

Policy on Proficiency Testing

PS1

The Irish National Accreditation Board (INAB) considers the participation of laboratories in external proficiency testing / inter-laboratory comparisons an important mechanism for demonstrating the technical competence of a laboratory and monitoring the integrity of test / calibration results. This statement sets out the policy of the Irish National Accreditation Board with respect to participation in proficiency testing / inter-laboratory comparisons. This document relates to applicant and accredited laboratories, including medical, testing, and calibration laboratories (ISO 15189 and ISO/IEC 17025). **See Appendix I and II for specific requirements re ISO 15189 and ISO 17025 laboratories respectively.**

This document may also relate to Inspection Bodies (ISO 17020) as proficiency testing may also be applicable in many types of Inspection.

It is the responsibility of laboratories and inspection bodies to source suitable proficiency test providers or arrange inter-laboratory comparisons as needed.

1) Policy

It is the policy of the Irish National Accreditation Board to accept all proficiency testing/inter-laboratory comparisons recognised by the signatories to the EA and ILAC Multilateral Agreements. It is the policy of the Irish National Accreditation Board that all accredited laboratories participate in proficiency testing/inter-laboratory comparisons relevant to their scope of accreditation.

2) Terminology

2.1) *Proficiency testing* (PT) is the evaluation of participant (testing or calibration laboratory) performance against pre-established criteria by means of inter-laboratory comparisons. (ISO/IEC 17043 3.7)

2.2) *External Quality Assurance* (EQA) is considered to be equivalent to Proficiency Testing.

Inter Laboratory comparison (ILC) is the organisation, performance, evaluation of calibrations/tests (measurements) on the same or similar calibration / test items by two or more laboratories in accordance with predetermined conditions.

3) Statement

- 3.1) It is INAB policy that all applicant and accredited testing/calibration laboratories are required to participate in appropriate PT/ILCs and achieve a satisfactory performance.
- 3.2) INAB recommends that proficiency testing scheme providers accredited to ISO 17043 are used by laboratories, where possible.
- 3.3) Laboratories shall develop a plan for the level and frequency of participation in PT, over the five year re-assessment cycle. The plan shall be regularly reviewed and shall be updated when:
 - 3.3.1) Changes in staffing, volume of work
 - 3.3.2) Changes to work activities, extensions to scope
 - 3.3.3) Change in laboratory equipment, methodologies etc.
 - 3.3.4) Location of testing for example; site laboratory, main laboratory
- 3.4) The plan shall be based on a comprehensive risk assessment which will consider (among other measures) the volume of testing/calibration, the frequency of testing/calibration, the significance and final use of the testing/calibration result where a higher level of assurance may be required (e.g. medical testing, forensic science), accreditation of flexible scopes.
- 3.5) The plan shall be developed in consideration of all regulatory or professional body requirements.
- 3.6) The plan shall cover each applicant and accredited high level CRM code (e.g. 710, 1051) and shall ensure all applicant and accredited measurement techniques are included. All staff performing accredited testing/calibration shall be included in the plan
- 3.7) Laboratories preparing for initial accreditation or wishing to extend their scope of accreditation are required to participate in and achieve satisfactory performance in a PT/ILC where such schemes are available and relevant to their scope of accreditation before a recommendation for accreditation can be considered. The INAB policy on PT/ILC participation for flexible scopes of accreditation is documented in PS11.
- 3.8) Refer to the appendices for specific PT/ILC requirements.
- 3.9) Where no appropriate proficiency testing or inter-laboratory comparison is available, the laboratory will be required to demonstrate the validity of its tests and calibrations by other means such as replicate testing, use of certified? reference materials, calibrations using the same or a different method, analysis of blind samples etc.
- 3.10) The INAB assessment team will review at each surveillance visit the laboratory's plan as per 3.3 and performance in proficiency testing / inter-laboratory comparisons. Laboratories are required to monitor and review their on-going PT/ILC participation and performance and have appropriate acceptance criteria and a procedure for investigating flagged (or anomalous) results and implementing corrective actions when these acceptance criteria are not met. A written record of these activities shall be maintained. The laboratory shall ensure that it does not claim accreditation for any tests that may be affected by the events that caused "out of specification" proficiency testing / inter-laboratory comparison results until it is satisfied that the investigation into the anomalous result has fully resolved the issue. In the event that the laboratory establishes that test results are compromised, they shall inform INAB and seek voluntary suspension for the test(s) in question' (please refer to INAB Terms and Conditions and R1 regulations.).
- 3.11) If at any time the laboratory's performance in proficiency testing / inter-laboratory comparisons in the opinion of INAB, casts doubt on the integrity of test results, INAB may suspend the relevant tests from the laboratory's scope of accreditation. The laboratory will be required to provide INAB 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.

Notes:

Laboratories may also refer to the EPTIS database for availability of proficiency testing schemes. EPTIS is the European Proficiency Testing Information System which is supported by the European co-operation for Accreditation (EA), EUROLAB and Eurachem and sponsored by the European Commission. EPTIS Website: www.eptis.org

References:

- **ISO/IEC 17025:2005/2017** General requirements for the competence of testing and calibration laboratories
- **ISO 15189:2012** Medical laboratories – Particular requirements for quality and competence
- **ISO/IEC 17043:2010** Conformity assessment – General Requirements for Proficiency Testing
- **ISO/IEC 17020:2012** Conformity assessment – Requirement's for the operation of various types of bodies performing inspection
- **EA-4/18:2010** Guidance on the level and frequency of proficiency testing participation
- **ILAC P9:11/2010** Policy for Participation in Proficiency Testing Activities
- **ISO/IEC 17011:2017** Requirements for bodies providing assessment and accreditation of conformity assessment bodies

4) Contact

For further information about this statement please contact an INAB officer at **The Irish National Accreditation Board**.

Phone: +353 1 614 7000
E-mail: inab@inab.ie
Website: www.inab.ie

Appendix I - Medical Laboratories (ISO 15189:2012)

Part I: Participation for EQA & ILC for immunohistochemistry staining methods in histopathology laboratories.

Part II: Participation in EQA for histopathologists

Introduction

ISO 15189 requires laboratories to participate in an inter-laboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results. The laboratory shall establish a documented procedure for inter-laboratory comparison participation that includes defined responsibilities and instructions for participation, and any other performance criteria that differ from the criteria used in the - comparison programme. Clause 5.6.3.2 states that wherever an ILC is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results.

Part I: Participation for EQA & ILC for immunohistochemistry staining methods in histopathology laboratories.

INAB scopes of accreditation for histopathology laboratories are defined by immunohistochemistry staining method(s) (and a list of antibodies applicable and in use in the particular laboratory) and special histochemical antibodies. It is INAB policy that a laboratory shall participate in an EQA scheme for its immuno-histochemical staining methodology and special histochemical antibodies.

The laboratory must participate in an EQA scheme for the immuno-histochemical staining methodology in use for any particular antibody and must comply with the requirements of this document. However, if an EQA scheme does not exist for a particular immunohistochemistry antibody but the underlying staining methodology complies with ISO 15189 then an ILC is not always necessary.

This policy document describes the situation where an EQA scheme does not exist for a particular immunohistochemistry antibody. This is applicable only for immuno-histochemical staining. **The policy does not apply to special histochemistry antibodies where by a formal EQA or ILC will continue to be required for each stain on the scope of accreditation.**

Policy

- This policy is applicable only for immuno-histochemical staining.
- An annual review of available EQA schemes shall be completed by the laboratory, to ensure active participation in any available EQA scheme for a particular immunohistochemistry antibody.
- The laboratory must continue to apply for an extension to scope when / if new immunohistochemistry antibodies are in use in the laboratory. Accreditation can only be claimed for those immunohistochemistry antibodies which are listed on the INAB published scope document. It is the responsibility of the laboratory to ensure the scope of accreditation is current and applicable to the scope of their services.
- All histochemistry antibodies detected have potential diagnostic and therapeutic implications. However, it is acknowledged that some are more closely linked to a therapeutic option than others. Such antibodies shall be included in an external EQA scheme and / or an ILC. Accreditation cannot be claimed for such antibodies until successful participation in the EQA / ILC has been demonstrated. Examples include hormone receptors, HER 2, CD20, CD117, microsatellite instability markers and any immunostain for which the use of a specific drug is conditional on the results of an immuno-histochemical antibody.
- In the absence of an appropriate EQA option for individual immunohistochemistry antibodies, the following approach to internal quality control is acceptable to demonstrate the validity of the testing / staining :
 1. Verification, optimisation and batch acceptance of antibodies prior to their use on clinical cases. This shall include assessment and approval by both medical and senior scientific staff.

2. Audit trail for antibody validation / verification for any antibody in use, complying with corresponding SOP.
3. IQC for each test to include use of appropriate control material from either commercial sources or previous test material.
4. Maintenance of IQC records and control slides which shall reflect assessment by staff in both medical and scientific disciplines.
5. SOP describing management of poor performance on IQC with evidence of appropriate remedial action where it has occurred, ensuring involvement of clinical staff.
6. Records for shall be available and auditable by both the laboratory and INAB, as required.

Part II: Participation in EQA for histopathologists

All histopathologists signing accredited test reports shall participate in General EQA schemes available.

There must be a minimum of two histopathologists participating in corresponding specific specialist EQA schemes (see below), to ensure deputy cover is available at all times

- Cytology.
- Medical Renal Pathology
- Paediatric Pathology
- Perinatal Pathology
- Neuropathology
- Breast screening Pathology (BreastCheck designated laboratories only)

Appendix II – Testing & Calibration Laboratories (ISO/IEC 17025)

Part I: Specific requirements in relation to stack emissions laboratories

Introduction

ISO/IEC 17025 requires laboratories to have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring may include the participation in inter-laboratory comparisons or proficiency testing programmes, but also other means including e.g. the regular use of certified reference materials or replicate tests or calibrations using the same or different methods. These methods provide a mechanism for the laboratory to demonstrate its competence to its clients, the accreditation body, the regulatory authority and organisations providing recognition. The requirements in this appendix have been agreed with the designated competent authority for this area, Environmental Protection Agency (EPA).

The stack emissions testing laboratories shall ensure participation in all of the following PT schemes:

1. Annual participation in a particulate stack emissions PT scheme to assess performance in the weighing of foil shims and simulated particulate test probe wash.
2. Annual participation in a calibration gas proficiency testing PT scheme. This assesses performance using certified gas cylinders
3. Participation in a gas measurement PT scheme, which is conducted at a stack simulator facility. This is to test the complete emissions measuring system from sampling probe to analyser. Successful participation for such a scheme is required once in every accreditation cycle and before initial accreditation can be awarded.