

METHODICAL GUIDELINE FOR ACCREDITATION**MSA – I/ 03****WITNESS ASSESSMENT OF INSPECTION BODIES**

Approved by: **Ing. Štefan Král, PhD.**
Director SNAS

Effective from: 20.12.2024	Edition: 4 Updating: 0	Document label: MSA – I/03
-------------------------------	---------------------------------	-------------------------------

- **This document was created electronically** -

Elaborated by: **Ing. Stanislav Musil, PhD.**

Date of elaboration: 12.12.2024

Verifies by: **RNDr. Lívía Kijovská, PhD.**

By coming into force of this MSA expired the validity of **MSA-I/03 from 01.06.2021.**

This MSA has not been proof-read.

This MSA may not be reproduced and copied for resale

Access to MSA: <https://www.snas.sk/>

Content

1	INTRODUCTION	4
2	ABBREVIATIONS USED	4
3	RELATED DOCEMENTS	4
4	WITNESS ASSESSMENT PROCEDURE	4
5	PROCEDURE FOR THE PURPOSES OF AUTHORIZATION/ NOTIFICATION ACCORDING TO DOCUMENT EA 2/17M (MSA-N/01)	7
6	INSPECTION PROCEDURE IN THE FIELD OF ORGANIC PRODUCTION.....	8
7	INSPECTION PROCEDURE FOR THE PURPOSES OF COMPLIANCE WITH NOTIFICATION REQUIEREMENTS/ ACCREDITATION FOR THE PURPOSES OF NOTIFICATION ACT. N° 146/2023 COLL. ON AIR PROTECTION AND DECREE N° 299/2023 COLL.....	9

1 INTRODUCTION

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

2 ABBREVIATIONS USED

MSA Methodical 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 the accreditation

4 WITNESS ASSESSMENT PROCEDURE

4.1 The witness assessment is a part of the accreditation process in inspection bodies. The aim of the witness assessment is the evaluation of compliance of documented procedures in practice and the assurance that the inspection results are reliable.

4.2 The content of the witness assessment is the witnessing of operational performance of the inspection field (sub-field), 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 of 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 There are assessed all fields/subfields and all sites during 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 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 is obliged to ensure the entry for SNAS assessors to the premises, where the witness assessment will 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

5.2 If a new applicant applies for accreditation for the purposes of notification for an IO, a documentation assessment, an on-site assessment and a witness assessment shall be carried out for individual field/subfields, which is the standard procedure of SNAS in providing accreditation services in all fields of accreditation.

5.3 During the first accreditation or extension of accreditation for the purposes of notification for an IO that does not yet have a customer for some field/subfields of inspection, the witness assessment shall be carried out in the form of a simulated witness assessment for each field/subfields of inspection, while the witness assessment shall take into account Table No. 5 MSA-N/01 - Modules from Decision 768/2008/EC, which, based on the witness assessment, may provide assurance of competence for other modules for which accreditation is requested.

5.4 Based on the request of the regulator UNMS SR, witness assessments (surveillances + re-accreditation) for each field/subfield of inspection are planned and carried out within the accreditation cycle for the purposes of notification for an IO.

5.5 If, during the validity of the accreditation, the accredited IO requests an extension of the granted scope of accreditation to another field/subfields (EU directive, government

regulation, etc.), or a new conformity assessment module in an already accredited sub-area, a witness simulated assessment in the new sub-area (EU directive, government regulation, etc.) shall be carried out, or a new conformity assessment module shall be assessed in an already accredited subfields of inspection.

5.6 In the case that the inspection body carries out conformity assessment activities using its own internal resources, or subcontracted, the IO shall comply with the applicable requirements of the relevant international standards and other documents in accordance with EA 2/17M (MSA-N/01) where relevant, or as required by the regulator and applicable as follows:

- a) additional applicable requirements of EN ISO/IEC 17025, if testing is required. For this purpose, compliance with Chapters 6 and 7 (except Article 7.9) of EN ISO/IEC 17025: 2017 shall be demonstrated.
- b) competence, where required, to assess and approve the manufacturer's quality system. For this purpose, compliance with Articles 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 must be demonstrated.
- c) the competence to carry out assessment and decision-making procedures based on the results of tests and/or inspections, where the essential requirements are met and/or harmonized standards have been applied, where required. For this purpose, compliance with Articles 4.1.2, 4.1.3, 7.5 and 7.6 of EN ISO/IEC 17065: 2012 must 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.