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NAB-MALTA

TECHNICAL GUIDE

ATG10 - Proficiency Testing and Interlaboratory Comparisons

Policy of the NAB-MALTA

Revision 6 **June 2021**

FOREWORD

Accreditation is the mechanism to assure customers of the competence of Conformity Assessment Bodies (CABs) including laboratories, inspection bodies and certification bodies.

The National Accreditation Board of the Malta (NAB-MALTA) is the single national accreditation body appointed as per Article 4 of Regulation (EC) 765/2008 with responsibility for accreditation in accordance with the relevant normative documents. It operates a management system which complies with the requirements established in EN ISO/IEC 17011.

International trade relies on certificates and reports issued by competent bodies. Confidence in certificates and reports is achieved by accreditation. Confidence in accreditation is based on a series of confidence building steps between the accreditation bodies and accredited conformity assessment bodies and the assurance given by the accreditation body that the accredited conformity assessment body constantly implements the relevant criteria and maintains and continuously develops its competence as defined in the relevant standard. This assurance is achieved through accreditation which includes regular assessments and other types of accreditation activities.

The services of the NAB-MALTA are accessible to all applicants whose requests fall within the current activities as offered by the NAB-MALTA. Access is not conditional upon the size of the applicant laboratory or membership of any association or group.

For the scope of this guide, the masculine gender shall also refer to the feminine gender.

SCOPE OF PUBLICATION

This publication has been drawn up to outline the policy of the NAB-MALTA with respect to participation in proficiency testing and/or interlaboratory comparisons. It is applicable to applicant and accredited laboratories. It is also applicable to inspection bodies that carry out testing as part of an accredited inspection activity.

This is a mandatory document which will come into effect as from the date of publication.

CONTENTS

1. PURPOSE

1.1 This publication outlines the policy of the NAB-MALTA on the participation in proficiency testing and interlaboratory comparisons.

2. INTRODUCTION

2.1 EN ISO/IEC 17025 Clause 7.7 "Ensuring the validity of results" requires laboratories to have a procedure for monitoring the validity results. In particular, EN ISO/IEC 17025 Clause 7.7.2 requires that laboratories shall monitor their performance by comparisons with results of other laboratories, where available and appropriate. Such monitoring shall be planned and reviewed and shall include participation in proficiency testing and participation in interlaboratory comparisons other than proficiency testing.

2.2 The NAB-MALTA considers the participation of laboratories in proficiency testing and interlaboratory comparisons as an important and critical activity for monitoring the integrity of results.

2.3 Proficiency testing and interlaboratory comparisons are widely used for several purposes and their use is increasing internationally. Typical purposes for such proficiency testing and interlaboratory comparisons include:

a) evaluation of the performance of laboratories for specific tests or measurements and monitoring laboratories' continuing performance;
b) identification of problems in laboratories and initiation of actions for improvement which, for example, may be related to inadequate test or measurement procedures, effectiveness of staff training and supervision, or calibration of equipment;
c) establishment of the effectiveness and comparability of test or measurement methods;
d) provision of additional confidence to laboratory customers;
e) identification of interlaboratory differences;
f) education of participating laboratories based on the outcomes of such comparisons;
g) validation of uncertainty claims;
h) evaluation of the performance characteristics of a method – often described as collaborative trials;
i) assignment of values to reference materials and assessment of their suitability for use in specific test or measurement procedures; and
j) support for statements of the equivalence of measurements of National Metrology Institutes through "key comparisons" and supplementary comparisons conducted on behalf of the

International Bureau of Weights and Measurement (BIPM) and associated regional metrology organizations.

Proficiency testing involves the use of interlaboratory comparisons for the determination of laboratory performance, as listed in a) to g) above. Proficiency testing does not usually address h), i) and j) because laboratory competence is assumed in these applications, but these applications can be used to provide independent demonstrations of laboratory competence.

3. DEFINITIONS

Note: The main definitions related to proficiency testing may be found in Clause 3 (Definitions) of **EN ISO/IEC 17043** (Conformity Assessment – General requirements for proficiency testing) and it is recommended that laboratories refer to this standard.

3.1 **Proficiency testing (PT)** is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

3.2 **Interlaboratory comparison (ILC)** is the organisation, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

3.3 **Measurement Technique** is the process of testing/calibrating/identifying the property, including any pre-treatment required to present the sample, as received by the laboratory, to the measuring device. (e.g. ICP-MS, Rockwell Hardness, PCR, Microscopy, Force Measurement)

3.4 **Property** is the quantity being measured (e.g. Arsenic, Fat, Creatinine, Length, Hardness, Force).

3.5 **Product** is the item that the measurement technique is being applied to (e.g. Soil, Vegetables, Serum, Polystyrene, Concrete).

3.6 **Level of participation** refers to the number of sub-disciplines that an organisation identifies within its scope, and therefore the number of specific proficiency tests that should be considered for participation

3.7 **Frequency of participation** refers to how often a laboratory determines that it needs to participate in PT for a given sub-discipline, this may vary from sub-discipline to sub discipline within a laboratory and between laboratories with the same sub-disciplines

3.8 **Sub-discipline** is an area of technical competence defined by a minimum of one Measurement Technique, Property and Product, which are related (e.g. determination of arsenic in soil by ICP-MS).

4. NAB-MALTA POLICY

4.1 It is the policy of the NAB-MALTA that all applicant and accredited laboratories participate in appropriate proficiency testing/interlaboratory comparisons, where such schemes are readily available and relevant to their scope of accreditation.

4.1.1 Participation in a proficiency testing/interlaboratory comparisons means that the laboratory has completed the proficiency test/ interlaboratory comparisons, evaluated the PT/interlaboratory comparisons results and taken the necessary actions.

4.2 The laboratory shall be prepared to justify non-participation in readily available proficiency testing schemes, where one or more appropriate schemes exist. In most cases the frequency of participation is specified by the scheme. Laboratories would be required to justify less frequent participation.

4.3 It is the policy of the NAB-MALTA to accept proficiency testing/interlaboratory comparisons:

a) organised by PT providers which are accredited to EN ISO/IEC 17043 by accreditation bodies which are recognized by NAB-MALTA;
b) organised by recognised independent organisations such as ILAC, EA, APLAC and IRMM;
c) which have been organised by EA MLA or ILAC MRA signatories;
d) organised by a sufficient number of laboratories as a one off or continual exercise[1];
e) organised by PT providers which are not accredited but which are accepted by the sector and have demonstrated appropriate reliability.

4.3.1 The NAB-MALTA is ready to accept the submission of an internal sample or object to another or more external laboratories for the purposes of data comparison as a PT where:

- A readily available PT scheme as indicated in 4.3 is not available;
- A laboratory needs to complement its participation in such PT scheme for any reason.

[1] Refer to **EA 4/21 '**Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation'

5. NAB-MALTA POLICY ON LEVEL AND FREQUENCY OF PARTICIPATION

5.1 In order for the laboratory to evaluate the level of participation in PT schemes it should identify groups of sets of measurement techniques, properties and products on which the outcome of a PT for one of these sets can be directly correlated to the others sets of measurement techniques, properties and products contained within the group. These groups of sets of measurement techniques, properties and products are termed a sub-discipline.

Notes:

(1) A sub-discipline may contain more than one measurement technique, property or product as long as equivalence and comparability can be demonstrated.

(2) The first consideration for a laboratory, when determining a sub-discipline, is that it should generally not contain different technical competences. Different technical competences can usually be identified by the need for different qualifications, training, and use of different equipment, knowledge or experience.

(3) When determining a sub-discipline, a stepwise approach working up from measurement technique through properties to products, may be used. This is because it is more likely that there will be several products and/or properties associated with one measurement technique within a given sub-discipline than vice versa:

(i) With reference to the measurement technique: It is possible but not common to include different measurement techniques in the same sub-discipline.

(ii) With reference to the property to be measured, determined or identified: It may be possible to include more than one property (parameter) in the same sub-discipline.

(iii) With reference to products to be tested: It may be possible to include different products in the same sub-discipline provided that the matrices, objects or materials included, are of equivalent nature.

5.2 When a laboratory determines that more than one measurement technique, property or product is classified under the same sub-discipline, the laboratory shall be required to justify and demonstrate equivalence. This can usually be done by for example through method validation data or use of the same standard method.

5.3 After that the laboratory has identified its sub-disciplines (and therefore its level of participation), the laboratory shall be required to determine the "frequency" of participation, based on level of risk and should set a minimum frequency of participation for each sub-discipline.

5.3.1 The level of risk can be determined by considering:

- Number of tests/calibrations/measurements undertaken
- Turnover of technical staff
- Experience and knowledge of technical staff
- Source of Traceability (e.g. availability of reference materials, national standards, etc.)
- Known stability/instability of the measurement technique
- Significance and final use of testing/calibration data (e.g. forensic science represents an area requiring a high level of assurance)
- When statements of conformity are required and changes in related specifications are made
- Risks and opportunities associated with the laboratory activities, in particular those which will prevent, or reduce, undesired impacts and potential failures in the laboratory activities and achieve improvement

5.4 The CABs shall be able to justify the technical arguments that have led them to the decision on the "level" and "frequency" of participation in PT and it is recommended that laboratories document this justification.

5.5 Once the "level" and "frequency" of participation is established, laboratories are expected to develop a **proficiency testing strategy** which takes into account all the appropriate factors including:

- Analysis of its other QA measures;
- The level of risk presented by the laboratory;
- The sector in which they operate or the methodology;
- The availability of different types of proficiency testing / interlaboratory comparisons;
- Legislative or client requirements;
- Suitability of other QA/QC measures were not PTs are available or difficult to participate in, due to the technical characteristics of the measurement or the number of existing laboratories in the sector is low or for any other justified reason.

The strategy shall cover a minimum period of 5 years and shall be reviewed for its continual suitability as a minimum on an annual basis or more frequently as necessary.

6. GENERAL REQUIREMENTS

6.1 It is the responsibility of the laboratory to regularly check on available schemes and determine which schemes are most appropriate for its scope of accreditation.

6.2 The laboratory shall maintain a plan of its intended participations in PT schemes (this is normally part of the strategy as per Clause 5.5, based on its strategy adopted, over a 5-year period).

6.3 Laboratories preparing for accreditation shall be required to achieve satisfactory performance in proficiency testing or interlaboratory comparison, where such schemes are available and relevant to their scope of accreditation, before accreditation can be granted.

6.4 Where no appropriate proficiency testing or interlaboratory comparison is available, the laboratory shall be required to demonstrate the validity of its tests and calibrations by other means such as replicate tests or calibrations using the same or a different method.

6.5 The laboratory is required to provide NAB-MALTA with a summary report on its participation in proficiency testing / interlaboratory comparisons prior to each visit by NAB-MALTA by completing **NABG32** "Proficiency Testing and Interlaboratory Comparison Summary form". This report shall be made available to NAB-MALTA within the timeframes specified in **ATG12**. In case of an initial assessment this should be provided as an attachment to the accreditation application form. The summary report shall be completed in full and shall contain the following:

- date of proficiency testing / interlaboratory comparisons already carried out;
- organiser (where applicable);
- test materials / measured quantities / parameters;
- matrices;
- acceptable criteria;
- results (satisfactory / questionable / unsatisfactory);
- corrective actions (where applicable).

6.6 The NAB-MALTA assessment team shall review the laboratory's performance in proficiency testing/ interlaboratory comparisons at each on-site assessment and/or any other assessment activity, as necessary.

6.7 The laboratory policy for participation in proficiency testing schemes or interlaboratory comparisons as a form of external quality control should be adequately described in the quality management system documentation of the laboratory. This particularly concerns justifications for frequency and levels of participation, planning, performance/operation, evaluation, corrective action, documentation and its storage.

6.8 Laboratories shall have appropriate acceptance criteria and a procedure for investigating the root cause of problems and for implementing corrective actions when these acceptance criteria are not met. A written record of these activities shall be maintained.

6.8.1 The laboratory shall ensure that it does not claim accreditation for any tests/calibrations that could be affected by the events that caused "out of specification" proficiency testing/interlaboratory comparison results until it is satisfied that the investigation into the anomalous result has fully resolved the issue.

6.9 If, in the opinion of NAB-MALTA, the laboratory's performance in proficiency testing/ interlaboratory comparisons casts doubt on the integrity of test results, the NAB-MALTA may suspend the relevant tests from the laboratory's scope of accreditation. The laboratory shall be required to provide the NAB-MALTA with written evidence that the problem has been identified and satisfactorily rectified (which may include demonstrated satisfactory performance in subsequent proficiency testing/ inter laboratory comparisons) before re-instatement of accreditation can be considered.

6.10 In case where a PT provider does not fall under any of the points listed 4.3 the laboratories shall evaluate the PT scheme providers in which they voluntarily participate and should satisfy itself of their competence. **EN ISO/IEC 17043** contains recommendations and guidance on the requirements for the operation of PT schemes. This document should be used as a basis for such evaluation.

6.11 In certain instances the NAB-MALTA may require that a laboratory participates in a particular scheme or exercise. In particular, calibration and testing laboratories may be nominated to participate in regional or national PTs and other laboratory comparisons, where available and appropriate. Other instances include those where participation is established as a mandatory requirement either by regulators and competent authorities or specific sector schemes and/or where the scheme is deemed necessary to prove the technical competence of the laboratory.

6.12 If the laboratory organises interlaboratory comparisons it should ensure to follow the basic principles set out in EN ISO/IEC 17043.

7. REFERENCES

Publication Ref.	Publication Title
EA-4/18	Guidance on the level and frequency of proficiency testing participation
EA-4/21	Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation
ILAC P9	ILAC Policy for Participation in Proficiency Testing Activities
EN ISO/IEC 17043:2010	Conformity assessment - General requirements for proficiency testing

END