

**National Accreditation
Agency of Ukraine**

Approved by
NAAU Decree
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MANAGEMENT SYSTEM

Procedure

“Performing the on-site assessment of certification bodies and inspection bodies”

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1. Purpose

The procedure “Performing on-site assessment of certification bodies and inspection bodies” (hereinafter – Procedure) defines the order of organization and performing the on-site assessment of certification/inspection bodies (hereinafter – CAB).

2. Scope

This Procedure applies to NAAU management, the department for accreditation of conformity assessment bodies, department for surveillance of conformity assessment bodies, **department for quality and international cooperation** and accreditation personnel involved in CABs accreditation activities and monitoring by the means of surveillance.

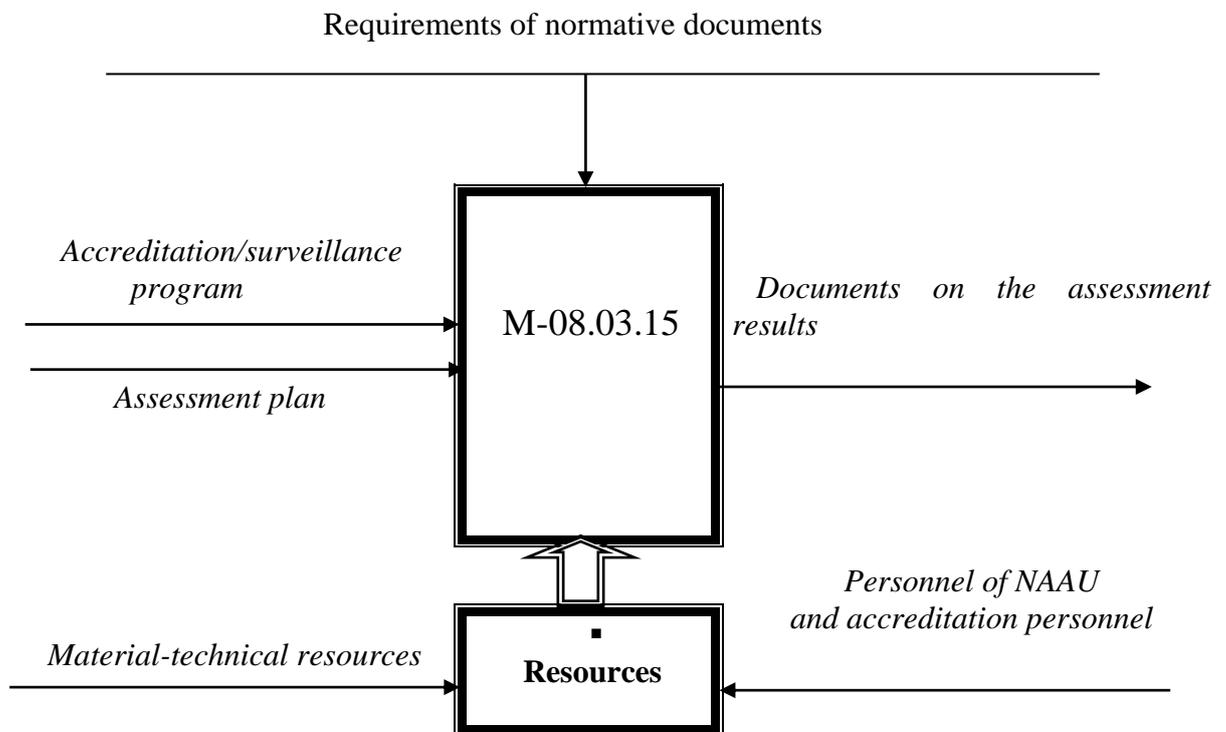
3. General provisions

3.1 This Procedure is developed taking into account the requirements of the Law of Ukraine “On accreditation of conformity assessment bodies” dated on 17.05.2001 №2407-III and requirements of the international and European documents in accreditation [1-8].

3.2 Flow chart of the process of performing the on-site assessment is given in Annex 1.

4. Process description

Model of the on-site assessment process



4.1 The main provisions

4.1.1 The main purpose of on-site assessment is to detect conformity of conformity assessment body with the accreditation requirements.

4.1.2 As a result of on-site assessment it is determined the possibility of providing accreditation or denial the accreditation or the confirmation of conformity with the established requirements during the monitoring through the surveillance or extraordinary assessment for accredited CAB's.

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4.1.3 CAB’s denial of on-site assessment if it was not informed to NAAU groundless reasons regarding postponement of assessment or non-payment of accreditation works can be the reason for cancellation of the application for accreditation/ temporary suspension or withdrawal of accreditation certificate (during the monitoring through the surveillance or extraordinary assessment) according to NAAU Policy on groundless delay by CAB of conducting of accreditation works by NAAU (GD-08.00.17).

4.1.4 During the on-site assessment, assessment team members shall use only official documents.

4.1.5 NAAU bears full responsibility for the on-site assessment, even in case, if assessment team leader is not NAAU staff employee.

4.1.6 Duration and content of on-site assessment is determined by the assessment Plan.

4.1.7 Re-assessment on-site is the on-site assessment with the aim to confirm elimination of nonconformities, which is conducted in accordance with this Procedure.

4.2. Preparation and conclusion of contracts

4.2.1 Responsible executor of **the Sector for Register** concludes an Agreement with an applicant and sub-contractors for on-site assessment according to the procedure “The order of work with contracts” (P-08.08.06).

4.3 Drawing up the Assessment Plan, informing the applicant and preparation for the on-site assessment

4.3.1 The person in charge from the **Division for Accreditation of Certification and Inspection Bodies** or the Division for Surveillance of Accredited Certification **and Inspection Bodies** (hereinafter – person in charge) draws up the Assessment Plan (F-08.03.26) aided by the team leader.

4.3.2 Planning shall:

- a) be based on the accreditation program data (F-08.03.07)/ surveillance program (F-08.03.35), that define assessment area and establish distribution of duties among team members when on-site assessment is carrying out;
- b) to set the assessment field;
- c) to determine the distribution of duties among team members during the on-site assessment;
- d) to identify all organization measures needed for coordination with CAB.

4.3.3. Defining the assessment field

The assessment field shall be defined taking into consideration the approved membership of the assessment team (F-08.00.05) and the assessment program (F-08.03.07) /surveillance program (F-08.03.35).

The assessment field may be subdivisions of a CAB, specified persons, processes of quality management system, activities etc.

4.3.4 Distribution of duties among team members during the on-site assessment is defined similar to the clause 4.3.3 of this Procedure.

4.3.5 If necessary to cover branches of CABs, the assessment plan shall identify:

- a) dates of performing assessment of every branch;
- b) an assessment field for every branch;
- c) assessment team members who are evaluating every branch;
- d) time and means necessary for movement among branches etc.

Criteria for planning assessments of branches are given in the Table 1.

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Table 1

Initial assessment	Surveillance after accredited CAB	Reassessment
All premises of a CAB / applicant (main premise and branches) where key activities are performed (note to the clause 7.5.7 of ISO/IEC 17011:2004) shall be covered by the on-site assessment concerning every key activity.	<ol style="list-style-type: none"> 1. Main premise and selectively defined branches. 2. Every branch shall be covered by assessment at least once over a validity period of the accreditation certificate. That is, assessment of branches shall be equally distributed between the initial accreditation and re-accreditation. 	<ol style="list-style-type: none"> 1. The branches are included selectively but no less than 50%. 2. Selectiveness is applied during the on-site assessment concerning the every key activity taking into account experience of previous assessments, branches (sites) where non-conformities were founded during surveillance are included mainly.

4.3.6 Every member of the assessment team signs the CAB's assessment plan as a evidence of acquaintance with it and responsibility for its performance.

4.3.7 The person in charge sends 2 (two) copies of the CAB's assessment plan (F-08.03.26) for coordination (it may be performed by fax or e-mail with subsequent approval by the Applicant on a paper carrier).

4.3.8 Both copies of the CAB's assessment plan are approved in NAAU.

4.3.9 With the aim to prepare properly for on-site assessment an assessment team leader shall receive and inspect respective documents of a CAB (Management Manual, procedures of testing/calibration, other documents of management system, statutory documents etc.). as well as to provide the assessment team members with the necessary documents for inspection before starting to perform work. At the same time, team members shall independently inspect on the NAAU web-site the current versions of NAAU procedures necessary for work of the assessment team.

4.4 On-site assessment of a CAB

4.4.1 The preliminary meeting

4.4.1.1 Before the start of on-site assessment, assessment team leader performs:

- final allocation of responsibilities among the members of the group auditors and clarifies with them all uncertain issue concerning on-site assessment;
- instruction on the order to assessment, filling of forms of documents that are used during assessment.

4.4.1.2 Members of the assessment team and CAB's representatives shall be present at the preliminary meeting. Representatives of an applicant and other interested parties may be also invited to the preliminary meeting.

4.4.1.3 During the preliminary meeting the team leader must highlight the following issues:

- a) presentation of the assessment team members outlining their established duties;
- b) confirmation of purposes of the assessment and accreditation criteria;
- c) confirmation of the assessment schedule;
- d) confirmation of methods of information exchange;
- e) confirmation that CAB will give all necessary information during accreditation;
- f) confirmation of resources availability and provision of work conditions for the assessment team (GD-15.00.02);
- g) confirmation of the subject of confidentiality;

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- h) confirmation of corresponding actions related to occupational safety and health, incidents and personal safety of the assessment team members (GD-15.00.02);
- i) confirmation of presence, roles and personalities of any accompanying persons;
- j) information on conditions under which assessment may be suspended;
- k) information on procedure of appeals concerning conducting the assessment or its conclusions.

4.4.1.4 Preliminary meeting is conducted and recorded with registering the participants (F-08.00.11) in 2 copies.

4.4.1.5 During the preliminary meeting the team leader is also required to inform CAB about the necessity of filling surveillance forms (F-09.00.08) and the questionnaire (P-9.8.24) during the time - not later than five days after receiving from NAAU the decision based on the results of assessment.

4.4.2 Assessment of competence

4.4.2.1 During the on-site assessment the assessment team shall collect evidences on CAB's conformity with accreditation requirements according to the assessment Plan.

4.4.2.2 Methods of data gathering are:

- a) interview;
- b) witnessing;
- c) review of the documents and registered data.

4.4.2.3 During the on-site assessment of the certification body the schemes of conformity assessment are evaluated in accordance with the criteria determined in GD-08.08.29 and a correct reference to the schemes in documents of a CAB needs to be checked.

4.4.2.4 Information sources can change in accordance with the activity scope and include the following:

- interview with personnel and other persons;
- witnessing for the activity, working environment and conditions of the work;
- documents (policies, objectives, plans, procedures, instructions, contracts, decrees, job descriptions, records regarding personnel, etc.);
- records (minutes of meetings, monitoring reports, journals, cases of certificated clients, etc.);
- database and web-sites.
- reports from other sources (for example, feedback from clients, other suitable information from external parties, evaluation of suppliers, etc.)

4.4.2.5 An assessor who discovered nonconformities shall register them in protocols of nonconformities (F-08.00.38) in two copies. An assessor shall familiarize the CAB representative with the content of a nonconformity under the signature of the protocol of nonconformity.

4.4.2.6 Every protocol of non-conformity shall contain description of a nonconformity only with one requirement of accreditation. Formulation of a nonconformity shall include only the description of an actual situation in the CAB regarding the defined requirement and shall not include opinion of assessor in relation to how this requirement can be fulfilled.

4.4.2.7 Every protocol of nonconformity shall have unique identification (number of protocol and total number of protocols). A Team Leader together with an assessor who discovered nonconformity provides identification of every protocol of nonconformity.

4.4.2.8 In the case of appearing of doubts in relation to nonconformities the Team Leader shall appeal to NAAU for explanation.

4.4.3 Intermediate meetings of the assessment team

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4.4.3.1 The Team Leader shall call at least one intermediate meeting before the final meeting.

4.4.3.2 During intermediate meetings (for example, at the end of the day) the assessors exchange gathered information, analyze it and team leader makes decision on possible changes in the Assessment Plan. In such way team leader shall document these changes in the annex to the assessment Plan for his signature and to acquaint team members and the management of CAB.

4.4.4 Final meeting

4.4.4.1 Members of the assessment team and CAB representatives shall be present at the final meeting. Representatives of applicant and other interested parties may be invited to the final meeting.

4.4.4.2 The team leader heads the final meeting to submit the data and conclusions of the assessment in such way that CAB can understand and approve them and, if necessary, with the aim to agree concerning the term during which the CAB submits evidence of implementation of corrective action.

4.4.4.3 Assessment Team Leader must:

- Inform CAB's top management and personnel present at the meeting with the results of the evaluation;

- acquaint CAB with the procedure of elimination the concerns according to the results of on-site assessment;

- when identified during the assessment nonconformities with the requirements of the standard in the CAB's activity, which can negatively affect on the decision regarding the accreditation/surveillance, the violation by a CAB terms of the Agreement with NAAU, Assessment Team Leader informs the CAB's management about the possibility of making decision by NAAU concerning refusal of accreditation or suspension / withdrawal of the accreditation certificate;

- when identify during assessment nonconformities, which can be eliminated but need additional on-site assessment after their elimination, Team Leader informs the CAB's management concerning the necessity of conducting on-site reassessment of a CAB after performing corrective actions.

- discuss all differences over on-site assessment results between assessment team and CAB's representatives and, if possible, to agree. In case of disagreement of views of the parties, the differences are recorded in the minutes of the final meeting.

4.4.4.4 The final meeting is recorded (F-08.00.12) with registering those present in 2 copies.

4.4.5 Informing an applicant about results of the on-site assessment

In order to inform the applicant about results of conformity assessment an assessment team leaves for him one copy of the preliminary meeting protocol, final meeting protocol that contains conclusions of the team on the results of assessment and leaves one original of protocols of nonconformities. Second original of protocols of nonconformities the team leader provides to NAAU.

4.4.6 Reporting in NAAU

Upon completion of the on-site assessment, leader of assessment team on accreditation in the term of 3 working days prepares and submits to NAAU information about nonconformities found during the on-site assessment through the office note.

4.5 Analysis of gathered data, drawing up reports and the act of the on-site assessment

4.5.1 The assessment team shall review all data gathered during the document review and the on-site assessment of a CAB. The analysis shall define the degree of competence and conformity of a CAB with the accreditation requirements.

4.5.2 Every member of the assessment team, except for the team leader, draws up a report according to the form F-08.XX.13 taking into account provisions of the p.4.3.3 of this Procedure.

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4.5.3 Term of providing to the team leader reports (F-08.XX.13) by assessment team members and, if necessary, Letters on evaluation (F-08.XX.10) on paper and electronic media (shall be signed by the team leader or the person in charge and can be used for decision making) shall not exceed 10 (ten) work days after on-site assessment.

4.5.4 The team leader draws up the act of the on-site assessment according to the F-08.0X.28 in 2 (two) copies and submits to NAAU the set of documents which contains the Act and gathered data. When drawing up the Act, positive conclusion (recommendations) on accreditation is possible if nonconformities are eliminated.

The term of providing by the team leader to NAAU the Act of the on-site assessment shall not exceed 14 (fourteen) work days after completion of the on-site assessment.

4.5.5 During the on-site assessment for accreditation of a CAB an assessment team leader together with assessors on accreditation and experts who are included in the assessment team, ensure the provision of adequate information concerning the performed on-site assessment for drawing up a surveillance program and re-assessment program of a CAB (F-08.XX.41) which include:

a) for product certification bodies – planning of CAB’s certification schemes assessment and witnessing over performance of certification activities by a CAB by: similar types of products according to the directions sectors of economic activity and services by the sphere of accreditation.

b) for management systems certification bodies – planning of CAB’s certification schemes assessment and witnessing over performance of certification activities by a CAB by: standards for management systems and directions of economic activities (clusters) for the sphere of accreditation.

c) for personnel certification bodies - planning of CAB’s certification schemes assessment and witnessing over performance of certification activities by a CAB by: name of personnel and normative documents that establish qualification characteristics, the requirements for the competence of personnel by the sphere of accreditation;

d) for inspection bodies – planning of the inspection sphere assessment and witnessing over performance of inspection activities by a CAB by normative documents which establish a method and procedure of inspection by the sphere of accreditation.

Surveillance program and re-assessment program of a CAB (F-08.XX.41) is drawn up by a person in charge on the stage of preparation of a decision on granting accreditation and is given to a CAB together with the Accreditation Certificate and the General Agreement.

4.6 Elimination of nonconformities

4.6.1 Every assessment team member, who found a non-conformity, is responsible for the control of implementation of corrective actions which are done to eliminate such a non-conformity.

4.6.2 A person in charge controls the terms that are foreseen for elimination of non-conformities and informs an applicant about it (if necessary).

The terms of elimination of non-conformities based on the results of on-site assessment shall not exceed:

a) for initial accreditation, reaccreditation and extending of accreditation – 3 (three) months after the completion of the on-site assessment;

b) for surveillance of accredited CABs – 1 (one) month after the completion of the on-site assessment.

4.6.3 An applicant shall give documental confirmation of non-conformities elimination in the form of evidences of execution of corrective actions and other appropriate information, which could help to identify conformity with the requirements and competence of a CAB.

4.6.4 The result of assessment of sufficiency and efficiency of the implemented corrective actions is registered in the protocol of non-conformity (F-08.00.38) by an assessor/expert, who drawn up the protocol of non-conformity, or by a team leader.

4.6.5 After completion of work a team leader submits to NAAU the set of documents which shall include:

a) assessment plan of a CAB (F-08.03.26);

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- b) lists of key questions (F-08.00.37) of members of the assessment team (if necessary);
- c) checklist of assessment (F-08.XX.10) of members of the assessment team (if necessary);
- d) protocol of the preliminary meeting (F-08.00.11);
- e) protocol of the final meeting (F-08.00.12);
- f) report of an assessor/expert on the on-site assessment performance (F-08.XX.13) of every member of the assessment team;
- g) act on the on-site assessment (F-08.XX.28) in 2 (two) copies;
- h) protocols of non-conformities (F-08.00.38) with documental evidences of corrective actions implementation;
- i) list of registered data checked for confirmation of the CAB's competence (F-08.XX.33);
- j) surveillance program and reassessment program of a CAB (F-08.XX.41);
- k) other information based on the on-site assessment.

4.7 Reassessment on-site

4.7.1 In case if the control of corrective actions implementation needs the additional visit to a CAB (reassessment on-site), the assessment team leader shall:

- a) to inform an applicant about the possibility of decision-making concerning the reassessment during the final meeting;
- b) to document the given information in the protocol of the final meeting (F-08.00.12);
- c) to give argumentation concerning the necessity of additional assessment in the act on the on-site assessment (F-08.XX.28).
- d) to give argumentation concerning the necessity of additional assessment in the protocol of nonconformities

4.7.2 An applicant is informed by a letter about the decision on the on-site reassessment. A letter is prepared by a person in charge and agreed according to the prescribed procedures.

4.7.3 Drafting and signing of an additional agreement with an applicant and, if necessary, with one of the assessment team members is performed by a person in charge of the **Sector for Register** according to the Procedure "Order of work with contracts" (P-08.08.06).

4.7.4 The on-site reassessment is performed within no more than two (2) work days.

4.7.5. The on-site reassessment is performed according to the clause 4.3-4.5 of this Procedure.

4.7.6. Further actions after the on-site reassessment is performed according to the p. 4.5.1, 4.5.2.1 a) and c) and 4.5.3 of this Procedure

4.7.7 If checking of corrective actions implementation is performed during the on-site reassessment, this fact shall be stated in the protocol of nonconformity (F-08.00.38).

5. Matrix of responsibility in regard to the on-site reassessment of a CAB

Stage number according to the Flow chart (Annex 1)	Person in charge of the Sector for Register	Person in charge	Assessment Team Leader	Assessment Team members
1	E			
2		E	P	
3, 4			C,E	E
5		E		-
6-7			E	E

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8		E		-
9			C,E	E
10	P	E		

Explanations:

C – Controls the accuracy of performance

E – Executes the stage of work

P – Participates

6 Responsible for the process functioning

Head of the Department for accreditation of CABs **or** Head of the Department for surveillance of accredited CABs is responsible for the process functioning.

7 References

The Procedure has references to the following documents:

1. ISO/IEC 17011:2004 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies.
2. ДСТУ ISO 19011:2002 Guidelines for auditing management systems.
3. "EA7/04 M Legal Compliance as a part of accredited ISO 14001:2004 certification.
4. IAF MD1: 2007 IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling.
5. IAF MD2:2007 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems.
6. IAF MD3:2008 IAF Mandatory Document for Advanced Surveillance and Recertification Procedures.
7. IAF MD4:2008 IAF Mandatory Document for the use of Computer Assisted Auditing Techniques (“CAAT”) for Accredited Certification of Management Systems.
8. IAF MD5:2013 Duration of QMS and EMS Audits.
9. IAF MD 8:2011 Application of ISO/IEC 17011 in Medical Device Quality Management Systems (ISO 13485).
10. IAF MD 9:2011 Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485).
11. IAF MD 10:2013 Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021: 2011.
12. IAF MD 11:2013 Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS).
13. IAF GD 5:2006 IAF Guidance on the Application of ISO/IEC Guide 65:1996.
14. IAF GD 24:2009 IAF Guidance on the Application of ISO/IEC 17024:2003.
15. ILAC P15:06/2014 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies.
16. IAF/ILAC A5:11/2013 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements):Application of ISO/IEC 17011:2004.
17. P-08.08.06 The order of work with contracts.
18. GD-15.00.02 General provisions for ensuring the proper working conditions of accreditation personnel during the performance of accreditation works.
19. F-08.00.05 Composition of the assessment team for evaluation of a CAB.
20. F-08.03.07 Accreditation program of a certification body / inspection body.
21. F-08.0X.10 Checklist of the assessment.
22. F-08.00.11 Protocol of the preliminary meeting on the performance of the on-site assessment of a CAB.

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23. F-08.00.12 Protocol of the final meeting on the performance of the on-site assessment of a CAB.
24. F-08.0X.13 Assessor's report on the performance of the on-site assessment.
25. F-08.00.24 Decision based on the results of the Act of given information and documentation review.
26. F-08.00.25 Decision based on the results of the Act of document review.
27. F-08.03.26 Assessment plan.
28. F-08.0X.28 Act on the on-site assessment.
29. F-08.00.37 Checklists of control questions for the on-site assessment.
30. F-08.00.38 Protocol of nonconformity.
31. F-08.03.35 Surveillance program of the accredited certification body / inspection body.
32. F-08.XX.01 Report of an assessor on accreditation concerning conducting of witness.
33. F-08.0X.33 List of registered data evaluated during the on-site assessment for the confirmation of CAB's competence.
34. F-08.0X.41 Program of surveillance and reassessment of a CAB.

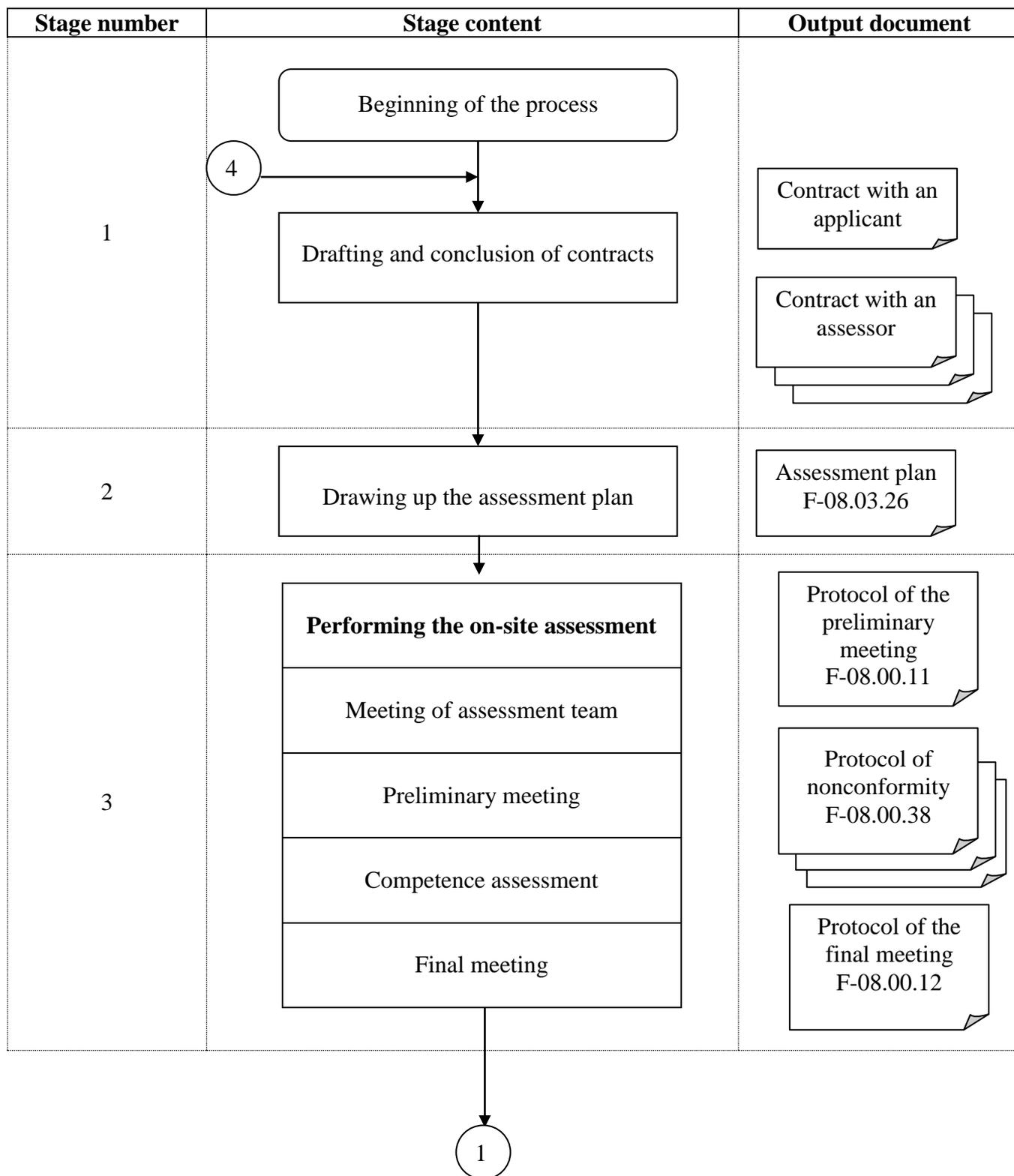
8 Developer

Chief Specialist of the Division for Quality
and Work with Personnel on Accreditation

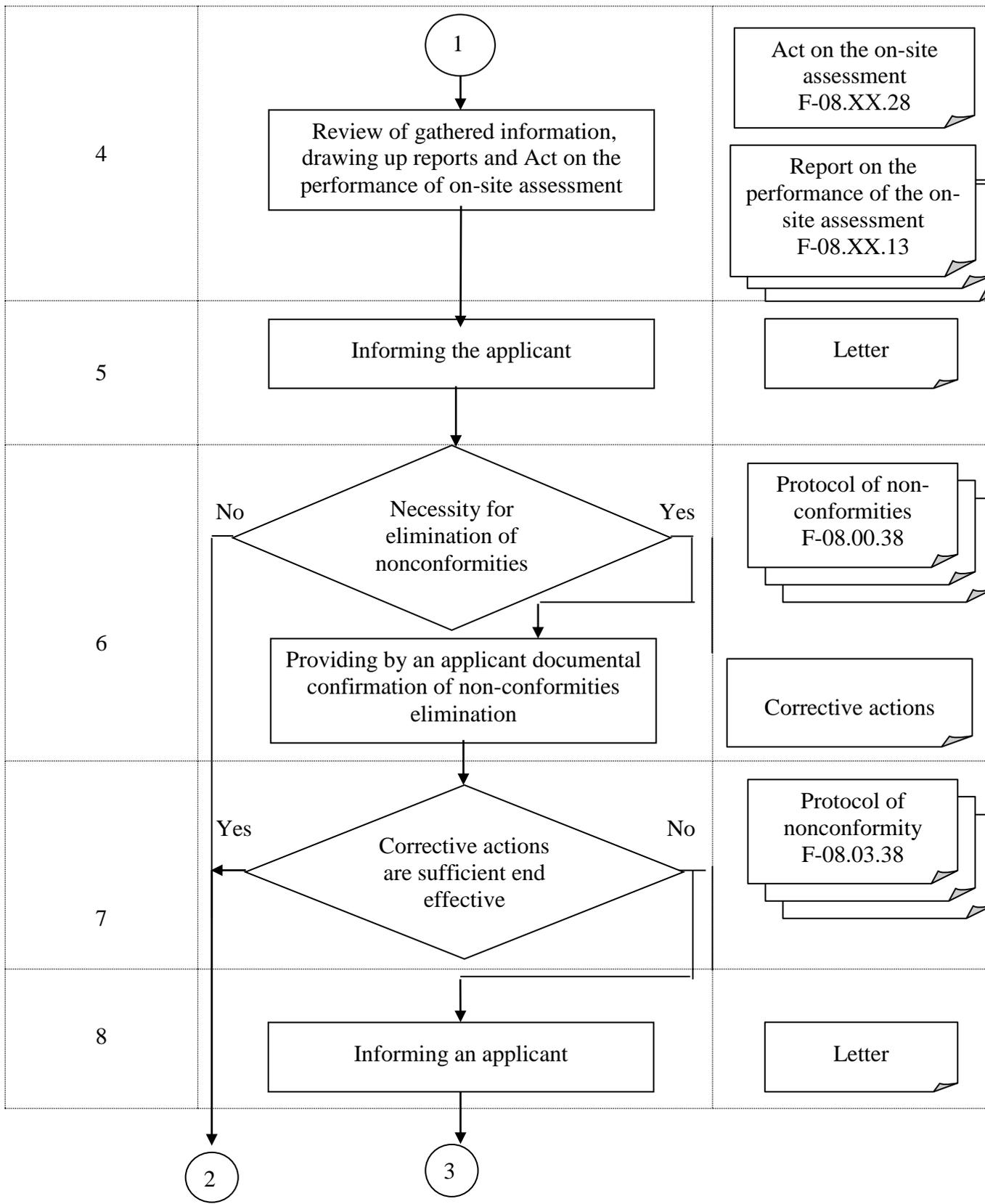
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Flow chart of process

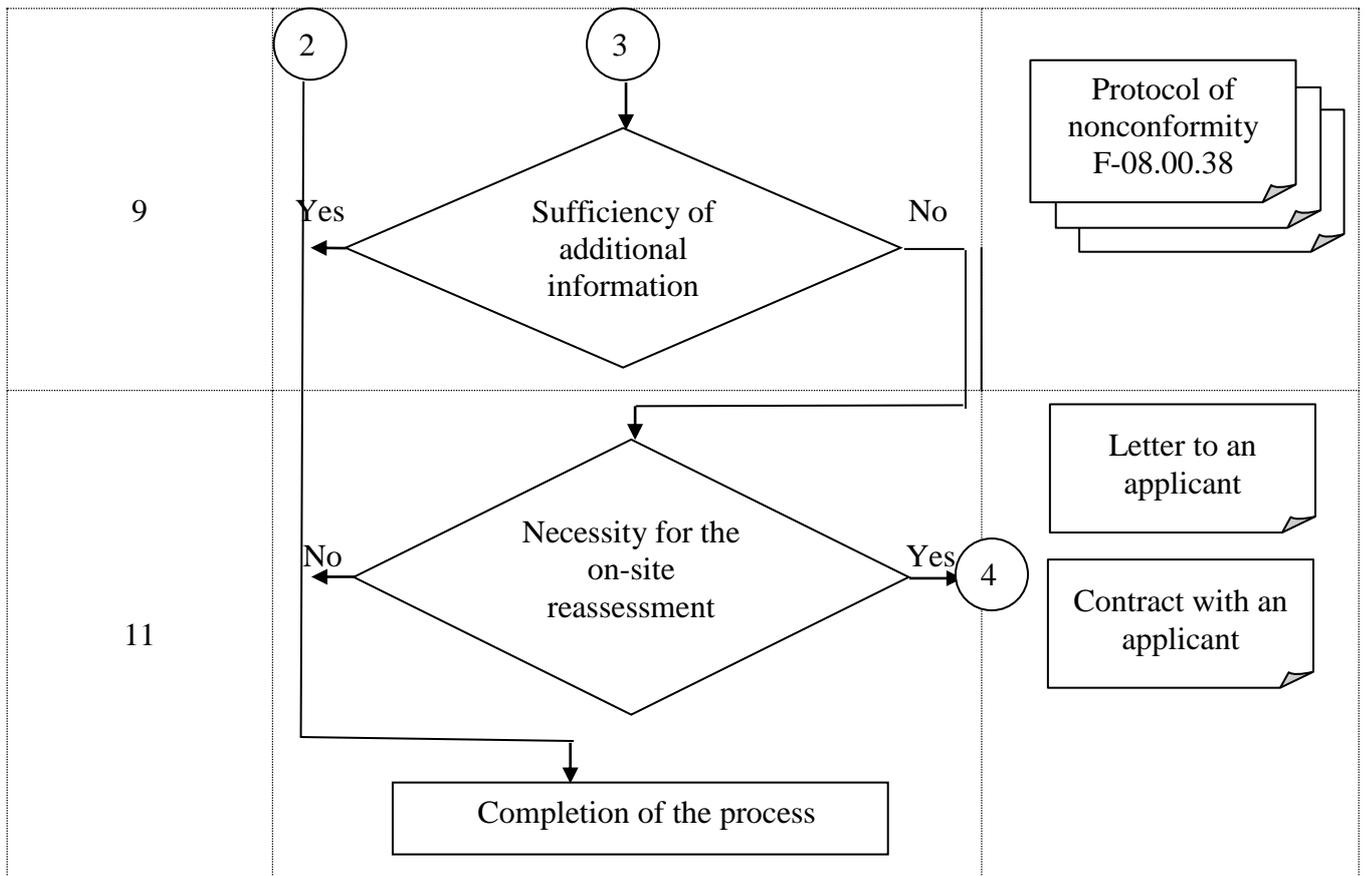


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- Act on the on-site assessment
F-08.XX.28
- Report on the performance of the on-site assessment
F-08.XX.13
- Letter
- Protocol of non-conformities
F-08.00.38
- Corrective actions
- Protocol of nonconformity
F-08.03.38
- Letter

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