

National Accreditation

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Agency of Ukraine

NAAU Decree

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MANAGEMENT SYSTEM

*Procedure of
“Organization and carrying out monitoring through surveillance for
accredited certification/inspection bodies and extraordinary
assessments”*

Procedure of “Organizational and carrying out monitoring through surveillance for accredited certification/inspection bodies and extraordinary assessments		NAAU
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1. Scope

1.1. The Procedure applies to NAAU management, department for Surveillance of accredited conformity assessment bodies, division for surveillance of accredited certification and inspection bodies, department for accreditation of conformity assessment bodies, sector for records and archive keeping, department for international cooperation and quality and accreditation personnel involved in the work of the monitoring through the surveillance.

1.2. The procedure is applied during the monitoring through the Surveillance (hereinafter - Surveillance) and monitoring through an extraordinary assessment (hereinafter - Extraordinary assessment) after the accredited NAAU certification/inspection bodies (hereinafter - CAB) for compliance the requirements of normative documents on accreditation in accordance with Article 11 of the Law of Ukraine "On accreditation of conformity assessment bodies."

2. Normative References

This Procedure is elaborated taking into account 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 [2-7].

3. General provisions

3.1. Monitoring through surveillance or extraordinary assessment is carried out by NAAU for the purpose of providing constant conformance of the CAB to the requirements set during accreditation.

3.2. Monitoring through surveillance or extraordinary assessment for the state and activity of the CAB is carried out NAAU, if it necessary, with the involvement the specialists of other organizations for the purpose of providing continued compliance CAB requirements for the purpose of providing constant conformance of the CAB to the requirements set during accreditation.

3.3. To the monitoring through surveillance or extraordinary assessment can be involved the representatives of enterprises and individuals as auditors on accreditation or experts on the basis of relevant agreements and contracts

3.4. Surveillance always provides for on-site assessment and witnessing for the conformity assessment bodies services on conformity assessment according to the accreditation scope. Term of on-site assessment performance and witness are determined by assessment plan.

3.5. For accredited CAB the periodicity and date of the planned surveillance with on-site assessment is determined in accordance with the "NAAU Policy on surveillance after accredited conformity assessment bodies". The number and scope of supervision are determined by surveillance program and CAB's re-assessment (F-08.XX.41).

3.6. In case of appeals submitted in the orders established by the legislation, or complaints regarding the activity of accredited CAB, NAAU considers them and, if it necessary, carries out the monitoring through extraordinary assessment. Monitoring through extraordinary assessment on behalf of the central executive bodies and state supervisory bodies carries out in a manner determined by M-08.00.19 "The organization and monitoring through extraordinary score for accredited conformity assessment bodies in accordance with the proxy of central executive bodies, the requirements of state supervisory bodies and law enforcement bodies".

3.7. Number of extraordinary assessment of CAB doesn't influence on the amount and periodicity of planned surveillances.

3.8. In case of appeals or complaints regarding the activity of CAB for the same period

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with the same issue, at one and the same basis extraordinary re-assessment of CAB is not carrying out.

3.9 According to the Procedure “Suspending or withdrawing accreditation” (P 08.00.20) unreasonable delay of CAB to carry out surveillance or extraordinary assessment, the negative results of the consideration of NAAU complaints (appeals) regarding the CAB activities, identifying nonconformity in the work of CAB to the criterias of accreditation and violation of the requirements of Agreement with NAAU, etc are basis for:

- suspends term of validity of accreditation certificate;
- withdraws term of validity of accreditation certificate.

3.10. Block schemes of the process of surveillance and extraordinary assessment are in Annexes 1 and 2.

4. Process description

4.1 Planning and preparing for carrying out surveillance after the accredited CAB and witnessing

4.1.1 Three months before the beginning of a quarter of the year, head of the Division for Surveillance of Accredited Certification and Inspection Bodies forms up a draft schedule for surveillance (F-08.xx.34) of accredited certification and inspection bodies (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 approved schedule (and any changes made to it) is delivered by the Sector for records and archives keeping to the attention of the Head of the 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 Certification and Inspection Bodies in cooperation with heads of other NAAU structural divisions, which personal is involved in CAB surveillance activities, determines candidates for assessment team leaders, agrees them with the head of the Department and introduces team leaders with the approved schedules. 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 Certification and Inspection Bodies provides the Sector for Register with the approved schedule that includes data on team leaders for further group forming and agreements conclusion.

4.1.9 In compliance with the provisions of IAF MD 15, every CAB accredited by NAAU against ISO/IEC 17021, shall provide NAAU with the following information at the beginning of every year:

- The number of certificates that are in force at the end of December.

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- The number of auditors.
- The number of reissued certificates according to IAF MD 2.
- The number of postponed audits.
- The number of provided audit days.

Note: If one certificate is issued for three management systems, this counts as three certificates (one for every management systems). If one of the certificates for a certain management system covers several locations, it is counted as one. However, if those several locations have separate certificates, they are counted separately.

4.1.10 For the implementation of provisions, stated in 4.1.8, the head of the Department for Surveillance of Accredited CABs is obliged to organize corresponding appeals to CABs in December of each year.

4.2. Appointment of the team, program and assessment plan

4.2.1 Responsible executor of the division on accreditation matters, registration and issuance of accreditation certificates forms assessment team on accreditation in accordance with the procedure “Forming Assessment Team and Informing Applicant” P 08.08.07 after carrying out the analysis of the documents of CAB taking into account surveillance programs and CAB’s re-assessment (F-08.XX.41).

The responsible executor must provide that for the separate names of production (directions of economies, personnel names, inspection scopes) in defined CAB accreditation scope planned to be evaluated during the surveillance after the accredited CAB in accordance with the list of registered data (F- 08.0X.42), assessor or expert with the respective qualification is involved.

Responsible specialist for contract work draws up drafts of contracts with assessors (experts) and CAB, and sends these documents to the CAB for informing and approval.

4.2.2 After earnings of funds the head of the registry sector gives approved composition of the team to the Head of the Department for surveillance of accredited conformity assessment bodies.

4.2.3 Appointed responsible executor prepares the program of surveillance (F.08.XX.35).

The program of surveillance for accredited CAB (F-3.8.35) must:

a) contain references on the points of normative documents (ND), which may assess the compliance of activity of accredited CAB to the accreditation requirements.

Shall to be covered by the program of assessment the points of ND in relation to:
 carrying out the internal audits;
 analyzing from the management ;
 complaints and appeals;
 use of the national mark of accreditation;
 personnel and confirmation of its competence.

b) contain the names of production (directions of economies, personnel names, inspection scopes) in defined CAB accreditation scope planned to be evaluated in accordance with the list of registered data (F-08.XX.33);

c) to take into account the remarks are given in the documents that drawn up during the last assessment (act of on-site assessment protocol of nonconformity, recommendations of the TSAC representatives on CAB accreditation, etc.);

d) to take into account changes that have occurred in the status and activity of the CAB since last assessment.

e) to contain the analysis of amendments of the CAB to the conformity assessment schemes since the last assessment and their acceptability in accordance with the assessment criteria determined in the GD-08.08.29;

f) contain stage of work on surveillance by the conformity assessment bodies assessment services according to the accreditation scope and taking into account the surveillance program

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and CAB's reassessment (F-08.XX.41);

g) contain the planned surveillances according to the procedure P-08.03.21;

h) be based on information, received according to cl. 4.1.8 of this procedure.

4.2.4 Analysis of CAB documentation, the results of previous assessments, drafting of assessment plan and informing the applicant

4.2.4.1 **Assessment team leader draws up the plan of assessment (F-08.03.26)**

While drawing up the assessment plan for certification/inspection bodies, the **assessment team leader** for conducting surveillance should ensure that for some names of products (directions of economies, personnel names, inspection scopes) in determined CAB's accreditation scope, that planned to be verified during the surveillance for the accredited CAB, an assessor or expert of proper qualification was involved.

4.2.4.2 The assessment plan is drawn up on the bases of approved assessment program (F-08.03.35) and proposals of the leader of assessment team after the familiarization with the CAB case that is stored in the Registry of NAAU.

Access to the materials of specific CAB estimates that are stored in the NAAU Registry with the purpose of analyzing is carried out in accordance with established procedures.

4.2.4.3 . The Assessment plan must cover all the managerial procedures essential for coordination with CAB.

For example, if it is necessary that the planned surveillance cover the CAB's branches it can cover the dates of each branch surveillance, surveillance criteria for each branch, time and facilities needed for the movement between branches etc.

4.2.4.4 The assessment plan foresees separation of duties (assessment area) between members of assessment team concerning the chapters of the assessment program (F-03.08.35). The objects of the separation can be the subdivisions of CAB, personnel of CAB, processes of management/quality system of CAB, names of products (directions of economies, personnel names, inspection scopes) in defined CAB accreditation scope planned to be evaluated, etc.)

4.3 On-site assessment. Collected materials analysis, drawing up of the report and the statement

4.3.1 On-site assessment performance, drawing up the reports (F-08.XX.13) and the statement (F-08.XX.28) is carried out according to the procedure "Certification and inspections bodies on-site assessment" (P-08.03.15) except for the cases mentioned below.

4.3.2 The surveillance for the conformity assessment bodies assessment services according to the accreditation scope and taking into account the surveillance program and CAB's reassessment (F-08.XX.XX) is carrying out in accordance with the procedure "Conducting of Witnessing" (P-08.03.21).

4.3.3 The term for submission by the members of assessment team the reports (F-08.HH.13) to the assessment team leader and, if it necessary, the list of control questions (F-08.00.37), assessment letters (F-08.0X.10), protocols of nonconformities (F-08.00.38) shall not exceed 10 (ten) working days from the date of the end of on-site assessment.

4.3.4 The lead assessor must submit the set of documents according to the surveillance results to NAAU no later than 14 (fourteen) work days.

When it is detected during the assessment fundamental and / or systematic nonconformities to the requirements of the standard in the CAB 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 two (2) 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 CAB activity that can negatively influence on the assessment results, violation by CAB the conditions of the

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Agreement, NAAU adopts appropriate decision.

4.3.5 Nonconformities elimination term according to the results of surveillance of CAB must not exceed 1 (one) month from the date of on-site assessment completion.

4.3.5 Re-assessment on-site according to the results of surveillance on-site is carried out (if it necessary) in the order determined by this Procedure “Performing the on-site assessment of certification bodies and inspection bodies” (P-08.03.15).

4.4. Preparation and making up the decision according to the results of the surveillance and informing the applicant and stakeholders.

4.4.1. The responsible executor must in five days review the submitted set of documents and prepare decision according to the results of the surveillance and to prepare draft decision (F-08.03.36) in 2 copies and to submit it on the consideration of NAAU management.

The responsibility of the persons who are involved into the decision making process according to the results of surveillance/ extraordinary assessment for the activity of CAB is determined in the clause 8.2.8 of the Management Manual.

p.8.2.8 Guidelines on management.

4.4.2. One copy of the approved Decision (F-08.00.36) and one copy of the Statement (F-08.XX.28) are sent to CAB and the copy of the decision is given to the registry sector.

4.4.3. In the case of decision making about temporary suspension of the accreditation certificate (withdrawal) according to the Procedure “Temporary suspension or (withdrawal) of the accreditation certificate ”(P 08.00.20) or reducing the scope of accreditation according to the Procedure “Reducing the accreditation scope ” (P 08.00.17) except the applicant additionally informed the stakeholders by placing the information on the official NAAU website and sending letters (if it necessary).

4.4.4 The responsible executor must in five days send to the CAB 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 CAB activities (F-08.XX.36) and information regarding the necessity of on-site re-assessment. (if it necessary).

4.5 Order of carrying out the extraordinary assessments for the appeals related with the activity of CAB

4.5.1 On admission appeals and complaints, submitted in the occasions established by the legislation related with the activity of accredited CAB and detected violations of the requirements on accreditation, NAAU considers them in terms are defined by applicable legislation.

4.5.2 NAAU considers the justification of the appeal. In case of the absence of proofs of previous appeal, in case of acceptability, NAAU in written form suggests the applicant on violated issue to address directly to the CAB , with the exception of review the requests (appeals) of people's deputies of Ukraine, the requirements of law enforcement and state supervisory bodies.

4.5.3 According to the results of reviewing the appeals and complaints that are considered in accordance with the Procedure "The order of complaints reviewing " (P-14.08.01) and the conclusion of Commission on appeals of NAAU adopted a decision concerning taking the measures to the CAB including temporary suspension (withdrawal) according to M-08.00.20 ("Temporary suspension (withdrawal) in accordance with the P- 08.00.20 (Temporary suspension or (withdrawal) of the accreditation certificate ") and monitoring through surveillance or extraordinary assessment.

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4.5.4. Extraordinary assessment is carrying out on the basis of NAAU decree.

4.5.5. Carrying out of extraordinary assessment includes:

- formation of surveillance program (F.08.03.35) and assessment team in accordance with P 08.08.07;

formation of contracts in accordance with P 08.08.06;

-Analysis of CAB documents, results of previous assessments, drafting of assessment plan in accordance with paragraph 4.2.4 of this Procedure;

- Assessment on-site (if it necessary - re-assessment for checking the elimination of CAB nonconformities), the analysis of the collected materials, drafting of reports, act and decision-making for the results of assessment in the order determined by paragraphs 4.3-4.4 of this Procedure.

4.5.6 Surveillance Program (F-08.03.35) should contain only the requirements of chapters of normative documents on accreditation, that must be verified with the purpose of facts checking that led to the violation and became the basis for the realization of this action.

4.5.7. In the case of an appeal or complaint to the beginning of the planned surveillance, NAAU can carry out an extraordinary assessment in accordance with the program, which will be covered all points of normative document which are to be under planned surveillance with consideration of issues indicated in the appeal (complaint). In this case, the next planned surveillance is not carrying out.

4.5.8 In the case of non-admission by CAB the members of assessment team to the verification during the extraordinary on-site assessment, the head of verification records this fact in the minutes of previous meeting (F-08.00.11), which is signed by all members of the assessment team.

In case of abandonment of CAB representative (s) in signature of the documents issued by assessment team during the on-site assessment, the head of the verification records facts in the minutes of final meeting (F-08.00.12), which is signed by all members of the assessment team.

4.5.9 The members of the assessment team have the right to record the process of carrying out the extraordinary on-site assessment or each separate action by means of audio and video technique, without impeding of carrying out such verification.

4.5.10 Responsible executor must:

a) review the content of granted set of documents in two days term;

b) prepare drafts decisions for the results of assessment according to the established procedures;

c) send to the CAB one (1) copy of act about carrying out the on-site assessment and decision making by NAAU for the results of verification.

In case of preparation by responsible executor the draft of negative decision, the issue is submitted for consideration of the appropriate commission and in accordance with commission's conclusions is adopted the decision according to the procedures "Reducing the Accreditation Scope of CAB" (P-08.00.17), "Temporary suspending or withdrawing of accreditation certificate" (P-08.00.20).

4.5.11 In case of negative conclusions and decisions of NAAU upon the results of consideration appeals (complaints) and carrying out the extraordinary assessment the responsible executor during the work day one copy of decision gives to the registry sector for bringing in the information to the Register of accredited CAB.

4.5.12 The registry sector:

- Prepares a letter to the complainant, a letter to stakeholders in case of making decisions by NAAU according to the procedures of " Reducing the accreditation scope " (M-08.00.17), " Temporary suspension or (withdrawal) of the accreditation certificate "(M-08.00.20) and gives them for sending;

- Provides the information to the press-secretary for placing the information on NAAU website.

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4.6. Giving a file the Register upon the results of the surveillance

4.6.1 After elimination of all nonconformities the responsible executor prepares the file to give it the Register.

4.6.2 The file must comprise:

- File description (F-08.03.29);
- assessment team membership (F-08.00.05);
- Surveillance program (F-08.03.35);
- The assessment plan (F-08.03.26);
- The preliminary meeting report (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;
- The final meeting report (F-08.00.12);
- Assessment team members on-site assessment reports (F-08.XX.13) (except for the lead assessor)
- Assessment team members lists of questions (F-08.00.37) (if exist);
- Assessment team members checklists (F-08.XX.10) (if exist);
- List of registered data that was assessed during surveillance after accredited CAB (F-08.XX.33);
- The Statement on the on-site assessment (F-08.XX.28);
- The report of the assessment team leader about the conduction of witnessing (F-08.XX.01);
- Decision on the results of the surveillance (F-08.00.36);
- Letters (if exist);
- Other information by the assessment team leader decision.

4.6.3 The formed case is transmited to the registry sector during 2 days after a final decisions upon the results of surveillance, including the finishing of consideration the corrective measures conducted by CAB with the purpose of elimination the nonconformities (with the exception when the responsible executor is in permanent business trip).

5. Responsible for the process functioning

The Head of the division for certification/inspection bodies accreditation is responsible for the process functioning.

6. References

The Procedure comprises 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. ILAC-P15:06/2004 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies;
4. IAF/ILAC A5:11/2013 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements):Application of ISO/IEC 17011:2004;
5. IAF GD 5:2006 IAF Guidance on the Application of ISO/IEC Guide 65:1996;
6. IAF GD 24:2009 IAF Guidance on the Application of ISO/IEC 17024:2003;
7. EA-7/04 M Legal Compliance as a part of accredited ISO 14001: 2004 certification.
8. IAF MD – IAF documents on accreditation of management systems certification bodies in compliance with ISO/IEC 17021.
9. P-08.08.06 « The order of work with contracts»;

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10. P-08.08.07 « Appointment of the assessment team on accreditation and informing the applicant»;
11. P-08.03.15 “Certification/inspection body on-site assessment”;
12. P-08.00.17 “Reducing the Accreditation Scope of CAB”
13. P-08.00.20 “Order of suspension or withdrawal of accreditation certificate”;
14. M-08.03.21 «Conducting surveillance”
15. GD-08.00.16 The NAAU Policy on surveillance after accredited conformity assessment bodies;
16. F-08.XX.01 The report on conduction of witnessing
17. F-08.00.05 “Assessment team membership”;
18. F-08.00.06 “List on the representatives to the assessment team”;
19. F-08.XX.10 «Assessment list»;
20. F-08.00.11 «The preliminary meeting report on the CAB on-site assessment»;
21. F-08.00.12 «The final meeting report on the CAB on-site assessment»;
22. F-08.00.13 «The assessor report on the assessment on-site»;
23. F-08.3.26 «Assessment plan»;
24. F-08.00.27 «General Agreement between NAAU and CAB»;
25. F-08.XX.28 «Statement on the on site assessment»;
26. F-08.03.29 «File description»;
27. F-08.3.34 «The schedule of monitoring by means of planned surveillances after accredited certification/inspection bodies»;
28. F-08.03.35 «Program of surveillance after accredited SB/IB»;
29. F-08.03.36.«Decision on the results of the surveillance/ extraordinary assessment after accredited CAB»;
30. F-08.3.1 “Decision on the temporary suspension or (withdrawal) of the accreditation certificate”
31. F-08.00.37 «List of questions»;
32. F-08.03.38 «The nonconformities report»;
33. F- 08.XX.41 Program on surveillance and CAB’s re-assessment
34. F-08.XX.33 «List of registered data that was assessed to confirm CAB competence».

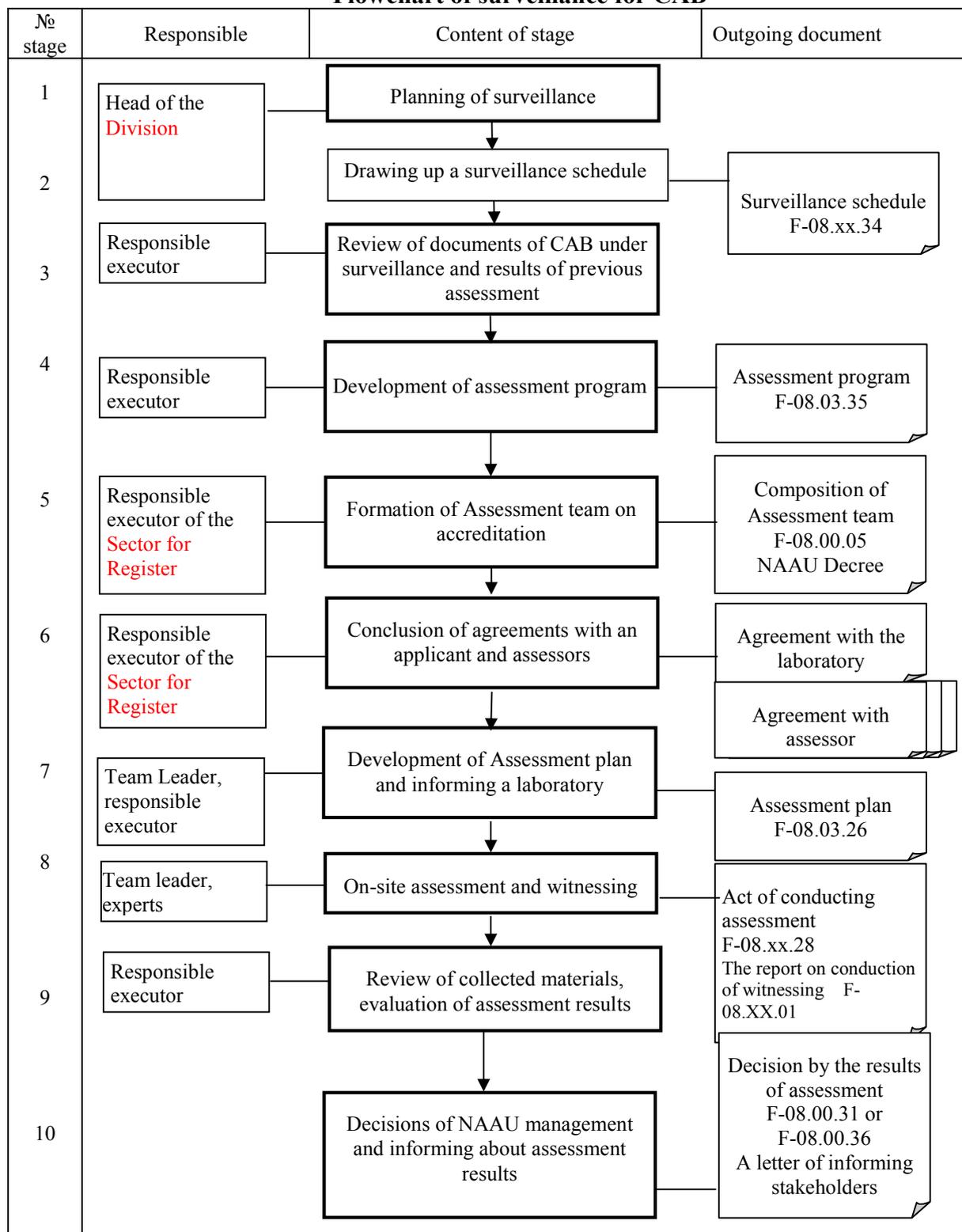
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Flowchart of surveillance for CAB



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Flowchart of extraordinary assessment of CAB

