

METHODICAL GUIDELINE FOR ACCREDITATION

MSA – CP/ 03

WITNESS ASSESSMENT OF CERTIFICATION BODIES CERTIFYING PRODUCTS

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1 INTRODUCTION

1.1 FOREWORD

This methodical guideline regulates the procedure for witness assessment of bodies certifying products according to ISO/IEC 17065: 2012 and it is obligatory for all employees of the accreditation body and applicants for accreditation.

1.2 REFERENCES

EA-2/17M	EA Document on Accreditation for Notification Purposes
EA-3/12M	EA Policy for the accreditation of certification of organic production
EA-6/02M	EA Guidelines on the use of ISO/IEC 17065 and ISO/IEC 17021-1 for certification to EN ISO 3834
eIDAS	Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC
ERA 1172/002	Sectorial scheme for accreditation and recognition of ECM certification bodies under Regulation (EU) 2019/779
ERA 1172/003	Certification scheme for ECM and outsourced maintenance functions under Regulation (EU) 2019/779
ISO/IEC 17000	Conformity assessment - Vocabulary and general principles
ISO/IEC 17020	Conformity assessment Requirements for activities of various types of bodies performing inspection
ISO/IEC 17021-1	Conformity assessment Requirements for bodies providing audit and certification of management systems
ISO/IEC 17025:	General requirements for the competence of testing and calibration laboratories
ISO/IEC 17065	Conformity assessment - Requirements for bodies certifying products, processes and services
MSA-04	Procedure for the accreditation
MSA-CP/01	Scope and scope specification of accreditation of bodies certifying products
MSA-CP/05	Application of ETSI EN 319 403 V2.2.2 (2015-08) by assessment of CAB certifying products according to eIDAS
MSA-CP/06	Application of document ERA 1172/002 V3.1 in assessment of certification bodies certifying products according to the ECM certification scheme
MSA-CS/08	EA Guidelines on the use of ISO/IEC 17065 and ISO/IEC 17021-1 for Certification to EN ISO 3834 (EA-6/02 M)
MSA-N/01	EA Document on Accreditation for Notification Purposes
PL-33	EA Policy for the Accreditation of Organic Production Certification (EA-3/12M)

PL-56	EA Policy for the accreditation of Certification Bodies providing certification of PDO, PGI, and TSG
TD SFCS 1006	Requirements for certification bodies certifying according to PEFC International Standard for Chain of Custody
TD SFCS 1007	PEFC Trademarks Rules – Requirements
Technical document	Technical document ERA - Requirements for conformity
MNB – Assessment	assessment bodies seeking notification
scheme 000MRA1044	

1.3 DEFINITIONS

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

Witness assessment - Observation of a conformity assessment body by an accreditation body while performing conformity assessment activities within the scope of its accreditation.

1.4 ABBREVIATIONS

CP	Certification body certifying products
EN	European Standard
GD	Guidance Document
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MSA	Methodical guideline for accreditation
NO	Notified body
NBÚ	National Security Authority
PS	Assessment group
UNMS SR	Slovak Office for Standards, Metrology and Testing

2 WITNESS ASSESSMENT PROCEDURE GENERALLY

Witness assessment is an integral part of the assessment process, during which is monitored and evaluated the procedure of CP during the performance of evaluation activities of products, processes and services. Evaluations activities of products in accordance with ISO/IEC 17065: 2012 can be performed as an audit, inspection or testing. At the request of the regulator, witness assessment may also be carried out, beyond the minimum number defined in MSA-N/01, of other assessment activities that are part of the certification scheme and that are carried out by the certification body at the manufacturer's premises or in the premises where the certified products are located (e.g. for modules A1, A2, C1, C2).

2.1 When witnessing the performance of the **audit** of the production quality assurance system, the PS evaluates the performance criteria of the witness assessments taking into account the relevant requirements of the **ISO/IEC 17021-1** standard in accordance with Annex B, MSA-N/01 (EA-2/17M).

2.2 When witnessing evaluation activities in the form of **testing**, the PS evaluates the general criteria for the performance of witness assessments, taking into account the relevant requirements of **ISO/IEC 17025** in accordance with Annex B, MSA-N/01 (EA-2/17M).

2.3 When witnessing assessment activities by **inspection**, the PS shall evaluate the general criteria for the performance of witness assessments, taking into account the relevant requirements of **ISO/IEC 17020** in accordance with Annex B, MSA-N/01 (EA-2/17M).

2.4 PS evaluates the overall course of evaluation activities of products, processes or services, the effectiveness and the method of their performance (compliance with the evaluation plan, communication skills, consistency, presentation skills and personal behaviour).

2.5 During the accreditation, one witness assessment is carried out for relevant certification scheme (according to MSA-CP/01).

During the re-accreditation, the witness assessment is carried out for minimum one certification scheme which is subject to the re-accreditation.

During the extension of accreditation scope, the witness assessment is carried out for each relevant certification scheme in the range of activities that are subject to the extension.

During the surveillance, the witness assessment is carried out minimum one for each relevant certification scheme which is subject to the surveillance.

The relevant certification scheme **in the unregulated area** is one which contains evaluating activities performed by personnel of CP by the manufacturer of the product. In the case of multiple certification schemes including within the same evaluating activities, the witness assessment will be carried out for only one of them.

The relevant certification scheme **in the regulated area** is any scheme/system/module that is included in the scope of accreditation and is listed in Tables 5 or 6 of MSA-N/01 in the column “Required witness assessment”. According to Tables 5 or 6, the CAB’s competence can be confirmed for other modules listed there based on the performance of one witness assessment,

3 WITNESS ASSESSMENT PROCEDURE FOR APPLICANTS FOR AUTHORIZATION/NOTIFICATION

3.1 If a new applicant applies for granting of accreditation for notification purpose for CP, the documentation assessment, the assessment on site and the witness assessment shall be carried out on several product groups in relevant certification schemes. This is the standard SNAS procedure on providing of accreditation services in all fields of accreditation.

3.2 In the case of initial accreditation or extension of accreditation for notification purpose for CP, which has not a client for some product groups yet, but for reason to get this client, needs to be notified first, the witness assessment may be performed after the granting of accreditation, but latest by the date of the first surveillance after the granting of accreditation.

3.3 In the case of a witness assessment for module B (according to Decision 768/2008/EC), a separate accreditation service "Witness assessment" is not performed for the certification body certifying products, but is performed as part of the on-site assessment. In doing so, the CAB is requested to ensure (both personally and technically) a demonstration of the performance of the assessment activity on the example of a specific client and certified product at the time of the on-site assessment. The assessment team will evaluate this action as the performance of a witness assessment and document it in the reports Other findings of the expert(s) and in the Summary Report prepared by the lead assessor.

3.4 Acting on requirement by regulator UNMS SR, on accreditation for notification purpose for CP shall be the witness assessments in one accreditation period planned and carried out for each product group in relevant certification schemes.

3.5 If during validity of an accreditation applies CP for extension of granted scope by additionally item within the frame of granted product group, at which this product group has been witness assessed in current accreditation period, there is no need to carry out a witness assessment for this item in current accreditation period. In such a case may be carried out assessment of fulfilling of accreditation requirements and competency of CP using another assessment's techniques without witness assessment, if there were founded by subject during assessment no risks or grave failures and granted scope can be extended by another item within the frame of granted product group.

3.6 If during validity of an accreditation applies CP for extension of granted scope by additionally item within the frame of granted product group, at which this product group had not been witness assessed in current accreditation period, after a deal with CP shall be carried out:

- Witness assessment for given item with relevant certification scheme, which is object of this extension (if possible) or
- Witness assessment for another item with relevant certification scheme within granted accreditation for given product group.

In any case, the requirements set out in MSA – N/ 01, Annex C (criteria for selection of witness assessments) must always be met during the accreditation cycle.

3.7 If during validity of an accreditation applies CP for extension of granted scope by additionally product group, witness assessment for a given product group in the relevant certification schemes shall be carried out in accordance with the procedure described in Art. 3.2.

4 PROCEDURES FOR PERFORMANCE OF WITNESS ASSESSMENT IN SPECIFIC CERTIFICATION SCHEMES

4.1 When assessing the maintenance requirements for rolling stock under Commission Implementing Regulation (EU) 2019/779 on ECM, witness assessments shall be carried out in accordance with the ERA 1172/002 V3.1 accreditation scheme and the ERA 1172/003 certification scheme and MSA-CP/06.

4.2 When assessing the requirements for organic production according to EA-3/12M, the witness assessments shall be carried out under the requirements of the policy of PL-33: EA Policy on the Accreditation of certification of organic production.

4.3 When assessing the requirements for welding processes according to EA-6/02M (MSA-CS/08), requirements of this document are taken into account.

4.4 When assessing the requirements for Chain of Custody of forest products by TD SFCS 1006 and TD SFCS 1007 there are not any additional requirements for performance of witness assessments beyond the general requirements for certification of products.

4.5 When assessing the requirements of the Regulations (EU) 910/2014 (eIDAS), Certification Scheme NBÚ SR and MSA-CP/05 are taken into account. SNAS performs by CP accredited in the scheme eIDAS in 5 year accreditation cycle 2 surveillances and subsequent reaccreditation. If the accredited CP has within the scope of accreditation other product groups than eIDAS, this group will be in contrast to other product groups subject of every surveillance performed by SNAS. Witness assessments will be carried out whenever the first accreditation, reaccreditation and surveillances at least once within the accreditation cycle, performed that during one accreditation cycle fails witness assessment for the same client repeatedly.

4.6 When assessing the requirements for the interoperability of the railway system – IOD, the Technical document MNB - Assessment scheme 000MRA1044 is taken into account.

4.7 When assessing the requirements for agricultural products, foodstuffs, spirit drinks, aromatised wines or wine products with a protected designation of origin (PDO/PDO), a protected geographical indication (PGI/PGI) or a traditional speciality guaranteed (TSG/TSG), document EA-3/02M (PL-56) is taken into account.

5 AUDIT/INSPECTION PLAN AND WITNESS ASSESSMENT REPORT

The assessed CP is obliged to enter the Audit/Inspection Plan into the AIS system no later than 2 weeks before the planned witness assessment, resp. inspections to the witness assessment in question. In the event that the audit or inspection is to take place abroad, the assessed CP is obliged to report this to SNAS at least 6 weeks in advance and to submit the Audit/Inspection Plan to the AIS at least 4 weeks in advance.

From the witness assessment a Report from the witness assessment is elaborated. In the report, the course of the evaluation activities of products, processes and services is evaluated and their compliance with regulations valid in the CP, documented in CP's documentation.

Witness assessment report contains at least:

- number of the service
- standard according to which the accreditation is carried out,
- PS members and their functions,
- name and the address of the organization - applicant for accreditation/accredited CP,
- name and the address of the CP,
- date of the witness assessment,
- type of accreditation service, a part of which is the witness assessment,
- item of the scope of accreditation, witnessed assessed persons (members of the evaluation team) and the name and address of the applicant for certification, evaluation of the performance of activity (evaluation of products, processes and services) and compliance with certification procedures of CP, including the preparatory phase, overall conclusion of the witness assessment and preparation of audit/inspection report,
- identified nonconformities and risks during the witness audit
- summary of the assessment.