

**National Accreditation  
Agency of Ukraine**

**Approved**  
NAAU Decree dated  
24.03.2015 № 195-Я

## MANAGEMENT SYSTEM

*Procedure*  
*“Organization and performing of monitoring  
by the means of reassessment of  
certification/inspection bodies”*

<b>Procedure “Organization and performing of surveillance by the means of reassessment of certification/inspection bodies”</b>			<b>NAAU</b>
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## 1. Purpose

1.1 The Procedure “Organization and performing of monitoring by the means of reassessment of certification/ inspection bodies (hereinafter – Procedure) is a constituent part of management system and is intended for creation, implementation and actualization of management system as well as for providing of resulting and effective functioning of processes that operate in the National Accreditation Agency of Ukraine (hereinafter – NAAU).

1.2 The Procedure establishes the order of performing reassessment of certification/ inspection bodies (hereinafter CAB) accredited by NAAU.

## 2. Scope

2.1 This Procedure applies to 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 to the CAB’s reassessment.

This Procedure is elaborated taking into account the Law of Ukraine “On Accreditation of Conformity Assessment Bodies” and the requirements of the European and international documents [2-18].

## 3. General provisions

3.1. CAB’s reassessment shall cover all requirements that were assessed during initial assessment. This means that selective assessment of particular requirements or areas of CAB, which is applied during surveillance for accredited CAB’s, can’t be used during performance of reassessment.

3.2. CAB’s reassessment is similar to initial assessment taking into account the information collected during the previous assessments. Reassessment is intended to assess the compliance with all requirements of accreditation for relevant type of CAB, based on verification of representative samples of certification/inspection activity.

3.3. The process of CAB’s reassessment includes the following main stages:

- receipt, incoming control and registration of application;
- appointment of the assessment team on accreditation and informing the applicant;
- review of information and documents submitted by the applicant, the results of previous assessments, drawing up the assessment program;
- drawing up the assessment plan and informing the applicant;
- carrying out on-site assessment of the CAB;
- evaluation of accreditation work results and making the decision on CAB’s accreditation.

## 4. Process description

### 4.1 Reception, incoming inspection, registration of application

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4.1.1 The applicant submits application for reassessment to NAAU according to the stated form “Application for accreditation of CAB” (F-08.00.02), and a set of documents in accordance with “List of documents enclosed to application for accreditation” (F-08.xx.03).

4.1.2 Registration of an application for accreditation performed according to the procedure requests should be performed according to the method " Reception, incoming inspection, registration of application " (P-8.8.03).

#### **4.2 Appointment of the assessment team and informing the applicant**

4.2.1 Responsible executor from **the Sector for Quality** prepares and coordinates the composition of the assessment team Accreditation (hereinafter - the assessment team), which will assess the applicant. If necessary, assessors may be involved to the team according to Procedure “Appointment of the assessment team and informing the applicant” (P-08.08.07) taking into account the assessment scope according to program on surveillance and reassessment of the CAB (F-08.xx.41), approved when granting the accreditation to this CAB.

4.2.2 The applicant is informed in advance about team membership according to Procedure (P-08.08.07).

4.2.3 Preparation and concluding of contract and sub-contracting parties is carried out according to Procedure Order of work with contracts” (P-08.08.06).

#### **4.3. Drawing up of accreditation program, review of documents submitted by applicant, results of previous assessments**

4.3.1 Assessors Team Leader draws up a program accreditation is (F-08.03.07), which takes into account the distribution of areas of assessment between members of the group auditors.

4.3.2 Appointed assessment team submitted records and documents in accordance with Procedure “Review of documents and records supplied by the applicant of certification body/inspection body” (P-08.03.11).

During the review of information and documentation submitted by the applicant, the assessment team reviews the results of last surveillance for accredited CAB. Access of assessors to the assessment materials of a certain CAB, that are hold in the NAAU’s Register is conducted according to the Instruction “The order of registration of accreditation certificates of conformity assessment bodies and maintenance of the Register of accredited conformity assessment bodies’ (IN-08.08.02).

4.3.3 In case of the positive results of review, accreditation works continue and the on-site assessment is conducted. In case of the negative results of review may be conducted re-analysis of the documents after obtaining finalized documents.

#### **4.4 Drawing up of assessment plan and informing the applicant**

Assessors Team Leader draws up assessment plan (F-08.03.26) according to the approved Program on accreditation (F-08.03.07), sends Plan to the applicant, who should agree or announce reasonable objections concerning the Plan within five working days from the moment of its receipt .

#### **4.5 Carrying out of CABs on-site assessment**

4.5.1 CAB’s on-site assessment is carried out in accordance with the assessment plan according to the Procedure “Carrying out on-site assessment of certification and inspection bodies” (P-08.03.15).

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4.5.2 If CAB has subsidiaries, during reassessment the main office is assessed necessarily and subsidiaries are selectively assessed.

#### **4.6 Evaluation of results of accreditation works and decision making on CAB's accreditation**

4.6.1 Evaluation of reassessment results, decision making on accreditation, drawing up and issuance of accreditation certificate together with accreditation scope is performed according to c.8.2.7-8.2.8 of NAAU Management Manual.

### **5. Responsible for the process functioning**

The Head of the **Division for accreditation of certification and inspection bodies** is responsible for the process functioning.

### **6. References**

This Procedure includes references to the following documents:

1. ISO/IEC 17011-2004 “Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies“.
2. NAAU Management Manual
3. ДСТУ ISO 19011:2012 “Guidelines for auditing management systems”
4. EA7/04 Legal Compliance as a part of accredited ISO 14001:2004 certification.
5. IAF MD1:2007 IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling.
6. IAF MD2:2007 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems.
7. IAF MD3:2008 IAF Mandatory Document for Advanced Surveillance and Recertification Procedures.
8. IAF MD4:2008 IAF Mandatory Document for the use of Computer Assisted Auditing Techniques (“CAAT”) for Accredited Certification of Management Systems.
9. IAF MD 5:2013 Duration of QMS and EMS Audits.
10. IAF MD 8:2011 Application of ISO/IEC 17011 in Medical Device Quality Management Systems (ISO 13485).
11. IAF MD 9:2011 Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485).
12. IAF MD 10:2013 Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021: 2011.
13. IAF MD 11:2013 Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS).
14. IAF MD 12:2013 Assessment of Certification Activities for Cross-Frontier Accreditation.
15. IAF GD 5:2006 IAF Guidance on the Application of ISO/IEC Guide 65:1996.
16. IAF GD 24:2004 IAF Guidance on the Application of ISO/IEC 17024:2003.
17. ILAC P15:06/2014 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies.

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18. IAF/ILAC A5:11/2013 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004.
19. MM Management Manual
20. F-08.00.02 Application for accreditation of conformity assessment body
21. P-08.08.03 Acceptance, incoming check, registration of application
22. P-08.08.05 Examination of submitted documents and records enclosed to the application
23. P-08.08.07 Appointment of the assessment team and informing the applicant
24. P-08.08.06 Order of work with contracts
25. P-08.03.11 Review of documents and records supplied by the applicant of certification body/inspection body
26. IN-08.08.02 “Order of conformity assessment bodies accreditation certificates registration and maintenance of accredited conformity assessment bodies Register”.
27. P-08.03.15 “Carrying out on-site assessment of certification/inspection bodies”
28. F-08.03.03 “The list of the documents, that attached to the application on accreditation of products certification bodies, processes and services on compliance with requirements ДСТУ EN 45011”.
29. F-08.10.03 “The list of the documents, that attached to the application on accreditation of Management systems certification bodies (ISO/IEC 17021:2011).
30. F-08.11.03 “The list of the documents, that attached to the application on accreditation of inspection bodies on compliance with requirements ISO/IEC 17020:2012.
31. F-08.12.03 “The list of the documents, that attached to the application on accreditation of products certification bodies, processes and services on compliance with requirements ISO/IEC 17065:2012.
32. F-08.14.03 “The list of the documents, that attached to the application on accreditation of Personnel certification bodies on compliance with requirements ISO/IEC 17024:2012
33. F-08.03.07 “Program on accreditation of certification/inspection bodies”.
34. F-08.03.41 “The Program on surveillance and reassessment of certification body”.
35. F-08.11.41 “The Program on surveillance and reassessment inspection body, accredited according to the requirements of ISO/IEC 17020:2012”.

## 7. Developer

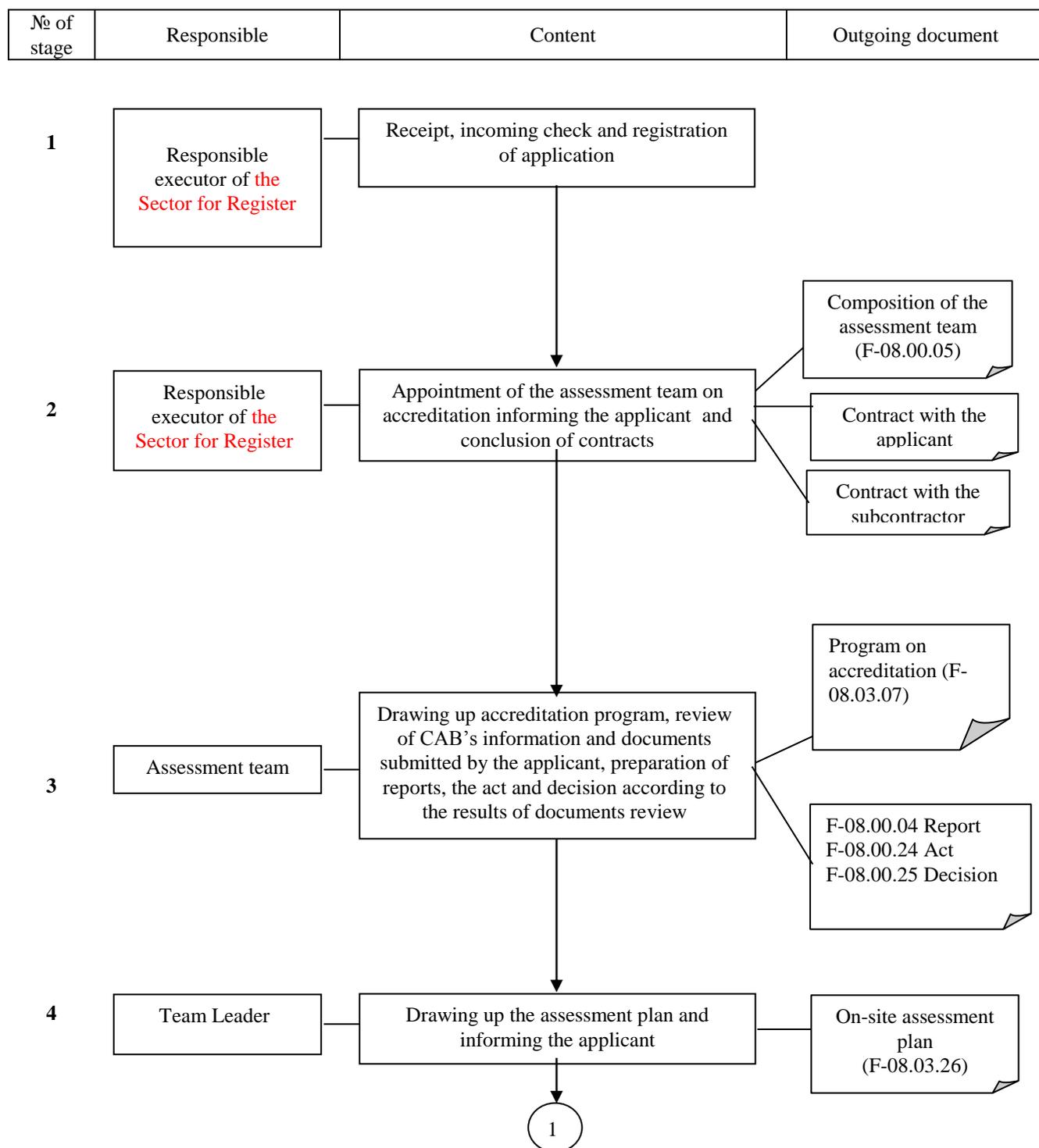
Chief Specialist of the Division for Quality  
and Accreditation Personnel Support

O. Romanovych

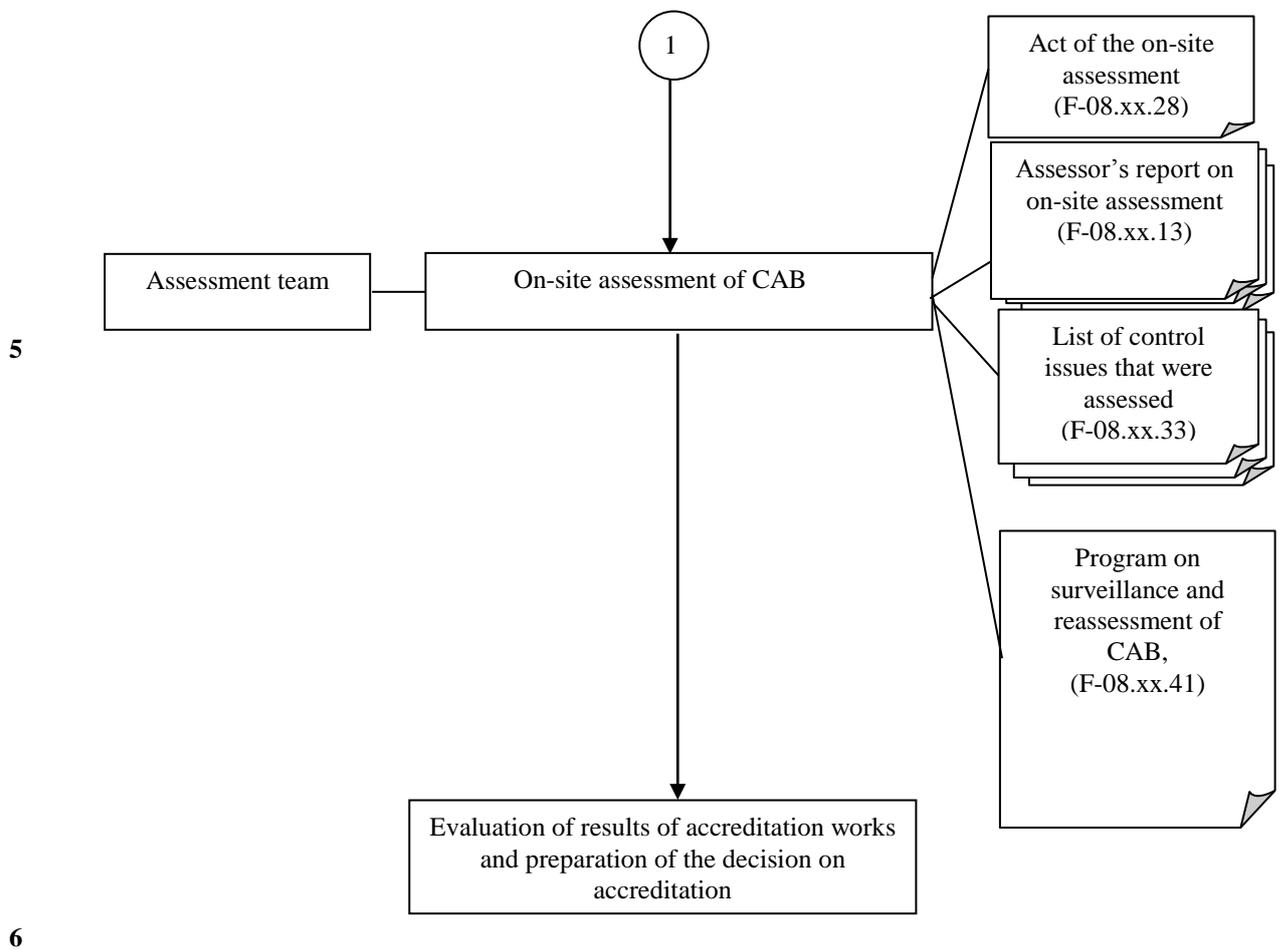
Annex 1

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## Flow chart of the basic stages of CAB's reassessment



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