Policy on witnessing activities and scope management for certification and validation/verification bodies PS22

1 Purpose

In order to conform to ISO/IEC 17011 clauses 7.4.5 and 7.9.2 and IAF MD17:2019, INAB shall:

- ensure that appropriate mechanisms and criteria are in place to assess the applicant scope of accreditation (initial or extension) in a consistent way; and
- ensure that appropriate mechanisms and criteria are in place to assess the accredited scope during each accreditation cycle.

2 Scope

This statement sets out INAB policy on the witnessing of management system, product, personnel and validation/verification audits, and the rationale behind award of accreditation (or extension to scope of accreditation) in different industry sectors. It additionally sets out INAB policy on accredited scope management.

This document applies to the accreditation of:

- Management systems certification,
- Product certification;
- Certification of persons; and
- Validation/verification

under the respective EA[1] and IAF[2] multi-lateral agreements (MLAs), excepting those provisions that conflict with what is established in applicable standards, other EA or IAF documents, specifications set by scheme owners or regulators, and legislation.

3 Definitions

For the purpose of this document, the following definitions apply:

3.1 **Witnessing**: activity performed by an accreditation body (AB) whereby it observes, without interfering, an audit performed by a conformity assessment body (CAB).

3.2 **Post-audit review**: activity performed by an AB whereby it reviews and evaluates records and documents pertaining to a given certification file/decision, in order to determine whether appropriate procedures were followed and implemented. This may be conducted at the CAB premises, with the appropriate CAB staff and/or auditors, although it may be performed by correspondence if appropriate and agreed.

3.3 **Conformity assessment body (CAB)**: For the purposes of this document, a conformity assessment body is a certification or validation/verification body.

4 Purpose of witnessing

Witnessing normally has the following objectives:

- To verify implementation by the auditors of CAB procedures and forms;

[1] European co-operation for accreditation
[2] International accreditation forum

- To verify effectiveness of the procedures adopted by the CAB, with particular reference to the use of auditors with the necessary competence (planning, job assignment, records handling);
- To verify that audits undertaken by the CAB are effective, taking into account the certification criteria and requirements of ISO/IEC 17021-1, ISO/IEC 17065, ISO/IEC 17024, ISO/IEC 17029 and ISO 14065;
- To contribute to obtaining a representative sample for the evaluation of competence of the CAB; and
- To enable a recommendation on award, maintenance or removal of accreditation.

The main reasons for witnessing are to accomplish the objectives stated above, although witnessing can also be triggered by, for example, the receipt of complaints, claims, disputes, and market or regulator feedback.

5 Approach

5.1 INAB has a witnessing program, covering each applicant or accredited scope, for each accreditation cycle. The program is periodically reviewed and updated as needed. INAB publication P7 provides further detail on this requirement which is designed to ensure that the entire scope of accreditation is assessed over a 5-year accreditation cycle.

5.2 When developing the program, consideration is given to the need to assess cross-frontier activities, based on the size of the CAB operations, their criticality, and feedback from the local AB. If witnessing is needed, INAB will cooperate with the local AB as set out under the international cross-frontier policies.

5.3 Before witnessing each activity, INAB will assemble an appropriate assessment team, competent for the given accreditation standard and certification scope. The procedure shall follow ISO/IEC 17011 clause 7.5.4, as applicable. Normally, the full on-site audit shall be witnessed, unless objectives for a particular activity can be satisfied with a partial witnessing.

5.4 The CAB must explain to its client that witnessing will be performed by INAB (INAB Terms and Conditions refer), noting that it should not affect the normal course of the audit, since INAB assessors will not interfere or ask questions directly of the client.

5.5 Refusal by a CAB (including refusal originating from a CAB client) for a given witnessing shall be analysed individually. If a CAB client refuses INAB witnessing, in order to avoid sanctions, the CAB may have to withdraw certification. Note that a CAB shall not issue non-accredited management systems certificates in scopes for which it is accredited. If sanctions are imposed on a CB resulting in certificate withdrawal then other ABs and all scheme owners who may be impacted shall be notified, if their identity is known. An accredited certificate shall not be issued if, in order to avoid having its audit witnessed, the CAB's client transfers the certificate to another CB or if the CB intends to reissue the same certificate under the coverage of another AB.

5.6 When requested, the CAB must provide to INAB the complete and updated schedule of planned audits (dates, location, audit team composition, audit type and scope, etc.), in order to allow INAB to select the audit to witness and to enable adequate time to assemble an assessment team. If delay or refusal compromises coverage of the accredited scope, INAB may suspend or withdraw the part of the scope coverage affected due to failure to affirm ongoing competence.

5.7 If the CAB modifies the audit team composition, scope of the audit or audit duration after it has been chosen by INAB, this must be justified. If the justification is not acceptable to INAB, the need for a supplementary audit with the previously selected audit team shall be evaluated.

5.8 It is the responsibility of the CAB to inform its client, to explain the witnessing procedure, and to get the client's agreement.

5.9 INAB witnessing teams are expected to observe the following procedures:

- Once the audit has begun, the team members should not interfere with the normal course of the audit. However, that shouldn't prevent the INAB assessment team from acting in a sociable manner;
- If INAB assessment team needs clarification on actions taken by the CAB auditors, this will normally be made at the end of the audit. However, clarification may be sought during the audit, if such questioning does not influence the outcome of the audit;
- Findings to the CAB audit team will not be reported or disclosed before the end of the witnessing;
- Direct questioning of the CAB client will not take place. However, the INAB assessment team may ask the CAB audit team to pass on any documents that they have examined, so the INAB team can see what has been audited. Access to the client's documentation reviewed by the CAB's audit team shall be promptly provided to INAB's assessors upon request;
- Any information collected during the witnessing of an audit is confidential and shall be treated by INAB assessors accordingly.

5.10 A private meeting between the INAB assessment team and the CAB audit team will normally take place as soon as possible after the witnessing. The purpose of this meeting is to provide INAB feedback and conclusions including the INAB's reporting process, the CAB response/reaction process and INAB's decision making process, and also to get clarification and additional information;

5.11 INAB preliminary findings will be reported at this stage, although later confirmation may need to be provided by the CAB, and in particular if the CAB report (and decision) is requested, when relevant to the objective and scope of the witnessing;

5.12 A separate report is completed by INAB for each activity witnessed. Such reports will be sent to the CAB as soon as practicable after the witnessed activity.

5.13 It is the responsibility of the CAB's client to inform, in advance, the audit team and INAB assessors of all applicable safety requirements. INAB assessors shall conform to safety rules make known to them by the CAB's client. However, it is expected that INAB assessors shall take immediate action at any time to avoid injury, including leaving the area or the client's premises if necessary.

5.14 If at any time during the assessment of a CAB audit the INAB assessor observes a potential condition he or she considers to be an imminent risk of high severity (e.g. to health and safety or environment) the INAB assessor shall request an immediate private meeting with the CAB's audit team leader to inform him or her of the potential threat, with the expectation that the CAB's audit team leader will address the threat with the client in accordance with the CAB's process and any legal obligation.

6 Description of INAB scopes

6.1 *Management Systems*

INAB utilises a system for describing scopes of accreditation based on the classification of QMS scopes given in the document IAF ID1 and this is supplemented by the use of NACE codes (version 2) to provide more detailed information when this is required. 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. 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 INAB 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 be performed.

Note: IAF codes were commonly referred to as EA codes in the past as they had originated from within an EA publication.

6.2 *Product Certification*

The classification system used in product certification is based on the product or process being certified.
For bodies certifying organic production in accordance with European regulations, the scope of accreditation shall be defined by the product categories in the current regulation.

6.3 *Certification of persons*

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

6.4 *Validation/verification*

The classification system used for greenhouse gas (GHG) verification is based on Commission Regulation 600/2012, Annex I.

7 ISO/IEC 17021-1 Management Systems Scopes

INAB 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 organisations 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.

7.1 Initial assessment

7.1.1 INAB shall perform a witnessing activity in each technical cluster of each MS scheme. The programme will continue until after the first five years of accreditation and after the CAB has demonstrated sufficient experience and performance for a modified programme.

7.1.2 INAB 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 INAB will not generally witness these provided the CAB has documentary evidence to support the application for accreditation.

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

1. INAB can grant accreditation for non-critical code/s of the technical codes of the cluster for which the witnessing was performed, or

2. INAB 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.

7.1.4 For initial accreditation for each MS scheme, INAB 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.

7.1.5 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).

7.1.6 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), INAB can consider removing the necessity of another witnessing activity.

7.2 **Examples**

QMS ISO 9001 (Appendix 1): 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.

EMS ISO 14001 (Appendix 2): 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 non-critical codes be added to the scope provided there was documentary evidence to support the application.

OHSMS ISO 45001 (Appendix 3): 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.

EnMS ISO 50001 (Appendix 4): 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.

FSMS ISO 22000/FSSC 22000 (Appendix 5): Clusters are based on ISO 22003 requirements and IAF MD 16.

For the accreditation of a given food 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.

ISMS ISO 27001: Scopes for ISMS are not presented per IAF code but apply generally to all sectors.

Medical devices ISO 13485 (Appendix 6): 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.

7.3 **Extensions to scope:**

INAB 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. INAB 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 Ireland or overseas, the business expands rapidly, etc.

7.4 **Surveillance activities**

When the CAB has demonstrated sufficient experience and performance to enable INAB to justify reduction of witnessing frequency for a modified programme, INAB 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 in a period not exceeding 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.

Complemented by file review at head office, INAB 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 INAB will seek to witness a minimum of one audit per management system per year. INAB reserves the right to increase this figure if for instance new auditors have been hired, the CAB is auditing in foreign locations or assessment via file review across all scopes is not possible, 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.

For FSMS accreditation, please note the explanation in Appendix 5.

7.5 **Reassessment activities**

INAB aims to assess all clusters as indicated in section 7.4 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 INAB shall reduce the scope of accreditation.

INAB recognises that other standards and schemes are suitable for accreditation under ISO/IEC 17021-1. Section 7 is not exhaustive in that regard and INAB shall develop such criteria as it considers necessary, when appropriate.

8 Minimum Documentation to demonstrate competence ISO 17021-1

The documents to be provided to INAB in advance of an agreed witnessed audit are documented in INAB policy PS10.
However, 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 INAB on request:

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

9 ISO/IEC 17065 (Product), ISO/IEC 17024 (Persons), ISO/IEC 17029 (Validation/verification) and ISO 14065 (Greenhouse Gas Emission) Scopes

The principle of witnessing activities applies to applicant and accredited CABs certifying product, personnel and validation/verification 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, supplemented by file review at the CB's head office. 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.

For notified bodies each product area is witnessed over the accreditation cycle. Where there are broad categories of products e.g. in the areas of accreditation for notification purposes, the product areas are sampled according to product group. For example:

- For construction products - aggregates, structural timber, concrete are required to be witnessed during the accreditation cycle but one witness could cover a number of harmonised standards within that group.
- For PPE – protective clothing, protective equipment against falls from a height, protective eyewear, protective helmets, buoyancy aids are required to be witnessed.

For control bodies certifying organic production, assessment, witnessing and surveillance shall be performed according to EA-3/12.

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

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

10 Notified Bodies

The witnessing of notified bodies will follow the same approach as that of the applicable accreditation standard and will take into account the requirements of EA 2/17-M.

10.1 Initial assessment

INAB will seek to witness a representative sample of the scope in advance. INAB recognises 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.

Reference: European Commission - Guidance papers on accreditation (Version July 2014), Section 6.2**.**

11 INAB Assessment Teams

While INAB reserves the right to compose its assessment teams as appropriate, the CAB might expect the following guiding policy:

- For all schemes the teams for witnessing shall comprise a lead assessor and technical expert or a technical assessor who has the appropriate competence.
- INAB will consider the need for extra technical assistance where required.

12 Scope Management

INAB scopes of accreditation are precisely defined. For management systems certification the INAB approach to clustering for management systems certification is reflected on the INAB scopes. It is therefore possible for a CAB to attain accreditation for a full code by a combination of mandatory witnessing and documentation review (as outlined in Section 7 above). It is not permitted to make claims of accreditation (either at contract review or in publicly accessible material) and/or issue accredited certificates within sectors not on the INAB scope of accreditation.

For other product and personnel certification and validation/verification, each scheme is uniquely identified on the INAB scope of accreditation and any additions/amendments shall be managed through the process in 8 above.

13 Contact

For further information about this statement please contact an assessment manager at the Irish National Accreditation Board.

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14 Document Status and Implementation

Mandatory INAB document for all applicant and accredited certification and validation/ verification bodies.

Implementation is from date of publication.

Appendix 1: Quality Management Systems (ISO 9001) Activities

IAF code	NACE code[1]	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 fibres**		
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		
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

[1]INAB shall populate scopes appropriately

Appendix 2: Environmental Management Systems (ISO 14001) Activities

IAF code	NACE code[1]	Description of economic sector/activity, according to IAF ID1	Technical cluster	Critical Code
1		**Agriculture, forestry and fishing**	Agriculture, forestry, fishing	1
3		**Food products, beverages and tobacco**	Food	3
30		Hotels and restaurants		
17		Limited to "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**		
2		**Mining and quarrying**	Mining and quarrying	2
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 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"		
25		**Electricity supply**	Supply	25 or 26
26		**Gas supply**		
27		Water supply		
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

[1]INAB shall populate scopes appropriately

Appendix 3: Occupational Health and Safety (ISO 45001) Activities

IAF code	NACE code[1]	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		
24		**Recycling**	Transport and waste management	[31 (limited to dangerous goods), and 24] or 39 (limited to NACE 37, 38.1, 38.2, 39)
31		**Transport, storage and communication**		
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

[1]INAB shall populate scopes appropriately.

Appendix 4: Energy Management Systems (ISO 50001) Activities

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

Note: For more detailed information on EnMS technical areas refer to ISO 50003:2014.

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

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

Appendix 6: Medical Device Quality Management Systems (ISO 13485) activities

Main technical areas	*Technical areas*
Non-Active Medical Devices	General non-active, non-implantable medical devices
	Non-active implants
	Devices for wound care
	Non-active dental devices and accessories
	Non-active medical devices other than specified above
Active Medical Devices (Non-Implantable)	General active medical devices
	Devices for imaging
	Monitoring devices
	Devices for radiation therapy and thermo therapy
	Active (non-implantable) medical devices other than specified above
Active Implantable Medical Devices	General active implantable medical devices
	Implantable medical devices other than specified above
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
	In Vitro Diagnostic Instruments and software
	IVD medical devices other than specified above
Sterilisation Method for Medical Devices	Ethylene oxide gas sterilization (EOG)
	Moist heat
	Aseptic processing
	Radiation sterilisation (e.g. gamma, x-ray, electron beam)
	Low temperature steam and formaldehyde sterilization
	Thermic sterilisation with dry heat
	Sterilisation with hydrogen peroxide.
	Sterilisation method other than specified above
Devices Incorporating / Utilising Specific Substances / Technologies	Medical devices incorporating medicinal substances
	Medical devices utilizing tissues of animal origin
	Medical devices incorporating derivatives of human blood
	Medical devices utilising micromechanics
	Medical devices utilising nanomaterials
	Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed
	Medical devices incorporating or utilising specific substances/technologies/elements, other than specified above.
Parts or Services	Raw materials
	Components
	Subassemblies
	Calibration services
	Distribution services
	Maintenance services
	Transportation services
	Other services