

National Accreditation
Agency of Ukraine

Approved
by the decree of NAAU
dated 16.06.2015 № 198-Я

MANAGEMENT SYSTEM

Procedure “Conducting of Witnessing”

Procedure “Conducting of Witnessing”			NAAU	
Revision 13 dated 16.06.2015	Developed by:	Checked by:	Page	1
	O. Hromenko	V. Kراسиuk	Total number	14

1. Scope

1.1 This Procedure applies to NAAU departments involved in witnessing process and accreditation personnel.

1.2 The Procedure is used during witnessing of CABs' rendering conformity assessment services in compliance with the scope of accreditation.

1.3. This Procedure does not apply to accreditation of laboratories.

2. Terms and definitions

2.1 Definitions stated in ДСТУ ISO/IEC 17011:2005, ДСТУ ISO 17011:2005 and ISO/IEC 17000:2004 are used in this Procedure.

2.2 The following abbreviations are used in this Procedure:

- NAAU – National Accreditation Agency of Ukraine;
- CAB – conformity assessment body.

3. General provisions

3.1 Procedure for conducting of witnessing is developed taking into account the Law of Ukraine “On accreditation of conformity assessment bodies” and the requirements of the documents on accreditation [1-4];

3.2 Witnessing is carried out by NAAU in order to identify conformity of CAB to the requirements for accreditation. Witnessing is carried out by a team leader with involving of experts in a relevant scope or assessors having competence in a relevant scope.

3.3 CAB's refusal to perform witnessing and non-payment for witnessing is a ground for:

- refusal in accreditation;
- suspension of accreditation;
- withdrawal of accreditation.

3.4. Objective of witnessing is:

- to verify implementation by the assessors of a CAB's procedures and forms;
- to verify the effectiveness of procedures adopted by a CAB with a specific reference to the use of assessors with the required competence (planning, job assignment, records handling);
- to verify that assessments undertaken by a CAB are effective, considering the certification criteria and requirements of ISO/IEC 17021, ISO/IEC 17065, ISO/IEC 17024 and ISO/IEC 17020;
- to enable recommendations on rendering, maintenance and withdrawal of accreditation.

The main reason for witnessing is the need to accomplish the above-mentioned objective, although witnessing can also be triggered by, for example, the receipt of complaints, appeals, controversial issues, etc.

3.5. A CAB shall provide its client with an explanation that witnessing is to be conducted by NAAU, noting that it shall not affect the normal course of assessment, since NAAU representatives will not interfere with or put questions directly to a client. Refusal by a CAB (specifically refusal originating from a CAB's client) from a specific witnessing shall be analyzed separately. Unless fully justified, the refusal shall result in a certificate being issued for a client without reference to accreditation.

3.6. In order to ensure the adequate preparation for witnessing a CAB shall submit to NAAU all required for this information (e.g., procedures, evidence of assessors' competence, plan, assessment program etc.).

3.7. The object of witnessing shall be determined by NAAU upon the information given in the **CAB's application and in the period of one month before the planned surveillance of CAB**

Procedure “Conducting of Witnessing”			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	2
			Total number	18

The location of witnessing is the object of conformity assessment being on the territory of Ukraine or, upon receiving the consent of a CAB, beyond its borders.

4. Determining the number of witnessed audits.

4.1 For management system certification bodies

During initial accreditation:

- one witnessing within each of the clusters identified in **Appendix 2 for certification scheme OHSAS 18001**. When selecting scopes a preference shall be given to scopes that require more stringent requirements for the competence because of the high risk or **provisions of legal regulation (marked in black)**, while the total number of witness audits for a CAB shall not be less than 2;

- **for bodies that certify management systems against ISO 9001 and/or ISO 14001, IAF MD 17 is used.**

- for bodies certifying management systems for compliance with ISO 22000 the EA-3/11 shall be applied;

- for bodies certifying quality management systems for medical devices **against ISO 13485 (Appendix 6), IAF MD 8 is used. During the initial assessment the witnessing for basic technical areas (with the biggest degree of risk) listed in the table from Appendix 6 is performed. During the reassessment and surveillance the witnessing activities are performed according to the Program for surveillance and reassessment (F-08.03.41).**

- for bodies performing accreditation in accordance with EnMS ISO 50001 (Appendix 3) – clusters are divided into three groups: complex energy clusters, high demand energy users and regular energy users. It is required that all CAB’s clients that are complex energy users shall be witnessed before being added to the scope of accreditation. Applicants for accreditation within the high demand and regular energy clusters can be assessed via witnessing or by documentary evidence;

- for bodies performing certification in accordance with FSMS ISO 22003 (Appendix 4): clusters are based on the requirements of ISO 22003 and mandatory document EA 3/11. All applications within codes A to M shall be witnessed in each case;

- for bodies performing certification in accordance with ISMS ISO 27001 (Appendix 5): cluster codes currently follow IAF ID1. A CAB shall develop technical areas that encompass IAF codes (or parts thereof) and witnessing will be mandatory within these technical areas. A CAB shall develop a rationale for choosing technical area and have records to demonstrate that all CAB’s personnel have the necessary competence to fulfill their role within the organization for each technical area.

During extension of the scope of CAB’s accreditation

NAAU requires witnessing of any code that is indicated as being critical in the attached Appendices should a CAB apply to extend its scope of accreditation in that area. Extensions for non-critical codes may be proceeded without further witnessing provided that a code from that cluster has already been accredited. In the event that no code from the clusters has been accredited then a witnessed audit will be required.

IAF MD 17 is used for ISO 9001 and ISO 14001 management systems.

During monitoring by way of surveillance

NAAU requires **witnessing for each CAB. The number of witnessing is defined in the Program for surveillance and re-evaluation of certification body (F-08.03.41). During the surveillance, witnessing is carrying out primarily for fields of economy that were not witnessed during the initial accreditation**

Procedure “Conducting of Witnessing”			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	3
			Total number	18

NAAU preserves the right to expand **the number of witnessing** if, for instance, new auditors **were hired for work** in CAB or due to other factors (e.g., complaints, appeals, **requests** etc.).

- For bodies certifying quality management systems for medical devices (ISO 13485) the IAF MD 8 shall be applied. **During surveillance, the witnessing activities are performed according to the Program for surveillance and reassessment (F-08.03.41).** During surveillance, NAAU shall ensure that at least one witnessing is performed for every basic technical scope for the accreditation cycle.

For **surveillance** of FSMS – IAF MD 16 is applied.

Witnessing for ISO 9001 and ISO 14001 (planning for accreditation cycle, preparation, execution) is carried out taking into account the provisions of IAF MD 17:2015 Witnessing Activities for the Accreditation of Management Systems Certification Bodies.

During re-accreditation:

- one witnessing (a choice is made while taking into account the results of previous witnessed audits) of one of the scopes marked in black (Appendix 2);

- for bodies certifying management systems for compliance with ISO 22000 the **IAF MD 16** shall be applied;

- for bodies certifying quality management systems for medical devices (ISO 13485) the IAF MD 8 shall be applied.

During the reassessment, witnessing is performed in accordance with the Program for surveillance and reassessment (F-08.03.41).

4.2 For personnel certification bodies

For initial assessment, all schemes shall be witnessed at least twice what is necessary in order to make a recommendation for award of accreditation.

For surveillance and re-assessment, all schemes shall be witnessed over the accreditation cycle with the maximum number of CAB's **personnel** witnessed. **The number of witnessing is defined in the Program for surveillance and re-evaluation of certification body (F-08.03.41).**

The objects for witnessing may be:

- examination;
- CB's decision making process regarding certification.

4.3 For inspection bodies

During initial accreditation and re-accreditation

NAAU assesses all inspection methods which inspection body applies for.

While planning witnessed audits during initial accreditation and re-accreditation, NAAU establishes:

- for inspection bodies using methods of non-destructive testing – two witnessed audits in different methods of non-destructive testing. While making a choice of inspection procedures to be witnessed it a preference shall be given to methods that require more competence (for example, ultrasound, radiography) or non-standardized methods;

- for vehicles' inspection bodies with the purpose of state technical supervision – 1 witnessed audit of road vehicles' inspection process according to the applied scope of accreditation and 1 witnessed audit – in the field of state technical supervision of tractors, motor vehicle chassis, mobile agricultural, road-building and land reclamation machinery, agricultural equipment, other mechanisms;

- for other inspection bodies – 2 witnessed audits in different inspection processes (different inspection procedures). While making a choice of inspection procedures to be witnessed a preference shall be given to more complex inspection methods or non-standardized methods.

Procedure "Conducting of Witnessing"			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Kراسиuk	Page	4
			Total number	18

During monitoring by way of surveillance:

Witnessing of all inspection methods determined by the scope of accreditation (a choice is made while taking into account results of previous witnessed audits) shall be carried out by NAAU over the accreditation cycle (during planned surveillances).

4.4 For bodies certifying products, processes and services

For initial assessment, all schemes shall be witnessed which is necessary in order to make a recommendation for award of accreditation.

For surveillance and re-assessment, all schemes shall be witnessed over the accreditation cycle with the maximum number of CAB's auditors witnessed. **The number of witnessing is defined in the Program for surveillance and re-evaluation of certification body (F-08.03.41).**

The objects for witnessing may be any activity performed by a CB out of office. For instance:

- observation/control of products' manufacturing processes;
- on-site assessment of client's rendering services (e.g., hotel services, barbering services etc.);
- sampling and identification of samples for testing;
- accuracy of marking of certified stationary products (e.g., for stationary equipment).

For bodies certifying organic products the assessment, witnessing and surveillance shall be carried out in accordance with the EA-3/11.

5. Process description

5.1 The process begins with submission by CAB of application letter F-08.03.53 for witnessing performance.

5.2 Head of department appoints a person in charge.

5.3. Assessor for witnessing of assessment is appointed by a Head of department usually from among agreed assessment team F-08.00.05 taking into account the competence according to clause 3.2.3 of P-08.08.07.

5.4. A person in charge prepares a contract with a CAB according to the Procedure P-08.08.06.

5.5. If necessary, a person in charge prepares a contract with subcontractors according to the Procedure P-08.08.06.

5.6. A person in charge **(if necessary)** informs a CAB in writing about witnessing by fax or via e-mail. The necessity of witnessing is justified in a cover letter attached to the decision F-08.00.25.

If the CAB or its client refuse to provide witnessing, measures outlined by IAF MD 17 are applied:

- **suspension of accreditation certificate,**
- **suspension (or withdrawal) of accredited certificate,**
- **prohibition of the accreditation or certification reference usage.**

5.7 The commencement of works shall begin after a CAB has paid an invoice according to a contract on witnessing of assessment **or a contract on carrying out of works on monitoring through the surveillance.**

5.8 Witness audits shall be conducted in compliance with the following rules.

5.8.1 With the purpose of a proper preparation, the assessment team shall receive beforehand the audit plan, results of the previous audit, evidence of auditor competence and justification of the number of auditor days.

Procedure "Conducting of Witnessing"			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	5
			Total number	18

5.8.2 Team members shall not interfere with a normal course of the audit. However, it shall not prevent NAAU assessment team from communicating during their work and **get access to corresponding CAB's client documents on request.**

5.8.3 If NAAU assessment team requires explanation on the actions performed by CAB's auditors, this is usually done at the end of the audit. However, an explanation may be requested during the audit if such questions do not affect results of an audit.

5.8.4 The meeting between NAAU assessment team and CAB's audit team usually occurs as soon as possible after witnessing has been completed. The purpose of this meeting is for NAAU to obtain answers and summarize the outcomes as well as to provide explanations and additional information.

5.8.5 At this stage NAAU shall announce preliminary results (including non-conformities), although a CAB may be required to provide evidence later, especially when a CAB is required to provide a report (and solutions).

5.8.6 The results shall be neither announced nor disclosed to CAB's audit team before the end of witnessing.

5.8.7 A direct survey of the client shall not take place. However, NAAU assessment team may request CAB's audit team to transmit any documents they have learned so that NAAU team could see what exactly has been checked.

5.8.8 In the event of non-conformity being found a non-conformity report shall be drawn up (F-08.00.38), the original of which is given to a head of the audit of a CAB.

5.9 An assessor shall submit to NAAU the witnessing report (F-08.XX.01) and copies of non-conformities within one week after the end of witnessing.

5.10 A person in charge shall analyze the report for compliance with the requirements of this procedure promptly after he has received it; provided there are no remarks he shall then transfer it to the Head of division on accreditation of certification bodies for familiarization. After a Head of division has been acquainted, the report shall be attached to a CAB's file. If the report does not meet the requirements of this procedure, a person in charge shall return the report to the assessor who has conducted surveillance for revision. The time period for revision of the report shall not exceed one week.

5.11 Informing of the CAB on the results of work done shall be made by providing the report. Informing could be made by fax or via email.

5.12 A CAB shall not later than in 1 month after the completion of the audit to provide NAAU with information about corrective actions.

5.13 Block diagram of the process of witnessing of the assessment is given in Appendix 1.

6. Person in charge of the process' functioning

Heads of the relevant departments and divisions are responsible for the process functioning.

7. References

There are references to the following documents in this Procedure:

1. ДІСІ ISO/IEC 17011:2005 «General requirements for accreditation bodies accrediting conformity assessment bodies».
2. AF MD 8:2015 Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485) (Issue 2, issued on 08 January 2015; Application from 08 January 2016)
3. IAF MD16:2014 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies (Issue 1, Version 2, issued on 19 January 2015; Application from 15 December 2016)

Procedure "Conducting of Witnessing"			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	6
			Total number	18

4. IAF MD 17:2015 Witnessing Activities for the Accreditation of Management Systems Certification Bodies (Issue 1, Version 2, issued on 09 January 2015; Application from 07 January 2018)
5. EA-3/11- Food Safety Management Systems – Scope of Accreditation.
6. IAF ID1:2014 IAF Informative Document for QMS and EMS Scopes of Accreditation.
7. P-08.08.06 "Order of contract handling".
8. P-08.08.07 "Appointment of assessment team and informing an applicant".
9. F-08.03.53 "CAB application letter on witnessing".
10. F-08.03.05 "Assessor team membership for CAB assessment".
11. F-08.03.01 "Assessor's report on witnessing from assessment conducted by product certification body".
12. F-08.07.01–WTV (Wheeled Transport Vehicle) "Assessor's report on witnessing from assessment conducted by WTV inspection body".
13. F-08.07.01–ACM (Agricultural Machinery) "Assessor's report on witnessing from assessment conducted by ACM inspection body".
14. F-08.10.01 ""Assessor's report on witnessing from assessment conducted by management certification body".
15. F-08.14.01 "Assessor's report on witnessing from assessment conducted by personnel certification body".
16. F-08.00.25 "Decision on results of document review statement consideration".
17. F-08.03.41 "Program for surveillance and re-evaluation of certification body".

8. Drafter

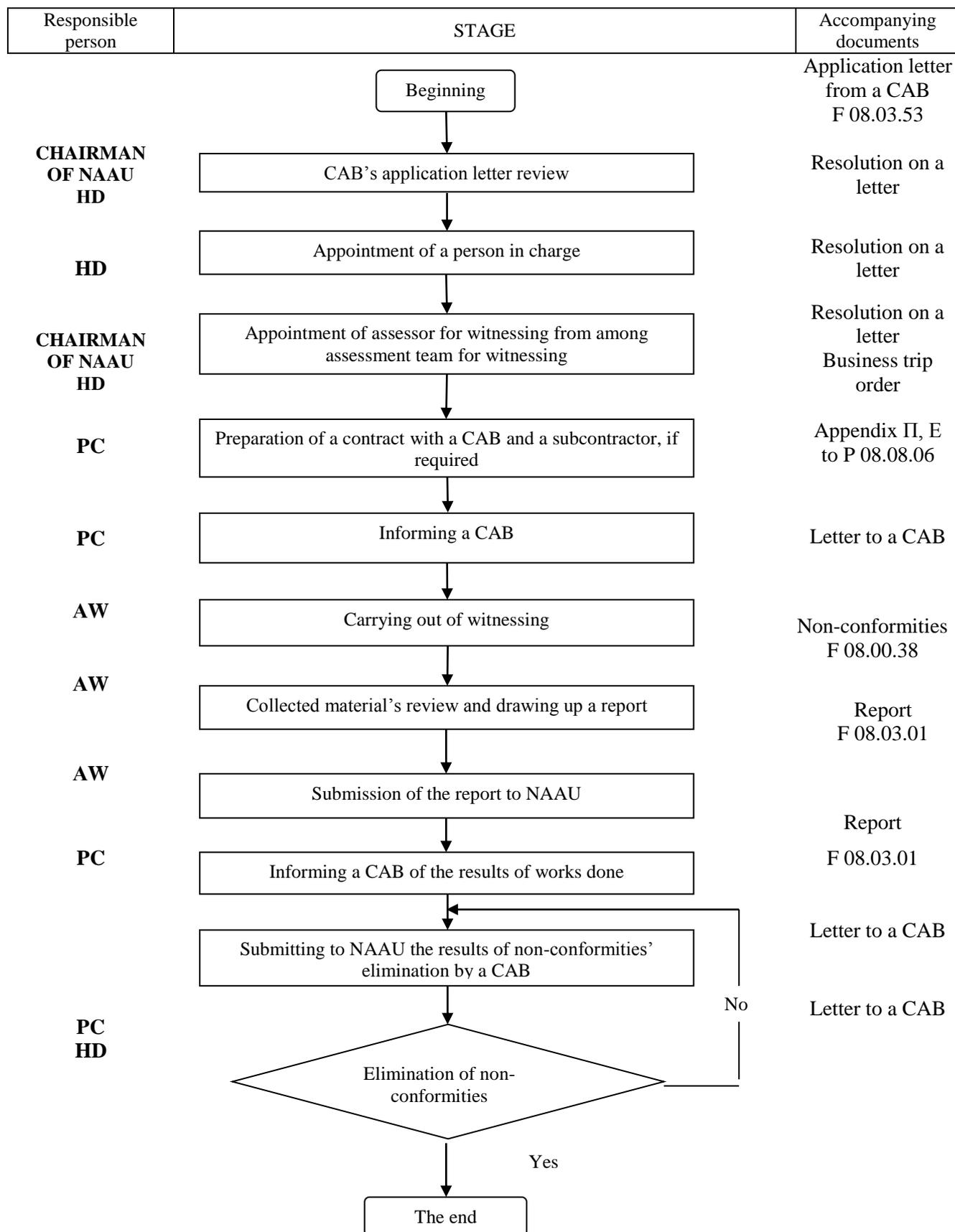
Head of the Sector for Quality

O. Hromenko

Procedure "Conducting of Witnessing"			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Kراسиuk	Page	7
			Total number	18

FLOW-CHART

HD – Head of division;
 PC – person in charge;
 AW – assessor who performs witnessing.



Procedure "Conducting of Witnessing"			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	8
			Total number	18

Determination of necessity of witnessing of management system certification bodies according to
declared sector of economy and standards

№	Sector of economy	NACE Code	Cluster	Standard
				OHSAS 18001
1	Agriculture, fishing	A, B	C.1	
2	Mining and quarrying	C	C.1	
3	Food products, beverage and tobacco	DA	C.5	
4	Textiles and textile products	DB	C.3	
5	Leather and leather products	DC	C.3	
6	Wood and wood products	DD	C.3	
7 (partly)	Pulp, paper and paper products	DE 21.1	C.5	
7 (partly)	Pulp, paper and paper products	DE 21.2	C.3	
8	Publishing companies	DE 22.1	C.3	
9	Printing companies	DE 22.2 DE 22.3	C.3	
10	Manufacture of coke and refined petroleum products	DF 23.1 DF 23.2	C.5	
11	Nuclear fuel	DF 23.3	C.4	
12	Chemicals, chemical products and fibres	DG	C.5	
13	Pharmaceuticals	DG minus 24.4	C.5	
14	Rubber and plastic products	DH	C.3	
15	Non—metallic mineral products	DI minus 26.5, 26.6	C.5	
16	Concrete, cement, lime, plaster etc	DI 26.5, 26.6	C.5	
17	Basic metals and fabricated metal products	DJ	C.1 або C.3	
18	Machinery and equipment	DK	C.3	
19	Electrical and optical equipment	DL	C.3	
20	Shipbuilding	DM 35.1	C.3	
21	Aerospace	DM 35.3	C.3	
22	Other transport equipment	DM 34, 35.2, 35.4,35.5	C.3	
23	Manufacturing not elsewhere classified	DN 36	C.3	
24	Recycling	DN 37	C.5	
25	Electricity supply	E 40.1	C.5	
26	Gas supply	E 40.2	C.5	
27	Water supply	E 41, 40.3	C.5	
28	Construction	F	C.3	
29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	G	C.2	
30	Hotels and restaurants	H	C.2	
31	Transport, storage and communication	I	C.2	
32	Financial intermediation; real estate; renting	J K 70, 71	C.2	
33	Information technology	K 72	C.2	
Procedure “Conducting of Witnessing”			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	9
			Total number	18

34	Engineering services	K 73, 74.2	C.2	
35	Other services	K 74 minus 74.2	C.2	
36	Public administration	L	C.2	
37	Education	M	C.2	
38	Health and social work	N	C.2	
39	Other social services	O	C.2	
39 (partly)	Sanitary services, waste removal and destruction	O 90	C.5	

C.1	Primary processing
C.2	Services
C.3	Production
C.4	Production of nuclear fuel
C.5	Reprocessing
	Priority scopes for witnessing within the frame of cluster

Procedure “Conducting of Witnessing”			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Kراسиuk	Page	10
			Total number	18

Energy Management Systems (ISO 50001) Activities

IAF sector	NACE code	Description	Cluster	Critical code
2	05, 06, 07, 08, 09	Mining and quarrying	C	2 10 12 17 (part) 25
10	19	Manufacture of coke and refined petroleum products		
12	20	Chemicals, chemical products and fibres		
17 (part)	24 except 24.46	Manufacture of basic metals		
25	35.1	Electricity supply		
1	01, 02, 03	Agriculture, forestry and fishing	H	
3	10, 11, 12	Food products, beverages and tobaccos		
7 (part)	17.1	Pulp and paper		
11	24.46	Nuclear fuel		
13	21	Pharmaceuticals		
15	23, except 23.5 and 23.6	Non-metallic mineral products		
16	23.5, 23.6	Concrete, cement, lime, plaster, etc.		
17 (part)	25 except 25.4, 33.11	Manufacture of fabricated metal products, except		
20	30.1, 33.15	Shipbuilding		
21	30.3, 33.16	Aerospace		
22	29, 30.2, 30.9, 33.17	Other transport equipment		
38	86.1	Hospitals		
31 (part)	49, 50, 51	Transport		
4	13, 14	Textiles and textile products		
5	15	Leather and leather products		
6	16	Wood and wood products		
7 (part)	17.2	Paper products		
8	58.1, 59.2	Publishing of books, periodicals and other publishing activities, sound recording and music publishing activities		
9	18	Printing companies		

Procedure "Conducting of Witnessing"			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	11
			Total number	18

14	22	Rubber and plastic products		
18	24.5, 28, 30.4, 33.12, 33.2	Machinery and equipment		
19	26, 27, 33.13, 33.14, 95.	Electrical and optical equipment		
23	31, 32, 33.19	Manufacturing not elsewhere classified		
24	38.3	Recycling		
26	35.2	Gas supply		
27	35.3, 36	Water supply		
28	41, 42, 43	Construction		
29	45, 46, 47, 95.2	Wholesale and retail trade; Repair of motor vehicles, motor cycles and personal and household goods		
30	55, 56	Hotels and restaurants		
31 (part)	52, 53, 61	Storage and communication		
32	64, 65, 66, 68, 77	Financial mediation; real estate; renting		
33	58.2, 62, 63.1	Information technology		
34	71, 72, 74 except 74.2 and 74.3	Engineering services; research and development; other professional, scientific and technical		
35	69, 70, 73, 74.2, 74.3, 78, 80, 81, 82	Other professional services		
36	84	Public administration		
37	85	Education		
38	75, 86, 87, 88	Health and social work		
39 (part)	37, 38.1, 38.2, 39	Sewerage and waste collection treatment and disposal		
39 (part)	59.1, 60, 63.9, 79, 90, 91, 92, 93, 94, 96	Other social services		

Explanation of the cluster codes for the activities listed above:

- C Complex energy users
- H High demand energy users
- R Regular energy users

Procedure “Conducting of Witnessing”			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by:	Checked by:	Page	12
	O. Hromenko	V. Krasiuk	Total number	18

Appendix 4

Appendix 4 is withdrawn.

The usage of the following document is required: IAF MD “Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies” clause 7.5.6 Witnessing.

Appendix 5

Energy Management Systems (ISO 50001) Activities

IAF Sector	NACE Code	Description
1	01, 02, 03	Agriculture, forestry and fishing
2	05, 06, 07, 08, 09	Mining and quarrying
3	10, 11, 12	Food products, beverages and tobacco
4	13, 14	Textiles and textile products
5	15	Leather and leather products
6	16	Wood and wood products
7	17	Pulp, paper and paper products
8	58.1, 59.2	Publishing companies
9	18	Printing companies
10	19	Manufacture of coke and refined petroleum products
11	24.46	Nuclear fuel
12	20	Chemicals, chemical products and fibres
13		Pharmaceuticals
14		Rubber and plastic products
15	23, except 23.5 and 23.6	Non-metallic mineral products
16	23.5, 23.6	Concrete, cement, lime, plaster, etc.
17	24 except 24.46, 25 except 25.4, 33.11	Basic metals and fabricated metal products

Procedure “Conducting of Witnessing”			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	13
			Total number	18

18	25.4, 28, 30.4, 33.12, 33.2	Machinery and equipment
19	26, 27, 33.13, 33.14, 95.1	Electrical and optical equipment
20	30.1, 33.15	Shipbuilding
21	30.3, 33.16	Aerospace
22	29, 30.2, 30.9, 33.17	Other transport equipment
23	31, 32, 33.19	Manufacturing not elsewhere classified
24	38.3	Recycling
25	35.1	Electricity supply
26	35.2	Gas supply
27	35.3, 36	Water supply
28	41, 42, 43	Construction
29	45,46,47,95.2	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods
30	55, 56	Hotels and restaurants
31	49, 50, 51, 52, 53, 61	Transport, storage and communication
32	64, 65, 66, 68, 77	Financial intermediation; real estate; renting
33	58.2, 62, 63.1	Information technology
34	71, 72, 74 except 74.2 and 74.3	Engineering services
35	69, 70, 73, 74.2, 74.3, 78, 80, 81, 82	Other services
36	84	Public administration
37	85	Education
38	75, 86, 87, 88	Health and social work
39	37, 38.1, 38.2, 39, 59.1, 60, 63.9, 79,	Other social services

IAF codes and NACE are utilized for describing a CAB's scope of accreditation. NAAU recognizes that for ISMS a concept of technical areas may include a number of the codes listed in each CAB is required to identify which codes (or parts thereof) are included in each technical area.

Procedure "Conducting of Witnessing"			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by:	Checked by:	Page	14
	O. Hromenko	V. Kراسиuk	Total number	18

Management systems of medical devices safety (ISO 13485)
Risk level classes of medical devices

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas	Class of risk level
1.1 Non-active Medical Devices	General non-active, nonimplantable medical devices	<ul style="list-style-type: none"> - Non-active devices for anaesthesia, emergency and intensive care - Non-active devices for injection, infusion, transfusion and dialysis - Non-active orthopedic and rehabilitation devices - Non-active medical devices with measuring function - Non-active ophthalmologic devices - Non-active instruments - Contraceptive medical devices - Non-active medical devices for disinfecting, cleaning, rinsing - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) - Non-active medical devices for ingestion 	IIb
	Non-active implants	<ul style="list-style-type: none"> - Non-active cardiovascular implants - Non-active orthopedic implants - Non-active functional implants - Non-active soft tissue implants 	III
	Devices for wound care	<ul style="list-style-type: none"> - Bandages and wound dressings - Suture material and clamps - Other medical devices for wound care 	IIa
	Non-active dental devices and accessories	<ul style="list-style-type: none"> - Non-active dental devices/equipment and instruments - Dental materials - Dental implants 	IIa
	Non-active medical devices other than specified above		I

Procedure "Conducting of Witnessing"			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	15
			Total number	18

1.2 Active Medical Devices (NonImplantable)	General active medical devices	<ul style="list-style-type: none"> - Devices for extra-corporal circulation, infusion and haemopheresis - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - Devices for stimulation or inhibition - Active surgical devices - Active ophthalmologic devices - Active dental devices - Active devices for disinfection and sterilization - Active rehabilitation devices and active prostheses - Active devices for patient positioning and transport - Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) - Software - Medical gas supply systems and parts thereof 	III
	Devices for imaging	<ul style="list-style-type: none"> - Devices utilizing ionizing radiation - Devices utilizing non-ionizing radiation 	IIb
	Monitoring devices	- Monitoring devices of non-vital physiological parameters	IIa
		- Monitoring devices of vital physiological parameters	IIb
	Devices for radiation therapy and thermo therapy	<ul style="list-style-type: none"> - Devices utilising ionizing radiation - Devices utilising non-ionizing radiation - Devices for hyperthermia / hypothermia - Devices for (extracorporal) shock-wave therapy (lithotripsy) 	IIb
Active (non-implantable) medical devices other than specified above		IIb	
1.3 Active Implantable Medical Devices	General active implantable medical devices	<ul style="list-style-type: none"> - Active implantable medical devices for stimulation / inhibition - Active implantable medical devices delivering drugs or other substances - Active implantable medical devices 	III

Procedure "Conducting of Witnessing"			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	16
			Total number	18

		substituting or replacing organ functions	
	Implantable medical devices other than specified above		III
1.4 In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/ Haemostasis/ Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing		I
	In Vitro Diagnostic Instruments and software		I
	IVD medical devices other than specified above		I
1.5 Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)		IIb
	Moist heat		IIa
	Aseptic processing		IIa
	Radiation sterilization (e.g. gamma, x-ray, electron beam)		IIb
	Sterilization method other than specified above		IIa
1.6 Devices incorporating/utilizing specific substances/technologies	Medical devices incorporating medicinal substances		III
	Medical devices utilizing tissues of animal origin		III
	Medical devices incorporating derivatives of human blood		III
	Medical devices utilizing micromechanics		III
	Medical devices utilizing nanomaterials		III

Procedure “Conducting of Witnessing”			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Krasiuk	Page	17
			Total number	18

	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed		III
--	--	--	-----

The table is developed according to IAF MD 8:2011, ДСТУ 4388:2005, Technical Regulation on medical devices (Cabinet of Ministers of Ukraine Resolution No. 753 dated 2 October 2013 – Council Directive 93/42/EEC of 14 June 1993).

Class of medical devices safety level depending on the potential risk of application:

I	Medical device with low risk application
IIa	Medical device with medium risk application
IIb	Medical device with increased risk
III	Medical device with a high degree of risk

Procedure “Conducting of Witnessing”			NAAU	
P-08.03.21				
Revision 13 dated 16.06.2015	Developed by: O. Hromenko	Checked by: V. Kراسиuk	Page	18
			Total number	18