**INSTITUTE FOR ACCREDITATION OF THE REPUBLIC OF NORTH MACEDONIA**

# Regulation on the Requirements for Participation in Proficiency Testing, Interlaboratory Comparisons, and External Quality Assessment Programmes

**Regulation: R 06**

Pursuant to Article 14, Paragraph 1, Indent 1 of the Law on Accreditation ("Official Gazette of the Republic of Macedonia", No. 120/2009, 53/2011, and 41/2014) and Article 13, Paragraph 2 of the Statute of the Institute for accreditation of the Republic of North Macedonia, the Council of the Institute for Accreditation of the Republic of North Macedonia at its meeting held on November 13, 2020, adopted the following:

# REGULATION ON THE REQUIREMENTS FOR PARTICIPATION IN PROFICIENCY TESTING, INTERLABORATORY COMPARISONS, AND EXTERNAL QUALITY ASSESSMENT PROGRAMMES

## 1. General provisions

### Article 1

This Regulation shall prescribe the general requirements on the use and participation in proficiency testing schemes, interlaboratory comparisons, or external quality assessment programmes, in the accreditation process.

The requirements shall apply to accredited laboratories and those seeking accreditation and also to accredited inspection and certification bodies related to testing or calibrations performed by them, where relevant.

In the context of this document, the term "laboratories" shall refer to all laboratory types – i.e. testing, calibration and medical laboratories.

## 2. Definitions

### Article 2

"The proficiency testing (hereinafter: PT) shall refer to the assessment of the participant's performance against pre-established criteria by means of interlaboratory comparisons" [1].

"Interlaboratory comparison (hereinafter: ILC) shall refer to organization, performance and assessment of measurements or tests on the same or similar samples by two or more laboratories in accordance with predetermined requirements" [1].

"External quality assessment (hereinafter: EQA). The external quality assessment programmes (such as those intended for laboratory medicine examinations) shall refer to continuous schemes that include long term follow-up of laboratory performance. Some EQA programmes assess performance of pre-analytical and post-analytical phases of testing, as well as the analytical phase itself" [1].

"Sub-discipline shall refer to an area of technical competence of the testing laboratory, defined by a minimum of one measurement technique, property (parameter, measuring unit) and product, which are related. (E.g. establishing arsenic in soil by ICP-MS)" [2].

## 3. General Rules

### Article 3

The laboratory can confirm its technical competence by applying external (participation in PT, EQA and ILC) and internal measures for quality control of the results [3], [4].

Participation in proficiency testing schemes (PT) or in External Quality Assessment (EQA) Programmes represents a powerful and effective tool to confirm the technical competence of a specific laboratory for performing testing and calibration [5].

Technical competence can also be demonstrated by successful participation in interlaboratory comparisons (ILC) that have been organized for purposes other than PT, such as:

- to assess the properties of the performance of the method;
- to characterize a reference material;
- to compare the results of two or more laboratories on their own initiative;
- to support statements of the equivalence of measurement of National Measuring Institutes [6].

Other (internal) measures to confirm the technical competence of the laboratory or for quality control of the results, can include:

- using of (certified) reference material or quality control materials;
- retesting or recalibration with the same methods;
- retesting or recalibration with the different methods;
- retesting or recalibration of the retained samples;
- comparison of the analyses conducted with different techniques;
- use of alternative instruments that are calibrated and ensure traceability of the results;
- functional checks of measuring instruments or test instruments;
- inter-checks of the measuring equipment;
- establishing the correlation of the results for various characteristics of the samples;
- review of the results;
- intra-laboratory comparisons;
- the application of control cards;
- analysis of blank trials [3].

## Article 4

By way of applying external measures, a specific laboratory can confirm its competency in front of IARNM, its clients and stakeholders, implement new verified methods, identify the newest trends, and consider the necessity of taking corrective measures.

Also, the results from participating in PT, ILC, and EQA can be used by the laboratory in education purposes and as a risk management tool.

## Article 5

The laboratory must select the appropriate scheme depending on its own needs and available PT, ILC and EQA organization schemes, compatible with the sample types that are most commonly handled by the laboratory. Where applicable, the laboratory shall select a scheme organized in accordance with ISO/IEC 17043 [1], [5].

If there aren't any appropriate PT/ILC/EQA schemes, the comparisons between two or more laboratories organized by them can be accepted. An interlaboratory comparison of two laboratories (bilateral comparison) can be made between laboratories with proven competence. Laboratories that are not accredited and need to prove the validity of the results by submitting an application are required to participate in a comparison with at least 3 accredited laboratories (if possible). The organization of such comparisons should, as much as possible, fulfil the requirements for the organization and performance of ILS of international standards. [6]

*Note 1: For calibration laboratories, comparisons may also be accepted between two non-accredited laboratories, if one is a National Metrology Institute.*

## Article 6

Besides the participation in PT, ILC, and EQA, the laboratory shall, also, use the other (internal) measures for quality control, to fully demonstrate its technical competence.

**Article 7**

The laboratory shall plan the quality control and shall submit a plan for participation in the external and for using the internal measures for quality control of the results (OB 05-18-2) to IARNM, in relation to its scope (fixed and/or flexible) and to regularly review it depending on the changes in staffing, methodology, instrumentation etc.

**Article 8**

The laboratory shall keep records for the analysis of the results related to the usage of external and internal measures for quality control. The records of the results analysis shall include at least the following: the person who participated in PT/ILC/EQA or carried out the internal measure for quality control, description of the product/material for testing/calibration or the material for quality control, the method/technique used, the assigned value (if applicable), description of the scheme or he quality control measure, the results of the testing/calibration, the criteria for evaluation (for acceptance of the results), measures (in accordance with the internal procedure for handling unconformities and corrective measures) as well as preventive measures, if required.

**Article 9**

In the course of the accreditation procedure, the appropriateness of selected scheme, the plan for participation in external and for using internal measures for quality control of the results, the records of the analysis of the results as well as the corrective and preventive measures taken shall be subject to obligatory verification by IARNM.

**Article 10**

PT, ILC and EQA shall not replace the surveillance and assessment, as they cover only a part of the accreditation procedure.

## 4. Requirements for participation in PT, ILC, and EQA

**Article 11**

The positive participation in appropriate schemes for PT, ILC, and EQA (where there is possible) shall represent a precondition for obtaining and maintaining the laboratory's accreditation. If the laboratory wants to confirm the validity of the results, it has to participate continually, in an adequate manner, in PT, ILC and EQA schemes.

In view of Paragraph 1 of this Article, the laboratory shall have a policy for participation in PT, ILC, and EQA, concerning planning, performance, assessment of the results, and implementation of necessary corrective measures, documentation of the same and their storage. The policy shall be described in the quality manual and in an appropriate procedure [3], [4].

**Article 12**

In line with the recommendations of European and international organizations for accreditation, the laboratory shall have satisfactory participation in suitable PT, ILC, and EQA schemes at least once for each sub-discipline prior to gaining the accreditation, within the respective field, or within the sub-disciplines it has defined. For the other parameters (products, items) within the areas/sub-disciplines for which the laboratory has applied for accreditation or scope extension, it should demonstrate that it applies the other quality control measures. Furthermore, the participation of the laboratory should be in accordance with the plan referred to

in Article 7 of this Regulation. However, after receiving the accreditation, a minimum participation in appropriate PT or ILS schemes is recommended at least once more for each sub-discipline within the accredited range for a period of one accreditation cycle (4 years).

*Note 2: In a period of 4 years PT, ILS, and EQA should be rotated (as appropriate) for each accredited method based on an analyte, a matrix, and a technique (e.g. quantification of analyte-aflatoxin in a different matrix - in cereals, animal food, milk using a technique such as HPLC).*

In defining the level and frequency of participation in PT, ILC, and EQA and the preparation of the plan, the laboratories might take into consideration the principle of division of the range of methods into sub-disciplines. This aspect is described in detail in the guide of the European Co-operation Organization, EA 4/18, Guidance on the level and frequency of proficiency testing participation that is available in Macedonian language too, and published on the IARNM's website [2]. When defining sub-disciplines, care should be taken not to introduce measurement techniques, properties or products of testing/calibration from different areas of testing/calibration.

*Note 3: According to EA 4/18 Guidance on the level and frequency of proficiency testing participation, a sub-discipline may contain more than one measurement technique, property or product if equivalence and comparability can be demonstrated.*

Also, in defining the level and frequency of participation in PT, ILC, and EQA, the laboratories shall take into account the requirements given by national regulatory bodies, suitable international organizations, the industry or business sector (if such requirements exist) [5].

**Article 13**

When extending the scope and reaccreditation, the same rules given in Article 12 of this Regulation shall apply.

**Article 14**

IARNM shall require from any specific laboratory to participate in PT, ILC, and EQA schemes in shorter intervals, if there are significant changes in the laboratory's staff, the accreditation scope, or in case of identified nonconformities. In addition, IARNM may request participation in PT, ILC, and EQA for certain test methods, if the technical assessor deems them necessary to confirm the purpose of the method or the reliability of the result.

**Article 15**

During the accreditation procedure, a particular laboratory may be required to test or calibrate a specimen with specified properties, which is provided by the assessor.

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**Article 16**

During the application for accreditation or before each assessment, the laboratory shall submit to IARNM a completed report from its participation in PT, ILC, or EQA - OB 05-18 which shall contain the name of scheme/organizer and the number of participants, execution date, field, testing/calibration product/material/specimen, parameters/analyts, methods/techniques, results and acceptable criteria and corrective and preventive measures taken.

Also, when applying for accreditation or before each assessment, the laboratory shall submit to IARNM a completed OB 05 18-2 Plan for participation in proficiency testing schemes (PT), interlaboratory comparisons (ILC), and external quality assessment programs (EQA) and application of internal measures for quality control of the results, in which they state the planned

external (participation in PT, ILC and EQA) and internal measures for quality control of the results.

**Article 17**

If a certain laboratory's participation in PT/ILC/EQA schemes is unsuccessful and if adequate corrective actions are not undertaken within one month after receiving the results/reports or if the laboratory has several unsuccessful participations in a sequence, IARNM can:

- Require the laboratory to participate in other Proficiency Testing schemes or Interlaboratory Comparisons;
- Perform an additional surveillance, or
- Suspend or withdraw the accreditation of the laboratory or to reject the granting of accreditation.

**Article 18**

Data about available PT, ILC, and EQA schemes can be found at the EPTIS's web site (European Proficiency Testing Information System), as well as within other relevant institutions such as, EURL, OIE, and others.

**Article 19**

IARNM shall keep records on an annual basis for any participation in PT, ILC, and EQA schemes.

## 5. Transitional and final provisions

**Article 20**

With the entry into force of this Regulation, the Regulation on the requirements for participation in proficiency testing and interlaboratory comparisons dated 30.06.2015 shall cease to be valid.

**Article 21**

This Regulation shall enter into force on the day of its adoption.

Date: November 13, 2020

Authorized signatory
Vice-President of the Council of IARNM
Tatjana Tasevska m.p.

REFERENCES

[1] МКС EN ISO/IEC 17043:2010 – Оцена на сообразност - Општи барања за тестирање на оспособеност
[2] EA-4/18 INF: 2010 – Guidance on the level and frequency of proficiency testing participation
[3] МКС EN ISO/IEC 17025:2018 – Општи барања за компетентност на лаборатории за тестирање и калибрација.
[4] МКС EN ISO 15189:2013 – Медицински лаборатории – Посебни барања за квалитет и компетентност.
[5] ILAC-P9:11/2010 – ILAC Policy for Participation in Proficiency Testing Activities.
[6] EA-4/21 INF 2018 Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation.