information and documents" (F-08.00.04) where introduce list of reviewed documents and observations on them in accordance with the requirements and findings of the document review.

3.7.3 Team memebers submit reposrts to the team leader on electronic media with compliance with confidentiality issues. Team leader doesn't draw up "The assessor report on review of submitted information and documents" (F-08.00.04), but draws up to "Statement on review of the documents " (F-08.00.24) where introduces list of reviewed documents and his remarks on on-site assessment after analyzing team members reports.

3.8 Formation of the laboratory documentation analysis results

3.8.1 The statement on documents review along with the assessors reports are submitted to NAAU on electronic or hard copies confidentially. The responsible executor of the division on accreditation of laboratories prepares the draft "The decision according to results consideration of the statement on documents review" (F-08.00.25).

According to the documents analysis the possibility of accreditation works continuation is determined namely the decision on the following is being taken:

- Compliance of the documents with regulatory requirements for accreditation;
- Re-analysis of documents;
- Further work on accreditation;
- The need to evaluate laboratory on site (while expanding the scope of accreditation or the amendment).

Responsibility of persons involved in the adoption of Decisions on the act of the documentation analysis (P-08.00.25) determined in p.8.2.8 of the NAAU Management Manual.

3.8.2 Responsible executor of the Division for laboratories accreditation sends to the applicant one copy of of the statement on review of documentation and one copy of the approved statement, and another copy is attached to the laboratory file.

4 The matrix of responsibility for document review process

Stages of works performance	Head of the Division for laboratories accreditation	Responsible executor	Team leader	Team member
Stage 3.3	C	T		
Stage 3.4			T	
Stage 3.5			T	
Stage 3.6			C, T	T
Stage 3.7			C, T	T
Stage 3.8			T	
Stage 3.9	C	T		

Explanations:
C – Controls execution and corectness of performance
E – Executes work stages
A – Analyses

5 Responsible for the process functioning

The Head of the division on accreditation of laboratories is responsible for the functioning of the laboratory documentation review process.

6 References

The Procedure comprises the references to the following documents:

1. ДСТУ ISO/IEC 17025-2001 «General requirements to the competence of testing and calibration laboratories»
2. ISO/IEC 17011:2004 «Conformity assessment-General requirements for accreditation bodies accrediting coformity assessment bodies»
3. IAF/ILAC A5:11/2013 “IAF/ILAC Multi-Lateral Mutual Recognition Arrangement (Arrangements): Application of ISO/IEC 17011:2004".
4. P-08.08.03 Procedure “Reception, incoming, registration of application”
5. F-08.00.04 “Assessor’s report on the analysis of documents”
6. F-08.00.24 “ Statement on review of CAB documents”
7. F-08.00.25 “The decision according to results consideration of the statement on review of documents”;
8. F-08.01.07 "Accreditation program of testing laboratory”
9. F-08.02.07 "Accreditation program of calibration laboratory”

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Annex 1

Flowchart of the basic stages of laboratory documents review

Stage	Responsible	Activity	Documents
3.3	Responsible executor	Receipt and transmission of documentation for review of the team leader	Set of laboratory documents
3.4	Assessors team leader	Distribution of documentation among team members	Accreditation program F-08.0X.07
3.5 3.6	Assessors/experts on accreditation	Technical and Terminological documentation review	Reports F-08.00.04
3.7	Assessors/experts on accreditation	Reports drafting and reports submitting to the team leader	Reports F-08.00.04
3.7	Assessors team leader	Drawing up conclusions according to the results of the review of submitted information and documents	Statement F-08.00.24
3.8	Responsible executor of the TL Accreditation Division	Drawing up decision according to the results of the review of submitted information and documents	Decision F-08.00.25
3.8	Responsible executor of the TL Accreditation Division	Submitting to the applicant Statement and Decision	Statement F-08.00.24 Decision F-08.00.25