

**National Accreditation Agency
of Ukraine**

Approved by
NAAU Decree
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MANAGEMENT SYSTEM

Procedure

*“Review of documents and records supplied by the applicant
of certification body/inspection body”*

Procedure “Review of documents and records supplied by the applicant of certification body/inspection body”			NAAU
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1 Purpose

Procedure “Review of documents and records supplied by the applicant of certification body/ inspection body” (hereinafter – Procedure) is a constituent part of management system of NAAU and describes the process of review of documents and records supplied by the applicant for accreditation to NAAU, monitoring by means of re-evaluation and is carried out for accreditation of certification bodies of products, processes, services, quality systems, environmental management systems, personnel certification bodies and inspection bodies (herinafter - CAB).

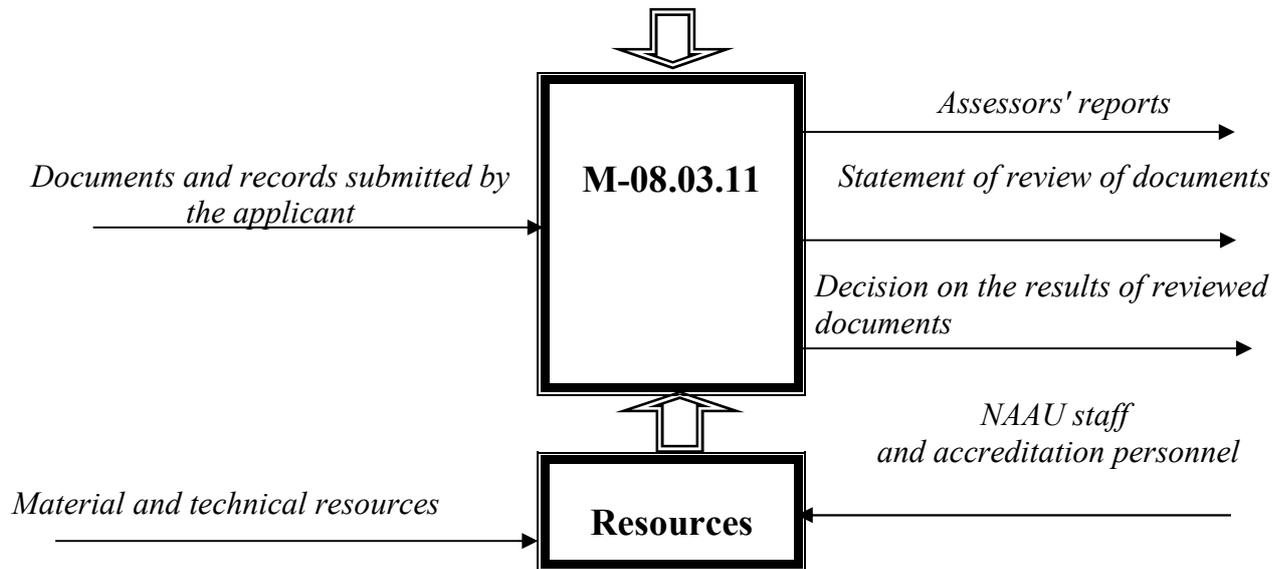
2 Scope

This Procedure applies to the department for accreditation of conformity assessment bodies, department for surveillance of conformity assessment bodies, division for accreditation issues, division for quality and international relationship, and a personnel on accreditation, which registration and issuance of accreditation certificates and accreditation personnel involved in CABs accreditation activities and monitoring by the means of re-evaluation or expansion of accreditation scope CABs.

3 Process description

3.1 Documents review model

The normative-legal acts
and normative documents requirements



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3.2 General provisions

3.2.1 A flow block of CAB document and record review (hereinafter – document analysis) is available in Annex 1.

3.2.2 Review of the documents is performed to conform CAB’s compliance with the requirements of normative documents for accreditation of a CAB taking into account the requirements of european and international documents.

3.2.3 Review of documents is performed by the appointed assessment team on accreditation (hereinafter - assessment team)

3.2.4 The possibility of subsequent CAB accreditation works is determined on the review results.

3.2.5 The main objects of review are the following documents and registered data CABs:

- application for accreditation;
- questionnaire;
- survey list;
- statutory documents of the aplicant, certificate of state registration of legal entities and Certificate of registration payer of value added tax;
- Organizational chart;
- document that guarantees the possibility of damages caused as a result of activities;
- information about the involvement of subcontractors;
- documented management system with a full set of procedures;
- “Certification Order”;
- “Quality Manual”;
- “Scope of Accreditation” stated draft;
- records on CAB personnel and certification assessors;
- data availability and outcome of appeals and complaints;
- information about certificates (issued by group of products);
- for certification of management systems bodies - the list of certified organizations for economies (including the location and description of the field of certification);
- for inspection bodies - declaration of the independence of the inspection body under types (A,B,C), a list of techniques and equipment used for work inspection, with date of last calibration certificates, list issued and/or inspection reports, declaration of the right to ensure confidentiality;
- for personnel certification bodies - information about examiners;
- another documents provided by applicant to NAAU according to the list of documents enclosed to CAB application for accreditation.

3.2.6 During the review of NAAU documents an enquiry to CAB can be done to get additional records and documents and information related to CAB functioning and activity according to it’s declared scope of accreditation.

3.2.7 Review of documents and records supplied by the applicant is carried out in the following order:

- documents transfer to the assessment team leader for review;
- documents distribution among assessment team members;
- examination of records about declared status of CAB;
- technical analysis of documents;
- terminological analysis of documents;

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- drawing up conclusions on the review results and possibility to continue CAB accreditation works;
- formalize assessors' reports on document review performance and transfer them to the team leader;
- team leader formalizes statement of document review and passes it to NAAU;
- prepare decision;
- informing the applicant about results of works carried out.

3.2.8 During the review the protection of confidentiality of information contained in the documents shall be ensured.

3.3 Receiving and transfer the documents for review

3.3.1 Registry sector transfers application with documents set to the head of department of conformity assessment bodies to analyze documents CABs.

3.3.2 A responsible executor of the related division of accreditation of certification and inspection bodies transfers documents in paper and electronic version to the team leader of assessment team.

3.4 Documents distribution among assessment team members

The team leader of the assessment team assigns duties among assessment team members and draws up assessment program of CAB F-08.03.07. According to assessment program of CAB F-08.03.07 the team leader distributes documents among team members for review.

3.5 Verification of records concerning declared CAB status of applicant

This verification is performed by the analysis of information, which is in statutory and other documents concerning applicants' availability of organizational structure in CAB and the rights for certification work management in the declared scope of accreditation and on CAB compliance with the requirements, set to the "third part"

3.6 Review of documents

3.6.1 Review of documents includes:

- analysis of documents formalization;
- technical analysis of document contents;
- terminological analysis of documents.

3.6.2 Analysis of document formalization includes the following:

- verification legalization of covering paper, names, forms and titles of their columns;
- verification availability of a number of necessary document forms;
- control availability of obligatory chapters in supplied documents.

3.6.3 Technical review of CABs documents contents is carried out in accordance with submitted documents verification:

- requirements and provisions of specific normative documents, according to which CAB accreditation is performed;
- requirements of active national, regional and international standards of production, management system, personnel etc;
- general and specific requirements to CAB accreditation established by NAAU or by international and European organizations of accreditation.

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3.6.3.1 During review of the draft “Scope of Accreditation” the following actions are performed:

- analysis of correctness of signs and titles of normative documents (hereinafter - ND);
- analysis of ND validity;
- analysis of completeness and correctness of mentioned branches of accreditations for specific type of CAB.

3.6.3.2 Review of “Quality Manual”, CAB Questionnaire and “Order of Certification” are carried out by analysis of completeness of information given in the documents in the amount necessary for certification functioning in declared scope of accreditation according to the requirements of ND for accreditation and supplied records on compliance with accreditation requirements.

3.6.3.3 During review of CAB’s data staff is evaluate the sufficiency of personnel with necessary education, technical knowledge and experience for certification functioning in declared scope of accreditation is assesed during analysis of contents of information about personnel of CAB including assessors for certification.

3.6.3.4 Analysis of contents of questionnaire is carried out to get additional records about CAB:

- corporative affiliation;
- ND fund;
- records about subcontractors;
- activity in other accreditation systems, availability of special authority, licences, etc;
- records about person who is responsible for internal quality system;
- actually availability of testing laboratory.

3.6.4 Terminological analysis of documents

3.6.4.1 Basic objects of terminological analysis:

- research terms;
- the names of production (processes, services), kinds of economic activities, types of inspections, name of stuff, etc;
- technical terms.

3.6.4.2 During terminological analysis of documents are evaluat of correct usage of research, technical and other terms in the supplied documents their conformity is determined with the terms that are used in particular ND (normative documents) according to declared scope of accreditation and also their conformity with the standard of scientific and technical terms, requirements and provision of ND on certification.

3.7 Drawing up conclusion on the document review results

3.7.1 Conclusion on the review results and possibilities to continue CAB accreditation works should be based on CAB assessment on the following points:

- CAB status;
- advisability of the choice expediency of CAB scope of accreditation;
- quality policy;
- CAB structure and the distribution of certification functions among subdivisions and CAB specialists;
- staff competence;
- availability of documentary procedures in certification carrying out;

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- material and technical support in certification works performance;
- availability of agreements with organizations CAB deals with during certification works performance;

3.7.2 On the basis of the above mentioned and on the basis of review of the information and documentation submitted by an applicant, every assessment team member except team leader, draws up the “Assessor's report on the review of documentation” (F-08.00.04), where write the list of reviewed documents and observations on them in accordance with the requirements of the standard, and the findings from the analysis of documents.

3.7.3 Team members submit reports to the assessment team leader on paper and electronic carriers meeting the requirements of confidentiality. Assessment team leader doesn't draw up the “Assessors's report on the review of the submitted information and documentation ” (F-08.00.04), but draws up “Act on the document review” (F-08.00.24), where write the list of reviewed documents and observations on them in accordance with the requirements of the standard, and the findings from the analysis of documents.

3.8 Drawing up CAB's documents review results

3.8.1 Act of the document review together with the assessment report are transferred to NAAU on paper and electronic version carrier under conditions of confidentiality. A person in charge of the Division for accreditation certification and inspection bodies prepares the draft "Decision on the results of analysis of the act on document review" (F-08.00.25).

After analysis of reviewing determined the possibility continue the work of accreditation CAB, namely decisions on:

- documents conformity to regulatory of requirement documents of accreditation;
- conduction of re-analysis of documents;
- conduction of further work of accreditation;
- necessity of conduction CAB assessment in place.

Responsibility of persons involved in decision making on the results of analysis of the Act on submitted information and documentation review (F-08.00.25) is determined in the cl.8.2.8 of the NAAU Management Manual.

3.8.2 A person in charge of the Division for accreditation of certification and inspection bodies / Division for accreditation of inspection bodies sends to an applicant one example of the Act of document review with one example of the Decision confirmed by the NAAU Chairman and other example attached to the CAB case.

4 Matrix of responsibility of document review

Stages of work	Head of the Division for accreditation OS and OI	A person in charge	Assessment Team Leader	Assessment team member
Stage 3.3	C	P		
Stage 3.4			P	
Stage 3.5			P	
Stage 3.6			P, C	P
Stage 3.7			P, C	P

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Stage 3.8			P	
Stage 3.9	C	P		

Symbols:

C – Controls the performance and its correctness

P – Performs the work stage

A – Analyses

5 Responsible for process functioning

The Head of relevant accreditation department of certification and inspection bodies is responsible for CAB documents review functioning

6 References

There are such references on the following documents:

- EA7/04 Legal Compliance as a part of accredited ISO 14001:2004 certification.
- IAF MD1:2007 IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling.
- IAF MD2:2007 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems.
- IAF MD3:2008 IAF Mandatory Document for Advanced Surveillance and Recertification Procedures.
- IAF MD4:2008 IAF Mandatory Document for the use of Computer Assisted Auditing Techniques (“CAAT”) for Accredited Certification of Management Systems.
- IAF MD 5:2013 Duration of QMS and EMS Audits.
- IAF MD 7:2010 Harmonisation of Sanctions.
- IAF MD 8:2011 Application of ISO/IEC 17011 in Medical Device Quality Management Systems (ISO 13485).
- IAF MD 9:2011 Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485).
- IAF MD 10:2013 Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021: 2011.
- IAF MD 11:2013 Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS).
- IAF MD 12: 2013 Assessment of Certification Activities for Cross-Frontier Accreditation.
- ILAC P15:06/2014 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies.
- IAF/ILAC A5:11/2013 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004.
- F-08.00.04 “Assessor accreditation report on documents analysis”
- F-08.03.07 “Programme of certification/inspection body accreditation”
- F-08.00.24 “CABs documents analysis act”.
- F-08.00.25 “Decision on the results on processing act on documents analysis ”.

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7 Developed by

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Appendix 1

Flow-chart of basic stages of CAB document review process

Stage	Executive	Activities	Documentary
3.3	A person in charge of the Division for accreditation	Receiving and transfer of documents for review of team leader	Application with documents set
3.4	Team leader	Documents distribution among team members	Accreditation Program F-08.03.07
3.5	Team leader	Examination of records about declared CAB status	Act F-08.00.24
3.6 3.7	Assessors on accreditation / experts	Technical and terminological analysis of documents	F-08.XX.10
3.8	Assessors on accreditation / experts	Drawing up reports and their submission to an assessment team leader Drawing up the conclusion of the review results and possibilities to continue CAB accreditation works	Reports F-08.00.04
3.8	Assessment team leader	Drawing up conclusions on the basis of the submitted information and documentation results	Act F-08.00.24
3.9	A person in charge of the Division for accreditation of CB/IB	Drawing up the Decision on the basis of the submitted information and documentation results	Decision F-08.00.25
3.9	A person in charge of the Division for	Sending to an applicant the Act and Decision	Act F-08.00.25 Decision 08.00.25
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