



NEMZETI AKKREDITÁLÓ HATÓSÁG

National Accreditation System

NAH regulation on taking up new accreditation activities and introducing the changes of the accreditation requirements

NAR-35

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1. Objective / Scope

Present Regulation regulates the extension of the accreditation scope of the National Accreditation Authority (hereinafter: NAH) with taking into account the provisions of EA-1/22.

The accreditation scope may be extended when there are new demands and when the accreditation requirements are modified.

The new demands of the parties concerned in accreditation may occur in the following ways:

- New laws are introduced by the authorities of the government on legally regulated area about the approval of products (including services) in the fields of safety, health protection, environment protection to prevent fraud and ensure the fairness of market competition;
- On areas not regulated legally several industrial sectors may introduce – partly within certain economic units, and partly within the whole sector – conformity assessment and approval systems which aim at achieving a minimal technical standard, making comparison available, and ensuring the same completion conditions.

Present Regulation also contains the steps and activities needed to be done when the requirements serving as the basis of accreditation are changed (standard transition).

In the national accreditation system the normative documents, profession specific requirements and guidelines listed in the Table specified in Section 2 of NAR-01 shall be applied for the organisations and natural persons eligible for accreditation as listed in Section 5 of Act CXXIV of 2015 on the organisation, duties and powers of the Hungarian Accreditation Authority (hereinafter: the Act).

NAH may adopt and/or cooperate in the preparation of applicable or guideline documents. NAH ensures that these documents be prepared by persons or committees having the necessary competence, and if expedient, NAH arranges for the participation of the interested parties in the preparation. If there are international documents applicable for this purpose NAH applies those documents.

Information on the accreditation activity and the conformity assessment scheme:

With regard to the new conformity assessment scheme to be introduced, the question NAH shall ask is not that whether the conformity assessment organisation may perform the new conformity scheme to be introduced, but whether the new conformity assessment scheme may be added to the accreditation activities. We differentiate between the conformity assessment system and conformity assessment scheme.

2. Definitions

- **Accreditation activity:** the activity of the accreditation body, according to which the conformity assessment scheme of a conformity assessment organisation is assessed.
- **Conformity assessment system:** rules, procedures and management for carrying out conformity assessment

NOTE: Conformity assessment systems may be operated at international, regional, national or sub-national level.

- **Conformity assessment scheme:** conformity assessment system related to specified objects of conformity assessment, to which the same specified requirements, specific rules and procedures apply.

NOTE Conformity assessment schemes may be operated at international, regional, national or sub-national level.

- **Scope of accreditation:** actual conformity assessment services, for which the accreditation was applied or granted. (Definition specified in Section 3 of MSZ EN ISO/IEC 17011 standard)
- **Extending accreditation:** process of extending the scope of accreditation (Definition specified in Section 3 of MSZ EN ISO/IEC 17011 standard)

3. NAH policy on adding new accreditation activity and conformity assessment scheme

NAH is the national accreditation body of Hungary. NAH carries out its activities in Hungary according to Regulation (EC) 765/2008 and the national accreditation law. As the extension or expansion of the scope of accreditation with new accreditation activities has become more and more important, NAH supports the introduction of those when a demand is received from the economic or other interested parties. By adding new accreditation and conformity assessment schemes NAH tries to strengthen the trust in accreditation for the wider public.

With regard to this, NAH determines the following points:

1. NAH accredits the conformity assessment organisations according to harmonized standards. NAH offers new accreditation activity, for which a proper harmonized standard was developed, in the accreditation activity programme of NAH.
2. NAH launches a new accreditation activity or conformity assessment scheme only if the demand and need for the scheme or activity is justified and ensured.
3. NAH supports the standardisation by launching a new accreditation activity or conformity assessment scheme to ensure the involvement of the interested parties in the biggest possible extent.
4. When deciding on the launch of a new accreditation activity or conformity assessment scheme NAH proceeds impartially and without being influenced.
5. In order to facilitate the free movement of goods within the EU and in the world NAH supports the launch of new national or international conformity assessment schemes.
6. NAH tries to assess and introduce these new accreditation activities and conformity assessment schemes transparently and effectively.
7. NAH launches the new accreditation activity or conformity assessment scheme, namely the extension of the scope of accreditation, on the basis of information exchange with other European accreditation bodies and the EA, according to the relevant provisions of EA (EA-1/22).

The need to launch a new accreditation activity or conformity assessment scheme may arise from different causes:

1. On the basis of the law, legislative provisions (national and/or European), which require accredited status for an activity which did not need accreditation before (e.g. UV protection regulation, construction product regulation, etc.).
2. Introduction of a new conformity assessment standard (e.g.: ISO 14065).
3. On specific fields of expertise, the conformity assessment activity is detailed in standards (e.g. ISO 50001, EN 9104, ISO/TS 22003)
4. The need to add a new, own conformity assessment schemes of scheme owners into the accreditation (e.g. British Retail Consortium).

5. Introduction of new conformity assessment schemes of conformity assessment organisations (with special regard to the product certification organisations, processes and services, person certification organisations).

4. Process of launching a new accreditation activity and/or conformity assessment scheme

4.1 Receipt of demand for new accreditation scope, analysis of survey of obligations

New demand may arise in the following cases:

- Changes of legislation,
- Changes of standards,
- Changes of other EA, ILAC, IAF documents,
- Demands of other market players.

The deputy general director collects the information on the new accreditation scopes and analysis it with the help of the heads of departments.

A report is prepared about the necessary conditions. On the basis of the report the general director and the deputy general director decides whether NAH shall undertake to prepare for the new scope.

We differentiate between the new accreditation activity and conformity assessment scheme, which form the basis of the extension and expansion of the accreditation activity of NAH.

4.2 Launching a new accreditation activity

The given harmonised accreditation requirement standard specifies the general requirements for the conformity assessment organisation, it forms the basis for the NAH accreditation in the individual categories.

A new accreditation activity may be initiated by legislation makers or international accreditation organisations (EA, ILAC, IAF).

EA, IAF and/or ILAC carry out the assessment of new accreditation activities which are not based on harmonised standards. NAH adopts the results of the assessment.

NAH cooperates with standardisation organisations, as well as with EA, ILAC and IAF bodies in the development and approval of new accreditation activities. NAH offers its new accreditation

activities to the interested parties. In case a multilateral arrangement introduces the mutual recognition of a new accreditation activity in the scope of accreditation, NAH requests to become signatory to that arrangement and if necessary, undergoes the relevant expert assessment procedure.

When introducing a new accreditation activity, NAH takes into account the following process steps:

1. Information and coordination with the Accreditation Council about the new accreditation activity.
2. Analysis of the competence of NAH, whether the expansion of the accreditation activity can be implemented, taking into account the resources.
3. If necessary, cooperation with the national and/or international bodies with regard to the introduction of the new accreditation activity into the accreditation.
4. If necessary, establishing one or more new professional committees to develop the professional and accreditation rules.
5. Involving the authorities relating to the new accreditation activity and other bodies (if necessary) to develop the applicable rules.
6. Extending the assessment team with new experts and assessors in the field of the new accreditation activity.
7. Training of the NAH employees and the members of the assessment team concerned.
8. Hiring new member(s) for the accreditation committee (if necessary) for the new accreditation activity.
9. Launching the new accreditation activity.
10. Requesting the signing of a multilateral arrangement for the mutual recognition of the new accreditation activity.

4.3. Launching a conformity assessment scheme

NAH carries out the launch and the analysis of accreditation of the new conformity assessment scheme by observing the requirements of EA-1/22.

NAH adds the new conformity assessment schemes made by legislation makers into its accreditation activities.

The new conformity assessment schemes assessed by EA, IAF, ILAC or other accreditation bodies (MLA) are not assessed by NAH. NAH acknowledges the result of the assessment and decides on its addition.

The new conformity assessment schemes made by interest safeguarding associations, groups, certification organisations, manufacturers or other organisations, the so called “private interest” conformity assessment schemes are analysed by NAH whether they can be added into accreditation. NAH evaluates the analysis and decides on launching the new scheme. The organisation shall apply for the launch of the “private interest” conformity assessment scheme. NAH calls the attention of the conformity assessment scheme owners to Annex 2 of EA-1/22.

4.3.1. Procedure of launching a new conformity assessment scheme

The launch of the new conformity assessment scheme is carried out as follows:

1. Application of the scheme owner for the evaluation of the new conformity assessment scheme for accreditation.
2. The applicant shall provide NAH with all the information and documents necessary for the evaluation of the new scheme and for making the decision.
3. The documents prepared for the analysis (evaluation) of the program and for the decision making of the management of NAH shall meet the framework conditions and requirements specified in Appendix 1 of present Regulation. NAH may involve both external (Accreditation Council, Professional Committee) and internal (e.g. Accreditation Committee, Professional Advisory Body) bodies, authorities and other interested parties in the analysis and evaluation of the scheme. The provisions specified in Section 4.4 are applicable for the schemes applied internationally.
4. Decision on the launch of the new conformity assessment scheme.
5. Notification of the applicant about the decision and publication of the decision on the website of NAH.
6. If necessary, cooperation with national and/or international bodies in connection with the launch of the new scheme.
7. If necessary, cooperation with professional committees to develop the uniformly applicable professional and accreditation rules, requirements.
8. Extending the assessment team with experts, assessors according to the new scheme.
9. Training of the NAH employees and the members of the assessment team.
10. Finding new members for the Accreditation Committee (if necessary).
11. Adding the new scheme into the NAH accreditation activities.

4.4. Cooperation with EA and other international accreditation bodies

The cooperation of NAH with EA is performed according to EA-1/22 regulation. The following points are relevant for the scheme owner:

1. NAH analysis and decides on the addition of the conformity assessment scheme of only national (domestic) application to the accreditation activities. In case of such schemes, NAH does not involve EA or other accreditation bodies in the decision making.

2. In case of internationally applied schemes NAH determined that national accreditation body, the so called “home AB”, which carried out the first evaluation and monitored the possible subsequent changes of the scheme. In this case only that accreditation body cooperated with the scheme owner.
3. If these schemes specify requirements for the accreditation body, which requirements stem from EN ISO/IEC 17011 standard, Regulation (EC) 765/2008, or mandatory EA, IAF, ILAC documents, these requirements shall be approved by the general meeting of EA before the scheme is analysed or evaluated. This may significantly extend the process of the evaluation of the scheme.
4. EA may make available the results of the first scheme evaluation of the given accreditation body (home AB). EA gives 30 days to its members to comment on the results. The new scheme can be added to the accreditation activity of the home AB only after the end of the comment period and only if the negative feedback received during that period has been cleared away.
5. In case other accreditation bodies add the new accreditation activity to their scope of activities at the same time as the home AB, they shall notify the home AB about it.
6. Every accreditation body shall give information on its website about the addition of a new accreditation scheme to its scope of activities.
7. The scheme owners may ask their questions only from the home AB.
8. The schemes of which application scope is extended from domestic, national level to international level undergo the process specified in points 2-4.

5. Changes in the accreditation requirements

When the accreditation requirements are modified, NAH follows the guidelines of the international organisations.

On the basis of the guidelines of the international organisations NAH prepares its own rules on the introduction of the modified requirement systems. The rules contain the policy of NAH and the tasks of NAH and of the accredited organisations and natural persons necessary for the successful introduction, and the deadlines for the tasks.

5.1. Tasks of NAH for the transition period

On the basis of the modified requirements and the international guidelines NAH determines the steps and deadlines for the accredited organisations and natural persons to ensure time for safe preparation and the assessment of meeting the requirements.

NAH informs the accredited and applicant organisations and natural persons about the changes of the requirements on its website.

NAH prepares the transition plan on the basis of which NAH calls on the accredited organisations and natural persons to prepare and submit their own transition plans within the given deadline.

NAH evaluates and summarizes the received transition plans and prepares its own transition programme.

In case the requirements are modified, the European and international accreditation organisations determine a transition period. After the expiry of the transition period, the accreditation of the accredited organisations and natural persons not meeting the new requirements are revoked by NAH on the basis of the recommendation of the Accreditation Committee, or the revoking may be requested voluntarily.

During the transition period the accredited organisation shall take into account the issue date of the relevant standard when determining the expiry date of the certifications given according to the relevant standard. Accordingly, the expiry date may not be later than the end of the transition period, and the certifications given according to the invalid standard become invalid.

NAH confirms conformity of the certification activity of the accredited organisation or natural person in the framework of the due accreditation procedure, the annual surveillance procedure or the extraordinary surveillance procedure. The accredited organisation or natural person may issue new certification according to the new standard only after the successful transition.

In order to ensure the transition of the accredited management system certification organisations within the given deadline NAH determines deadlines for the planning of the assessment processes and informs the accredited party about the following:

- a) deadline for submitting the application for accreditation and surveillance for the certification according to the standard;
- b) deadline for submitting the application for extraordinary surveillance to assess the conformity of the certification organisations;
- c) final deadline for submitting the application for accreditation and surveillance according to the previous standard;
- d) deadline for submitting the application according to the new standard.

In case the above deadlines are not met, NAH cannot ensure that the certification organisations meet the accreditation requirements of the management system certification according to the new standard within the deadlines specified by IAF.

5.2. Tasks of the accredited parties for the transition period

In order for NAH to plan the accreditation programme of the transition to the new standard and thus ensure the accredited transition processes and the conditions adjusted to the plans of the accredited parties, the accredited organisations and natural persons shall submit to the NAH Office the schedule of preparation and transition to the certification according to the new standard within the deadline specified by NAH.

When preparing the transition schedule, the accredited parties shall take into consideration the following:

- training the internal staff, auditors, assessment of competences, documented proof of preparedness;
- method of informing the existing and future clients about the transition period and requirements;
- timely review and schedule of auditing and certification activities;

- review of the certification period and the transition cycle;
- schedule of certification decisions necessary for the updating of the certifications.

6 Closing provisions

- 6.1. Present regulation was issued by the general director of NAH in general director order No. 21/2016.
- 6.2. Present regulation enters into force on 22 August 2016.
- 6.3. The provisions of the regulations are applicable from the entry into force.
- 6.4. The publication of the regulation on the website of NAH (www.nah.gov.hu) is considered publication.
- 6.5. The questions not regulated herein are governed by the provisions of Act CXXIV of 2015. In case Act CXXIV of 2015 does not specify a specific provision, the provisions of Act CXL of 2004 are governing.

7 APPENDICES:

Appendix A: Framework conditions and requirements for scheme owners

Appendix B: Information to be provided by scheme owners

Appendix A

Framework conditions and requirements for scheme owners

1. The scheme owner shall be legally identified.
2. The scheme owner shall be authorised to define and modify the requirements of the conformity assessment scheme.
3. The scheme owner shall be authorised to represent the scheme at NAH..
4. The scheme owner shall have market relevance and market support for the scheme. These may include state initiatives and regulatory demands.
5. The submitted new accreditation scheme shall belong to the scope of an internationally accepted conformity assessment standard according to which NAH performs the accreditation (e.g. ISO/IEC 17020 and 17021).
6. The requirements of the scheme must not conflict with or exclude the provisions of the standards specified in point 5.
7. In case the submitted new scheme specifies requirements for the accreditation body, those requirements cannot conflict with Regulation (EC) 765/2008, MSZ EN ISO/IEC 17011 standard and the mandatory regulations of EA, ILAC, IAF or NAH. For further scheme requirements relating to MSZ EN ISO/IEC 17011 standard it is necessary to have the approval of the general meeting of EA, for which the basis is served by EA (HHC). In case a national conformity assessment scheme having further requirements for MSZ EN ISO/IEC 17011 standard is extended to international level, it will be mandatory for other accreditation bodies only if the general meeting of EA has approved.
8. The new conformity assessment scheme shall not conflict with legislative requirements and shall not certify their satisfaction.
9. The scheme owner shall recognise the result of those conformity assessment organisations which have been accredited according to a multilateral mutual recognition arrangement, if those organisations meet the requirements of the new scheme.
10. The scheme owner shall confirm that the scheme has been validated. The validation shall contain the following in a documented manner:
 11. Description of the objective of the scheme.
 12. Description of the requirements of the scheme.
 13. Analysis of the suitability of the requirements for the satisfaction of the objectives of the scheme.
 14. Description of the methods used for the satisfaction of the requirements.
 15. Analysis of the suitability of the methods for the satisfaction of the requirements.

16. Decision on the applicable conformity assessment, including the indication of the standard applicable for the conformity assessment.
17. Analysis of the suitability of the standard selected for the conformity assessment scheme.
18. The scheme owner shall stipulate and guarantee that the conformity assessment organisation uses the scheme as defined originally, no limitation or modification may be done.
19. The scheme owner is responsible for providing the necessary information about the relevant developments of the scheme, in particular the information about the changes of the requirements, for the “active” accreditation bodies and accredited conformity assessment organisations.

Appendix B

Information to be provided by scheme owners

1. Is the scheme owner ready to accept NAH as the single assessor of the scheme?
2. Is the scheme used only on national level?
3. Is the scheme being used by an accredited conformity assessment organisation of an EA member?
4. The scheme owner shall provide the following information:
 - Name, and if applicable, abbreviated name
 - Type of legal entity
 - Principal seat and Internet address
 - Member (if applicable) and membership rules
 - Brief description of scheme owner
 - Description of other relevant activities of scheme owner
 - Relationship with other organisations and authorities on national and European level (if applicable)
 - Technical activity scopes (e.g. aviation, food safety)
 - Conformity assessment procedure offered by the scheme owner (e.g. product certification, inspection)
 - Geographical area of the recognition of the scheme owner (e.g. Hungary, Europe, worldwide).
5. Besides the accreditation, does the scheme owner require recognition / certification granted by the scheme owner which is mandatory for the conformity assessment organisation? (If yes, please attach the necessary documents).
6. Justification of the necessity and market support of the new scheme.
7. Which conformity assessment procedure shall be used according to the scheme (e.g. product certification? Inspection?)? Please, give the reasons and attach the documents.
8. Does the scheme owner or the organisation of the scheme owner perform conformity assessment surveillance (or similar procedures)? If yes, list the procedures and attach the documents.

9. If the answer to question 8 is yes: Does the scheme owner require the surveillance specified in point 8 to be taken into account and accepted in the accreditation procedure? If yes, list the procedures and attach the documents.
10. Does the scheme owner require NAH to cooperate with EA, which is not related to the accreditation of the conformity assessment organisation? If yes, describe the cooperation and attach the documents.
11. Does the scheme owner have special requirements for the accreditation body? If yes, list the requirements and attach the documents.
12. What is the subject of the conformity assessment? Please, give as many details as possible (the subject of the conformity assessment may be: product, service, device, process, system, persons and places).
13. What are the special requirements for the subject of the conformity assessment?

Notes:

- The requirements shall be worded clearly and understandably so that the organisations that will use them should have clear and uniform understanding of the points.
 - The requirements shall be given as results, with professionally defined thresholds and margins of tolerance.
 - The requirements shall be defined unambiguously (with objective, specific and professionally founded terms).
14. Are the measurement values given in SI measurement units?
 15. If the conformity assessment scheme contains sampling the applicable sampling method shall be defined (for the repeatability and correlation of the results those sampling methods shall be applied which are defined in international standards and based on statistical methods).
 16. Are there inspection or control procedures in the scheme? If yes, where are they documented?
 17. Does the conformity assessment scheme contain the following critical scheme elements (according to Appendix A of MSZ EN ISO/IEC 17000 standard):
 - Selection of the subject of the conformity assessment, including the selection of the requirements to be assessed just as the information collection and sampling activities.
 - Provision of one or more communication methods (e.g. inspection, audit) to meet the requirements specified for the subject of the conformity assessment.
 - Confirmation of evidence that the requirements of the subject of the conformity assessment are met, or any related permission, inspection.

- Inspection of the interval and scope of supervision activity and repeatability surveillance (if relevant) to determine whether further specific requirements are met in the subject of the conformity assessment.

18. Does the scheme involve the usage of conformity assessment mark/symbol? If yes, the scheme owner shall prove that the mark/symbol is protected and the rules of the usage of mark/symbol are specified. The scheme owner shall ensure and control that these rules are observed.

19. It shall be proven that the scheme was prepared and developed by competent persons. The competence shall cover the professional knowledge and the applied conformity assessment procedures.

20. It shall be proven that the parties interested in the scheme were identified and involved.

21. It shall be proven that the scheme was validated. Validation shall at least demonstrate that the scheme went fully through a testing stage in order to prove the suitability for the planned purpose.

Questions to be considered:

- Can the conformity assessment be used as originally defined from the practical point of view?

- Were the requirements determined in a way to ensure the repeatability and reliability of the results?