



SNAS

SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA

METHODICAL GUIDELINE FOR ACCREDITATION

**SCOPE AND SCOPE SPECIFICATION
OF ACCREDITATION OF BODIES
CERTIFYING MANAGEMENT SYSTEMS**

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BRATISLAVA

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*Elaborated by: Ing. Pavol Kothaj
Ing. Mária Jana Obernauer, MSc.*

Verified by: Ing. Gizela Pelechová

Approved by: Mgr. Martin Senčák

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1 INTRODUCTION

1.1 FOREWORD

This methodical guideline defines the scope and the scope specification of accreditation of bodies certifying management systems according to ISO/IEC 17021-1:2015 and it is obligatory for all employees of the accreditation body and applicants for accreditation.

1.2 REFERENCES

ISO/IEC 17021-1: 2015	Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 1: Requirements
ISO/TS 22003: 2013	Food safety management systems. Requirements for bodies providing audit and certification of food safety management systems
ISO 50003: 2014	Energy management systems. Requirements for bodies providing audit and certification of energy management systems
MSA-02	SNAS logo and marks
MSA-04	Procedure for the accreditation
MSA-CS/08	Guidelines on the use of EN 45011 and EN 17021 for certification to EN ISO 3834 (EA-6/02)
MSA-CS/13	IAF mandatory document for the application of ISO/IEC 17021-1 in the field of medical device quality management systems (ISO 13485) (IAF MD9)
MSA-CS/15	Witness assessment of bodies certifying management systems in accordance with IAF MD 17: 2015

1.3 DEFINITIONS

Definitions in this MSA are in compliance with the definitions laid down in the References.

1.4 ABBREVIATIONS

ABMS	Anti-bribery Management Systems
BCMS	Business Continuity Management Systems
CS	Certification Body Certifying Management Systems
EMS	Environmental Management Systems
EnMS	Energy management systems
FSMS	Food Safety Management Systems
IAF	International Accreditation Forum
ISMS	Information Security Management Systems
ITSMS	Information Technology Service Management Systems
MSA	Methodical Guideline for Accreditation
NACE	Classification of Economic Activities
OH&SMS	Occupational Health and Safety Management Systems
QMS	Quality Management Systems
QMS-EoW	End-of-waste Management system

QMS-MD	Quality Management Systems for Medical Devices
QMS-W	Quality Management Systems for Welding
SFCS	Sustainable Forest Management Systems

2 SCOPE AND SCOPE SPECIFICATION OF ACCREDITATION

2.1 SCOPE OF ACCREDITATION

Scope of accreditation is a general definition of activities of an organization, accredited or seeking accreditation.

Scope of accreditation of the certification body certifying management systems is a performance of certification as follows:

- Quality Management Systems according to ISO 9001,
- End-of-waste Management System according to ISO 9001, Council Regulation (EU) No. 333/2011, Commission Regulation (EU) No. 1179/2012 and Commission Regulation (EU) No. 715/2013,
- Quality Management Systems for Welding according to ISO 9001 and ISO 3834,
- Sustainable Forest Management Systems according to SFCS,
- Quality Management Systems for Medical Devices according to ISO 13485,
- Environmental Management Systems according to ISO 14001,
- Occupational Health and Safety Management Systems according to ISO 45001,
- Information Security Management Systems according to ISO/IEC 27001,
- Food Safety Management Systems according to ISO 22000,
- Energy management systems according to ISO 50001,
- Anti-bribery Management Systems according to ISO 37001,
- Business Continuity Management Systems according to ISO 22301,
- Information Technology Service Management Systems according to ISO/IEC 20000-1.

The characteristics of the scope of accreditation will be laid down in the accreditation certificate too.

2.2 SCOPE SPECIFICATION OF ACCREDITATION/SPECIFICATION OF ACTIVITIES

The scope specification of accreditation is a detailed description of the activities for performance of which is an organization accredited.

The specification of activities is a range of activities accreditation of which an organization seeks and which, as for form, is identical with the scope specification of accreditation.

The scope specification of accreditation is laid down in the application for accreditation and it will be laid down in the annex to the accreditation certificate too.

The CS scopes specification of accreditation are defined according to the classification of economic activities (NACE codes) set by the Regulation of the European Parliament and the Council (EC) No. 1893/2006 (QMS, QMS-EoW, QMS-W, EMS, OHSAS, BCMS), according to ISO 50003 (EnMS), according to ISO/TS 22003 (FSMS), resp. according to IAF MD 9 (QMS-MD). Scopes of accreditation for SFCS, ISMS, ABMS and ITSMS are not specified in more detail.

The CS scope specification of accreditation is expressed as table consisting of all activities, for which the CS may be accredited and it is stated in Annexes from 1 to 9. Informative Annex 10 gives an example of positioning the EA codes in the technical areas for EnMS.

In case, that Certification Body has more workplaces, where certification activities are exercised, under the table with the scope accreditation shall state follow:

Workplaces of Certification Body, where certification activities are exercised (workplaces, where key activities are exercised, are marked with star):

№	Name and address of workplace

3 ANNEXES

Annex 1

- **Quality Management Systems (QMS),**
- **Quality Management Systems for Welding (QMS-W),**
- **Environmental Management Systems (EMS),**
- **Occupational Health and Safety Management Systems (OH&SMS),**
- **Business continuity management system (BCMS) .**

№	Code		Name of activity
	EA	NACE	
1	1	01	Crop and animal production, hunting and related service activities
		02	Forestry and logging
		03	Fishing and aquaculture
2	2	05	Mining of coal and lignite
		06	Extraction of crude petroleum and natural gas
		07	Mining of metal ores
		08	Other mining and quarrying
		09	Mining support service activities
3	3	10	Manufacture of food products
		11	Manufacture of beverages
		12	Manufacture of tobacco products
4	4	13	Manufacture of textiles
		14	Manufacture of wearing apparel
5	5	15	Manufacture of leather, and related products
6	6	16	Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials

№	Code		Name of activity
	EA	NACE	
7	7	17	Manufacture of paper and paper products
8	8	58.1	Publishing of books, periodicals and other publishing activities
		59.2	Sound recording and music publishing activities
9	9	18	Printing and reproduction of recorded media
10	10	19	Manufacture of coke and refined petroleum products
11	11	24.46	Processing of nuclear fuel
12	12	20	Manufacture of chemicals and chemical products
13	13	21	Manufacture of basic pharmaceutical products and pharmaceutical preparations
14	14	22	Manufacture of rubber and plastic products
15	15	23 excl. of 23.5, 23.6	Manufacture of other non-metallic mineral products
16	16	23.5	Manufacture of cement, lime and plaster
		23.6	Manufacture of articles of concrete, cement and plaster
17	17	24 excl. of 24.46	Manufacture of basic metals
		25 excl. of 25.4	Manufacture of fabricated metal products, except machinery and equipment
		33.11	Repair of fabricated metal products
18	18	25.4	Manufacture of weapons and ammunition
		28	Manufacture of machinery and equipment n. e. c.
		30.4	Manufacture of military fighting vehicles
		33.12	Repair of machinery
19	19	33.2	Installation of industrial machinery and equipment
		26	Manufacture of computer, electronic and optical products
		27	Manufacture of electrical equipment
		33.13	Repair of electronic and optical equipment
		33.14	Repair of electrical equipment
20	20	95.1	Repair of computers and communication equipment
		30.1	Building of ships and boats
		33.15	Repair and maintenance of ships and boats
21	21	30.3	Manufacture of air and spacecraft and related machinery
		33.16	Repair and maintenance of aircraft and spacecraft
22	22	29	Manufacture of motor vehicles, trailers and semi-trailers
		30.2	Manufacture of railway, locomotives and rolling stock
		30.9	Manufacture of transport equipment n. e. c.
		33.17	Repair and maintenance of other transport equipment
23	23	31	Manufacture of furniture
		32	Other manufacturing
		33.19	Repair of other equipment
24	24	38.3	Materials recovery

№	Code		Name of activity
	EA	NACE	
25	25	35.1	Electric power generation, transmission and distribution
26	26	35.2	Manufacture of gas; distribution of gaseous fuels through mains
27	27	35.3 36	Steam and air conditioning supply Water collection, treatment and supply
28	28	41 42 43	Construction of buildings Civil engineering Specialized construction activities
29	29	45 46 47 95.2	Wholesale and retail trade and repair of motor vehicles and motorcycles Wholesale trade, except of motor vehicles and motorcycles Retail trade, except of motor vehicles and motorcycles Repair of personal and household goods
30	30	55 56	Accommodation Food and beverage service activities
31	31	49 50 51 52 53 61	Land transport and transport via pipelines Water transport Air transport Warehousing and support activities for transportation Postal and courier activities Telecommunications
32	32	64 65 66 68 77	Financial service activities, except insurance and pension funding Insurance, reinsurance and pension funding, except compulsory social security Activities auxiliary to financial services and insurance activities Real estate activities Rental and leasing activities
33	33	58.2 62 63.1	Software publishing Computer programming, consultancy and related activities Data processing, hosting and related activities; web portals
34	34	71 72 74 excl. of 74.2 and 74.3	Architectural and engineering activities; technical testing and analysis Scientific research and development Other professional, scientific and technical activities
35	35	69 70 73 74.2 74.3 78	Legal and accounting activities Activities of head offices; management consultancy activities Advertising and market research Photographic activities Translation and interpretation activities Employment activities

№	Code		Name of activity
	EA	NACE	
		80 81 82	Security and investigation activities Services to buildings and landscape activities Office administrative, office support and other business support activities
36	36	84	Public administration and defence; compulsory social security
37	37	85	Education
38	38	75 86 87 88	Veterinary activities Human health activities Residential care activities Social work activities without accommodation
39	39	37 38.1 38.2 39 59.1 60 63.9 79 90 91 92 93 94 96	Sewerage Waste collection Waste treatment and disposal Remediation activities and other waste management services Motion picture, video and television programme activities Programming and broadcasting activities Other information service activities Travel agency, tour operator reservation service and related activities Creative, arts and entertainment activities Libraries, archives, museums and other cultural activities Gambling and betting activities Sports activities and amusement and recreation activities Activities of membership organizations Other personal service activities

Annex 2

 ▪ **Sustainable Forest Management Systems (SFCS)**

№	Code		Name of activity
	EA	NACE	
1	-	-	Sustainable Forest Management Systems

Annex 3

 ▪ **Information Security Management Systems (ISMS)**

№	Code		Name of activity
	EA	NACE	
1	-	-	Information Security Management Systems

Annex 4

 ▪ **Anti-bribery Management Systems (ABMS)**

№	Code		Name of activity
	EA	NACE	
1	-	-	Anti-bribery Management Systems

Annex 5

 ▪ **Information Technology Service Management Systems (ITSMS)**

№	Code		Name of activity
	EA	NACE	
1	-	-	Information technology Service Management Systems

Annex 6

 ▪ **Quality Management Systems for Medical Devices (QMS-MD)**

Note: Detailed tables comprehensive of “Product Categories Covered by the Technical Areas” are in normative Annex A, MSA-CS/13.

№	Code	Main Technical Areas	Technical Areas
1	<u>MD 1.1</u>	1. Non-active Medical Devices	General non-active, non-implantable medical devices
2	<u>MD 1.2</u>		Non-active implants
3	<u>MD 1.3</u>		Devices for wound care
4	<u>MD 1.4</u>		Non-active dental devices and accessories
5	<u>MD 1.5</u>		Non-active medical devices other than specified above
6	<u>MD 2.1</u>	2. Active Medical Devices (Non- Implantable)	General active medical devices
7	<u>MD 2.2</u>		Devices for imaging
8	<u>MD 2.3</u>		Monitoring devices
9	<u>MD 2.4</u>		Devices for radiation therapy and thermo therapy
10	<u>MD 2.5</u>		Active (non-implantable) medical devices other than specified above
11	<u>MD 3.1</u>	3. Active Implantable Medical Devices	General active implantable medical devices
12	<u>MD 3.2</u>		Implantable medical devices other than specified above
13	<u>MD 4.1</u>	4. In Vitro Diagnostic	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology)

		Medical Devices (IVD)	Haematology/Haemostasis/ Immunochemistry Microbiology Infectious Immunology Histology/Cytology Genetic Testing	
14	<u>MD 4.2</u>		In Vitro Diagnostic Instruments and software	
15	<u>MD 4.3</u>		IVD medical devices other than specified above	
16	<u>MD 5.1</u>	5. Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)	
17	<u>MD 5.2</u>		Moist heat	
18	<u>MD 5.3</u>		Aseptic processing	
19	<u>MD 5.4</u>		Radiation sterilization (e.g. gamma, x-ray, electron beam)	
20	<u>MD 5.5</u>		Low temperature steam and formaldehyde sterilization	
21	<u>MD 5.6</u>		Thermic sterilization with dry heat	
22	<u>MD 5.7</u>		Sterilization with hydrogen peroxide	
23	<u>MD 5.8</u>		Sterilization method other than specified above	
24	<u>MD 6.1</u>		6. Devices incorporating / utilizing specific substances / technologies	Medical devices incorporating medicinal substances
25	<u>MD 6.2</u>			Medical devices utilizing tissues of animal origin
26	<u>MD 6.3</u>	Medical devices incorporating derivatives of human blood		
27	<u>MD 6.4</u>	Medical devices utilizing micromechanics		
28	<u>MD 6.5</u>	Medical devices utilizing nanomaterials		
29	<u>MD 6.6</u>	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed		
30	<u>MD 6.7</u>	Medical devices incorporating or utilizing specific substances / technologies / elements other than specified above		
31	<u>MD 7.1</u>	7. Parts or services	Raw materials	
32	<u>MD 7.2</u>		Components	
33	<u>MD 7.3</u>		Subassemblies	
34	<u>MD 7.4</u>		Calibration services	
35	<u>MD 7.5</u>		Distribution services	
36	<u>MD 7.6</u>		Maintenance services	
37	<u>MD 7.7</u>		Transportation services	
38	<u>MD 7.8</u>		Other services	

*Organizations providing calibration services should be accredited to ISO/IEC 17025.

Note: As for “Components, Subassemblies, Maintenance services, Other services (Consulting services related to medical devices)” listed in Main Technical Areas Table No: 31-38; the CAB shall be required to have accreditation of the scope of the technical areas listed in Table No: 1-30, when the degree of influence of an organization’s parts or service are clearly intended to support medical devices (e.g. fasteners marketed with a clear intent to support implanted medical devices) or instances of contract manufacturers making nearly complete medical devices.

- **Food Safety Management Systems (FSMS) in conformity with ISO/TS 22003**

Food chain categories (HACCP system applies the same categories)

Note: In Accreditation scope is not declare „Subcategory“.

Cluster	Category		Subcategory	
1. Farming	A	Farming of Animals	AI	Farming of Animals for Meat / Milk / Eggs / Honey
			AII	Farming of Fish and Seafood
	B	Farming of Plants	BI	Farming of Plants (other than grains and pulses)
			BII	Farming of Grains and Pulses
2. Food and feed processing	C	Food Manufacturing	CI	Processing of perishable animal products
			CII	Processing of perishable plant products
			CIII	Processing of perishable animal and plant products (mixed products)
			CIV	Processing of ambient stable products
	D	Animal Feed Production	DI	Production of Feed
			DII	Production of Pet Food
3. Catering	E	Catering		
4. Retail, transport and storage	F	Distribution	FI	Retail / Wholesale
			FII	Food Broking / Trading
	G	Provision of Transport and Storage Service	GI	Provision of Transport and Storage Services for Perishable Food and Feed
			GII	Provision of Transport and Storage Services for Ambient Stable Food and Feed
5. Auxilliary services	H	Services		
	I	Production of Food Packaging and Packaging Material		
	J	Equipment manufacturing		
6. Biochemical	K	Production of (Bio) Chemicals		

Annex 8

- **End-of-waste Management system (QMS-EoW)**

No	Code		Name of activity
	EA	NACE	
1	15	23.1	Manufacture of glass and glass products
2	17	24 excl. of 24.46	Manufacture of basic metals
3	24	38.3	Materials recovery
4	39	38.1 38.2	Waste collection Waste treatment and disposal

Annex 9
▪ Energy management systems (EnMS)

Note: In Accreditation scope is not declare "Examples" and "Typical energy use".

Technical area	Description	Examples	Typical energy use
Industry – light to medium	Manufacturing facilities producing consumer intermediates or end user oriented products	<ul style="list-style-type: none"> - clothing; - consumer electronics; - home appliances, furniture; - plastics; - fabrication; - speciality chemicals; - food processing; - water and wastewater treatment 	<ul style="list-style-type: none"> - process heating (electricity, natural gas, coal or other source); - machine drive (pumps, fans compressed air, materials handling); - steam systems; - small cooling towers; - other process uses; - building energy uses (lighting, HVAC, hot water, portable devices)
Industry – heavy	Manufacturing facilities requiring high capitalization and consuming large quantities of raw materials and energy	<ul style="list-style-type: none"> - chemicals; - steel and metals; - oil refining; - ship-building; - pulp and paper mills; - industrial machinery; - semiconductors; - cement and ceramic 	<ul style="list-style-type: none"> - process heating (electricity, natural gas, coal or other source, raw materials, intermediates); - process cooling and refrigeration; - machine drive (pumps, fans compressed air, materials handling); - steam systems; - large cooling towers; - transportation
Buildings	Facilities with standard commercial building practices	<ul style="list-style-type: none"> - offices; - lodging; - retail; - warehouse 	<ul style="list-style-type: none"> - portable devices; - water heating; - lighting; - heating and cooling systems, related fans; - pumping systems
Building complexes	Facilities with operations requiring specific expertise due to the complexity of	<ul style="list-style-type: none"> - health care facilities; - laboratories; - data centres; - educational campuses; 	<ul style="list-style-type: none"> - centralized and district heating and cooling systems; - portable devices;

Technical area	Description	Examples	Typical energy use
	energy sources and uses	- military and government campuses with integrated energy supply (district heating and cooling)	- water heating; - lighting; - local HVAC; - compressed air, materials handling systems; - elevator / lifts
Transport	System or means for transporting people or goods/cargo	- passenger services (vehicle, train, ship, airplanes); - municipalities; - trucking services; - fleets; - rail operations; - cruise lines; - airlines, airfreight	- mobile energy uses; - HVAC; - lighting; - portable devices; - materials handling; - sources (fuel oil, electricity, coal, etc.)
Mining	Open cast, underground and fluid extraction of raw materials and transport	- mineral separation; - hydrometallurgy; - smelting and refining; - oil and gas drilling operations; - gas and oil pipelines	- extraction; - transportation on (loaders, trucks and conveyors); - machine drive (pumps, fans compressed air, materials handling); - materials preparation (crushing, grinding, separation); - steam systems, condenser, and cooling towers
Agriculture	Livestock, seed or crops products	- farming; - seed production; - hauling of materials; - animal production	- extraction; - sources (fuel oils, electricity, natural gas, coal, etc.); - renewables (biomass, solar, geothermal, etc.); - transport; - motors; - drives (pumps, fans, material handling); - pumps; - water treatment; - dryers
Energy Supply	Energy generation (nuclear, CHP, electricity, renewable, etc.) and transport (transmission and distribution)	- power generation (coal, oil, natural gas, renewable, CHP, IGCC, etc.)	- raw materials transformation; - transmission and distribution turbines; - combustion; - steam systems; - condenser and cooling towers

Annex 10 (Informative)

Example of positioning the EA codes in the technical areas for EnMS

Technical area	Description	EA codes – NACE codes
Industry – light to medium	Manufacturing facilities producing consumer intermediates or end user oriented products	3 – 10, 11, 12 4 – 13, 14 5 – 15 6 – 16 7 – 17.2 8 – 58.1, 58.2 9 – 18 14 – 22 17 – 24 okrem 24.46, 25 okrem 25.4, 33.11 18 – 25.4, 28, 30.4, 33.12, 33.2 19 – 26, 27, 33.13, 33.14, 95.1 23 – 31, 32, 33.19 24 – 38.3 27 – 36 28 – 41, 42, 43 29 – 45, 46, 47, 95.2 30 – 55, 56 31 – 52, 61
Industry – heavy	Manufacturing facilities requiring high capitalization and consuming large quantities of raw materials and energy	7 – 17.1 10 – 19 11 – 24.46 12 – 20 13 – 21 15 – 23 (except 23.5 a 23.6) 16 – 23.5 a 23.6 17 – 24 except 24.46, 25 except 25.4, 33.11 18 – 25.4, 28, 30.4, 33.12, 33.2 19 – 26, 27, 33.13, 33.14, 95.1 20 – 30.1, 33.15 21 – 30.3, 33.16 22 – 29, 30.2, 30.9, 33.17 28 – 41, 42, 43
Buildings	Facilities with standard commercial building practices	32 – 64, 65, 66, 68, 77 33 – 58.2, 62, 63.1 34 – 71, 72, 74 except 74.2 a 74.3 35 – 69, 70, 73, 74.2, 74.3, 78, 80, 81, 82 36 – 84 37 – 85 38 – 75, 86 (except 86.1), 87, 88 39 – 37, 38.1, 38.2, 39, 59.1, 60, 63.9, 79, 90, 91, 92, 93, 94, 96
Building complexes	Facilities with operations requiring specific expertise due	36 – 84 37 – 85 38 – 86.1

	to the complexity of energy sources and uses	
Transport	System or means for transporting people or goods/cargo	31 – 49, 50, 51, 53
Mining	Open cast, underground and fluid extraction of raw materials and transport	2 – 05, 06, 07, 08, 09
Agriculture	Livestock, seed or crops products	1 – 01, 02, 03
Energy Supply	Energy generation (nuclear, CHP, electricity, renewable, etc.) and transport (transmission and distribution)	25 – 35.1 26 – 35.2 27 – 35.3
