NEMZETI AKKREDITÁLÓ HATÓSÁG

Hungarian Accreditation System

Requirements for the Accreditation of Flexible Scopes

NAR-31

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1. Objectives, reasons

The Hungarian Accreditation Authority (hereinafter: NAH) carries out the accreditation procedures according to the provisions of Act CXL of 2004 on the General Rules of Administration Proceedings and Services and Act CWWIV of 2015 on National Accreditation.

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. Besides, pursuant to Sections 5.4.3 and 5.5.5 of standard MSZ EN ISO/IEC 17025:2005 the testing and calibration laboratories may modify their methods internally developed for the accredited technical scope, or introduce the up-to-date versions of the standardised methods.

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

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

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

The main objective of present Requirements is to create a regulation framework for the accreditation of flexible scopes.

2. Application possibilities of flexible accreditation technical scope

The technical and personnel conditions of the accredited bodies are different; therefore it is necessary to distinguish between the two main groups of the application of flexible accreditation technical scope:

2.1. Standard methods, in case of the same technical content

In case of following the changes of the description or year identification of the applied standard methods, the technical content of the applied method does not change. From the point of view of present Requirements 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 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 the application are the same.

Note: In this case the organisation does not apply the originally applied standardised method as a part of the accredited technical scope.

2.2. In case of changes of the technical content

In order to satisfy the customer demands the changes of the technical content of the applied standard methods and the methods developed by the accredited bodies shall be followed.

2.2.1. Application possibilities of flexible accreditation technical scope for testing laboratories

TYPE OF FLEXIBILITY	Tested product / material	Tested/measured characteristic, type of test, measurement range	Identification of the testing/measurement method
BASIC CASE (FIX SCOPE	*Waters* (bottled potable water and mineral water, potable 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	WBSE-93:2013
Example 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	WBSE-93:2013
Example 2 (flexible for component, parameter)	Waters (bottled potable water and mineral water, potable 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	WBSE-93:2013
Example 3 (flexible for testing method)	Waters (bottled potable water and mineral water, potable 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	***(Flexible scope)***

EXAMPLE 1: flexibility in case of 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.

EXAMPLE 2: flexibility in case of the tested characteristic, component, parameter
A new component may be introduced into the testing parameters without changing the measurement principle and the matrix.

EXAMPLE 3: flexibility in case of the testing method
The flexible application of the testing method allows for the introduction of changes into the testing methods. A precondition of 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 may change the *measurement principle* only in 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.

In case of special, unforeseeable cases, the characteristics of the tested technical problem may require that the accredited body should use the combination of the 4 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.

2.2.2. Specific rules for medical diagnostic laboratories

The routine *in-vitro* medical diagnostic tests are mainly standard, as the application of the manufacturer's reagent kit qualifying as medical devices, the testing descriptions defined in the collection of methods published by the leading professional institutes (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.

***EXAMPLE 1:* standard methods in case of the same technical content**
When the manufacturer of the diagnostic kit is changed, but the content of the diagnostic kit, the purpose and principle of the test (measurement) are unchanged, because *the technical content of the two standards is the same*.

***EXAMPLE 2:* standards methods in case of changed technical content**
Transition to the application of the new version of a diagnostic kit: when the manufacturer carries out development in the application of the diagnostic kit (e.g. changes in the composition, quantity of the reagent), if the purpose of the method and the measurement principle are unchanged.

A) 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, if the purpose of the method and the measurement principle are unchanged.

B) The type of the growing medium applied in the culture method may change if the purpose of the method and the measurement principle are unchanged.

C) In case of antibiotics sensitivity tests, the introduction of sensitivity measurement to new antibiotics is allowed, if the purpose of the method and the measurement principle are unchanged.

D) Changes in the matrix of the culture method (new sample), if the purpose of the method and the measurement principle are unchanged.

E) In case the method is suitable to test further tumour markers (characteristics) for the requirements of the method without changing the measurement principle.

2.2.3. 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. In case a change occurs in the product requirement which affects the certification system, it can only be assessed in an extraordinary surveillance procedure. The product requirements may be given in normative documents (rules, standards, technical specifications).

(e.g. in case of standards the year of issue of the standard may change, or an amendment, correction may be published. The flexible accreditation scope is indicated by giving the standard without the year of issue. The reference in the certification is given with the year of issue (see MSZ EN ISO/IEC 17065:2013 Section 3.10).

In case of other technical specification relating to the product group of the accredited scope – if they have the same product specifications (characteristics) and the same certification system – flexible accreditation scope may be requested (e.g. construction products).

2.2.4. Specific rules for inspection bodies

In case of inspection bodies, if there is a change in the accredited scope in the requirements (different specifications, standards, legislative procedures and other documents) relating to the subject of the inspection, provided that the inspection procedure remains unchanged, or in case of different objects where the same inspection procedure is applied, flexible accreditation scope may be requested.

2.2.5. Specific rules for management systems certification bodies

In case of management systems certification bodies the flexible accreditation scope shall be defined within the NAH IAF codes. In case the management systems certification body has accredited status for a given IAF code, it may issue accredited certification for the TEÁOR codes belonging to that IAF code, provided that the management systems certification body can prove the TEÁOR code preparedness both on organisation and auditor level.

3. Accreditation requirements for the flexible scope

3.1. Standard methods in case of the same technical content

All accredited bodies may use it, for all the methods forming the accredited technical scope. The same technical content can be proved pursuant to Section 6.3.4 of the NAR-01 Regulation.

3.2. In case of changes in the technical content

Only that organisation 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 has successfully closed at least one accreditation cycle. (So accreditation for flexible scope may be requested for the first time at the first renewal).
- The organisation shall have a procedural instruction for the flexible accredited technical scope, in which it proves its eligibility for the introduction of the flexible technical scope.
- The organisation shall create, maintain and operate a quality 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 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) about 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:
  - selectivity
  - specificity
  - measurement range
  - linearity
  - reproducibility
  - sensitivity
  - detection limit
  - quantification limit

- undistortedness
- precision
- robustness

- The organisation shall prove its proficiency and preparedness (proficiency plan and certification, number of conformity assessment activities) after the introduction of the new/modified method.

3.3. Application for accreditation of flexible scope

The applicant shall apply for the flexible accreditation/scope extension procedure according to NAR-01 procedure of NAH, 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 concrete matrix and components already existing in the flexible technical scope at the time of the submission.

3.4. Handling the changes

If there is a change in the flexible accreditation scope with the approval of the responsible person 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 from the change the organisation is obliged to submit to NAH form NAD-102 about the change and attach the documents verifying the change (documentation of the validation/verification report) (Government Decree, paragraph (1) of Section 11).

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 about the change (Government Decree, paragraph (1) of Section 11).

4. Documents

- 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