NEMZETI AKKREDITÁLÓ HATÓSÁG

National Accreditation Scheme

Rules on the Preparation of Accreditation Audit Plans

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1. Introduction, purpose of the procedure

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 5 years. During the term of 5 years, NAH performs a plan of 3 surveillance procedures to audit the fulfilment of the accreditation requirements.

For planning the individual surveillance procedures, NAH prepares an accreditation audit plan comprising 5 years.

The purpose of this procedure is to regulate the preparation of the 5-year accreditation audit plans.

2. Related external regulations

- 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

3. General rules applicable to the preparation of accreditation audit plans

Following the award of the accredited status by the Deputy Director General of NAH, the accreditation desk officer prepares the accreditation audit plan for a term of 5 years including 3 surveillance procedures. The accreditation desk officer presents the completed plan to the accredited organisation, natural person.

The desk officer shall review, update and coordinate the accreditation audit plan 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 plan:

- In accreditation, re-accreditation procedures, assessment of a representative sample of all requirements in the standard and area applied for shall be performed;
- In surveillance procedures, it is always mandatory for the assessment team to assess the internal audit, the management review, impartiality ensured, competence, maintenance of competence, activities performed in areas designated for surveillance. When planning the area of surveillance procedures, the following further aspects shall be considered,

- Rules of law, standards, provisions of EA, ILAC, IAF documents;
- Proportionate distribution of the accredited scope in the three surveillance procedures;
- In the three surveillance procedures, the entire scope must be covered;
- 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).
- Findings of previous procedure, site assessment,
- Giving preference to activities that are performed by the accredited party proportionately in a larger number or at less frequency;
- Seasonal nature of activities;
- Giving preference to activities technically more complex and covering larger areas;
- Areas involving higher risks for the interested parties;
- The time demand of the accredited activity;
- Observation of a representative number of the staff, with special attention when key people leave the given area or 30% of those active in the given scope has changed;
- Reported changes by the accredited party.

Based on the accreditation audit plan, it is a responsibility of the accreditation desk officer and the lead assessor to plan the audit methods to be applied in the different accreditation and surveillance procedures and to prepare the programme of the site assessment (NAR-06).

Audit methods applied in accreditation, surveillance procedure may include:

- review of regulating and legal documents,
- review of documents presented at the site assessment,
- audit of activity presented at site assessment, which may be performed at their own site, at an external site, or may be an activity performed at the accredited party (witness),
- preparation of vertical assessment of documents at the site assessment,
- performing interviews at the site assessment,
- auditing the performance of participation in proficiency tests, the implementation of the proficiency test plan.

4. Specific rules applicable to the preparation of accreditation audit plans as defined by the accreditation categories

4.1. Specific rules applicable to testing laboratories, sampling organisations, calibration laboratories, medical laboratories

Audit plan of areas based on risk assessment priorities shall be planned jointly by the lead assessor and the accreditation desk officer in accordance with the following aspects, with attention to the entire accreditation cycle and covering all three surveillance procedures.

Risk assessment criteria:

- Consideration of highest risk factors
- Consideration of 3 year Proficiency work plan and consideration of proficiency tests completed with non-acceptable results
- Consideration of scopes with the most severe findings / largest number of findings in the accreditation procedure
- Consideration of problems discovered in the largest number in document review in the accreditation procedure
- Consideration of largest number of tests (since the previous assessment)
- Consideration of complexity (complex nature of the method)
- Consideration of the number of sites
- Observation of a representative number of staff with special attention when key people leave the given area or 30% of those active in the given scope has changed
- Consideration of areas affected by reported changes in measurement devices/equipment
- If complaint was received against the technical area by the accredited organisation
- In case of flexible scope, it is to be assessed in every surveillance

In laboratory area, the assessment team of NAH applies the following auditing, assessment methods in the surveillance procedures:

- review of documents presented at the site audit,
- audit of activity presented at site assessment, which may be performed at their own site, at an external site,
- interview at the site audit,
- vertical assessment at the site audit,
- auditing the performance of participation in proficiency tests, the implementation of the proficiency test plan.

In case of laboratories, planning is done by using the following forms:

The accreditation audit plan of testing laboratories, medical laboratories and sampling organisations is prepared by using Form NAD-153VL.

The accreditation audit plan of calibration laboratories is prepared by using Form NAD-153K

4.2. Specific rules applicable to product certification organisations

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

All product groups included in the plan shall be audited by witnessed assessment at least once during the accreditation cycle.

When compiling and updating the surveillance plan, the following aspects shall be considered also paying attention to the risk factors:

- complexity of the certified product, process, service,
- changes in applicable normative documents (e.g., standards, rules of law),
- auditing the new area requested at re-assessment,
- nature and area of reported changes (e.g., new staff involved in assessment, re-classifications, organisational changes, etc.),
- exclusively performed product circle certification,
- number of staff,
- complaints or feedback received from role players of the market and other interested parties,
- observation of critical, risky, sensitive area,
- certification activity performed in small number/in large number (based on annual statistical data),
- furthermore, other special aspects of the specific area

Witnessed assessment shall be performed in the following cases:

- if it is relevant as part of the certification system,
- in case of significant change in the applicable normative documents (e.g., standards),
- when new area to be accredited is applied for,
- critical, risky, sensitive area (e.g., only new staff is available),
- area affected by complaint,
- non-accredited area (e.g., testing activities) shall be assessed at initial or re-accreditation,

- based on information from interested parties,

Assessment methods applied:

- office review, documents review,
- interview,
- vertical assessment,
- observed site assessment (witness).

In case of product certification organisations, the plan is prepared by using Form NAD-153TT

4.3. Specific rules applicable to inspection organisations

Risk assessment criteria:

- 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 areas to be assessed with attention to the above selection criteria.
- 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. These sites can be, e.g.:

Aspects to be considered in selecting the areas for witness assessment:

- complexity of the inspection to be witnessed,
- witnessing a new person performing inspection,
- observation of a critical, risky, sensitive area,
- inspection activity performed only few times (based on annual statistical data).

Assessment methods applied:

- office review, documents review,
- interview,
- vertical assessment,
- observed site assessment (witness).

In an accreditation procedure, fundamental activities shall be assessed, which are the following:

a) development of policy, regulation;
b) development of process and/or procedure;

c) initial selection process of inspectors;
d) contract review;
e) planning conformity assessments;
f) review and approval of conformity assessments.
g) contract review irrespective of the centre;
h) documentation maintained not by the centre;
i) documentation of the management system maintained not by the centre;
j) maintenance and calibration of specific equipment held not at the centre,
k) documentation of inspection records.
l) choosing between complete observation of performance (witness) and its inspection reports, and/or enforcement of the documents, and/or quality inspection reports, and/or customer documents of the inspection organisation (vertical assessment).
m) In an initial and re-assessment procedure, a number of methods have to be selected and it has to be large enough to cover the most important or main methods in each area by assessment. In each activity area at least one main method and at least 25% of the inspection staff must be assessed irrespective of the geographical (regional) distribution of the inspection.
n) If, for any reasons, planned site observation cannot be implemented (due to the weather or other logistic constraints), the accreditation organisation may re-schedule the plan for the cycle. When new scope is accepted or site assessment becomes impossible in practice, observation of a simulation inspection can also be considered.
o) Skills, knowledge and performance of the individual inspectors shall also be assessed by the observation of their specific inspection activity in the procedure, and shall be compared with the documentation of the inspection organisation itself. The efficiency of the performance evaluation performed by the inspection organisation shall also be audited (to see if they apply robust quality assurance system).
p) For assessing personal competence, the suitable tools are the interview, the witness audit and the results of monitoring performed by the organisation itself.

In case of inspection organisations, the plan shall be prepared by using Form NAD-153 E

4.4. Specific rules applicable to persons certification organisations

Risk assessment criteria:

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

Assessment methods applied:

- By assessing documents at site office audit, by making interviews
- 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 plan shall be prepared by using Form NAD-153 SZT

4.5. Special rules applicable to management systems certification organisations

4.5.1. For QMS, EMS, OHSAS, AQAP management system certification bodies

The accreditation technical area of organisations certifying QMS, EMS, OHSAS, AQAP management systems is defined by 39 codes determined in Annex 1 of NAR-IAF ID Guidance 1.

Definition of the area of office site assessment:

In the accreditation procedure of the management system certification organisation, the full accredited scope must be covered by reviewing the documents of the procedures implemented in the site assessment and by the evaluation of the competence of staff. 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 site visit shall be held at the central site in each surveillance, and the site assessment of the other sites shall be planned in a manner enabling the assessment of each site at least once. 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.

Due to technical considerations, the National Accreditation Authority decided to generate 9 code groups out of the 39 technical areas (IAF codes) of the referenced guide on the basis of the similar operation of certified organisations and necessary competence of auditors. Code groups are contained in Annex 1.

When the accredited status is granted, the accreditation desk officer divides the area of the applicant intended to be accredited (IAF codes) according to the groups of codes. During the

accreditation cycle (the accreditation procedure and the surveillance procedures together), the assessment team must observe at least one certification or surveillance audit from each group of codes in order to have all the activities performed in the entire accredited scope presented or witnessed. The assessment team shall pay special attention to the critical areas.

If the accredited scope or scope applied for contains all the 39 IAF codes, and the IAF codes can be classified into 9 groups, the organisation shall present 3 witnessed site assessments (from 3 different groups of codes, 1 from each group of code).

In surveillance procedures, 2-3 witnessed site assessments (1 from each group of codes) shall be planned and maintained from the remaining groups of codes.

Witnessed site assessments shall be defined in a manner - both in accreditation and surveillance procedures - that at least one of them shall be a certification audit.

If the area to be accredited belongs to one group of codes, the assessment team shall hold 2 witnessed site audits in areas with different IAF codes within the same group of codes.

In case of extension of scope, the organisation shall present witnessed site audits for IAF codes that are the subject of the extension.

In case of QMS, EMS, OHSAS certification organisations, the plan shall be prepared by using Form NAD-153 IRT

4.5.2. 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 defined according to EA document IAF MD 16 in a manner that enables covering each main area by witnessing site visit in the accreditation cycle. That is, in the accreditation procedure, witnessing site assessments shall be presented in each code group. The witnessing site visits of the accreditation cycle shall be planned to allow the presentation of witnessing site visits in high risk food safety sectors, furthermore, the entire scope of accreditation must be covered. It should be avoided that repeated witnessed audits are held at the same client.

In case of FSMS certification organisations, the plan shall be prepared by using Form NAD-153ÉBIR

When accrediting the certification organisations of **medical device manufacturers'** quality management systems, witnessed audit shall be defined according to the provisions of IAF MD 8. That is, in the accreditation procedure, witnessing site audits shall be performed for all main technical areas applied for. When planning witnessed site assessment, preference shall be given to areas of high risk classification from among technical areas. Witness site assessment shall be part of each surveillance procedure and priority shall be given to witness site assessment of organisations manufacturing products of high risk classification. (E.g., active implantable medical devices, sterilisation, medical devices delivering drugs.) 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 medical device manufacturing organisations, the plan is prepared by using Form NAD-153OTEGY

When accrediting **energy management system** certification bodies, minimum 2 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. Its 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 not 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, planning shall be performed by using Form NAD-153EIR

Determination of witnessed site audit **for management systems with one area**. In the case of management systems with one area, 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.

4.6. Special rules applicable to EU ETS certification organisations

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

5. Closing provisions

The present rule of procedure is issued by the Deputy Director General in the interest of ensuring the continuity of the accredited management system certification activities by way of the Director General's Instruction No. 21/2016.

Publication on the website of the NAH (www.nah.gov.hu) shall constitute as publication of this Rule of Procedure.