

**National Accreditation
Agency of Ukraine**

Approved by
The NAAU Decree
dated 24.03.2015 № 195-Я

MANAGEMENT SYSTEM

Procedure

“For organizing and carrying out of monitoring by way of extraordinary assessment of accredited conformity assessment bodies in compliance with a task of central bodies of executive power, requests of state supervisory and law enforcement bodies”

(Approved by the decision of the NAAU Accreditation Council dated September 26, 2013)

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Scope of application

1.1 This procedure applies to the NAAU management, Department for Surveillance of Accredited Conformity Assessment Bodies, Department for Accreditation of Conformity Assessment Bodies, Division for Quality and International Relationships, Sector for Information, Technical and Communication Services and accreditation personnel involved in the carrying out of monitoring activities by way of extraordinary assessment.

1.2 The procedure is applied in the event of tasks' of the central bodies of executive power, requests of state supervisory and law enforcement bodies being given to NAAU regarding monitoring by way of extraordinary assessment of the conformity assessment bodies' (hereinafter – CAB) activities with respect to which a fact or information on the commitment of gross violations of the current legislation in the sphere of accreditation is established.

2 Normative references

This procedure is developed in accordance with the Law of Ukraine “On accreditation of conformity assessment bodies” dated 17.05.2001 №2407- III and in accordance with EA, ILAC, IAF (2-5).

3 General provisions

3.1 In the event of tasks' of the central bodies of executive power, requests of state supervisory and law enforcement bodies (hereinafter – task) being given to NAAU regarding extraordinary assessment of the conformity assessment bodies' (hereinafter – CAB) activities with respect to which the fact or information on the commitment of gross violations of the current legislation in the sphere of accreditation is established, NAAU shall consider them according to the order envisaged by this procedure.

3.2 Monitoring by way of extraordinary assessment of conformity assessment bodies' activities (hereinafter – extraordinary assessment) according to a task given is conducted by NAAU for the purpose of verification of the facts of commitment of gross violations of the current legislation in the sphere of CABs' accreditation and ensuring CAB's compliance with the requirements set out during accreditation on a regular basis.

3.3 Extraordinary assessment is conducted on the basis of the NAAU's decree while taking notice of the time-periods set out in a given task.

3.4 The number of extraordinary assessments of a CAB does not influence upon a number and intervals of scheduled surveillances.

3.5 Extraordinary assessment is conducted by NAAU, if required, with the involvement of specialists of other organizations. The representatives of enterprises and natural persons may be involved into extraordinary assessments as an accreditation assessors or experts on the basis of the respective agreements and contracts.

3.6 Extraordinary assessment always envisages an on-site assessment. A time-period of assessment is determined by the inspection plan of assessment (F-08.xx.26).

3.7 In the event of tasks' being received from various central bodies of executive power or the requests from state supervisory and law enforcement bodies regarding inspection of CAB's activity for the same period, on the same matter and ground, extraordinary re-assessment shall not take place.

4 Description of the process

4.1 Consideration of tasks of the central bodies of executive power or the requests of state supervisory and law enforcement bodies. Carrying out of extraordinary assessment.

4.1.1 In the event of a task being received by NAAU regarding extraordinary assessment of accredited CABs' activities with respect to which the fact or information on the commitment of gross violations of the

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current legislation in the sphere of accreditation, it shall be considered by the respective NAAU commission.

4.1.2 The relevant NAAU commission makes conclusions on the necessity of taking measures with respect to a CAB, including: temporary suspension or cancellation pursuant to the procedure “For temporary suspension or cancellation of accreditation certificate” (P-08.00.20), conducting monitoring by way of surveillance or extraordinary assessment. The NAAU Chairman shall make a final decision.

4.1.3 Extraordinary assessment shall include:

- approval of the NAAU’s decree on extraordinary assessment;
- formation of the assessors team in accordance with the procedure P-08.08.07 and surveillance program (F.08.xx.35);
- drawing up of contracts in compliance with the procedure P-08.08.06;
- analyzing of CAB’s documents, results of previous assessments, development of the assessment plan pursuant to the clause 4.2.4 of the procedures “For organizing and conducting monitoring by way of surveillance of accredited certification bodies, inspection bodies and extraordinary assessments” (P-08.03.13) and “For organizing and conducting monitoring by way of surveillance of accredited laboratories and extraordinary assessments” (P-08.01.12);
- on-site assessment (if necessary – re-assessment so as to verify the elimination of non-conformities), analysis of gathered materials, drawing up of reports, act or making the decisions upon the results of assessment in accordance with the order set out in clause 4.3-3.4 of the procedures “For organizing and conducting monitoring by way of surveillance of accredited certification bodies, inspection bodies and extraordinary assessments” (P-08.03.13) and “For organizing and conducting the monitoring by way of surveillance of accredited laboratories and extraordinary assessments” (P-08.01.12).

4.1.4 Surveillance program (F-08.xx.35) shall only encompass the requirements of the sections of normative documents on accreditation that are to be verified in order to examine the facts that have caused the violation and have become the reason for extraordinary assessment.

4.1.5 In the event of a task being received before the scheduled surveillance, NAAU may carry out extraordinary assessment in accordance with a program that shall apply to all clauses of a normative document subject to planned surveillance with the examination of issues mentioned in a task (complaint). In this case a planned surveillance shall not take place.

4.1.6 In the course of an extraordinary assessment being carried out on the grounds of received tasks, NAAU shall send a draft contract for monitoring performance by way of an extraordinary assessment, the composition of accreditation assessors and an assessment plan to a CAB via the electronic means of communication or by post with the notice of delivery to a place of the subject’s location. A CAB shall send its objections at the NAAU e-mail address during two working days from the moment when the documents have been received.

If a CAB has not sent a message regarding the results of the received documents’ review during two working days, a Head of the Division shall submit an official note on a third day to the NAAU Chairman with a proposal to temporarily suspend the accreditation certificate’s validity.

4.1.7 If required, the signing of a contract with a CAB shall take place the same day the extraordinary on-site assessment is conducted. Extraordinary on-site assessment activities shall be subject for payment by a CAB on conditions envisaged by a contract and Agreement between NAAU and a CAB.

4.1.8 If required, the representatives of local executive bodies, local bodies of self-governance, law enforcement bodies and other supervisory bodies may be involved, within the limits of their authority, into extraordinary assessment as observers upon their consent. The presence of the representatives is recorded in the minutes of the meetings.

4.1.9 In the event of non-admission by a CAB of the members of assessment team to the inspection during an extraordinary on-site assessment, a head of the inspection shall record this fact in the minutes of previous meeting (F-08.00.11), which is signed by all members of the assessment team.

In the event of refusal to sign the documents, drawn up by the assessment team during an on-site assessment, being received by a CAB’s representative (s), a head of the inspection shall record this fact in the minutes of a final meeting (F-08.00.12), which shall be signed by all members of the assessment team.

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4.1.10 Members of the assessment team shall be entitled to record the process of carrying out an extraordinary on-site assessment or each separate action by means of audio and video technique, while not hindering such inspection.

4.1.11 In the event of gross violations during the monitoring activities, a head of inspection shall be obliged to inform the NAAU management immediately. On the basis of the received information NAAU shall adopt the appropriate decision.

4.1.12 During the process of carrying out of extraordinary assessments, the time periods for the reports' submission (F-08.xx.13) to the assessment team leader by the members of assessment team should not exceed 2 working days, the time-period for the on-site assessment act's, developed according to F-08.xx.28 form in two examples and set's of documents submission by the assessment team leader to NAAU, shall not exceed 3 working days after the on-site assessment is finished.

Order for the drawing up of documents is carried out according to the Procedure "For certification and inspection bodies' on-site assessment" (P-08.03.15)

4.1.13 A responsible executor shall:

- a) review the content of the received set of documents within two days;
- b) prepare draft decisions upon the results of assessment according to the established procedures;
- c) send one (1) copy of on-site assessment act and decisions made by NAAU upon the results of inspection to a CAB.

In the event of preparing by a responsible executor of a negative decision, the issue shall be submitted for consideration by the appropriate commission and in accordance with its conclusions the Chairman shall make a decision.

4.1.14 In the event of negative conclusions and decisions of NAAU upon the results of consideration of appeals (complaints) and extraordinary assessment a responsible executor shall give one copy of the decision to the Division on Accreditation Matters, Registration and Issuance of Accreditation Certificates within one working day to the Register Sector for filling the information into the Register of accredited CABs.

4.1.15 Register Sector:

- prepare a letter to the complainant, a letter to stakeholders in the event of decisions being made by NAAU according to the procedures "For reducing a scope of accreditation" (P-08.00.17), "For temporary suspension or (cancellation) of the accreditation certificate "(P-08.00.20) and shall submit them for sending;

- provide the information to the Sector of Information, Technical and Communication Services for making the information available on NAAU website.

4.2 Taking decisions on temporary suspension or cancellation of accreditation certificate.

4.2.1 An accreditation certificate shall be temporary suspended by a Decision on the following grounds:

- facts of commitment of systematic violations by a CAB, as envisaged by a task of central bodies of executive power, letters of state supervisory and law enforcement bodies;

- finding of non-conformity with the accreditation criteria in the course of CAB's activities and violation of the requirements of the Agreement with NAAU committed by it;

- non-submitting by a CAB of the information to NAAU on the results of the consideration of the composition of accreditation assessment team, extraordinary assessment plan, or unjustifiable delay in their signing on a third day from the moment the documents have been received by a CAB;

- unjustifiable delay by a CAB in carrying out the extraordinary assessment activities, including non-conclusion of a contract for performance of works related to extraordinary assessment and non-payment to NAAU of all expenditures related to such works;

- non-admission of accreditation personnel by a CAB to extraordinary on-site assessment, including non-provision of all necessary documentation, information, recordings and non-ensuring of a free access to office and production facilities during an extraordinary assessment;

Decision on temporary suspension of validity or cancellation shall be made in accordance with the procedures "For temporary suspension or cancelation of accreditation certificate" (P-08.00.20) in

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compliance with the established form (F-08.00.31) and shall be submitted to a CAB and other interested parties.

Renewal of an accreditation certificate after its temporary suspension shall be done upon the results of analysis of CAB's documents on elimination of non-conformities and CAB's on-site assessment, if required. Decision on the renewal of an accreditation certificate of a CAB (F-08.00.52) shall be made by the procedure "For temporary suspension or cancelation of accreditation certificate" (P-08.00.20).

4.2.2 Cancellation of the accreditation certificate shall take place if:

- found violations may not be eliminated by a CAB during a time period, stipulated in the minutes of a final meeting;
- a CAB has not taken measures aimed at prevention of violation of the Agreement with NAAU in a timely manner, including the situation when a CAB has unjustifiably delayed the extraordinary assessment during 30 days, has not created conditions for its accomplishment;
- a CAB has not fulfilled the requirements of a contract for monitoring performance;
- the duration of the decision on temporary suspension of an accreditation certificate has come to an end.

The decision on temporary suspension of an accreditation certificate shall be drawn up pursuant to the procedure "For temporary suspension or cancelation of an accreditation certificate" (P-08.00.20) in compliance with the established form (F-08.00.31) and shall be submitted to a CAB and other interested parties.

Decision on cancellation of an accreditation certificate (F-08.00.31) shall be made by the NAAU Chairman. Renewal of an accreditation certificate after it has been cancelled shall not take place.

4.3. Submitting a file to the Register upon the results of surveillance

4.3.1 After elimination of all non-conformities and after final decisions have been made a responsible executor shall prepare the file to be submitted to the Register.

4.3.2 The file shall contain:

- a file description (F-08.0X.29);
- the composition of accreditation assessment team (F-08.00.05);
- a surveillance program (F-08.XX.35);
- an assessment plan (F-08.XX.26);
- preliminary meeting minutes (F-08.00.11);
- nonconformities report (F-08.03.38);
- documented evidence of elimination of nonconformities in the form of corrective actions and other appropriate information;
- final meeting minutes (F-08.00.12);
- assessment team members' on-site assessment reports (F-08.XX.13) (except for a team leader);
- assessment team members' lists of test questions (F-08.00.37) (if exist);
- assessment team members' checklists (F-08.XX.10) (if available);
- list of registered data that was verified during on-site assessment for surveillance of accredited CAB (F-08.XX.33);
- an on-site assessment act (F-08.XX.28);
- decision upon the results of surveillance (F-08.00.36);
- letters (if available);
- other information as decided by the assessment team leader.

4.3.3 The formed case shall be transferred to the Division on Accreditation Matters, Registration and Issuance of Accreditation Certificates within 2 days after final decisions upon the results of surveillance have been made, additionally, upon the results of analysis of corrective actions conducted by a CAB with the purpose of eliminating the nonconformities (except those cases when a responsible executor is in a permanent business trip).

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5. Person responsible for the process functioning

The Head of the Division for Supervisory Accredited Conformity Assessment Bodies shall be responsible for the process functioning.

6. References

The Procedure has references to the following documents:

1. The Law of Ukraine “On Accreditation of Conformity Assessment Bodies” dated 17.05.2001 №2407-III;
2. ISO/IEC 17011:2004 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies;
3. IAF/ILAC A5:11/2013 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004;
4. IAF GD 5:2006 IAF Guidance on the Application of ISO/IEC Guide 65:1996;
5. IAF GD 24:2009 IAF Guidance on the Application of ISO/IEC 17024:2003;
6. P-08.08.06 « For the order of working with contracts»;
7. P-08.08.07 «For the forming of composition of accreditation assessment team and informing the applicant»;
8. P-08.03.15 “For certification/inspection bodies’ on-site assessment”;
9. P-08.00.20 “For order of temporary suspension or cancellation of accreditation certificate”;
10. GD-08.00.16 The NAAU Policy “On surveillance of accredited conformity assessment bodies”;
11. P-08.00.05 “The group of assessors of assessment for CAB“;
12. P-08.00.06 “A letter to the applicant regarding the representatives in the accreditation assessment team”;
13. F-08.0X.10 «Assessment letter»;
14. F-08.00.11 «Minutes of the preliminary meeting on a CAB’s on-site assessment»;
15. F-08.00.12 «Minutes of the final meeting on a CAB’s on-site assessment»;
16. F-08.XX.13 «On-site assessment report»;
17. F-08.XX.26 «Assessment plan»;
18. F-08.XX.27 «Agreement between NAAU and a CAB»;
19. F-08.XX.28 «On-site assessment act»;
20. F-08.XX.29 «File description»;
21. F-08.XX.34 «Schedule for monitoring by way of planned surveillances of accredited certification and inspection bodies’ activities»;
22. F-08.XX.35 «Surveillance program for accredited CB/IB»;
23. F-08.00.36 «Decision on the results of surveillance/extraordinary assessment of accredited CAB’s activities»;
24. F-08.00.31 «Decision on temporary suspension or (cancellation) of an accreditation certificate«;
25. F-08.00.37 «List of test questions for on-site assessment»;
26. F-08.00.38 «Nonconformity report»;
27. F-08.XX.33 «List of registered data that was verified during on-site assessment for surveillance of accredited CAB ».

7. Developer

Head of the Division for Quality and
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