METHODOLOGICAL GUIDELINE FOR ACCREDITATION

MSA – I/ 03

ASSESSMENT OF INSPECTION BODIES

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Upon the entry into force of this MSA, the MSA-I/03 dated 20 December 2024 shall cease to be effective.

Content

1 INTRODUCTION

This methodological guideline defines the procedure for witness assessment of inspection bodies. The guideline is binding on SNAS, applicants for accreditation and accredited bodies.

2 ABBREVIATIONS USED

MSA Methodological Guideline for Accreditation
SNAS Slovak National Accreditation Service

3 RELATED DOCUMENTS

ISO/IEC 17020	Conformity assessment. Requirements for the operation of various types of bodies performing inspection
MSA - I/01	Scope and scope specification of accreditation of inspection bodies
MSA – I/02	Guideline for application of ISO/IEC 17020
MSA – 04	Procedure for Accreditation

4 WITNESS ASSESSMENT PROCEDURE

4.1 The witness assessment is a part of the accreditation process in inspection bodies. The objective of the witness assessment is to evaluate the implementation of documented procedures in practice and to ensure that the inspection results are reliable.

4.2 The witness assessment consists of observing the performance of inspection activities in the inspection field (subfield), which is declared in the scope of accreditation.

4.3 The scope and the character of the witness assessment shall be determined by the scope of accreditation, number and complexity of groups of the fields (sub-fields) of accreditation of inspection body. During the witness assessments the increased emphasis is put to those inspections that are more difficult and/or more serious in terms of their performance, safety, health or environmental protection.

4.4 When determining of a witness assessment the following criteria are considered:
- scope of accreditation
- number of output documents issued by individual inspectors
- total number of inspectors
- frequency of each type of inspection
- number of locations of the inspection body
- history of service performance during the accreditation cycle
- personnel certification or other confirmation of competence of inspectors
- training system of the inspection body
- effectiveness of internal monitoring of inspectors
- organizational stability and awareness of risks of activities of the inspection body
- other statutory requirements

4.5 The entire scope of accreditation is subject to the witness assessments. The witness assessment is performed during the period of validity of accreditation, while the choice of assessing fields (sub-fields) of inspection is performed on the basis of sampling:

a) accreditation - all fields (subfields) of inspection

b) re-accreditation - all fields (subfields) of inspection except those, which were assessed by witness assessment (surveillances, extension of accreditation) during the accreditation cycle assessments and if deficiencies have not been identified

c) extension of accreditation - all fields (subfields) of inspection which the extension is concerning of

d) surveillance - relative number of fields (subfields) of inspection from their total number (defined in the surveillance card)

Note:
Relative number means equal distribution of the witness assessments fields (subfields) of inspection so that it covers the entire scope of accreditation during in one accreditation cycle.
Accreditation cycle consists of surveillance and re-assessment. When is re-accreditation, can be assessed and those subjects of inspection, have already been assessed in the surveillances and accreditation extension.
If the case, they are similar principles or inspection methods within the field of inspection, only one witness assessment may be made.
With a large number of inspection body sites and a large number of sub-fields, sampling procedures may be used based on the risk associated with the activities or sites.

4.6 Where an applicant or accredited body has more individual sites, witnessing of the inspection shall be based on sampling:

a) accreditation - all sites and all fields (subfields) of inspection,

b) re-accreditation – all fields (subfields) of inspections and all sites, that all sites and fields /subfields of inspection are assessed using sampling procedures and the risk associated with the activities or sites, except those that have been assessed during the surveillance and extensions of the accreditation during accreditation cycle and where no deficiencies have been identified. All requirements of ISO / IEC 17020 are assessed during re-accreditation.

c) extension of accreditation – all fields (subfields) of inspection covered extension and relevant sites,

d) surveillance - performed under surveillance card. Witnessing in the Surveillance Card is planned so as to be within the accreditation cycle assessed all items of inspection and all sites.

4.7 All fields/subfields and all sites are assessed during the initial accreditation, except specific sub-fields with the same principle or inspection methods, where only one witness assessment per these subfields may be performed.

4.8 During re-accreditation and surveillance, if are in the scope of accreditation in part fields/subfields of inspection closer specified more subfields of inspections, one subfield is witnessing and other subfields are assessed expert interviews with inspectors and vertical audits of files. Based on previous assessments and the risk associated with

activities or sites, SNAS may also witness a more of witness subfield assessments within a single field of inspection.

4.9 If there are more than one site for accreditation and extension of accreditation within one sub-field of inspection, the witness assessment may be carried out by inspector/s from one site and all other sites shall be assessed by interview of inspectors from those other sites.

4.10 During the witness assessment the assessment group, for example, pays attention on following:

- whether the inspector has all necessary and up-dated methods, procedures, forms
- whether the inspector performs the inspection impartially, non-discriminatory, without prejudice
- keeping documented methods and procedures
- records of inspector
- suitability of equipment used
- handling of inspection items
- competence of inspector during evaluations of the findings
- elaboration of the report from inspection, etc.

4.11 If the accredited CAB is not able to ensure for the purposes of witness assessment some sub-fields of inspection to demonstrate its actual performance, it is possible to witness performance of simulated activity. However, this has to be performed as real inspection of a field/subfields of inspection and at the particular customer, regardless that some activities and/or procedures in relation to the customer are not performed (e.g. order).

4.12 SNAS determines the inspector who will be assessed by witness assessment at inspection. The choice and representative number of inspectors to be witnessed depends on the demonstrated stability of the services of the inspection body. When deciding which inspector will be assessed, account will be taken of:

- a new inspector
- qualification and experience
- the frequency of inspections carried out

Note:
When selecting an inspector, SNAS decides according to the following rules:

1) *problem inspectors of the sub-field;*
2) *new inspectors of the sub-field;*
3) *witness non-assessed inspectors in the sub-field;*
4) *inspectors less witnessed in the sub-field or less experienced in inspecting the sub-field*

4.13 If the inspection body has a large number of inspectors, not all the inspectors have to be assessed by witness assessment. In such a case their competence is verified based

on sampling by technical interview, which will be performed by assessment group. The interview can also be done in a group with a selected number of inspectors.

Note:
When selecting an inspector, SNAS decides according to the following rules:

1) problem inspectors of the sub-field;
2) new inspectors of the sub-field;
3) witness non-assessed inspectors in the sub-field;
4) inspectors less witnessed in the sub-field or less experienced in inspecting the sub-field

In the case of finding out the deficiencies in the interview, doubts about the competence of the inspector or doubts about the established management system, the number of conducted interviews will be increased at least to one more inspector for the given field (sub-field) of inspection.

4.14 CAB shall ensure that the SNAS assessors are granted access to the premises where the witness assessment is to be performed.

5 PROCEDURE FOR THE PURPOSES OF AUTHORIZATION/ NOTIFICATION ACCORDING TO DOCUMENT EA 2/17M (MSA-N/01)

5.1 In the case that the preferred standard for assessment for the purposes of authorization/notification is ISO/IEC 17020:2012, document EA 2/17M (MSA-N/01) shall be used for the assessment

The following principles shall be taken into account when planning and deciding on the required witness assessment:

1) Witness assessment is normally used as an assessment technique to determine the competent performance of all conformity assessment activities carried out on-site by the IB.

2) Other assessment techniques that may be used include record review and/or technical interviews. These should be used to supplement the information obtained during witness assessment and to broaden the sampling.

3) The results of the witness assessment of a single conformity assessment activity, or a combination of conformity assessment activities, may demonstrate and confirm the suitability and effectiveness of the IB's processes for the corresponding evaluation of comparable conformity assessment activities.

When applying these principles to the initial accreditation of an IB or to the extension of an IB's accreditation to new fields (subfields) of accreditation, all fields (subfields) of accreditation to be assessed, i.e. all applicable Directives or Regulations, shall be covered by the required witness assessment (Principle 1).

At the time of initial accreditation, extension of accreditation and throughout the accreditation cycle, all modules of all Directives/Regulations covered by the accreditation (Principle 2) shall be subject to witness assessment in accordance with the table 1. Modules that are not covered by witness assessment shall be assessed by means of record review.

Throughout the accreditation cycle, all modules of all Directives/Regulations covered by the accreditation shall be subject to witness assessment in accordance with the table 1 at the premises of an actual client. Modules that are not covered by witness assessment shall be assessed by means of a review of inspection files relating to existing clients.

The same principle applies to modules/activities that require the assessor's presence on site (Principle 3). Where certain modules within a single Directive/Regulation are very similar (e.g. Module D and Module E), the witness assessment may be limited to one of those modules (i.e. module grouping; see Table 1). In such cases, the more complex module should be selected.

It is considered highly unlikely that the witness assessments of activities performed under different Directives/Regulations can be effectively combined into a single witness assessment. However, where such an approach is adopted, SNAS shall document the reasons for and justification of this approach.

Witness assessments are normally conducted prior to the granting of accreditation or the extension of accreditation to the new conformity assessment activities. However, it is recognised that, in the field of accreditation for notification purposes, the availability of clients is very limited. Consequently, notified body applicants seeking accreditation before obtaining notification will normally have only limited opportunities to perform the relevant conformity assessment activities. Therefore, when granting initial accreditation or extending the accreditation of an inspection body, SNAS accepts alternative methods of conducting witness assessments (e.g. observation of inspection activities performed on site) as sufficient to assess the competence of the inspection body to perform the requested activities.

For the initial accreditation of an inspection body, accreditation may also be granted subject to the condition that the inspection body shall inform SNAS immediately upon receiving a request from its first client following notification. The inspection body shall cooperate with SNAS in arranging the first conformity assessment activities for the client to ensure that these activities are subject to witness assessment. SNAS shall have appropriate arrangements in place to ensure that no accredited inspection reports or certificates are issued until the relevant witness assessment has been satisfactorily completed. In such cases, SNAS shall identify those activities in the Scope of

Accreditation for which no inspection report or certificate may be issued without a witness assessment conducted by SNAS.

Where accreditation is granted with a deferred witness assessment, the following shall also apply:

1. The witness assessment shall be carried out no later than 18 months after the accreditation has been granted. If the witness assessment is not performed within this period, the accreditation for the relevant inspection body activity shall be withdrawn, as SNAS is unable to fully assess the continuing competence of the inspection body with respect to all applicable requirements.

2. Following the withdrawal of accreditation in accordance with the clause 1, the inspection body may re-apply for accreditation. However, an application for accreditation subject to the deferral of the witness assessment may not be submitted until two years have elapsed. Where the inspection body has a client available for witness assessment, it may apply for accreditation under the normal accreditation procedure without delay.

Table 1 – Modules under Decision No 768/2008/EC for which a witness assessment may provide assurance of competence for other modules included in the application for accreditation.

Module included in the Scope of accreditation	**Module description**	**Required witness assessment**
A1	Internal production control plus supervised product testing	A1 or A2 or C1 or C2 or B* or F or G
A2	*Internal production control plus supervised product checks at random intervals*	
B	*EU-type examination*	B* or G or H1
C	*Conformity to type based on internal production control*	C or D or E or H or A1 or A2 or C1 or C2 or D1 or E1or H1
C1	*Conformity to type based on internal production control plus supervised product testing*	C1 or C2 or A1 or A2 or B* or F or G
C2	*Conformity to type based on internal production control plus supervised product checks at random intervals*	
D	*Conformity to type based on quality assurance of the production process*	D or D1 or H or H1 or E or E1
D1	Quality assurance of the production process	D1 or H1 or E1
E	*Conformity to type based on product quality assurance*	E or E1 or D or D1 or H or H1
E1	Quality assurance of final product inspection and testing	E1 or D1 or H1

Module included in the Scope of accreditation	Module description	Required witness assessment
F	*Conformity to type based on product verification*	F or F1 or G
F1	Conformity based on product verification	F1 or G
G	*Conformity based on unit verification*	G or (B*+F1) or (B*+F)
H	*Conformity based on full quality assurance*	H or H1
H1	*Conformity based on full quality assurance plus design examination*	H1 or (B*+H)

B* EU-type examination (production type) *(as specified in the applicable EU legislation, e.g. the Pressure Equipment Directive (PED)*

5.2 For accreditation for notification purposes, the assessment activities to be performed for inspection bodies during the accreditation cycle (surveillance assessments and reassessment) shall be planned in accordance with the requirements specified in Clause 5.1.

5.3 Any modules under individual Directives or Regulations (fields or subfields of the inspection body's Scope of Accreditation) that are not assessed during the accreditation cycle (surveillance assessments and reassessment) shall be removed from the Scope of Accreditation.

5.4 In the case that the inspection body carries out conformity assessment activities using its own internal resources or through subcontracting, it shall comply with the applicable requirements of the preferred standards ISO/IEC 17020 and the additional requirements (+) of the applicable international standards, as specified in MSA-N/01 (EA-2/17 M), in accordance with the table 2

Table 2 – Additional requirements (+) of the applicable international standards to the preferred standard ISO/IEC 17020

Module	Description	Additional requirements
A	Internal production control	N/A
A1	Internal production control plus supervised product testing	t + cd
A2	Internal production control plus supervised product checks at random intervals	t + cd

Module	Description	Additional requirements
B	EU-type examination	t + cd
C	Conformity to type based on internal production control	N/A
C1	Conformity to type based on internal production control plus supervised product testing	t + cd
C2	Conformity to type based on internal production control plus supervised product checks at random intervals	t + cd
D	Conformity to type based on quality assurance of the production process	qa + cd
D1	Quality assurance of the production process	qa +cd
E	Conformity to type based on product quality assurance	qa +cd
E1	Quality assurance of final product inspection and testing	qa +cd
F	Conformity to type based on product verification	t + cd
F1	Conformity based on product verification	t + cd
G	Conformity based on unit verification	t + cd
H	Conformity based on full quality assurance	qa + cd
H1	Conformity based on full quality assurance plus design examination	qa + cd

t – Where testing is required, the applicable requirements of EN ISO/IEC 17025 shall apply. For this purpose, compliance with the applicable requirements of Clauses 6 and 7 (except Clause 7.9) of EN ISO/IEC 17025:2017 shall be demonstrated for the purposes of accreditation.

cd – Competence to perform evaluation procedures and make decisions based on the results of inspections, where the essential requirements and/or harmonised standards, where applicable, have been met. For this purpose, compliance with Clauses 4.1.2, 4.1.3, 7.5 and 7.6 of EN ISO/IEC 17065:2012 shall be demonstrated.

qa – Competence, where required, to assess and approve the manufacturer's quality management system. For this purpose, compliance with Clauses 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10, 9.1 to 9.4 and 9.6 of EN ISO/IEC 17021-1:2015 shall be demonstrated.

For the modules/activities under EU Directives or Regulations that do not have a direct equivalent among the corresponding modules set out in Decision No 768/2008/EC, the additional requirements applicable to the preferred standard ISO/IEC 17020 shall be assessed in accordance with the table 3.

Table 3 – Additional requirements (+) of the applicable international standards to ISO/IEC 17020 for accreditation for notification purposes where a notified body activity has no direct equivalent in the corresponding modules of Decision No 768/2008/EC

Directive/Regulation	Description	Additional requirements
92/42/EEC (HWB)	Module C	cd
2000/14/EC (Noise)	Annex VI – Internal production control with assessment of the technical documentation and periodic surveillance	cd+t
2000/14/EC (Noise)	Annex VII – Conformity based on unit verification	cd+t
2000/14/EC (Noise)	Annex VIII – Full quality assurance	qa
2006/42/EC (Machinery)	Annex IX – EC type-examination	cd+t
2006/42/EC (Machinery)	Annex X – Full quality assurance	qa
2010/35/EU (TPED)	Type examination in accordance with 1.8.7.2 of ADR	-
2010/35/EU (TPED)	Surveillance of manufacture and initial inspection and tests in accordance with 1.8.7.3 and 1.8.7.4 of ADR	-
2010/35/EU (TPED)	Periodic inspection Intermediate inspection and exceptional check in accordance with 1.8.7.6 of ADR	-
2010/35/EU (TPED)	Reassessment of conformity	-
2013/53/EU (RCD)	Module C1 – Conformity to type based on internal production control plus supervised product testing	cd+pk+t
2013/53/EU (RCD)	PCA – Post-construction assessment	cd+pk+t
2014/32/EU (MID)	Module A2 – Internal production control plus supervised product checks at random intervals	cd+pk+t
2014/33/EU (Lifts)	Annex V – Final inspection	t + cd
2014/34/EU (ATEX)	Module A – Internal production control (retention of the technical documentation)	cd
2014/68/EU (PED)	Approval of NDT personnel	ap
2014/68/EU (PED)	Approval of permanent joining personnel	ap
2014/68/EU (PED)	Approval of welding procedures	t
2014/68/EU (PED)	European approval of materials	t + cd
2014/68/EU (PED)	User inspectorates	-
2014/29/EU (SPVD)	Module C – Conformity to type based on internal production control	-

Directive/Regulation	Description	Additional requirements
92/42/EEC (HWB)	Module C	cd
2000/14/EC (Noise)	Annex VI – Internal production control with assessment of the technical documentation and periodic surveillance	cd+t
2000/14/EC (Noise)	Annex VII – Conformity based on unit verification	cd+t
2000/14/EC (Noise)	Annex VIII – Full quality assurance	qa
2006/42/EC (Machinery)	Annex IX – EC type-examination	cd+t
2006/42/EC (Machinery)	Annex X – Full quality assurance	qa
2010/35/EU (TPED)	Type examination in accordance with 1.8.7.2 of ADR	-
2010/35/EU (TPED)	Surveillance of manufacture and initial inspection and tests in accordance with 1.8.7.3 and 1.8.7.4 of ADR	-
(EU) 2016/797 (IOD)	All modules in accordance with Decision 2010/713/EU	ERA Mandatory Technical Document 000MRA1044
2023/1542/EU (Batteries)	Annex VIII, Module D1 – for Articles 7 and 8 only	cd+qa+v
2023/1542/EU (Batteries)	Annex VIII, Module D1 – for Articles 6 to 10, 12, 13 and 14	cd+qa+v
2023/1542/EU (Batteries)	Annex VIII, Module G – for Articles 7 and 8 only	cd+t+v
2023/1542/EU (Batteries)	Annex VIII, Module G – for Articles 6 to 10, 12, 13 and 14	cd+t+v
2023/1542/EU (Batteries)	Article 51 – Third-party verification of battery due diligence policies	Depends on the due diligence scheme recognised under Article 53 of Regulation (EU) 2023/1542
(EU) 2024/370 (DWD)	Modules B + D	cd+qa
(EU) 2024/1689 (AI)	Annex VII – Conformity based on quality management system assessment and assessment of the technical documentation	cd+qa
(EU) 2024/2847 (CRA)	Annex VIII, Part II – EU-type examination	cd+t

Directive/Regulation	Description	Additional requirements
92/42/EEC (HWB)	Module C	cd
2000/14/EC (Noise)	Annex VI – Internal production control with assessment of the technical documentation and periodic surveillance	cd+t
2000/14/EC (Noise)	Annex VII – Conformity based on unit verification	cd+t
2000/14/EC (Noise)	Annex VIII – Full quality assurance	qa
2006/42/EC (Machinery)	Annex IX – EC type-examination	cd+t
2006/42/EC (Machinery)	Annex X – Full quality assurance	qa
2010/35/EU (TPED)	Type examination in accordance with 1.8.7.2 of ADR	-
2010/35/EU (TPED)	Surveillance of manufacture and initial inspection and tests in accordance with 1.8.7.3 and 1.8.7.4 of ADR	-
(EU) 2024/2847 (CRA)	Annex VIII, Part IV – Conformity based on full quality assurance	cd+t

t – Where testing is required, the applicable requirements of EN ISO/IEC 17025 shall apply. For this purpose, compliance with the applicable requirements of Clauses 6 and 7 (except Clause 7.9) of EN ISO/IEC 17025:2017 shall be demonstrated for the purposes of accreditation.

cd – Competence to perform evaluation procedures and make certification decisions based on inspection results, where the essential requirements and/or harmonised standards, where applicable, have been met. For this purpose, compliance with Clauses 4.1.2, 4.1.3, 7.5 and 7.6 of EN ISO/IEC 17065:2012 shall be demonstrated.

qa – Competence, where required, to assess and approve the manufacturer's quality management system. For this purpose, compliance with Clauses 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10, 9.1 to 9.4 and 9.6 of EN ISO/IEC 17021-1:2015 shall be demonstrated.

ap – Competence to approve personnel in accordance with the applicable legislation. For this purpose, compliance with Clauses 5.2, 6.1, 6.2, 6.4, 8 and 9.1 to 9.6 of EN ISO/IEC 17024:2012 shall be demonstrated.

v – Competence to verify the declarations of economic operators in accordance with the applicable legislation. For this purpose, compliance with Clauses 7.3, 8, 9.2, 9.3, 9.4, 9.5, 9.6, 9.7, 9.8 and 9.11 of EN ISO/IEC 17029:2019 shall be demonstrated.

6 INSPECTION PROCEDURE IN THE FIELD OF ORGANIC PRODUCTION

6.1 The performance of activities in the field of organic production is defined by the legal provisions of Regulation No. 2018/848 of the European Parliament and of the Council (EU) of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007.

6.2 When assessing the requirements for organic production under EA-3/12, the inspection body's witness assessments shall take into account the requirements set out in Policy PL-33: EA Policy for the accreditation of organic production certification, as the inspection constitutes a subcontract of the COV.

6.3 The witness assessment shall be carried out in accordance with the procedure set out in point 4 of this Directive.

6.4 The requirements set out in this document shall subsequently be applied in the assessment by the accreditation body. The accredited body shall be the source of assessment in accordance with 6.2 of STN EN ISO/IEC 17065:2013 and shall act as a subcontractor for the COV.

6.5 With regard to the requirements of the document EA 3/12, regular assessments (surveillances and re-accreditation) of inspection bodies active in the field of organic production are usually carried out after 12 months.

6.6 In the case of using testing for conformity assessment without using a test report with reference to accreditation or without an accreditation mark, it is necessary to demonstrate compliance with the applicable requirements of chapters 6 and 7 of STN EN ISO/IEC 17025:2018, except for Article 7.9.

7 INSPECTION PROCEDURE FOR THE PURPOSES OF COMPLIANCE WITH NOTIFICATION REQUIREMENTS / ACCREDITATION FOR THE PURPOSES OF NOTIFICATION ACT. N° 146/2023 COLL. ON AIR PROTECTION AND DECREE N° 299/2023 COLL.

7.1 The performance of inspection activities for the purposes of Attestation of Compliance with Notification Requirements/Accreditation for Notification Purposes is defined by Act No. 146/2023 Coll. on Air Protection and Decree No. 299/2023 Coll.

7.2 The witness assessment is carried out in accordance with the procedure specified in point 4 of this Directive.

7.3 In the case that the scope of accreditation of the inspection body includes subfields that are for the purposes of Attestation of Compliance with Notification Requirements/Accreditation for Notification Purposes, together with the assessment of these subfields, the assessment of the notification criteria is also carried out. Notification

requirements are assessed administratively, but a witness assessment of the given subfield of the inspection body may also be used for their assessment.

7.4 Notification requirements may only be assessed by an assessor designated by the Ministry of the Environment of the Slovak Republic. Part of the assessment by the assessor is the completion of form Tl 257 "Control questions for entities fulfilling individual notification requirements under Act No. 146/2023 Coll. on air protection and Decree No. 299/2023 Coll.", which forms part of his report (Other findings).

7.5 The assessment of notification requirements is carried out as a separate service, which is not an inspection service and is a separate service in the AIS SNAS, while both services will refer to each other during the assessment.