

NAR-06

Annex No. 4

Competence of assessors, experts in the accreditation and surveillance procedure of MS certification

Edition 5

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Abbreviations used in the tables:

Ref. – NAH desk officer / LA – lead assessor / A – assessor / E – expert / AC – Accreditation Committee member

*: Recommended, but not mandatory

1. QMS

<i>QMS (MSZ EN ISO 9001:2015)</i>						
		<i>Accreditation activity</i>				
	<i>Criteria, expectation</i>	<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
<i>Education</i>	Higher education (university, college)	Desk officer	LA, A, E	LA, A, E	LA, A, E (including surveillance)	AC
	5 days' QMS auditor training closed by an exam and/or university lecturer experience minimum 2 years supported by evidence	Desk officer*	LA, A, E	LA, A, E	LA, A, E (including surveillance)	AC*
	QMS internal auditor training	Desk officer*	LA*, A*, E*	LA*, A*, E*	LA*, A*, E* (including surveillance)	AC*
<i>Practice</i>	5 years' professional experience, experience gathered in the development, operation, improvement or auditing of quality management systems (for each IAF code development of the QMS system supported by evidences of at least 3 certified customers, or lead auditor activity in the given special area with at least 3 audits at an accredited certification body supported with evidence), or at least 3 years' operation of QMS supported by evidence	Desk officer*	LA, A, E	LA, A, E	LA, A, E (including surveillance)	AC
<i>Knowledge</i>	Principles applicable to quality management and their knowledge, application of PDCA, process approach, risk-based approach, tools related to the quality management systems, methods and their applications, knowledge of Standards ISO/IEC 17021-1 and ISO/IEC 17021-3 and the relevant international requirements.	Desk officer	LA, A, E	LA, A, E	LA, A, E (including surveillance)	AC
<i>Skills</i>	ability to ask questions	Desk officer	LA, A, E	LA, A, E	LA, A, E	AC
	monitoring skill					
	communication skill					
	assessment of audit processes					
	assessment of persons' competencies					
	able to work independently					
willingness to cooperate						
<i>Attributes</i>	ethical behaviour	Desk officer,	LA, A, E	LA, A, E	LA, A, E	AC
	pursuit of objectives					
	firmness/determination					
	ability to identify key points					
	adaptability to different situations					

2. EMS

EMS (MSZ EN ISO 14001:2015)						
	<i>Criteria, expectation</i>	<i>Accreditation activity</i>				
		<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
Education	Higher education (university, college)	Desk officer	LA, A, E	LA, A, E	LA, A, E (including surveillance)	AC
	EMS 5 days' auditor training closed by an exam and/or university lecturer experience minimum 2 years supported by evidence	Desk officer*	LA, A, E	LA, A, E	LA, A, E (including surveillance)	AC*
	EMS internal auditor training	Desk officer*	LA*, A*, E*	LA*, A*, E*	LA*, A*, E (including surveillance) *	AC*
Experience	5 years' professional experience, experience gathered in the development, operation, improvement or auditing of environment management systems (for each IAF code development of the EMS system supported by evidences of at least 3 certified customers, or lead auditor activity in the given special area with at least 3 audits at an accredited certification body supported with evidence by the accredited certification body), or at least 3 years' operation of EMS supported by evidence	Desk officer*	LA, A, E	LA, A, E	LA, A, E	AC
Knowledge	Knowledge and evaluation of environmental terminology, metrics/measures, factors and impacts, evaluation of environmental legal requirements, knowledge of Standards ISO/IEC 17021-1 and ISO/IEC 17021-2 and the applicable international requirements, knowledge of emissions into the atmosphere, emission into the soil, water, knowledge of the exploitation of raw materials, energy, natural resources	Desk officer	LA, A, E	LA, A, E	LA, A, E	AC
Skills	ability to ask questions, risk-based approach	Desk officer	LA, A, E	LA, A, E	LA, A, E	AC
	assessment of preparation for emergency situations					
	monitoring skill					
	communication skill					
	assessment of audit processes					
	assessment of persons' competencies					
	able to work independently					
willingness to cooperate						
Attributes	ethical behaviour	Desk officer	LA, A, E	LA, V?, E	LA, A, E	AC
	pursuit of objectives					
	firmness/determination					
	ability to identify key points					
	adaptability to different situations					

3. OHSAS

		<i>OHSAS (MSZ 28001:2008)</i>				
		<i>Accreditation activity</i>				
<i>Criteria, expectation</i>		<i>Application re-view, assessment planning</i>	<i>Document re-view</i>	<i>Site visit assessment</i>	<i>Witness audit as-sessment</i>	<i>Review of as-sessment re-ports, decision-making</i>
<i>Education</i>	Higher education (university, college)	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	qualification degree in labour protection	Desk officer*	LA*, A, E	LA*, A, E	LA*, A	AC
	OHSAS 5 days' auditor training closed by an exam and/or university lecturer experience minimum 2 years supported by evidence	Desk officer*	LA, A, E	LA, A, E	LA, A	AC*
	OHSAS internal auditor training	Desk officer*	LA*, A*, E*	LA*, A*, E*	LA*, A*	AC*
<i>Practice</i>	5 years' professional experience in labour safety, experience gathered in the development, operation, improvement or auditing of OHSAS systems (for each IAF code development of the OHSAS system supported by evidences of at least 3 certified customers, or lead auditor activity in the given special area with at least 3 audits at an accredited certification body supported with evidence), or at least 3 years' operation of OHSAS supported by evidence	Desk officer*	LA, A, E	LA, A, E	LA, A	AC
<i>Knowledge</i>	Evaluation of hazards, risks related to labour safety and occupational health and safety, knowledge of legal regulations related to labour protection, knowledge of Standard ISO/IEC 17021-1 and technical specification ISO/IEC TS 17021-10, as well as the applicable international requirements, risk-based approach	Desk officer*	LA, A, E	LA, A, E	LA, A	AC
<i>Skills</i>	ability to ask questions	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	assessment of preparation for emergency situations					
	monitoring skill					
	communication skill					
	assessment of audit processes					
	assessment of persons' competencies					
	able to work independently					
willingness to cooperate						
<i>Attributes</i>	ethical behaviour	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	pursuit of objectives					
	firmness/determination					
	ability to identify key points					
	adaptability to different situations					

4. FSMS, with attention to requirements in IAF MD 16

<i>FSMS (MSZ EN ISO 22000:2005)</i>						
		<i>Accreditation activity</i>				
	<i>Criteria, expectation</i>	<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
<i>Education</i>	Higher education (university, college)	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	5 days' lead auditor training closed by an exam and/or HACCP auditor and/or university lecturer experience minimum 2 years supported by evidence	Desk officer*	LA*, A, E	LA*, A, E	LA*, A	AC
<i>Practice</i>	5 years' professional experience in food industry area, experience gathered in the development, operation, improvement or auditing of HACCP and FSMS systems (for each food safety chain category development of the HACCP/FSMS system supported by evidences of at least 3 certified customers, or lead auditor activity performed at an accredited certification body in the given technical area supported by at least 3 audits supported by evidence at an accredited certification body), or at least 3 years' operation of FSMS supported by evidence	Desk officer*	LA, A, E	LA, A, E	LA, A	AC*
<i>Knowledge</i>	Knowledge of prerequisite programmes (PRPs or OPRPs), identification of actual HACCP principles, applicable PRPs, food safety risks, control measures, products, processes and practices, related legal requirements (see note 2.) Knowledge of the business sector of the CAB customer	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	Knowledge of Standards ISO 17021-1 and ISO 22003 and the applicable international requirements	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	Knowledge of CAB certification processes	Desk officer*	LA, A, E	LA, A, E	LA, A	AC
	Knowledge of cultural and social habits related to the assessed categories and geographical areas	Desk officer*	LA, A, E	LA, A, E	LA, A	AC
<i>Skills</i>	ability to ask questions	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	assessment of preparation for emergency situations					
	monitoring skill					
	communication skill					
	assessment of audit processes					
	assessment of persons' competencies					
	able to work independently					
willingness to cooperate	Desk officer	LA, A, E	LA, A, E	LA, A	AC	
<i>Attitude</i>	ethical behaviour	Desk officer	LA, A, E	LA, A, E	LA, A	AC

<i>FSMS (MSZ EN ISO 22000:2005)</i>						
		<i>Accreditation activity</i>				
<i>Criteria, expectation</i>		<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
pursuit of objectives						
firmness/determination						
ability to identify key points						
adaptability to different situations						

Note 1: Where assessment is performed by a team, the whole of the team is expected to have the required competences and not each member of the team separately. When assessment is performed by one person, then this person is required to have all the enlisted competences.

Note 2: Understanding the legal requirements specified above means that the organisation (where the witness assessment takes place) is required to conform with either the food industry sector or the country/state/province where it is active.

Note 3: When a team is performing review of assessment reports and passes decision on accreditation, the whole of the team shall have the relevant knowledge and not every member of the team separately.

5. ISMS, with attention to the special requirements in IAF MD 13

<i>ISMS (MSZ EN ISO 27001:2014)</i>						
		<i>Accreditation requirements</i>				
<i>Criteria, expectation</i>		<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
<i>Education</i>	Higher education (university, college)	Desk of-ficer	LA, A, E	LA, A, E	LA, A	AC
	5 days' auditor training closed by an exam and/or university lecturer experience minimum 2 years supported by evidence	Desk of-ficer*	LA, A, E	LA, A, E	LA, A	AC
<i>Practice</i>	5 years professional experience in the field of information technology	Desk of-ficer*	LA, A, E	LA, A, E	LA, A	AC
<i>Knowledge</i>	Knowledge of Standards ISO 17021-1 and ISO 27006 and the applicable international requirements, technical terms	Desk of-ficer*	LA, A, E	LA, A, E	LA, A	AC
	Customer processes of the certification body and operation in respect of ISMS	Desk of-ficer*	LA, A, E	LA, A, E	LA, A	AC

<i>ISMS (MSZ EN ISO 27001:2014)</i>						
		<i>Accreditation requirements</i>				
<i>Criteria, expectation</i>		<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
knowledge of information and communication technology, information safety technologies and practices characteristic of the technical area, identification of threats and weak points of information security related defence and controls, knowledge of risk assessment and risk control, general, legal and regulating requirements related to ESMS		Desk officer*	LA, A, E	LA, A, E	LA, A	AC
<i>Skills</i>	ability to ask questions	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	monitoring skill					
	communication skill					
	assessment of audit processes					
	assessment of persons' competencies					
	able to work independently					
<i>Attributes</i>	willingness to cooperate	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	ethical behaviour					
	pursuit of objectives					
	firmness/determination					
	ability to identify key points					
adaptability to different situations						

6. EMS

<i>EMS (50001:2012)</i>						
		<i>Accreditation activity</i>				
<i>Criteria, expectation</i>		<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
<i>Education</i>	Higher education (university, college)	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	5 days' auditor training closed by an exam and/or university lecturer experience minimum 2 years supported by evidence	Desk officer*	LA, A, E	LA, A, E	LA, A	AC
<i>Practice</i>	5 years' professional experience in energetics, research work, TDK (students' scientific circle); 2 years evidenced experience	Desk officer*	LA*, A*, E*	LA*, A*, E*	LA*, A*	AC

<i>EMS (50001:2012)</i>						
		<i>Accreditation activity</i>				
	<i>Criteria, expectation</i>	<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
<i>Knowledge</i>	EMS principles, energy specific concepts, fundamental energy regulations, legal and other requirements related to energy supply, indicators of energy efficiency, energy premises, essential variables and static factors, joint energy systems, energy-efficiency measures, technologies, general measurement and control knowledge, measuring, control and analysis of energy data; knowledge of Standard series ISO 17021-1 and ISO 50000 and of the applicable international requirements, risk-based approach	Desk officer*	LA, A, E	LA, A, E	LA, A	AC
<i>Skills</i>	ability to ask questions	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	monitoring skill					
	communication skill					
	assessment of audit processes					
	assessment of persons' competencies					
	able to work independently					
<i>Attributes</i>	willingness to cooperate	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	ethical behaviour					
	pursuit of objectives					
	firmness/determination					
	ability to identify key points					
adaptability to different situations						

7. MSZ EN ISO 13485, with attention to requirements in IAF MD 8

<i>MSZ EN ISO 13485:2012 and EN ISO 13485:2016 Medical devices management system certification</i>						
		<i>Accreditation activity</i>				
	<i>Criteria, expectation</i>	<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
<i>Education</i>	Higher education (university, college)	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	5 days' QMS lead auditor training closed by an exam and/or interner auditor training on MSZ EN ISO 13485	Desk officer	LA, A, E	LA, A, E	LA, A	AC*

<i>MSZ EN ISO 13485:2012 and EN ISO 13485:2016 Medical devices management system certification</i>						
		<i>Accreditation activity</i>				
	<i>Criteria, expectation</i>	<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
	Training course on Standard ISO 13485 supported by evidence	Desk officer*	LA, A, E	LA, A, E	LA, A	AC
Practice	5 years' work experience in the area of medical device manufacturing and licensing	Desk officer*	LA*, A, E	LA*, A, E	LA*, A	AC*
Knowledge	Principles applicable to quality management and knowledge thereof, application of PDCA, process approach, tools, methods related to quality management systems and their applications	Desk officer*	LA, A, E	LA, A, E	LA, A	AC
	Legal and general regulatory requirements applicable to medical device manufacturers, medical devices, their planned use, review of their safety and risks, identification of medical devices including their complexity, technologies, planned use and risk rating knowledge of applicable documents GHTF SG4 and SG3; Standards ISO 17021-1 and ISO 13485; and knowledge/understanding the applicable international requirements	Desk officer*	LA*, A, E	LA*, A, E	LA*, A, E	AC
	Legal framework, including the regulatory requirements and their implementation, and the role of the auditing body	Desk officer*	LA, A, E (5 years' experience in the field of medical device manufacturing and licensing supported by evidence, furthermore, knowledge of European Union directives and related national rules on medical devices)	LA, A, E (5 years' experience in the field of medical device manufacturing and licensing supported by evidence, furthermore, knowledge of European Union directives and related national rules on medical devices)	LA, A	
Knowledge	Information on CAB processes and organisation to the auditing team and to support the determination of competence required for decision on certification	Desk officer*		LA, A, E (5 years' experience in medical device manufacturing and licensing area supported by evidence, knowledge supported by exam on IAF MD 9)		
	Understanding the products, processes and organisation of CAB customers				LA, A (Supporting experience in the given technical area by	

<i>MSZ EN ISO 13485:2012 and EN ISO 13485:2016 Medical devices management system certification</i>						
		<i>Accreditation activity</i>				
	<i>Criteria, expectation</i>	<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
					professional experience, practice	
	Identification of medical devices including their complexity, technologies, planned use and risk rating	Desk officer*	LA*, A, E	LA*, A, E (5 years' experience in medical device manufacturing and licensing supported by evidence, knowledge of risk assessment risk control suitable for application in medical device area)	LA*, A, E (5 years' experience in medical device manufacturing and licensing supported by evidence, knowledge of risk assessment risk control suitable for application in medical device area)	
	Identification and assessment of factors that may affect the appropriate certification programme of a medical device manufacturer requiring certification in regulatory environment	Desk officer*	LA*, A, E	LA*, A, E (5 years' experience supported by evidence in medical device manufacturing and licensing)	LA*, A	
<i>Skills</i>	Ability to provide evidence that the expertise of the CAB is suitable for the pursuit of the certification on manufacturers also taking into account the processes and products concerned			5 years' experience supported by evidence in the field of medical device manufacturing and licensing in the development, manufacturing, testing, conformity assessment or application	5 years' experience in the field of medical device manufacturing and licensing supported by evidence, demonstration of experience in the given technical area, technical experience, on the basis of experience	Training on Standard ISO 1348 supported by evidence
	Ability to demonstrate that CAB processes appropriately support the ISO 13485 system		Demonstration of expertise on the valid IAF MD docs by an exam	Demonstration of expertise on the valid IAF MD docs by an exam	Demonstration of expertise on the valid IAF MD	

<i>MSZ EN ISO 13485:2012 and EN ISO 13485:2016 Medical devices management system certification</i>						
		<i>Accreditation activity</i>				
	<i>Criteria, expectation</i>	<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
					docs by an exam	
	Assessment of the competences of certification personnel of medical devices	Desk officer*	LA, A, E	LA, A, E	LA, A	AC*
	Skill to determine the required and appropriate duration of the assessment	Desk officer				
	Understanding work performed as an accredited CAB		LA, A, E	LA, A, E	LA, A	AC
	Understanding IAF mandatory documents being part of the ISO 13485 system	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	ability to ask questions	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	monitoring skill					
	communication skill					
	assessment of audit processes					
	assessment of persons' competencies					
	able to work independently					
	willingness to cooperate					
<i>Attributes</i>	ethical behaviour	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	pursuit of objectives					
	firmness/determination					
	ability to identify key points					
	adaptability to different situations					

8. AQAP

<i>AQAP</i>						
		<i>Accreditation activity</i>				
	<i>Criteria, expectation</i>	<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
<i>Education</i>	Higher education (university, college)	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	5 days' QMS lead auditor training closed by an exam	Desk officer*	LA, A, E	LA, A, E	LA, A	AC*

	QMS internal auditor training	Desk officer*	LA*, A*, E*	LA*, A*, E*	LA*, A*	AC*
<i>Practice</i>	5 years' professional experience, experience gathered in the development, operation, improvement or auditing of quality management systems (for each IAF code development of the QMS system supported by evidences of at least 3 certified customers, or lead auditor activity in the given special area with at least 3 audits at an accredited certification body supported with evidence), or at least 3 years operation of QMS supported by evidence	Desk officer*	LA, A, E	LA, A, E	LA, A	AC*
<i>Knowledge</i>	Knowledge of AQAP requirements, quality management principles and their knowledge, application of PDCA, risk-based approach, process approach, tools, methods related to the quality management systems and their applications, knowledge of Standard ISO/IEC 17021-1 and knowledge of the applicable international requirements.	Desk officer*	LA, A, E	LA, A, E	LA, A	AC
<i>Skills</i>	ability to ask questions	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	monitoring skill					
	communication skill					
	assessment of audit processes					
	assessment of persons' competencies					
	able to work independently					
willingness to cooperate						
<i>Attributes</i>	ethical behaviour	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	pursuit of objectives					
	firmness/determination					
	ability to identify key points					
	adaptability to different situations					

9. HUNGARIAN HEALTH CARE STANDARDS

<i>MEES= Hungarian Health Care Standards</i>						
		<i>Accreditation activity</i>				
<i>Criteria, expectation</i>		<i>Application review, assessment planning</i>	<i>Document review</i>	<i>Site visit assessment</i>	<i>Witness audit assessment</i>	<i>Review of assessment reports, decision-making</i>
<i>Education</i>	Higher education (university, college)	Desk officer	LA, A, E	LA, A, E	LA, A	AC
	5 days' QMS auditor training closed by an exam and/or teaching experience in health care	Desk officer*	LA, A, E	LA, A, E	LA, A	AC
	QMS internal auditor training	Desk officer*	LA*, A*, E*	LA*, A*, E*	LA*, A*	AC*

<i>MEES= Hungarian Health Care Standards</i>						
		<i>Accreditation activity</i>				
	<i>Criteria, expectation</i>	<i>Applica- tion re- view, as- sessment planning</i>	<i>Document re- view</i>	<i>Site visit assess- ment</i>	<i>Witness audit as- sessment</i>	<i>Review of as- sessment re- ports, deci- sion-making</i>
<i>Practice</i>	5 years' professional experience in health care, experience gathered in the development, operation, improvement or auditing quality management systems in the area of health care,	Desk of- ficer*	LA, A, E	LA, A, E	LA, A	AC
<i>Knowledge</i>	Principles applicable to quality management and their knowledge and application in the health care services area, application of PDCA, process approach, risk-based approach, tools, methods related to quality management systems and their application, knowledge of Standard ISO 17021-1 and the applicable international requirements	Desk of- ficer*	LA, A, E	LA, A, E	LA, A	AC
<i>Skills</i>	ability to ask questions	Desk of- ficer	LA, A, E	LA, A, E	LA, A	AC
	monitoring skill					
	communication skill					
	assessment of audit processes					
	assessment of persons' competencies					
	able to work independently					
willingness to cooperate						
<i>Attributes</i>	ethical behaviour	Desk of- ficer	LA, A, E	LA, A, E	LA, A	AC
	pursuit of objectives					
	firmness/determination					
	ability to identify key points					
	adaptability to different situations					

Applicable documents:

https://www.nah.gov.hu/NAR_IR: Reference table of sectoral standards