National Accreditation Agency of Ukraine

Approved by
the Decree of NAAU
dated 24.03.2015 No 195-Я

MANAGEMENT SYSTEM

Procedure
"For carrying out an on-site assessment of a laboratory"

1. Purpose

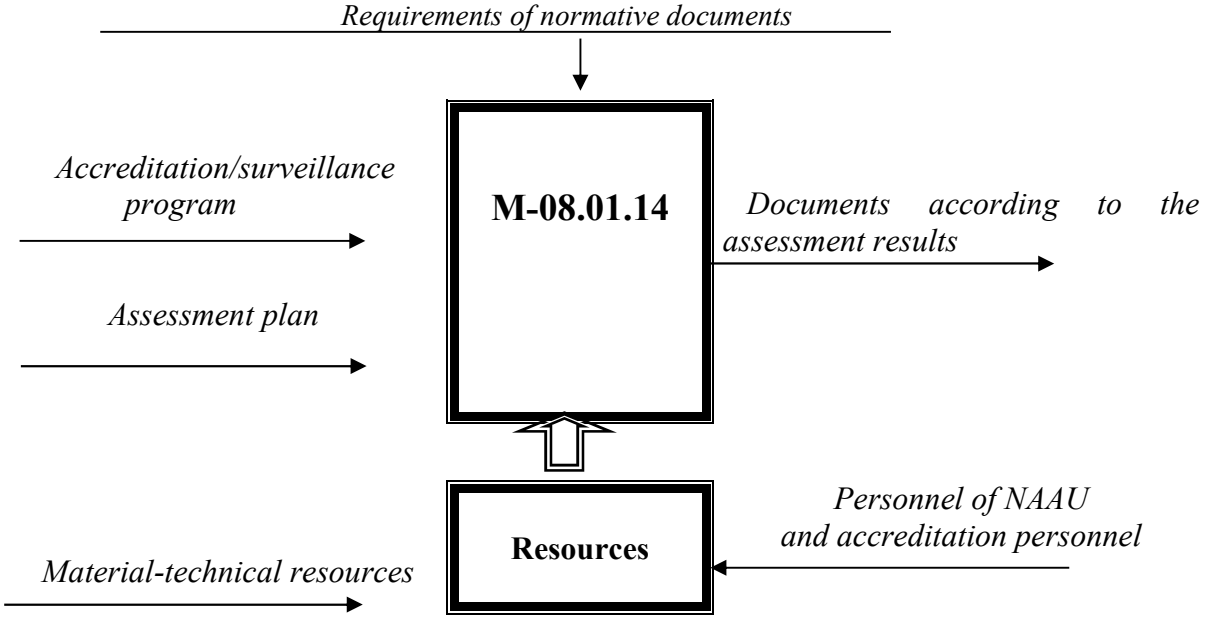
The procedure is used during on –site assessment (hereinafter – OSA) of testing laboratories (TL) and calibration laboratories (CL) (together – laboratories) with the purpose of accreditation and surveillance of accredited laboratories for compliance with a standard ДСТУ ISO/IEC 17025, while noting the requirements of IAF/ILAC A5.

2. Scope of application

The procedure applies to the NAAU Department for Accreditation of Conformity Assessment Bodies, Department for Surveillance for Accredited Conformity Assessment Bodies, Department for Quality and International Cooperation as well as accreditation personnel involved into accreditation of laboratories and monitoring by means of surveillance.

3. Process description

3.1 Model of the OSA process



3.2 General provisions

3.2.1 The main goal of on-site assessment is to determine conformity of the laboratory to the accreditation criteria.

3.2.2 As the result of on-site assessment, possibility of granting accreditation to laboratory or denial in accreditation is determined, confirmation of compliance with set requirements during surveillance after accredited laboratories as well.

3.2.3 Laboratory's denial from the on-site assessment (if NAAU wasn't informed about justified reasons on the postponement of the assessment term) or non-payment of the works on its conduction may be the reason for cancellation of the application for accreditation / temporary suspension or cancellation of the certificate on accreditation (during the monitoring through the surveillance or extraordinary assessment) according to the NAAU Policy on the unjustified delay of conducting by NAAU the accreditation activities from the side of a conformity assessment body.

3.2.4 The objects of OSA are the departments of laboratory, laboratory personnel, equipment, testing methods (measurement), methods and calibration results, premises, documentation and registered data.

3.2.5 On-site re-assessment is on-site assessment with a purpose to confirm the elimination of nonconformities and is performed by this Procedure.

3.2.6 NAAU bears full responsibility for on-site assessment, even if a team leader is not a staff employee of NAAU.

3.2.7 During the on-site assessment members of the assessment team shall use only official documents.

3.2.8 Duration and procedure of the assessment is defined by an assessment Plan.

3.3. Preparation and concluding of the contracts with the applicant and subcontractors

3.4.1. Responsible executor of the Sector for Register concludes contracts on on-site assessment with the applicant and subcontractors according to the Procedure "The order of work with contracts" (P-08.08.06).

3.4. Drawing up of the assessment plan and informing the applicant and preparation to the on-site assessment

3.4.1. Responsible executor of the Division for accreditation of laboratories or Division for surveillance for accredited laboratories (hereinafter – responsible executor) draws up an assessment plan (F-08.01.26 / F-08.02.26) with participation of a team leader that comprise preliminary coordinated dates of on-site assessment and allocation of responsibilities among assessment team members (hereinafter – assessment team) for every day of on-site assessment.

3.4.2. On-site assessment is carried out according to "Assessment Program" (F-08.01.07 /F-08.02.07) or the "Surveillance Program" (F-08.01.35/F-08.02.35) that comprise general allocation of responsibilities among assessment team members and "Assessment Plan" (F-08.01.26/ F-08.02.26).

3.4.3 Responsible executor sends 2 (two) copies of laboratory's assessment Plan (F-08.01.26 / F-08.02.26) for approval (can be realized by fax or email with further approval in the paper form by the Applicant). After approval two copies of the laboratory's assessment plan are approved in NAAU. Each member of the assessment team becomes familiar with laboratory's assessment Plan, signs it and bears responsibility for its execution.

3.4.4 For the purpose of proper preparation to OSA team leader shall receive and become familiar with relevant documents of the laboratory (Manual Management Procedures of testing / calibration and other documents of management system, statutory documents, etc.), and provide the members of assessment team all necessary documents for review prior to the beginning of work. Members of assessment team shall become familiar with the current revisions of NAAU Procedures necessary for the work of assessment team by their own on the NAAU web- site.

3.4.5 If it is needed to cover branches (remote units, divisions) of a laboratory, Assessment Plan shall determine:

a) dates of the assessment conducting of each branch;

b) sphere of the assessment for each branch;

c) members of the assessment team who verify each branch.

Criteria of planning the assessment of branches are given below in the Table 1.

Initial accreditation	Surveillance for accredited laboratory	Re-accreditation
All laboratory premises (main premise and branches), where key actions are carried out (see note to cl.7.5.7 of the ISO/IEC 17011:2004) shall be covered by the on-site assessment for each key action.	1. The main premise and selectively defined branch. 2. Each branch shall be covered by the assessment at least one (1) time during the term of the accreditation certificate validity. Thus, evaluation of branches shall be equally distributed during assessments during the cycle of accreditation.	All laboratory premises (main premise and branches), where key actions are carried out shall be covered by the on-site assessment for each key action.

3.5 Laboratory's on-site assessment

3.5.1 Preliminary meeting

3.5.1.1 Assessment team leader before the on-site assessment performs:

- final allocation of responsibilities among assessment team members and solves all uncertain matters concerning on-site assessment;
- instructions concerning the assessment order and forms of documents which are used during assessment.

3.5.1.2 On the introductory meeting members of assessment team and representatives of the laboratory shall be present, as well as representatives of an applicant and other stakeholders can be invited.

3.5.1.3 During the preliminary meeting:

- The accreditation team leader represents members of the assessment team to the top management of the laboratory;
- Review of extent and tasks of assessment are conducted;
- Short acquaintance with assessment methods, reporting, confidentiality issues and procedures applied is carried out;
- The official contacts between the assessment team and the representatives of testing laboratory are conducted;
- Availability of resources and equipment necessary for assessment team is ascertained;
- Means of information sharing and obligations of the laboratory to provide all necessary information are confirmed.
- The availability and the roles of accompanying people are confirmed;
- The information about the conditions under which the assessment may be suspended is communicate to the laboratory;
- The information about the procedure for submission of appeals concerning assessment or its conclusions;
- All issues related to the assessment plan are clarified;
- Date and time of the final meeting conducting and intermediate meetings (if necessary) of the assessment team are coordinated with the top management of the laboratory;
- Authorized representative of the laboratory conducts instruction to the members of the assessment team regarding safety rules in the laboratory.

3.5.1.4 The preliminary meeting is carried out and recorded with registration of people present on the meeting (F-08.00.11) in 2 copies.

3.5.1.5 In the course of preliminary assessment a accreditation team leader is also obliged to inform a laboratory of the necessity of filling in a monitoring form (F-09.00.08) and questionnaire (F-09.08.24) with the time-period of no more than 5 days after receipt of the NAAU's decision upon the results of assessment.

3.5.2 Review, evidence collecting and observation during assessment.

3.5.2.1 Evidence are collected by each assessor according to the "Assessment plan" by means of documents review, observation of activity of subdivisions and working environment according to the "List of control questions" F-08.00.37 and "Checklist" F-08.xx.10 (using of «Checklist» and "List of control questions" is not obligatory but can be usefull for experts involved in assessment of management system).

3.5.2.2 Laboratory management system functioning is assessed from the position of policy and practical implementation. The team members conduct assessment according to duty distribution in assessment program and plan. The lead assessor checks up main elements of the laboratory management system in accordance with the requirements of ДСТУ ISO/IEC 17025:2006 (sections 4 and/or 5). Other team members (assesors and experts) assess mainly practical implementation of technical requirements and testing methods. The lead assessor controls work of team members with the purpose to provide collection of sufficient nimber of objective evidences and proofs for cxonformance of laboratory activity to the accreditation requirements.

3.5.2.3 Sources of information can be changed according to the scope of activity and may include the following ones:

- interviews with staff and other persons;
- witnessing of activity, work environment and work conditions;
- documents (policies, objectives, plans, procedures, instructions, contracts, decrees, job descriptions, records on personnel, etc.);
- records (testing/calibrations protocols, magazines, minutes of meetings, monitoring reports, etc.);
- reports from other sources (eg. feedback from clients, other suitable information from external parties, evaluation of suppliers, etc.)
- database and web-sites.

Evidences are collected by means of horizontal and vertical audits;

- Evaluation of testing methods during on-site assessment is documented in F-08.01.33/ F-08.02.33;

- After carrying out all assessment the assessment team analyses all observations and decides what are to be formalized as nonconformities;

- Nonconformities are drawn up according to the "Protocol of nonconformity F-08.00.38 in two (2) copies;

- Nonconformities are recorded also even when they are not covered by the list of questions;

- During the assessment, if it promotes the optimal decision of tasks and is coordinated with the management of laboratory, the team member can make changes to allocation or responsibilities and assessment plan. In this case the assessment team leader shall document these changes in the annex to assessment plan with his signature and acquaintance team members and management of the laboratory with them.

3.5.2.4 In case of appearance of doubts concerning nonconformity the lead assessor shall address to NAAU for the clarifications.

3.5.2.5 In order to ensure the effectiveness of the assessment the lead assessor before the final meeting must conduct at least one interim meeting. During the interim meetings (for example, at the end of the day) assessors share the information that has been collected, analyze it and a team leader makes decision on possible changes in the assessment Plan, document these changes in the annex to assessment plan with his signature and acquaintance team

members and management of the laboratory with them.

3.5.3 Final meeting

3.5.3.1 At the final meeting should be attended the members of assessment team and the representatives of the laboratory. Also at the final meeting may be invited the representatives of the applicant and other parties.

3.5.3.2 Final meeting is carrying out under the chairmanship of the lead assessor for the presentation of on-site – assessment's results in such way that the representatives of the laboratory can understand them and confirm, and for informing about the period during which the laboratory submits the evidences of implementation of corrective actions.

3.5.3.3 Accreditation team leader shall:

- communicate to the top management of the laboratory and personnel present at the meeting the results of witnessing made during the assessment;
- communicate to the top management of the laboratory the procedure of removing concerns basing on the results of the on-site assessment;
- when during the assessment it is found nonconformities with the requirements of the standard in the laboratory activity that can negatively influence on the decision making regarding accreditation/surveillance, violation by a CAB the conditions of the Agreement with NAAU, team leader informs management of the laboratory about the possibility of adoption by NAAU the decision concerning the refusal of accreditation or suspension / cancellation of accreditation certificate;
- when during the assessment it is found nonconformities which can be eliminated but need the additional on-site assessment after their elimination, assessment team leader informs the management of the laboratory regarding the necessity of carrying out the additional on-site assessment of the laboratory after the carrying out corrective actions by the laboratory.
- discuss between assessment team and laboratory all differences concerning the results of on-site assessment and, if possible, agree. In case of disagreement of parties, the differences are registered in the minutes of the final meeting.

3.5.3.4 The final meeting is recorded (F-08.00.12) with registration of present persons in 2 copies.

3.5.4 Informing the applicant about the results of on-site assessment

In order to inform the applicant about the results of conformity assessment the assessment team leaves him the minutes of the preliminary meeting, minutes of the closing meeting that contains conclusions of the team according to the assessment results, as well as he leaves one original protocol of nonconformities. The second original protocol of nonconformities is given to NAAU by assessment team leader.

3.5.5 Reporting in NAAU

Upon completion of on-site assessment, team leader draws up and submits to NAAU an office note concerning the information about nonconformities that were established during on-site assessment.

3.6 Review of collected materials, drawing up the reports and on-site assessment statement

3.6.1 Members of the assessment team draw up "On-site assessment reports" F 08.01.13/ F-08.02.13 that together with the "Checklist" F-08.01.10/F-08.02.10 (if available) are submitted to the lead assessor on paper and electronic medium.

The term of submission by the team members to the lead assessor the reports and, if necessary, assessment letters shall not exceed 10 (ten) working days from the date of completion on-site assessment.

3.6.2 The lead assessor draws up "On-site assessment statement" (F-08.01.28 /F-08.02.28) that together with the documents according to the clause 3.6.1 of this Procedure is submitted to NAAU.

The term of submission by the team leader the Act on conducting on-site assessment to NAAU shall not exceed 14 (fourteen) working days beginning from the date of on-site assessment completion.

3.6.3. When the Act is drawing up, the availability of positive conclusion (recommendation) regarding accreditation is possible if nonconformities are eliminated.

3.6.4. During on-site assessment for laboratory's accreditation the lead assessor together with assessors and experts ,who are team members, provide sufficient number of information about conducted assessment for the elaboration of program for surveillance and re-assessment of laboratory (F-08.01.41/F-08.02.41), that includes a plan of testing methods assessment according to the accreditation scope during surveillance and next accreditation of laboratory. The program of surveillance and re-assessment of laboratory (F-08.01.41/F-08.02.41) is elaborated by a responsible executor and is provided to the laboratory together with accreditation certificate and General Agreement between NAAU and CAB.

3.7. Elimination of nonconformities

3.7.1 Each member of assessment team who detected the nonconformity, is responsible for verification of implementation of corrective actions for elimination these nonconformities.

3.7.2. Responsible executor controls compliance of the terms envisaged for elimination of nonconformities and informs about them an applicant (if it necessary).

The terms of elimination of nonconformities according to the results of on-site assessment shall not exceed:

a) During the initial accreditation, re-accreditation and expanding of the accreditation scope - 3 (three) months from the date of completion on-site assessment.
b) for the surveillance of accredited CAB - 1 (one) month from the date of completion on-site assessment.

3.7.3 The applicant must provide documentary confirmation of the elimination of nonconformities in the form of corrective actions and other relevant information that could help in determining the compliance with the requirements and laboratory's competence.

3.7.4 The result of assessment sufficiency and effectiveness of implemented corrective actions is registered in the protocols of nonconformity (F-08.00.38) by assessor / expert, who drew up the protocol of nonconformity, or by the team leader.

3.7.5 Upon completion of the works the lead assessor submits to NAAU a set of the documents, that must contain:

a) CAB's assessment plan (F-08.XX.26);
b) Assessment team members assessment letters (F-08.XX.10) (if necessary);
c) The preliminary meeting report (F-08.00.11);
d) The final meeting report (F-08.00.12);
e) The report of the assessor/expert about conducting of on-site assessment (F-08.XX.13) of each member of assessment team.
f) The list of registered data, assessment methods and results of on-site testing / calibration (F-08.XX.33);
g) The Act on the on-site assessment (F-08.XX.28) in 2 (two) copies;
h) The protocols of nonconformities (F-08.00.38) with documented evidence of effectiveness of implementation the corrective actions;
i) The program on surveillance and laboratory's reassessment (F-08.xx.41) – during the accreditation;
j) Other information according to the results of on-site assessment.

3.8 On-site reassessment

3.8.1 In case if the verification of implementation of the corrective actions requires additional visiting of CAB (on-site reassessment), team leader must:

a) inform an applicant about the opportunity of adoption the decision on the reassessment during the final meeting;

b) document information in the final protocol of the meeting (F-08.00.12);

c) give justifications concerning the necessity of additional assessment in the statement on carrying out the on-site assessment (F-08.XX.28);

d) give justifications concerning the necessity of additional assessment in the protocol of nonconformity (F-08.XX.38) and in office note to NAAU Chairman in case of such necessity according to the results of verification the CAB's corrective actions.

3.8.2 An applicant is informed about the decision concerning the on-site reassessment by letter. The letter is prepared by a responsible executor and is agreed in accordance with established procedures.

3.8.3 Drafting and signing an additional agreement with the applicant and if it necessary, with one of the members of assessment team carries out the responsible executor of the Sector for Register according to the procedure "The order of work with contracts" (P-08.08.06).

3.8.4 On-site reassessment is carried out for no more than 2 (two) working days.

3.8.5 On-site reassessment is carried out according to the clause 3.4-3.6 of this Procedure of taking into account p.3.2.6.

3.8.6 If the verification of implementation of the corrective actions was performed during the on-site reassessment, this fact must be stated in the protocol of nonconformity (F-08.00.38).

3 Matrix of responsibility on the process of documentation analysis

Stages of work	The responsible executor of the Sector for Register	The responsible executor	Team leader	Member of the assessment team
Stages 3.3	E			
Stages 3.4		E	P	
Stages 3.5			C,E	E
Stages 3.6			C,E	E
Stages 3.7			C,E	E
Stages 3.8	P	P	C,E	E

Symbols:

P – Participates

C – Controls the correctness of performance

E – Executes the stage of works

5 Responsible for the process functioning

The head of the Department for Accreditation of Conformity Assessment Bodies and the head of the Department for Surveillance of Conformity Assessment Bodies are the persons responsible for functioning of laboratories' on-site assessment process.

6 References

This procedure comprises references to the following documents:

1. ДСТУ ISO/IEC 17025 "General requirements for competence of testing and

calibration laboratories";

2. GD-08.00.17 "NAAU Policy on the unjustified delay of conducting by NAAU the accreditation activities from the side of a conformity assessment body ".
3. F-08.01.07 «Program of assessment of testing laboratories as conformity assessment body (CAB) on compliance with the requirements of ДСТУ ISO/IEC 17025»;
4. F-08.02.07 "Program of assessment of calibration laboratories as conformity assessment body (CAB) on compliance with the requirements of ДСТУ ISO/IEC 17025";
5. F-08.xx.10 "Check-list of testing laboratories as conformity assessment body (CAB) on compliance with the requirements of ДСТУ ISO/IEC 17025";
6. F-08.00.11 "Protocol of preliminary meeting on on-site assessment of conformity assessment body (CAB) on compliance with accreditation requirements";
7. F-08.00.12 "Protocol of final meeting on on-site assessment of conformity assessment body (CAB) on compliance with accreditation requirements ";
8. F-08.01.13 "Report on assessment on site of testing laboratory as conformity assessment body (CAB) on compliance with the requirements of ДСТУ ISO/IEC 17025";
9. F-08.02.13 "Report on assessment on site of calibration laboratory as conformity assessment body (CAB) on compliance with the requirements of ДСТУ ISO/IEC 17025";
10. F-08.01.26 "On-site assessment plan for testing laboratories as conformity assessment body (CAB) on compliance with the requirements of ДСТУ ISO/IEC 17025";
11. F-08.02.26 "On-site assessment plan for calibration laboratories as conformity assessment body (CAB) on compliance with the requirements of ДСТУ ISO/IEC 17025";
12. F - 08.01.28 "Statement on assessment on site of testing laboratory as conformity assessment body (CAB) on compliance with the requirements of ДСТУ ISO/IEC 17025";
13. 12. F-08.02.28 "Statement on assessment on site of calibration laboratory as conformity assessment body (CAB) on compliance with the requirements of ДСТУ ISO/IEC 17025".
14. F-08.01.33 «Data about assessment of test methods at carrying out on site assessment»;
15. F-08.02.33 "Data about assessment of calibration methods at carrying out on site assessment";
16. F-08.01.35 "Program of assessment after accredited testing laboratory";
17. F-08.02.35 "Program of assessment after accredited calibration laboratory";
18. F-08.00.37 "List of questions for on-site assessment";
19. F-08.00.38 "Protocol of nonconformity;
20. F-08.01.41 Program for surveillance and reassessment of testing laboratory, accredited according to the requirements of ДСТУ ISOIEC 17025.
21. F-08.02.41 Program for surveillance and reassessment of calibration laboratory, accredited according to the requirements of ДСТУ ISOIEC 17025.

7 Developed by

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