Hungarian Accreditation System

Rules of Procedure for the Accreditation of Flexible Scopes

NAR-31

Edition 2

Version 1

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List of amendments

Edition 2

The document has a completely new structure, therefore, it cannot be interpreted.

Chapter No.	Description of the change

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1. Purpose of the Regulation

The main objective of present rule of procedure is to create a regulation framework for the accreditation of flexible scopes. In the preparation of this regulation, the EA-2/15 M:2008 (EA Requirements For the Accreditation Of Flexible Scopes) issued by the European Co-operation for Accreditation (EA) and the mandatory document 'ILAC-G18:04/2010: Guideline for the Formulation of Scopes of Accreditation for Laboratories' were considered.

The legislative and customer demands and the rapid changes of the technical and standard background make it necessary to allow the accredited organisations not to repeat the accreditation procedures within one cycle (5 years) to follow the changes.

2. Personal and material scope

The personal scope of the present rule of procedure covers all parties involved in the accreditation procedure affecting flexible accreditation pursued by the National Accreditation Authority (NAH).

Material scope:

In case of **testing laboratories** the given rule of procedure shall be applied in accordance with and by taking into account the requirements of standard MSZ EN ISO 17025:2005.

In case of **medical laboratories** the given rule of procedure shall be applied in accordance with and by taking into account the requirements of standard MSZ EN ISO 15189:2013.

In case of **product certification bodies** the given rule of procedure shall be applied in accordance with and by taking into account the requirements of standard MSZ EN ISO 17065:2013.

In case of **inspection bodies** the given rule of procedure shall be applied in accordance with and by taking into account the requirements of standard MSZ EN ISO 17020:2012.

In regard of other accreditation standards, flexible accreditation cannot be interpreted.

3. Definitions

In interpreting the applicable concepts, NAH considers the EA-2/15 M:2008 Document (1.6. Terminology).

4. Description of the regulation

4.1. Application possibilities of flexible accreditation technical scope

4.1.1. When standard laboratory methods change, in case of the same technical content

In case of following the changes in the description or year identification of the applied standard methods, where the technical content of the applied method does not change. From the point of view of present rule of procedure the technical content of two standard methods is considered identical, if the applied measurement principle, the necessary technical devices, equipment, materials, the quality control requirements, the requirements for the personnel participating in the implementation and the key performance indices of the methods (with special regard - where applicable - to the measurement uncertainty and measurement range) are the same.

Explanation: The standardisation organisations periodically review the standards developed by them, and the national standardisation organisations (in Hungary: the Hungarian Standards Institution) introduce the standards developed by the standardisation organisation of the European Union, and at the same time withdraw the contradictory national standards. In practice, these changes often do not affect the technical content of the standards, thus the requirements for their application are the same.

In the present rule of procedure under the term standards we also include other normative documents (e.g., technical specifications).

4.1.2. Other changes in case of the same technical content

NAH manages the references in the accredited area where the updated publication, change is not followed by the change in the standard ID (e.g., rules of law, codex alimentarius, pharmacopea, and codex pabularis) as a flexible scope. Organisations are obliged to monitor changes, evaluate them and report them to NAH. The report must contain a demonstration/verification of the identical technical content.

4.1.3. In case of changes in the technical content

In the case of flexible technical content, changes in the technical content of the applied standardised methods and (unique) methods elaborated by accredited organisations are followed-up in order to satisfy the customer demands.

The borderlines of flexible scope must always be clear, that is, what is covered and what is not.

4.1.3.1 Application possibilities of flexible accreditation technical scope for testing laboratories

Type 1: flexibility in the application scope (product/material, matrix)

The changes may be introduced for certain products and materials. The implementation is possible if the same (already accredited) measurement techniques and testing methods are used for testing the fix parameters.

Type 2: flexibility in the tested characteristic, component, and parameter

This allows for the introduction of new components with regard to the test parameters, without changing the measurement principle and the matrixes.

Type 3: flexibility in the testing method

The flexible application of the testing method allows for the introduction of changes into the testing methods. A precondition for the introduction is that the measurement principle should remain unchanged in the testing method of a given product/material and given testing parameter. The organisation can change the measurement principle exclusively in the frame of an application for the extension of the scope. The organisation shall prove that the measurement principle is unchanged if the testing method has been modified.

TYPE OF FLEXIBILITY	Tested product / material	Tested/measured characteristic, type of test, measurement range	Identification of the testing/measurement method
BASE CASE (FIX SCOPE)	*Waters* (bottled drinking water and mineral water, drinking water, mineral and medicinal water, groundwater, surface water)	*Pesticide active substances and metabolites* HPLC-MS/MS propetamfos; propiconazole; propyzamide; propisochlor; propoxur; prosulfocarb; prosulfuron; rimsulfuron; rotenon; sanmarton minimum limit: 0.01 µg/l per component	KMD-86:2013
Type 1 (flexible for product/material, matrix)	*Waters* ***(Flexible scope)***	*Pesticide active substances and metabolites* HPLC-MS/MS propetamfos; propiconazole; propyzamide; propisochlor; propoxur; prosulfocarb; prosulfuron; rimsulfuron; rotenon; sanmarton minimum limit: 0.01 µg/l per component	KMD-15:2013
Type 2 (flexible for component, parameter)	Waters (bottled drinking water and mineral water, drinking water, mineral and medicinal water, groundwater, surface water)	*Pesticide active substances and metabolites* HPLC-MS/MS ***(Flexible scope)*** minimum limit: 0.01 µg/l per component may differ depending on the component	KMD-65:2013
Type 3 (flexible for testing method)	Waters (bottled drinking water and mineral water, drinking water, mineral and medicinal water, groundwater, surface water)	Pesticide active substances and metabolites HPLC-MS/MS propetamfos; propiconazole; propyzamide; propisochlor; propoxur; prosulfocarb; prosulfuron; rimsulfuron; rotenon; sanmarton minimum limit: 0.01 µg/l	***(Flexible scope)***

TYPE OF FLEXIBILITY	Tested product / material	Tested/measured characteristic, type of test, measurement range	Identification of the testing/measurement method
BASE CASE (FIX SCOPE)	Food stuff containing probiotics (yoghurt)	Lactobacillus delbrueckii subsp. bulgaricus Colony count Streptococcus thermophilus Colony count	MSZ ISO 7889:2009
Type 1 (flexible for product/material, matrix)	Food stuff containing probiotics **(Flexible scope)**	Lactobacillus delbrueckii subsp. bulgaricus Colony count Streptococcus thermophilus Colony count	MSZ ISO 7889:2009
Type 2 (flexible for component, parameter)	Food stuff containing probiotics (yoghurt)	**(Flexible scope)**	MSZ ISO 7889:2009
Type 3 (flexible for testing method)	Food stuff containing probiotics (yoghurt)	Lactobacillus delbrueckii subsp. bulgaricus Colony count Streptococcus thermophilus Colony count	**(Flexible scope)**

In case of special, unforeseeable cases, the characteristics of the tested technical task may require that the accredited body should use the combination of the three examples above. In this case, from professional point of view, one of the key questions is the determination of the permitted range of the difference, which shall be defined accurately for the flexibly applied scope.

Flexibility can be interpreted maximum in two categories at the same time.

4.1.3.2 Specific rules for medical diagnostic laboratories

In medical laboratories, flexible scope can be granted as follows.

Medical field	Tested product / material	Testing/applied technique (tested/measured characteristic)	Identification of the testing/measurement method
Clinical chemistry L1-1 Fix scope	serum plasma	Calcium spectrophotometry	MÓD-01: 2017 *name of manufacturer manufacturing number* according to manufacturing kit
Clinical chemistry L1-1 Flexible scope Type 1	serum plasma	Calcium spectrophotometry	MÓD-01 Flexible scope, **to follow up manufacturing kit**
Clinical chemistry L1-1	serum plasma	Calcium spectrophotometry	MÓD-01 Flexible scope **to follow up manufacturing kit** and *to follow-up changes*

Flexible scope Type 2			*affecting the applied measurement system.*

Flexible scope can be applied for the use of the manufacturer's reagent kit and the follow-up of changes affecting the applied measurement system or on the basis of descriptions of tests defined in the collection of methods published by the leading professional institute (e.g. KJB), or in the effective Pharmacopoeia.

The laboratory shall be prepared for the changes and the changes shall be introduced as planned; the laboratory shall have the reagents of the previous and new versions in a quantity necessary for the validating control.

Type 1:

Minor changes affecting the method; in order to obtain, maintain an accredited status, verification, comparative measurements and comparison in proficiency testing is needed.

E.g., The flexible scope is applicable to the change of the manufacturer's reagents kit.

Type 2:

Major changes affecting the method: to obtain, maintain the accredited status, in a number of cases, validation, furthermore comparative measurements and comparison at proficiency testing are needed.

E.g., Flexible scope for the use of the manufacturer's reagents kit and the follow-up of changes affecting the measuring system applied.

Further examples:

- In case there is a change in the manufacturer of the growing medium applied in the culture method, the laboratory may apply the growing medium of the new manufacturer.
- The type of the growing medium applied in the culture method may change.
- In case of sensitivity tests to antibiotics, the introduction of sensitivity measurements to new antibiotics.
- Changes in the matrix of the culture method (new sample).
- Testing tumour markers (characteristics) satisfying the requirements for the method.

4.1.3.3 Specific rules for product certification bodies

The product certification bodies may request the indication of flexibility for the requirement specified in the standards specified by the certification system or other normative documents relating to the product (product requirement) on the accredited detailed scope. The product requirements and the requirements for the certified organisation may change, but the activities, certification system of the certification body remain unchanged. The product requirements may be given in normative documents (rules of procedure, standards, and technical specifications). In case of standards the year of issue of the standard may change, furthermore an amendment, correction may be published. The flexible accreditation scope is indicated by giving the standard without the year of issue. In the certificates, reference to the standard shall be given with the year of issue (see MSZ EN ISO/IEC

17065:2013 Section 3.10). In case a change occurs in the product requirements which affects the certification process, it can only be assessed in an extraordinary surveillance procedure.

4.1.3.4 Specific rules for inspection bodies

In case of inspection bodies, if there is a change in the accredited scope (in different specifications, standards, rules of law and other documents) relating to the basis of inspection, flexible accreditation scope may be requested if the same inspection procedure is applied. If the changes also affect the inspection procedure, it can only be assessed in an extraordinary surveillance procedure.

4.2. Accreditation requirements for the flexible scope

4.2.1. Standard laboratory methods, other changes in case of the same technical content

Any accredited body under the personal scope of point 2 may use it, for all methods, requirements, procedures forming the accredited technical scope. The same technical content can be verified pursuant to point 12.3.4 of rules of Rule of Procedure NAR-01 on the rules of the accreditation and surveillance procedure, or the accredited organisation provides evidence at the surveillance procedure to support sameness described in point 2.1.

4.2.2. In case of changes in the technical content

Only those organisations may request it and only for that part, method or group of methods of the accredited technical scope which meet the following requirements:

- The organisation shall establish, maintain and operate a documented procedure for the flexible accredited technical scope whereby it can prove the suitability of the technical scope for introduction.
- The organisation shall create, maintain and operate a documented procedure for the personnel working in the flexible scope. The organisation shall ensure and prove the experience, competence of the personnel and specify the responsible persons (by giving their names) for each method, and the position and substitution of the responsible persons.
- The flexible accreditation technical scope shall form an integral part of the quality control system, of which surveillance shall pay special attention to all parts of the flexible accreditation (e.g. validation documents, method developments, records, observance of procedural rules, notes, quotations, internal audit, management inspection, etc.).
- The organisation shall keep records about the application of the flexible accreditation scope.

  The record shall contain at least the following:

  - identification of the applied method,
  - the changes per categories,
  - date of the introduction of the change,
  - validation/verification documents of the applicability of the difference,
  - permission of the responsible person(s) for the introduction of the change
  - training documents of the staff

In case of testing laboratories, especially the following:

- The organisation shall prepare the validation/verification documentation of the new flexible category (matrix, component, testing method). The documentation shall contain: validation/verification plan and report, plan for the introduction of the method, and the names of the persons responsible for the validation/verification.
- The following criteria shall be taken into account during the validation (if appropriate for the given testing method):
    - selectivity
    - specificity
    - measurement range
    - linearity
    - reproducibility
    - sensitivity
    - detection limit
    - quantification limit
    - undistortedness
    - precision
    - robustness
- Following the introduction of the new/modified method, the organisation shall prove its proficiency and competence (proficiency plan and certification, number of conformity assessment activities).

4.2.3. Application for accreditation of flexible scope

The applicant shall apply for the flexible accreditation/scope extension procedure according to NAH's NAR-01 procedure, by submitting the required documents (e.g. NAD-103 application, NAD-103-XX application appendix, documents regulating the flexible scope, etc.).

The applicant shall clearly mark the cell of NAD-103-XX application appendix with "flexible scope" mark for which the flexible accreditation is requested. In case of testing laboratories NAD-103-1A appendix shall contain the specific matrix and components already existing in the flexible technical scope at the time of the submission.

4.2.4. Handling changes

If there is a change in the flexible accreditation scope (after the introduction of the method), the organisation concerned is entitled to change the flexible accredited technical scope (measurement of a new component, change in the standard description, etc.).

Within 15 days dated from the change, the organisation is obliged to submit to NAH the form NAD-102 about significant changes and attach the documents verifying the change (documentation of the validation/verification report, records) (Article 14 (1) of Government Decree No. 424/2015. (XII. 23.)).

NAH checks the submitted changes and the fulfilment of the requirements in the surveillance procedures and at the renewal of the accredited status during the site visits.

If there is a change in the person responsible for the flexible scope, the organisation is obliged to submit to NAH form NAD-102 on reporting significant changes in accordance with Article 11 (1) of Government Decree.

4.2.5. Detailed Scope of Accreditation

In the Detailed Scope of Accreditation, in line with international practice, fix scope is not identified when flexible scope is indicated.

5. Related rules of procedure and rules of law

- Government Decree No. 424/2015. (XII.23.)
- EA-2/15 M:2008: EA Requirements for the Accreditation of Flexible Scopes
- ILAC-G18:04/2010: Guideline for the Formulation of Scopes of Accreditation for Laboratories
- NAR-01: The Rules of Procedure of Accreditation and Surveillance

6. Annexes

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7. Forms

NAD-103-XX Annexes to the application

NAD-102 Reporting significant changes