

National Accreditation
Agency of Ukraine

Approved
by NAAU Decree
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MANAGEMENT SYSTEM

Procedure
of organization and carrying out
surveillance for accredited laboratories
and extraordinary assessments

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1. Scope

1.1 The Procedure applies to the NAAU management, the Department for surveillance for conformity assessment bodies, the Division for surveillance for accredited laboratories, the Department for accreditation of conformity assessment bodies, the Sector for records and archives keeping, the Department for Quality and International Cooperation, as well as personnel on accreditation which is involved in conducting monitoring through surveillance.

1.2 The Procedure is used during conducting of monitoring through the surveillance (hereinafter – surveillance) and monitoring through the extraordinary assessment (hereinafter - extraordinary assessment) of the activity of accredited by NAAU **testing, calibration, medical (clinical and diagnostical) laboratories** (hereinafter – laboratories) on compliance with the requirements of ДСТУ ISO/IEC 17025-2006 according to the clause 11 of the Law of Ukraine “On Accreditation of Conformity Assessment Bodies”.

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 the requirements of the European and international documents [1-3]:

3. General provisions

3.1 Monitoring through the surveillance or extraordinary assessment is conducted by NAAU with the aim to ensure the continuous compliance of laboratories with the requirements which were established during accreditation.

3.2 Monitoring through the surveillance or extraordinary assessment of status and activity of **laboratories** is carried out by NAAU, if necessary, with involvement of experts from other organisations, to provide the constant conformity of **laboratories** with the requirements set during the accreditation process.

3.3 The representatives of enterprises as well as individual persons can be involved as assessors or experts on accreditation in monitoring through the surveillance or extraordinary assessment on the basis of relevant agreements and contracts.

3.4 The surveillance always includes the on-site assessment. The term of conducting assessment is determined by the Assessment Plan.

3.5 For accredited laboratories a frequency and date of the planned surveillance with on-site assessment are determined according to “NAAU Policy on monitoring of compliance of accredited conformity assessment bodies with the accreditation requirements through surveillance” (GD-08.00.16).

3.6 In the case of receipt of appeals submitted according to the legislation, or complaints related to the activities of accredited laboratories, NAAU considers them and, if necessary, the monitoring through extraordinary assessment is conducted.

Monitoring through extraordinary assessment by proxy of central executive bodies and of state control bodies is conducted in the manner prescribed by M-08.00.19 "The organization and monitoring through the extraordinary assessment of accredited conformity assessment bodies on behalf of the central executive bodies and state control bodies".

3.7 The number of extraordinary assessments of laboratories does not affect the amount and frequency of planned surveillances.

3.8 If appeals or complaints concerning the laboratory activities are received at the same time, related the same issue, and which are at the same basis, extraordinary re-assessment of the laboratory is not performed.

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3.9 In case of revealing of gross violations during the on-site assessment, an assessment leader shall immediately inform about that the NAAU management. On the basis of information received and conclusions of the appropriate commission, the Chairman makes a decision.

3.10 According to the Procedure "Temporary suspension or withdrawal of the accreditation certificate" (M 08.00.20), unreasonable delay of laboratory with performing surveillance or extraordinary assessment, negative results of NAAU consideration of complaints (appeals) on laboratory activities, identification of noncompliance with accreditation criteria in its work and violation of the Agreement with NAAU etc., are the basis for:

- Temporary suspension of the accreditation certificate;
- Cancellation of the accreditation certificate.

3.11 Block Schemas of the process of surveillance and extraordinary assessment are specified in Appendixes 1 and 2.

4. Process description

4.1 The planning of work on conducting surveillance for activities of accredited laboratories:

4.1.1 Three months before the beginning of a quarter of the year, head of the Division for Surveillance of Accredited Laboratories forms up draft schedule for surveillance (F-08.xx.34) of accredited laboratories (hereinafter – surveillance schedule) for the next quarter of the year.

4.1.2 Head of the Department for Surveillance of Accredited Conformity Assessment Bodies (hereinafter – head of the Department), Deputy Chairman on Accreditation Matters – Head of Department for Accreditation of Conformity assessment bodies, Head of the Department for Quality and International Cooperation, First Deputy Chairman are to be provided with draft schedules for review. If necessary, schedule is returned for revision.

4.1.3 Draft surveillance schedule is based on the data from the Register of accredited CABs, respective of the date the on-site assessment during the accreditation (initial or re-assessment) was performed.

4.1.4 The surveillance schedule is to be approved by a Decree of NAAU two months before quarter of the year under consideration. Changes to the schedule (if necessary) are implemented by a Decree of NAAU.

4.1.5 The schedule approved (any changes made to it) is delivered by the Sector for records and archives keeping to the attention of the Head of Department for surveillance for accredited conformity assessment bodies. Press Secretary of NAAU places it in the local network and on the official website of NAAU.

4.1.6 Head of the Division for surveillance of accredited laboratories in cooperation with heads of other NAAU structural divisions, which personal is involved in CAB surveillance activities, determines candidates of assessment team leaders, agrees them with the head of the Department and introduces team leaders with the approved schedule. The team leaders are to put their signatures under the schedule.

4.1.7 Team leaders provide cooperation with CABs concerning organizational and document support of the activities, in particular, forming letters to CABs with purpose of timely surveillance provision according to the schedule, taking into account provisions of management system documents.

4.1.8 Within 10 business days the head of the Division for Surveillance of Accredited Laboratories provides the Sector for Register with approved schedule with the approved schedule that includes data on team leaders for further group forming and agreements conclusion.

4.2 Formation of a team membership, assessment program and plan

4.2.1 A responsible executor of the Sector for Register forms a team of assessors on accreditation according to the Procedure "Forming Assessment Team and Informing Applicant" (P-08.08.07) after conducting analysis of documents laboratory and taking into account the laboratory assessment

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program (F-08.01.41 / F-08.02.41). An executor who is responsible for contractual work prepares draft agreements with assessors (experts) and laboratory, and sends these documents to the laboratory for informing and approval.

4.2.2 After receiving funds, a Head of the Sector for Register transmits the approved composition of the team to a Head of the Department for surveillance for accredited CABs.

4.2.3 Assigned responsible executor for surveillance prepares the surveillance program (F.08.xx.35).

Surveillance program (F.08.xx.35) shall:

- include the requirements of the sections of ДСТУ ISO/IEC 17025 2006, according to which one can trace functioning of a laboratory's quality management system and compliance of its activity with accreditation requirements;
- take into account the remarks given in the documents that were drawn up during accreditation of a laboratory (acts of analysis of laboratory documents, acts of a laboratory's on-site assessment, forms concerning data on evaluation of methods, nonconformity protocols, STCA representatives' recommendations on accreditation of TL etc.);
- include the list of testing methods / calibration procedures under assessment during surveillance according to the program of laboratory assessment (F-08.01.41/F-08.02.41) which was developed during accreditation;
- include requirements of c. 5.2 and 5.5 of ДСТУ ISO/IEC 17025:2006;
- include requirements of section 8.3 of ДСТУ ISO/IEC 17011:2006.

4.2.4 Review of laboratory documentation, results from previous assessments, drawing up an assessment plan and informing of an applicant.

4.2.4.1 **Assessment Team Leader draws up the assessment plan (F-08.xx.26).**

4.2.4.2 **The Assessment Plan is developed on the basis of approved Assessment Program (F-08.xx.35) after introduction to a laboratory file, which is kept in NAAU Register.**

Access to assessments' materials of particular laboratory that are stored in the Register NAAU for the purpose of review is carried out in accordance with established procedures

4.2.4.3 The assessment plan must include all organizational measures which are necessary for agreement with the laboratory.

For instance, where necessary to spread surveillance to the branches of laboratories, the assessment plan should include the date of surveillance of each branch, surveillance criteria for each branch, the time and the means that are necessary to reach the branches etc.

4.2.4.4 The assessment plan provides allocation of responsibilities between the members of the Assessment Team concerning sections of the Assessment program (F-08.01.26/F-08.02.26). The objects of allocation can be subdivisions of the laboratory, personnel, processes of the management system/quality, testing methods/measurement types etc. in the determined sphere of accreditation, which are planned to be assessed etc.

4.3 On-site assessment. Review of collected materials, drawing up of reports and the act

4.3.1 Conducting of the on-site assessment, review of the collected materials, drawing up of the reports (F-08.xx.13), the act during on-site assessment (F-08.xx.28) and evaluation of the assessment results are performed in accordance with the Procedure P-08.01.14 "The procedure of conducting on-site assessment of laboratories" (P-08.01.14) excluding the cases listed below.

4.3.2 The term of submission by Assessment Team Members to the Team Leader the reports (F-08.XX.13), data of evaluation of testing methods during the performance of on-site assessment (F-08.XX.33) and where necessary the list of control issues (F-08.00.37), protocols of nonconformities (F-08.00.38), shall not exceed 10 (ten) business days after the end of the on-site assessment.

When it is detected during the assessment fundamental and / or systematic nonconformities to the requirements of the standard in the laboratory activity that can negatively influence on the assessment

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results, violation by CAB the conditions of the Agreement with NAAU or during extraordinary assessment reporting period shall not exceed two (2) working days after the end of on-site assessment.

4.3.3 The term of submission by the Team Leader to NAAU the set of documents by the results of surveillance shall not exceed 14 (fourteen) business days.

When it is detected during the assessment fundamental and / or systematic nonconformities to the requirements of the standard in the laboratory activity that can negatively influence on the assessment results, violation by CAB the conditions of the Agreement with NAAU or during extraordinary assessment reporting period shall not exceed three (3) working days after the end of on-site assessment.

On the basis of received information about detected during the assessment fundamental and / or systematic nonconformities of the requirements of the standard in the laboratory activity that can negatively influence on the assessment results, violation by CAB the conditions of the Agreement, NAAU adopts appropriate decision.

4.3.4 The term of closure of nonconformities by the results of surveillance from the side of a laboratory shall not exceed 1 (one) month after the end of on-site assessment.

4.3.5 Re-assessment on-site by the results of surveillance is performed (if necessary) in the order, prescribed by Procedure “For carrying out an on-site assessment of a laboratory” (P-08.01.14).

4.4 Preparing and making a decision by the results of surveillance. Informing the applicant and stakeholders.

4.4.1 The responsible executor shall review within 5 (five) days the set of documents submitted to NAAU and by the results of surveillance and to prepare a decision (F-08.00.36) in 2 (two) copies and to submit it for consideration of NAAU management. The responsibility of persons involved in Decision making process basing on the results of surveillance / extraordinary assessment of CAB’s activity (F-08.00.36) is determined in the clause 8.2.8 of the Management Manual.

4.4.2 One copy of the approved decision (F-08.03.36) together with the copy of an act (F-08.XX.28) is sent to a laboratory and a copy of the decision is submitted to the Sector for Register.

4.4.3 In case of the decision on suspension of the accreditation certificate (withdrawal) according to the Procedure “Suspension or withdrawal of the accreditation certificate” (P-08.00.20) or restriction of the accreditation scope according to the Procedure “Restriction of the accreditation scope” (M-08.00.17), not only an applicant but also the stakeholders are informed by means of placing the information on the NAAU official web-site and sending letters (when necessary).

4.4.4 The responsible executor must in five days period send to the laboratory 1 (one) copy of the act on the on-site assessment (F-08.0X.28), Decision according to the results of surveillance / extraordinary assessment for laboratory activities (F-08.00.36) and information regarding the necessity of on-site re-assessment. (if it necessary).

4.5 The order of conducting extraordinary assessments on the appeals relating to the activities of the laboratory.

4.5.1 On admission appeals and complaints submitted in cases established by law, relating to the activities of accredited laboratories and violation of accreditation requirements which were found, NAAU considers them in terms established by current legislation.

4.5.2 NAAU considers justification of the appeal (complaint). If there are no evidence of the previous appeal, when appropriate, NAAU in written form offers the applicant of the relevant issue to appeal directly to the laboratory, except consideration of requests (appeals) of national deputies of Ukraine, the requirements of law enforcement and state control bodies.

4.5.3 On the results of consideration of appeals or complaints which were considered in accordance with the Procedure “The order of considering complaints” (P-14.08.01) and a decision of the NAAU Commission on appeals, the decision on the necessity of taking measures to laboratory is taken, including suspending (withdrawal) according to P-08.00.20 (“Suspension or withdrawal of

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accreditation certificate”) or conducting of monitoring through surveillance or extraordinary assessment.

4.5.4 Extraordinary assessment is conducted on the basis of NAAU decree.

4.5.5 Conducting of extraordinary assessment includes:

- forming of the surveillance program (F-08.xx.35) and Assessment Team according to the Procedure P-08.08.07;

- forming agreements according to the Procedure M-08.08.06;

- review of laboratory documentation, results of previous assessments, drawing up the Assessment Plan according to the c. 4.2.4 of this Procedure;

- on-site assessment (if necessary – reassessment for evaluation of closure of nonconformities by a laboratory), review of collected materials, preparing reports, an act and making a decision by the results of the assessment, which are conducted in the order established in the c. 4.3-4.4 of this Procedure.

4.5.6 The surveillance program (F-08.xx.35) shall include only the requirements of sections of normative documents on accreditation which are to be evaluated with the aim to verify facts which lead to violation and became the basis for this action.

4.5.7 In case of admission of an appeal or complaint before the planned surveillance, NAAU can conduct extraordinary assessment in accordance with the program which will cover all items of the normative document, which are to be under the planned surveillance with the consideration of issues identified in the appeal (complaint). In this case the next planned surveillance is not conducted.

4.5.8 If necessary, signing of the agreement with a laboratory is performed in the day of conducting extraordinary on-site assessment. Extraordinary on-site assessment activities are to be paid by the laboratory according to conditions established by the agreement and the General Agreement between NAAU and accredited laboratory.

4.5.9 When required, before conducting of extraordinary assessment, representatives of local authorities and local government bodies, law enforcement bodies and other control bodies by their consent, within the powers, can be involved as observers.

4.5.10 If a laboratory prevent the members of the Assessment Team to conduct extraordinary on-site assessment, a Team Leader records this fact in the protocol of preliminary meeting (F-08.00.11) which is signed by all members of the Assessment Team.

4.5.11 In case of rejection of authorized representative(s) of the laboratory to sign documents developed by the Assessment Team during in-site assessment, a Team Leader records these facts in the protocol of the final meeting (F-08.00.12) which is signed by all members of the Assessment Team.

4.5.12 Members of the Assessment Team have a right to record the process of extraordinary on-site assessment or each action by means of audio- and video technique, not preventing the performance of this assessment.

4.5.13 When conducting extraordinary assessments, the term of submission of the reports (F-08.0X.13) by the members of the Assessment Team to the Team Leader shall not exceed 2 (two) working days; the term of submission by a Team Leader to NAAU the act of on-site assessment according to the form F-08.0X.28 in 2 (two) copies and set of documents shall not exceed 3 (three) working days after the end of on-site assessment.

4.5.14 A responsible executor shall:

- a) analyse the content of submitted set of documents within 2 days;

- b) prepare draft decisions by the results of assessment according to established procedures;

- c) send to a laboratory 1 (one) copy of the act of on-site assessment and the decisions made by NAAU by the results of assessment.

If a responsible executor prepares a draft negative decision, issues are submitted for consideration of appropriate commission and according to its conclusions a decision is made according to the Procedure "Reducing the accreditation scope of CAB" (M-08.00.17), "Temporary suspending or withdrawing of accreditation certificate " (M-08.00.20).

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4.5.15 In case of negative conclusions and decisions of NAAU by the results of consideration of appeals (complaints) and conducting extraordinary assessment, a responsible executor within one working day submits one copy of the decision to the Sector for Register for inclusion of the information to the Register of accredited CABs.

4.5.16 The Sector for Register:

- prepares a letter to an complainant, a letter to stakeholders in case of NAAU decision according to the Procedures "Restriction of accreditation scope" (P-08.00.17), "Suspension or withdrawal of accreditation certificate" (P-08.00.20) and submits them for sending;
- gives the information to the Press Secretary of NAAU for placing the information in the NAAU web-site;

4.6 Handing of the file by the results of surveillance to the Register of NAAU.

4.6.1 Responsible executor forms the file according to the description of the file F-08.08.29 which includes;

- Assessment Program of TL F-08.xx.35;
- composition of the Assessment Team F-08.00.05;
- Assessment Plan of TL F-08.xx.26;
- reports on conducting of on-site assessment F-08.xx.13;
- act of the on-site assessment F-08.xx.28;
- protocols of nonconformities F-08.00.38 with the information about the closure of nonconformities;
- data of evaluation of testing/calibration methods during conducting of on-site assessment F-08.xx.33;
- control issues F-08.00.37 (if they are present);
- the protocol of the preliminary meeting F-08.00.11;
- the protocol of the final meeting F-08.00.12;
- the decisions by the results of assessment F-08.00.36;
- letters.

During surveillance an assessment letter (F-08.xx.10) is not used.

4.6.2 The formed case is referred to the Sector for Register no later than 2 days after the final decisions by the results of surveillance, including after the end of consideration of corrective actions performed by a laboratory with the purpose to eliminate nonconformities (except the case when a responsible executor is being in permanent business trip).

5 Responsible for the process functioning

The Head of the Division for surveillance for accredited laboratories is responsible for the surveillance process functioning.

7. References

This Procedure includes the references to the following documents:

1. DSTU ISO/IEC 17025:2006 "General requirements for the competence of testing and calibration laboratories".
2. ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
3. F-08.00.11 Protocol of preliminary meeting on conducting on-site assessment of CAB;
4. F-08.00.12 Protocol of closing meeting on conducting on-site assessment of CAB;
5. F-08.xx.13 "Assessor's report on the on-site assessment of CAB";
6. F-08.xx.26 "Assessment plan";
7. F-08.xx.28 "Act on the on-site assessment ";

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8. F-08.01.29 "Description of laboratory's file"
9. F-08.xx.33 "Evaluation of methods";
10. F-08.xx.34 "Schedule of planned surveillance";
11. F-08.xx.35 "Surveillance program of CAB";
12. F-08.00.36 "Decision by the results of surveillance/extraordinary assessment of CAB's activity";
13. F-08.00.37 "List of control issues for on-site assessment";
14. F-08.00.38 "Protocol of non-conformity No";
15. F-08.01.41 "Program of surveillance and re-assessment of CAB accredited on compliance with the requirements of ДСТУ ISOIEC 17025";
16. F-08.02.41 The program on surveillance and reassessment of the calibration laboratory accredited according to the requirements DSTU ISOIEC 17025
17. P-08.08.06 "Order of work with contracts";
18. P-08.08.07 "Appointment of the assessment team on accreditation and informing the applicant";
19. P-08.01.14 "Procedure of on-site assessment of a laboratory";
20. GD-08.00.16 "NAAU Policy on surveillance for accredited conformity assessment bodies".
21. P-08.00.17 "Reducing the Accreditation Scope of CAB "
22. P-08.00.20 "Temporary suspending or withdrawing of accreditation certificate"

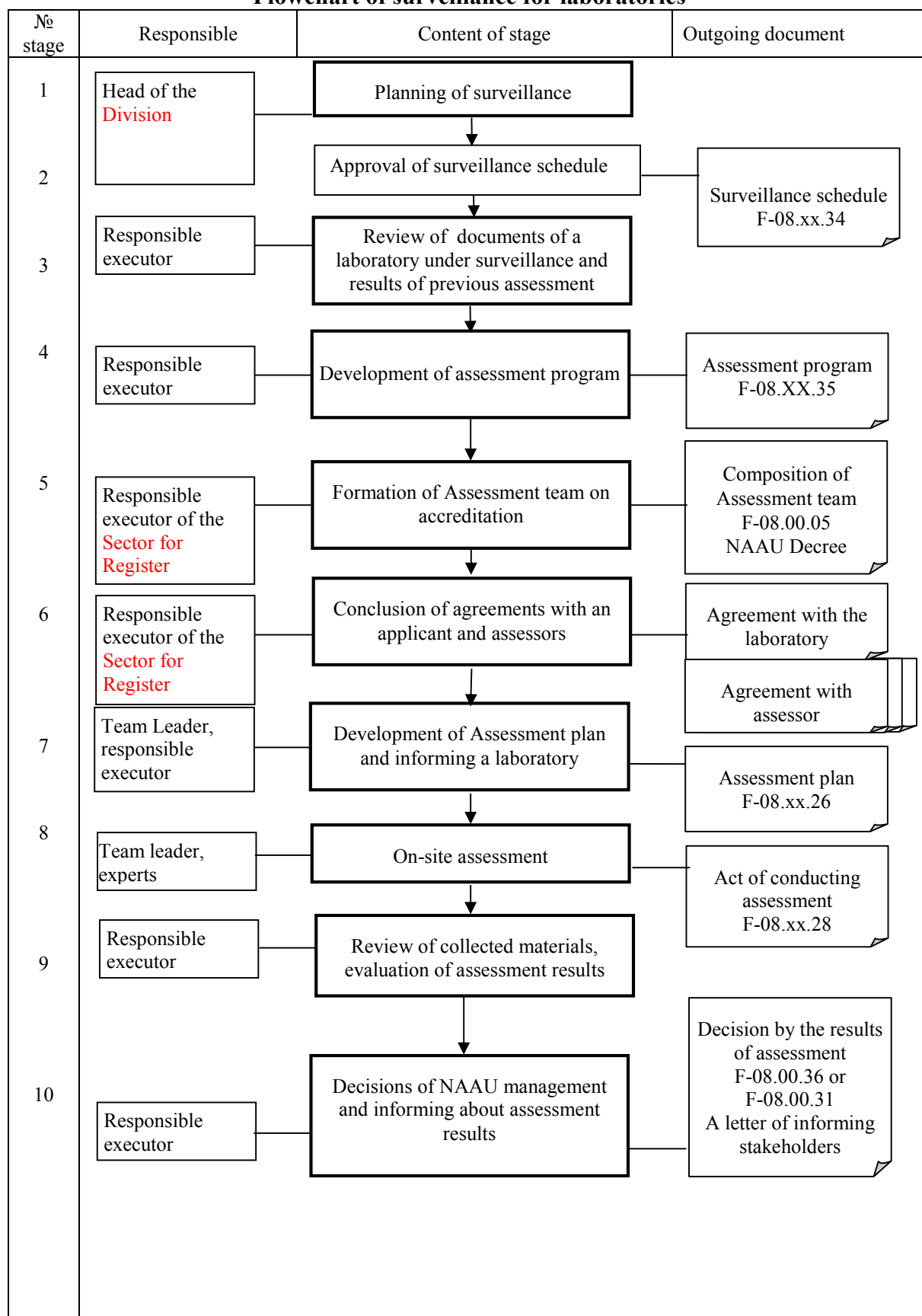
8. Developed by

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Flowchart of surveillance for laboratories



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Flowchart of extraordinary assessment of laboratories

№ stage	Responsible	Content of stage	Outgoing document
	NAAU management, Head of the Division	Consideration of an appeal or complaint	Conclusions of the Commission on appeals
	Responsible executor	Development of the Decree on conducting extraordinary assessment	NAAU Decree on conducting extraordinary assessment
	Responsible executor	Review of documents under surveillance and the results of previous assessments	
	Responsible executor	Development of Assessment program	Assessment program F-08.XX.35
	Responsible executor of the Sector for Register	Formation of Assessment team on accreditation	Composition of Assessment team F-08.00.05, NAAU Decree
	Responsible executor of the Sector for Register	Conclusion of agreements with an applicant and assessors	Agreement with a laboratory Agreement with assessor
	Team leader, experts, responsible executors	Development of Assessment plan and informing	Assessment plan F-08.xx.26
	Team leader, experts	On-site assessment	Act on conducting assessment F-08.xx.28
	Responsible executor	Review of collected materials, evaluation of assessment results	
		Decision of NAAU management and informing about assessment results	Decision by the results of the assessment F-08.00.36 or F-08.00.31 A letter of informing stakeholders

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