National Accreditation Scheme

Rules of Procedure on the Preparation of Accreditation Audit Cycle Programmes

NAR-25

Edition 3

Version 1

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List of amendments

Edition 3

These Rules of Procedure have been fully restructured, therefore, the list of amendments cannot be interpreted:

Chapter No.	Description of the change

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1. Purpose of the Regulation

As a result of the accreditation procedure pursued by the National Accreditation Authority (NAH), the organisations, natural persons are granted accredited status for a term of five years. During the term of five years, NAH performs a plan of three surveillance procedures to audit the fulfilment of the accreditation requirements.

For planning the individual surveillance procedures, NAH prepares an accreditation audit cycle programme comprising five years.

The purpose of these Rules of Procedure is to regulate the preparation of the 5-year accreditation audit cycle programmes.

2. Personal and material scope

The personal scope of the present Rules of Procedure covers all parties involved in the preparation and implementation of the audit cycle programmes of the procedure pursued by the National Accreditation Authority (NAH).

The **material scope** of the present Rules of Procedure covers all accreditation procedures, where IAF MD 17:2015 (Witnessing Activities for the Accreditation of Management Systems Certification Bodies) mandatory regulation is applicable.

3. Definitions

In interpreting the applicable concepts, NAH considers the Standard MSZ EN ISO/IEC 17011 and Document IAF MD 17:2015 (Definition 1) as the basis.

- Accreditation audit cycle programme (in short: cycle programme): series of assessment performed at the conformity assessment body during the accreditation cycle; ‘assessment programme’ as defined in ISO/IEC 17011:2017 (3.27).
- Assessment plan: detailed description of the site audit in the given procedure; ‘assessment plan’ as defined in ISO/IEC 17011:2017 (3.28).
- Witness audit: ‘witnessing’ as defined in ISO/IEC 17011:2017 (3.25).
- Coverage plan: activity to be assessed as compiled by the members of the assessment team when planning the site assessment of specific procedures.

4. Description of the regulation

4.1. General rules applicable to the preparation of accreditation audit cycle programmes

When the assessment phase is closed, the lead assessor – in cooperation with the expert and accreditation desk officer – shall prepare the *accreditation audit* ***cycle programme*** for the 5-year cycle, including three surveillance procedures. The accreditation desk officer presents the completed plan to the accredited organisation, natural person.

The lead assessor shall review, update and coordinate the accreditation audit cycle programme with the accredited party before the launch of every surveillance procedure.

The following aspects shall be considered when preparing, reviewing, and updating the accreditation audit cycle programme:

- In accreditation, re-accreditation procedures, assessment of a representative sample of all requirements in the standard and scope applied for shall be performed;
- In surveillance procedures, it is always mandatory for the assessment team to assess the policy of the organisation, the internal audit, the management review, impartiality ensured, competences, maintenance of competences, activities performed in areas designated for surveillance. When planning the area of surveillance procedures, the following further aspects shall be considered,
    - Requirements and possible changes of applicable rules of law, standards, EA, ILAC, IAF documents;
    - Proportionate distribution of the accredited scope in the three surveillance procedures;
    - During the three surveillance procedures, the entire scope shall be assessed;
    - Area specific groups;
    - Number of sites. In case of multi-site organisations, sites performing key activities shall be assessed in each surveillance procedure. Other sites performing non-key activities shall be assessed at least once during the accreditation cycle.
    - Activities performed at external sites. If the organisation performs accredited activities at external sites as well, the activities performed at the external site shall also be audited. The frequency shall depend on the quantity of work performed at the external site. (e.g., auditing external measurements, external witnessed audits / witnesses).
    - Observation of a representative number of the staff, with special attention when key people (head of organisation unit, quality manager) leave the given area or 30% of those active in the given scope has changed;
    - Reported changes by the accredited party.

General risk assessment criteria:

- Results of *document review;* number and content of non-conformities and opportunities for improvement;
- Results of *former site assessments;* number and content of non-conformities and opportunities for improvement;
- Consideration of activities performed in larger number or rarely;
- Seasonal nature of activities;
- Activities technically more complex and covering larger areas;
- Areas involving higher risks for the interested parties;
- If complaint was received against a technical area against the accredited organisation

Based on the accreditation audit plan, it is a responsibility of the accreditation desk officer to plan the audit methods applied in the different accreditation and surveillance procedures.

4.2. Specific rules applicable to the preparation of accreditation audit cycle programmes as defined by the accreditation categories

4.2.1. Specific rules applicable to testing laboratories, sampling organisations, calibrating laboratories, medical laboratories

The scopes based on risk assessment priorities shall be planned by the lead assessor with the participation of the accreditation desk officer - in accordance with the following aspects - with attention to the entire accreditation cycle and covering all three surveillance procedures.

Specific risk assessment criteria:

- Consideration of Proficiency work plan and consideration of proficiency tests completed with non-acceptable results
- Consideration of largest number of tests (since the time of the previous assessment)
- Consideration of complexity (complex nature of the method)
- Consideration of areas affected by reported changes in measurement devices/equipment
- Changes in flexible scope shall be assessed in the next surveillance audit

The accreditation audit cycle programme of testing laboratories, medical laboratories and sampling organisations is compiled by the lead assessor by using Form NAD-153VL.

The accreditation audit cycle programme of calibration laboratories is compiled by the lead assessor by using Form NAD-153KL.

The preparation of the site assessment plans of the different procedures is a responsibility of the accreditation desk officer on the basis of the coverage plan determined by the experts/assessors appointed for the technical field (NAD-310).

4.2.2. Special rules applicable to **proficiency test** providers

The scopes based on risk assessment priorities shall be planned by the lead assessor with the participation of the accreditation desk officer - in accordance with the following aspects - with attention to the entire accreditation cycle and covering all three surveillance procedures.

Development of specific risk assessment criteria policy,

- elaboration, validation of the organisations, processes and procedures
- planning and approval of proficiency test providing activity (including the determination of the designated value, preparation, packaging, homogeneity, stability, distribution of the proficiency test items)

- assessment of testing activities (homogeneity, stability),
- assessment of the performance of sub-contractors and suppliers.

In case of proficiency test providers, the accreditation surveillance cycle programme is compiled by the lead assessor by using Form NAD-153JV.

4.2.3. Specific rules for **product certification** bodies

In case of larger accredited areas, planning shall be done by the lead assessor by establishing groups of products of similar attributes, manufacturing technology and certification system. Products, processes and services shall be classified into separate groups.

During an accreditation cycle, each product group shall be checked by at least one witnessed audit.

Specific risk assessment criteria:

- complexity of the certified product, process, service,
- exclusively performed product circle certification,

The accreditation audit cycle programme for product certification bodies shall be prepared by the lead assessor by using Form NAD-153TT.

4.2.4. Specific rules for **management systems certification bodies**

4.2.4.1 For QMS, EMS, OHSAS, AQAP management system certification bodies

The accreditation scopes of organisations certifying QMS, EMS, OHSAS, AQAP management systems is defined by the 39 codes in Annex 1 compiled on the basis of IAF ID 1 (IAF Informative Document For QMS and EMS Scopes of Accreditation)

Definition of the scope of office site assessment:

In case of management system scopes containing IAF codes, all IAF code scopes applied for must be audited. **With respect to NACE codes under the different IAF codes, the competence of the staff shall be audited.**

When accrediting a multi-site certification organisation, each site shall be site assessed. During the accreditation cycle, the central site shall be site visited in each surveillance, furthermore each site shall be assessed at least once in a cycle. If critical parts of the system certification process are performed independently at the different sites (application review, conclusion of contract, appointment, assessment of the auditors, review of audit documents), then site assessment shall be held in each surveillance procedure.

Planning witnessed site assessments:

According to Rules of Procedure NAR-01, in accreditation (extension of scope) and surveillance procedures, the procedure component to be applied for judging the competence of the organisation is the witnessed site assessment.

Pursuant to NAR-01, as part of the site assessment, the scope of the witnessed site assessment(s) shall be defined with a view to present and to observe all the activities of the accredited scope during the accreditation cycle.

To QMS, EMS certification bodies' witnessed site assessments, the requirements of IAF MD17:2015 are mandatory to be applied, whereas to the witnessed site assessment of OHSAS certification bodies, the requirements of document EA-3/13 M:2016 are mandatory to be applied.

For witnessed site assessments, the **certification body** shall submit the list of approved and planned audits including the date, the sites, the scope, composition of the audit team and the audit type when an application **is submitted** for accreditation, and **within 5 workdays** following the receipt of notification on due surveillance.

In an initial accreditation procedure, a witnessed site assessment shall be provided for **the critical code of each cluster** of each management system so that the National Accreditation Authority can award the status in that cluster. If witnessed site assessment is performed only for a non-critical code, the National Accreditation Authority can award accreditation in that cluster only for the non-critical code.

In case of an initial accreditation cycle, at least one witnessed site assessment shall be performed in each technical cluster or each management system (IAF MD 17 Requirement, points 5 and 6).

Furthermore, if the results of the witnessed site assessments are appropriate, then, in two subsequent accreditation cycles, witnessed site assessment shall be performed in each technical cluster of each management system at a minimum. Possibly certification or renewal audit shall be provided as witnessed site assessment.

In case of extension of scope, the certification body shall present witnessed site audits for the critical code of the cluster that is the subject of the extension. If it is already having accreditation for the critical code in the given cluster of the given management system, there is no need to present a new witnessed site assessment in the extension of scope procedure, but the competence of the personnel shall by all means be checked in the extension of scope procedure.

Before a witnessed site assessment, the certification body shall send the audit plan, the former audit reports in case of a surveillance audit, and the audit time calculation and justification as well as the proofs of the competences of the audit team to the assessment team of NAH. After the witnessed audit, the audit report prepared shall also be submitted.

Penalties: If a customer of the certification body refuses or rejects the participation of an assessor, expert of NAH in the witnessed site assessment, and it is not sufficiently supported by reasons, and it is not accepted by NAH, and it poses a threat to the coverage of the scope applied for or accredited, the certification body shall withdraw the accredited certificate, or in case the customer is not certified yet, the certification body cannot use the accreditation logo in the certificate to be issued in the future.

In such a case, when a certificate is withdrawn, organisations (other certification bodies, accreditation bodies) which may be affected, shall be notified, if their address is known. An accredited certificate cannot be issued if – in order to avoid the witnessing of their audit – the organisation expropriates the certificate to another certification organisation, or the certification organisation plans to re-issue the certificate under the coverage of another accreditation body.

For QMS, EMS, OHSAS certification organisations, the accreditation audit cycle programme shall be compiled by the lead assessor by using Form NAD-153IRT.

4.2.4.2 Additions to witnessed site audits of MS systems with a **number of areas** but not according to IAF codes and with **one area**, and persons certification

In case of management systems, where international requirements prescribe the performance of witnessed site assessment, the applicable requirements shall be applied. These regulations are the following:

For food safety management systems (FSMS), witnessing site visit shall be determined according to IAF MD 16 (Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems /FSMS/ Certification Bodies) in a manner that enables covering each main area by witnessing site visit in the accreditation cycle. That is, in the accreditation procedure, a witnessed site assessment shall be presented in each code group. The witnessed site visits of the accreditation cycle shall be planned to allow the presentation of witnessed site visits in high risk food safety sectors. If the organisation is accredited for the scope of food and feed processing, witnessed site assessment of this scope shall be presented in each surveillance procedure. In an accreditation cycle, the entire scope of accreditation shall be covered. It should be avoided that repeated witnessed audits are held at the same client.

In case of FSMS certification organisations, the accreditation audit cycle programme shall be compiled by the lead assessor by using Form NAD-153ÉBIR.

When accrediting the certification organisations certifying quality management systems of **medical device manufacturers**, the witnessed site assessment shall be determined on the basis of the requirements of IAF MD 8 (Application of ISO/IEC 17011 in the Field of Medical Device Quality Management Systems (ISO 13485)). That is, in the accreditation procedure, witnessed site audits shall be performed for all main technical scopes applied for. When planning witnessed site assessments, preference shall be given to areas of high risk classification from among technical areas. Each surveillance procedure shall contain a witnessed site assessment, and priority shall be given to the witnessed site assessments of organisations manufacturing high risk products in order to ensure that each technical field is covered by witnessed site audit in the accreditation cycle. It should be avoided that repeated witnessed audits are held at the same client.

<u>Risk classification of medical devices is as follows:</u>

*Medical device of **low** risk classification*

All medical devices which in respect of their intended purpose are:

- non-invasive and non-active devices,
- invasive device intended for transient or short-term use, in body crevice,
- an active device, which - with attention to its application - cannot be considered potentially hazardous.

*Medical device of **medium** risk classification*

All medical devices which in respect of their intended purpose:

- are surgically invasive devices intended for transient or short-term use, or an invasive device intended for long-term use in relation with body crevice,
- an active diagnostic tool which enables the diagnosis and observation of essential physiological processes,
- an active therapeutic device, which, with attention to the nature, density and application environment of energy cannot be considered potentially hazardous in the energy exchange with the human body.

*Medical device of **high** risk classification*

All medical devices which in respect of their intended purpose are:

- surgically invasive devices intended for long-term use,
- active diagnostic devices which enable the diagnosis and observation of essential physiological processes, the alteration of which may result in a direct threat to the patient,
- an active therapeutic device, which may potentially be considered as hazardous with attention to the energy exchange with the human body, the nature, density and application environment of energy,
- a medical device, which has a direct impact on the heart, the central circulatory system and/or the nervous system, whereby it may result in a direct threat to the patient,
- active implantable device.
- all devices which, as their integral part, contain human blood derivative or substance which when used separately can be considered medication,
- device intended for contraception.

In case of medical device manufacturing organisations, the accreditation audit cycle programmes are compiled by the lead assessor by using Form NAD-153ISO13485.

When accrediting **energy management system** certification bodies, minimum two of the scopes applied for should be covered by witnessed site audit. When selecting witnessed audit, attention should be paid to the number of EMS staff, energy consumption, energy uses, complexity factor and the identified critical areas (accreditation cycle audit plan form). The criteria for decision is that selected organisations to be certified should have the highest possible energy consumption, the most complex energy uses possible, the largest number of staff and activities as critical as possible. If energy supply is included among the areas for which accreditation is requested, that should be covered by witness audit as early as in the accreditation procedure. If witness audit is limited to activities that can be performed in office environment (e.g., energy trading, system management), and building, and/or assembly of buildings is included among the scopes for which accreditation is requested, no witness audit needs to be performed in the accreditation procedure. Each surveillance procedure shall contain a witnessed site assessment in order to ensure that each technical field is covered by witnessed site audit in the accreditation cycle. It should be avoided that repeated witnessed audits are held at the same client.

In case of EMS certification organisations, the accreditation audit cycle programme shall be compiled by the lead auditor by using Form NAD-153EIR.

4.2.4.3 Determination of witnessed site audit for management systems with one scope.

In the case of management systems with one scope, one certification audit shall be witnessed in the accreditation procedure, furthermore, during the accreditation cycle, the assessment team shall witness one audit in each surveillance procedure, which may be a certification or surveillance audit. Examples are e.g., ISMS and Hungarian Health Standards of Care (MEES) certification activities.

4.2.5. **Specific rules applicable to persons certification organisations**

Special risk assessment criteria:

- Assessment of the certification system;
- Competency of staff;
- Number of exams;

Special methods applied:

- In accreditation procedures, witnessed examination shall be performed for each persons certification category. In surveillance procedures, witnessed examination shall be planned for each audit in order to cover each certification activity by observed examination during the accreditation cycle.

In case of persons certification organisations, the accreditation audit cycle programmes shall be compiled by the lead assessor by using Form NAD-153SZT.

4.2.6. Specific rules for **inspection** bodies

Special risk assessment criteria:

- Classification of the organisation according to Annex ‘A’ of Standard MSZ EN ISO/IEC 17020.
- Competence knowledge performance of the individual inspectors

Special methods applied:

- First, the technical area groups are identified (fundamental or main method), of which minimum one must be assessed. The size of the sample selected for assessment can be determined in function of the number of sites, opportunities for witness, the size of area to be assessed.
- Inspection activity is usually performed on the sites of the customer. Not all sites where the inspection organisation performs activities need to be audited, but sites where the main activities are pursued shall be assessed. Such sites may be e.g., where policy is formulated, processes and the procedure are developed, inspectors are selected, contracts are reviewed, planning and compliance are approved, reviewed.

In case of inspection organisations, the accreditation audit cycle programmes is compiled by the lead assessor by using Form NAD-153L.

4.2.7. Special rules applicable to EMAS verifier organisations and natural persons

Rules applicable to EMAS verifier organisations and natural persons are contained in Regulation No. 1221/2009/EC.

In case of EMAS verifiers, the accreditation audit cycle programme is compiled by the lead assessor by using Form NAD-153EMAS.

4.2.8. Special rules applicable to EU ETS certification organisations

Special rules applicable to EU ETS certification organisations are contained in Rules of Procedure NAR-32.

In case of EU ETS verifiers, the accreditation audit cycle programme is compiled by the lead assessor by using Form NAD-153EUETS.

5. Related rules of procedure and rules of law

- Act CXXIV of 2015 on national accreditation (hereinafter: Natv.),
- Act CXCIX of 2011 on civil servants
- Government Decree No. 424/2015. (XII. 23.)
- Standard MSZ EN ISO/IEC 17011

6. Annexes

Annex No. 1 Code groups (in case of management system certification bodes) (NAR-25_01)

7. Forms

NAD-153VL - Accreditation Audit Cycle Programme. Testing laboratories

NAD-153KL - Accreditation Audit Cycle Programme. Calibration laboratories

NAD-153TT - Accreditation Audit Cycle Programme. Product certification bodies

NAD-153ELL - Accreditation Audit Cycle Programme. Inspection bodies

NAD-153SZT - Accreditation Audit Cycle Programme. Persons certification bodies

NAD-153IRT - Accreditation Audit Cycle Programme. Management systems certification bodies

NAD-153ÉBIR - Accreditation Audit Cycle Programme. FSMS certification bodies

NAD-153ISO13485 - Accreditation Audit Cycle Programme. ISO 13485 certification bodies

NAD-153EIR - Accreditation Audit Cycle Programme. ISO 50001 certification bodies

NAD-153EUETS - Accreditation Audit Cycle Programme. EU ETS verifiers

NAD-153JV - Accreditation Audit Cycle Programme. Proficiency test providers

NAD-310 – Planning coverage of the scope