National Accreditation Center of Iran

مرکز ملی تایید صلاحیت ایران

Witnessing Activities

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Changes History

Clause Numbers	Revision No	Revision Date	Summary of changes
Cover	01	April.2019	Changes related to No& date of revision
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All pages	02	Aug.2021	Changes related to New scope (MDQMS)
All pages	03	Jul 2023	Changes the date and revision No.

Contents

1. Objectives
These work instructions are used for all witnessing activity in NACI for CB department

2. Scope
This instructions is applicable to all processes within NACI.

3. Responsibilities
The vice president NACI is responsible for implementation, & the NACI President supervises adequate execution of these procedures.

4. References & Regulations
4.1 ISO/IEC 17000:2020 Conformity assessment -- Vocabulary and general principles

4.2 ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary

4.3 ISO/IEC17011:2017 Conformity assessment -- requirements for accreditation bodies accrediting Conformity assessment bodies

4.4 The NACI accreditation Manual NACI-M00.

4.5 ISO/TS 22003:2013 Food safety management systems -- Requirements for bodies providing audit and certification of food safety management systems, ISO 22003-1:2022

4.6 ISO/IEC 17021-1:2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems, Part 1 Requirements.

4.7 ISO/IEC 17021-2:2016 Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 2: Competence requirements for auditing and certification of environmental management systems.

4.8 ISO/IEC 17021-3:2017 Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 3: Competence requirements for auditing and certification of quality management systems.

4.9 ISO 50003:2021 Energy Management System – Requirements for bodies providing audit and certification of EnMS.

4.10 ISO/IEC Ts 17021-10:2018, Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 10: Competence requirements for auditing and certification bodies of occupational health and safety management system

4.11 ISO/IEC 17065:2012 Requirement for bodies certifying products, processes and services

4.12 ISO/IEC 17024:2012 General requirement for bodies operating certification of persons

4.13 IAF ID 1:2023 IAF Informative Document for QMS and EMS Scopes of Accreditation

4.14 IAF MD16: 2023 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies

4.15 IAF MD17:2023 Witnessing Activities for the Accreditation of Management Systems Certification Bodies

4.16 IAF MD 22:2023 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)

4.17 IAF MD 8:2023 Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485)

4.18 IAF ID13:2023 IAF Medical Device Nomenclature (IAF MDN) Including Medical Device Risk Classifications

5. Terms & Definitions

All terms & definitions in these procedures conform to those given in the references cited in Clause 4 above. In addition, the terms & definitions given below are applicable.

5.1 NACI: means the National Accreditation Center of Iran.

5.2 CB: Certification body applying for accreditation.

5.3 Witnessing

Witnessing of an audit is an activity performed by an Accreditation Body whereby it observes, without interfering and influencing, an audit performed by a Certification Body audit team.

6. Instructions-Description of NACI scopes

6.1 Description of NACI scopes

6.1.1 Management Systems

NACI utilizes a system for describing scopes of accreditation based on the classification of QMS and EMS scopes given in the document IAF ID1. In addition, a clustering approach has been adopted to align activities that are similar in nature depending on the management system in question. Some codes have been indicated as being more critical or complex than others and NACI pays particular attention to the granting of accreditation in these areas. Codes for FSMS and EnMs are based on ISO/TS 22003 and ISO 50003 respectively.

The management systems' classifications listed in the appendices to this document have been compiled from original source material produced, amongst others, by IAF. A grouping or clustering approach is used with the general principle that mandatory IAF codes require witnessing but non-mandatory codes within the same sectors as the mandatory codes can be added to the scope without for the need for a witnessed audit to beperformed.

Note: For some management systems a certification body may have the necessary competence to apply for a full IAF code and sometimes it may have the competence for part of an IAF code and this will be indicated by the use of NACE codes which will restrict the scope to certain sectors.

6.1.2 Product Certification

The classification system used in product certification is based on the product or process being certified.

6.1.3 Personnel Certification

The classification system used in personnel certification is based on the personnel scheme that is the subject of certification.

6.2 ISO 17021-1 Management Systems Scopes

NACI has a witnessing program, covering each applicant or accredited scope, for each accreditation cycle. The program is periodically reviewed and updated as needed. NACI requires applicant certification bodies to carry out a minimum of two witnessed audits per management system before accreditation can be awarded and also requires accredited organizations to perform a minimum of two witness audits as part of the surveillance cycle each year following the award of accreditation. If an accreditation body is accredited for more than one scheme then a witnessed audit in each scheme is required as part of surveillance activities per year.

In exceptional circumstances where the CAB is only involved with one scheme, has a small number of clients and a small number of auditors then the minimum number of witnessed audits for that CAB may be reduced to one.

6.2.1 Initial assessment:

6.2.1.1 NACI shall perform a witnessing activity in each technical cluster of each MS scheme. The programme will continue until the CAB has demonstrated sufficient experience and performance for a modified programme.

6.2.1.2 NACI requires a witnessed audit in applicant critical codes before accreditation can be granted within an overall requirement of a minimum of two successful witnessed audits.

An applicant CAB may apply for accreditation for the other non-critical codes within the same cluster and NACI will not generally witness these provided the CAB has documentary evidence to support the application for accreditation.

6.2.1.3 If it is not possible to perform a witnessing activity in the IAF code identified as critical:

- NACI can grant accreditation for non-critical code/s of the technical codes of the cluster for which the witnessing was performed, or
- NACI can grant accreditation for all codes in the cluster, on condition that:
  - The CAB has documentary evidence of competence for all codes in the cluster, and
  - The witnessing activity takes place before any certificate in the critical code/s based on accreditation is issued.

6.2.1.4 For initial accreditation for each MS scheme, NACI shall witness both stage 1 and stage 2 audits for at least one CAB client. If the CAB does not have any new clients, it is possible to witness one renewal or two surveillances which cover the key processes.

6.2.1.5 Accreditation may only be granted where the CAB has already taken decisions for certification or where the CAB has demonstrated competence by other means (e.g. demonstrating to have competent personnel for all specific certification functions –see Annex A of ISO/IEC 17021-1).

6.2.1.6 In the cases of integrated or combined management system audits, the scope of the witnessing shall be agreed with the CAB. If a witnessing activity has been recently performed in the same code, for a different purpose (e.g. ISO 13485), NACI can consider removing the necessity of another witnessing activity.

6.2.2 QMS ISO 9001 (Annex 1):

Example: For an application within the technical cluster "Food" the critical code is 3 which is "Food products, beverages and tobacco" and the non-critical codes are 1 and 30. For the full code to become accredited a witnessed audit would be required in code 3. Codes 1 and 30 would not be required to be witnessed but could be added to the scope provided the CAB has satisfactory documentary evidence of competence. If a non-critical code only is witnessed (e.g. code 1) then that code could be added to the scope and code 30 if documentary evidence available, but not code 3. Where a cluster has 2 or more critical codes, if there is a choice (i.e. code x 'or' code y) the critical code that has not been witnessed could also be added provided there was documentary evidence to support the application.

6.2.3 EMS ISO 14001 (Annex 2):

Example: Within technical clusters there may be more than one code that is mandatory to be witnessed or there may be a choice. Within the "Mechanical" cluster, codes 20 or 21 could be witnessed and this would suffice as the witnessing requirement within this cluster whereas within the cluster "Construction" there are 4 critical codes (code x 'and' code y etc.) and witnessing is mandatory for each code before it can be added to the scope. Witnessing of any of these would allow the remaining noncritical codes be added to the scope provided there was documentary evidence to support the application.

6.2.4 OH&SMS ISO 45001 (Annex 3):

Example: The rules are similar to QMS and EMS: within cluster there is a choice of witnessing where there is an 'or' but when there is an 'and' witnessing is mandatory for the critical codes before they can be added. Addition of non-critical codes without witnessing requires documentary evidence to support the application

6.2.5 EnMS ISO 50001 (Annex 4):

Example: This is divided into 8 technical clusters based on ISO 50003:2014. Technical clusters require witnessing to be added to the scope. Clusters 1 and 3 may be added without witnessing provided clusters 2 and 4 have been witnessed.

6.2.6 FSMS ISO 22000 /FSSC 22000 (Annex 5):

Example: Clusters are based on ISO 22003 requirements and IAF MD 16. For the accreditation of a given good chain category at least one witness assessment shall be performed in the cluster. For extensions inside a cluster, witnessing is not mandatory. At least one audit in cluster 2 shall be witness each year and at least one audit in each of the other clusters over during the accreditation cycle.

- NACI not grant accreditation for a given food chain category without at least one witness assessment performed in the cluster.
- This criteria is also applicable to extension of scopes. For extensions scope inside a cluster, witnessing is not mandatory. Witnessing is mandatory for extensions to categories in a new cluster.
- NACI shall witness at least one audit in cluster Food and Feed Processing (C+D) each year and at least one audit in each of the other clusters during the accreditation cycle (if covered by the accredited scope of the Certification Body).
- A single witness assessment could encompass different cluster if the activities of the witnessed company included both category and the Certification Body justify it. Wherever feasible, throughout its accreditation cycle, NACI ensure that witness assessments are performed in those subcategories (from those covered by the Certification Body scope) with the higher risks of food safety hazards.(describe in NACI-G06)
- A witness of an initial certification audit, including stage 1, should be undertaken as part of the initial accreditation. At least one of the witness audits per accreditation cycle should include an initial certification audit.
- NACI witnesses an audit team that has not been witnessed previously in that particular food chain category. Witness assessments shall avoid the repeated witnessing of the same Certification Body client company. NACI take into account previous results of witnessing to establish its witness Program.

6.2.7 Medical devices ISO 13485 (Annex 6):

In the case of initial assessment, the samples for witnessing of audits shall include one audit minimum in a higher risk class Technical Areas in each Main Technical Area (shown in Annex 6) covered under the scope of accreditation, taking into account an appropriate national or international risk classification scheme and/or criticality of the process (e.g. Sterilization or Parts or Services).

When developing a witnessing schedule, NACI consider, among other factors, the experience of the CAB (e.g. recognized for one or more medical device regulatory scheme(s)), in an effort to rationalize the witnessing schedule. Examples of typical regulatory schemes are:

I. (EU) 2017/745/746 – European MDR/IVDR Regulations

II. ASEAN Medical Device Directive (AMDD)

III. National Medical Regulations that utilize ISO 13485

- Example: For initial assessment, the witnessing of audits shall include at a minimum one audit in a higher risk class technical area in each main technical area. The witnessing program shall ensure, as a minimum, that one audit from each of the main technical areas under the scope of accreditation within an accreditation cycle is conducted prior to the expiry of accreditation. The sampling for witnessing shall give priority to higher risk technical areas.
- The risk classification given in Annex 6 of the technical areas to be witnessed will be taken as basis. Accordingly, the assessment is first witnessed in class D (high risk), if there is no technical area in that class, in class C (medium-high risk), and if there is no technical area in class B (medium-low risk), the assessment is witnessed.
- Surveillance and reassessment shall include on-site assessment as well as witnessing.
- The surveillance office assessments and witness assessment(s), unless required by regulations, shall be conducted at least once a year.
- The witnessing program shall ensure, as a minimum, that one audit from each of the Main Technical Areas (shown in Annex 6) under the scope of accreditation within an accreditation cycle (surveillances and/or reassessment) is conducted prior to the expiry of accreditation. The sampling for witnessing shall give priority to higher risk technical areas.
- Witness assessments should avoid the repeated witnessing of the same CAB client organization. The NACI shall take into account previous results of witnessing to establish its witness strategy.

6.3 Extensions to scope:

NACI will require 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 proceed without further witnessing provided that a code from that cluster has already been accredited. In the event that no code from the cluster is on the scope of accreditation then a witnessed audit will be required. NACI reserves the right to deviate from this policy and to require a witnessed audit if for instance (but not exclusively) a number of new auditors have been hired in CAB, the business expands rapidly, etc.

6.4 Surveillance activities:

When the CAB has demonstrated sufficient experience for a modified programme, NACI shall perform at least one witnessing activity in each technical cluster of each MS scheme, to be complemented with other assessment activities to guarantee that each technical cluster is assessed during two successive accreditation cycles. The witnessing frequency established in the 1st cycle may be reinstated if significant changes occur in the CABs' auditor qualification process, auditing practices or results and audit personnel.

NACI will seek to witness a minimum of two audits per CAB per year with the aim of completing all witnessing activities as indicated above. If the CAB is accredited for more than one management system then NACI will seek to witness a minimum of one audit per management system per year. NACI reserves the right to increase this figure if for instance new auditors have been hired, the CAB is auditing in foreign locations or other factors. In exceptional circumstances where the CAB is only involved with one scheme, has a small number of clients and a small number of auditors then the minimum number of witnessed audits for that CAB may be reduced to one, provided the witnessing activity can be completed as per the plan. This will be reviewed annually.

Note: For FSMS accreditation, please note the explanation in Annex 5.

6.5 Reassessment activities:

NACI aims to assess all clusters as indicated in section 6.4 with a priority being given to critical codes and observing as many CAB auditors as possible. Witnessing activities are supported by file review conducted at head office visits and these will be used to highlight any deficiencies and to target the witnessing activity where necessary.

The assessment program shall guarantee that competence is assessed throughout the scope in the accreditation cycle, for all IAF codes of each MS scheme through the performance of a witnessing activity or through file reviews at the CAB's office. If this assessment is not possible during the accreditation cycle, then the NACI shall reduce the scope of accreditation.

NACI recognizes that other standards and schemes are suitable for accreditation under ISO/IEC 17021-1. Section 6 is not exhaustive in that regard and NACI shall develop such criteria as it considers necessary, when appropriate.

6.6 Minimum Documentation to demonstrate competence ISO 17021-1

In order to assess CAB competence where witnessing is not performed (for initial, extension and on-going accreditation surveillance purposes), the following documentation shall be provided to NACI on request:

- Defined technical areas;
- Defined auditor and decision maker competence;
- Evidence that competence criteria are met.

6.7 ISO 17065, ISO 17024 Scopes

The principle of witnessing activities applies to applicant and accredited CABs certifying product, personnel schemes.

For initial assessments including extensions to scope, all schemes shall be witnessed with a minimum of 2 witnessing activities 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 personnel witnessed; the minimum number of witnessing activities is 2 per year. In exceptional circumstances, for example in product certification where the CAB has one scheme accredited and a limited auditor pool, one annual witnessed audit may be sufficient. This shall be reviewed on an annual basis.

Where a scheme has been reviewed, NACI reserves the right to determine the extent of witnessing required to satisfactorily determine continued accreditation.

NACI will request such documentation as it considers necessary to assess applicant and accredited scopes.

6.8 Initial assessment:

NACI will seek to witness a representative sample of the scope in advance. NACI recognizes that these audits may be simulations (in the product area) as the CAB will not yet have achieved notification. Accreditation is granted conditional on a witness of the notified activity being performed within a period defined by the decision maker.

Note: Witness assessments should avoid the repeated witnessing of the same CAB client organization. The AB shall take into account previous results of witnessing to establish its witness strategy

7. Related Documents

7.1 Document control procedures **NACI-P01**

8. Forms & Records

8.1 Document Control List form **NACI-F101**
8.2 Document Proposal or Review form **NACI –F103**
8.3 Document Distribution form **NACI- F104**
8.4 All records related to these procedures are maintained on form **NACI-F105**
8.5 NACI Guidelines on Witness Assessment **NACI-G04**

9. Recipients

As per distribution list form **NACI –F104**

10. Annexes

Annex 1: Quality Management Systems (ISO 9001) Activities
Annex 2: Environmental Management Systems (ISO 14001) Activities
Annex 3: Occupational Health and Safety (ISO 45001) Activities
Annex 4: Energy Management Systems (ISO 50001) Activities
Annex 5: Food Safety Management Systems (ISO 22000) Activities
Annex 6: Medical Device Quality Management Systems (ISO 13485) activities

11. Withdrawn Documents

Not applicable

Annex 1: Quality Management Systems (ISO 9001) Activities

IAF code	Description of economic sector/activity, according to IAF ID1	Technical cluster	Critical Code
1	Agriculture, forestry and fishing	Food	3
3	**Food products, beverages and tobacco**		
30	Hotels and restaurants		
17	Basic metals and fabricated metal products	Mechanical	20 or 22
18	Machinery and equipment		
19	Electrical and optical equipment		
20	**Shipbuilding**		
22	**Other transport equipment**		
7	Limited to "Paper products"	Paper	9
8	Publishing companies		
9	**Printing companies**		
2	**Mining and quarrying**	Minerals	2 or 15
15	**Non-metallic mineral products**		
16	Concrete, cement, lime, plaster, etc.		
28	**Construction**	Construction	28
34	Engineering services		
4	Textiles and textile products	Goods production	5 or 14
5	**Leather and leather products**		
6	Wood and wood products		
14	**Rubber and plastic products**		
23	Manufacturing not elsewhere classified		
7	Limited to "Pulp and pulp manufacturing"	Chemicals	12
10	Manufacture of coke and refined petroleum products		
12	**Chemicals, chemical products and fibers**		
25	Electricity supply	Supply	26
26	**Gas supply**		
27	Water supply		
24	**Recycling**	Transport and waste management	24
31	Transport, storage and communication		
39	Other social services		

Annex 1: Quality Management Systems (ISO 9001) Activities (cont'd)

IAF code	Description of economic sector/activity, according to IAF ID1	Technical cluster	Critical
29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	Services	33 or 37
32	Financial intermediation; real estate; renting		
33	**Information technology**		
35	Other services		
36	Public administration		
37	**Education**		
11	**Nuclear fuel**	Nuclear	11
13	**Pharmaceuticals**	Pharmaceutical	13
21	**Aerospace**	Aerospace	21
38	**Health and social work**	Health	38

Annex 2: Environmental Management Systems (ISO 14001) Activities

IAF code	Description of economic sector/activity, according	Technical cluster	Critical Code
1	**Agriculture, forestry and fishing**	Agriculture, forestry and fishing	1
3	**Food products, beverages and tobacco**	Food	3
30	Hotels and restaurants		
17	Fabricated metal products	Mechanical	20 or 21
18	Machinery and equipment		
19	Electrical and optical equipment		
20	Shipbuilding		
21	**Aerospace**		
22	**Other transport equipment**		
7	Limited to “Paper products”	Paper	9
8	Publishing companies		
9	**Printing companies**		
28	**Construction**	Construction	28
34	Engineering services		
4	**Textiles and textile products**	Goods production	4 and 5
5	**Leather and leather products**		
6	Wood and wood products		
23	Manufacturing not elsewhere classified		
7	**Limited to “Pulp and pulp manufacturing”**	Chemicals	7 and 10 and 12 and 13
10	**Manufacture of coke and refined petroleum**		
12	**Chemicals, chemical products and fibers**		
13	**Pharmaceuticals**		
14	Rubber and plastic products		
15	Non-metallic mineral products		
16	Concrete, cement, lime, plaster, etc.		
17	Limited to “Base metals production”		
2	**Mining and quarrying**	**Mining and quarrying**	**2**
25	**Electricity supply**	Supply	25 or 26
26	**Gas supply**		
27	Water supply		

Annex 2: Environmental Management Systems (ISO 14001) Activities (cont'd)

IAF code	Description of economic sector/activity, according to IAF ID1	Technical cluster	Critical code
31	Transport, storage and communication	Transport & Waste management	24 and 39 (limited to NACE 37, 38.1, 38.2, 39)
24	**Recycling**		
39	**Other social services**		
29	**Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods**	Services	29 or 35 or 36
32	Financial intermediation; real estate; renting		
33	Information technology		
35	**Other services**		
36	**Public administration**		
37	Education		
11	**Nuclear fuel**	Nuclear	11
38	**Health and social work**	Health	38

Annex 3: Occupational Health and Safety Management Systems (ISO 45001) Activities

IAF code	Description of economic sector/activity, according to IAF ID1	Technical cluster	Critical Code
1	**Agriculture, forestry and fishing**	Agriculture, forestry and fishing	1
3	**Food products, beverages and tobacco**	Food	3
30	Hotels and restaurants		
17	Limited to "fabricated metal products"	Mechanical	20 and 21
18	Machinery and equipment		
19	Electrical and optical equipment		
20	**Shipbuilding**		
21	Aerospace		
22	**Other transport equipment**		
7	Limited to "paper products"	Paper	9
8	Publishing companies		
9	**Printing companies**		
28	**Construction**	Construction	28
34	Engineering services		
4	**Textiles and textile products**	Goods production	[4 (with dyeing) and 5 (with tanning)] or 6
5	**Leather and leather products**		
6	**Wood and wood products**		
23	Manufacturing not elsewhere classified		
7	**Limited to "pulp and paper manufacturing"**	Chemicals	[7 and 10 and 12 and 13 and 16] or 17
10	**Manufacture of coke and refined petroleum products**		
12	**Chemicals, chemical products and fibres**		
13	**Pharmaceuticals**		
14	Rubber and plastic products		
15	**Non-metallic mineral products**		
16	**Concrete, cement, lime, plaster, etc.**		
17	**Limited to "base metals production"**		
2	**Mining and quarrying**	Mining and quarrying	2
25	**Electricity supply**	Supply	25 or 26
26	**Gas supply**		
27	Water supply		

Annex 3: Occupational Health and Safety Management Systems (ISO 45001) Activities (cont'd)

IAF code	Description of economic sector/activity, according to IAF ID1	Technical cluster	Critical Code
31	**Transport, storage and communication**	Transport and waste management	[31 (limited to dangerous goods), and 24] or 39 (limited to NACE 37, 38.1, 38.2, 39)
24	**Recycling**		
39	**Other social services**		
29	**Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods**	Services	29 or 35 or 36
32	Financial intermediation; real estate; renting		
33	Information technology		
35	**Other services**		
36	**Public administration**		
37	Education		
11	**Nuclear fuel**	Nuclear	11
38	**Health and social work**	Health	38

Annex 4: Energy Management Systems (ISO 50001) Activities

Technical cluster		Description	Critical code
Industry	Light to Medium	Manufacturing facilities producing consumer intermediates or end user oriented products	2
	Heavy	Manufacturing facilities requiring high capitalization and consuming large quantities of raw materials and energy	
Buildings	Buildings	Facilities with standard commercial building practices	4
	Building complexes	Facilities with operations requiring specific expertise due to the complexity of energy sources and uses	
Transport		System or means for transporting people or goods/cargo	5
Mining		Open cast, underground and fluid extraction of raw materials and transport	6
Agriculture		Livestock, seed or crops products	7
Energy supply		Energy generation (nuclear, CHP, electricity, renewable, etc.) and transport (transmission and distribution)	8

Annex 5: Food Safety Management Systems (ISO 22000) Activities

In Table A.1, Annex A of ISO/TS 22003:2013 the food categories are grouped into the following clusters:

1. Farming of animals (A)
2. Farming of plants (B)
3. Food manufacturing (C)
4. Animal feed production (D)
5. Catering (E)
6. Distribution (F)
7. Provision of transport and storage services (G)
8. Services (H)
9. Production of food packaging and packaging material (I)
10. Equipment manufacturing (J)
11. Production of (bio) chemicals (K)

Witnessing is conducted according to requirements of IAF MD 16:2015.

In this certification body, IAF MD 16 shall be complied with when defining the witnessing of audits. The certification scope shall be grouped in clusters of categories, as follows:

FSMS witness scopes to be accredited are grouped into the following 6 Clusters:

1. Farming (A+B)
2. Food and Feed Processing (C+D)
3. Catering (Hotel and restaurant services) (E)
4. Retail, Transport and Storage (F+G)
5. Auxiliary Industries (H+I+J)
6. (Bio) Chemicals (K)

The grant/extension of accreditation for a category shall not be possible without witnessing at least one audit in the cluster. Priority shall be given to a higher risk sector in assuring safe food. Witnessing is not mandatory for extension to a category within the cluster. Audits from all clusters shall be witnessed during one accreditation cycle. During each witnessing (surveillance, re-assessment) of the certification body, the audit in the cluster shall be witnessed.
Witnessing of categories in other clusters shall be planned so as to witness at least one category in each cluster within the context of accreditation cycle. At least one witnessing in the assessment period shall cover witnessing of audit level 1 and 2.

The above-mentioned shall be the minimum requirements that NACI will adapt to the specific situation in individual certification body.

Annex6: Medical Device Quality Management Systems (ISO 13485) activities

Main technical areas	*Technical areas*	Risk category
1.1 Non-Active Medical Devices	General non-active, non-implantable medical devices	B
	Non-active implants	C
	Devices for wound care	B
	Non-active dental devices and accessories	C
	Non-active medical devices other than specified above	B-C
1.2 Active Medical Devices (Non-Implantable)	General active medical devices	C
	Devices for imaging	C
	Monitoring devices	B
	Devices for radiation therapy and thermotherapy	C
	Active (non-implantable) medical devices other than specified above	B-C
1.3 Active Implantable Medical	General active implantable medical devices	D
	Implantable medical devices other than specified above	C-D
1.4 In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry	D
	Immunochemistry (Immunology)	C
	Hematology/ Hemostasis/ Immunohematology	C
	Microbiology	C
	Infectious Immunology	B
	Histology/Cytology	C
	Genetic Testing	B
	In Vitro Diagnostic Instruments and software	B-C
	IVD medical devices other than specified above	C
1.5 Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)	B
	Moist heat	B
	Aseptic processing	B
	Radiation sterilization (e.g., gamma, x-ray, electron beam)	B
	Low temperature steam and formaldehyde sterilization	B
	Thermic sterilization with dry heat	B
	Sterilization with hydrogen peroxide.	B
	Sterilization method other than specified above	B
1.6 Devices Incorporating / Utilizing Specific Substances / Technologies	Medical devices incorporating medicinal substances	C
	Medical devices utilizing tissues of animal origin	C
	Medical devices incorporating derivatives of human blood	D
	Medical devices utilizing micromechanics	B
	Medical devices utilizing nanomaterials	C
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed	C
	Medical devices incorporating or utilizing specific Substances/technologies/elements, other than specified above.	C
1.7 Parts or Services	Raw materials	C
	Components✳	B
	Subassemblies✳	A-B
	Calibration services[1]	B
	Distribution services	A-B
	Maintenance services✳	B
	Transportation services	B
	Other services✳	A-B

[1] Organizations providing calibration services must be accredited in accordance with the requirements of ISO/IEC 17025.

Based on GHTF (Global Harmonization Task Force) risk classification can be used. For detailed risk classification on a product/service basis, refer to IAF ID 13:2023.
- High Risk: D, - Medium-High Risk: C, - Medium-Low Risk: B, - Low Risk: A

Note 1: Main Technical Areas in **Table 1.1-1.6** apply to finished medical devices. A finished medical device is defined as any device or medical device accessory that is fit for use or functional, whether or not it is packaged, labeled, or sterilized.
Table 1.7 is used for scoping when the CB requires an accreditation scope that involves the production of parts that are not manufacturing activities or that are not classified or clearly associated with a finished medical device.
In addition to the scope of a medical device specified in ISO 13485, if the document chooses to treat products or services as a medical device, this must be supported by Specifications or Guidelines issued by the Regulatory Authority.

Note 2: *For "components, Subassemblies, maintenance services, other services (medical device-related consultancy services)" listed in table 1.7 of the main technical areas; If the effectiveness of the organization's parts or service is clearly for the purpose of supporting medical devices (e.g. fasteners marketed for the express purpose of supporting implantable medical devices), or if there are instances where contract manufacturers produce nearly complete medical devices, the IAF may use technical equipment listed in Tables 1.1-1.6. It is necessary to have accreditation scope in the fields.

7.4.3 IAF; When applying for the accreditation scope for the "other not defined above" technical field, it must submit to NACI the list and risk classification of medical devices in the description of this technical field. The information presented should also include a brief description of the intended use of the medical device. The technical field “Other not defined above” may be used when no other categories are applicable.
Risk classification of medical devices should be determined according to appropriate legal sources. For example;
--(EU) 2017/745/746 -European MDR/IVDR
-ASEAN MedicalDevices Directive (AMDD)
-National Classification Regulations

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