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. **Proficiency testing** determines the performance of individual laboratories for specific tests or measurements and is used as a tool to monitor laboratories' continuing performance and to monitor 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 Appendices I and II for specific requirements re ISO 15189 and ISO/IEC 17025 laboratories respectively.

This document may also apply 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 signatories to 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 Proficiency testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043:2023, 3.7).

2.2) External quality assessment (EQA): evaluation of participant performance against preestablished criteria by means of interlaboratory comparisons (ISO 15189:2022, 3.10).

2.3) Inter-laboratory comparison (ILC) is the design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions (ISO/IEC 17043:2023, 3.4).

3) Statement

3.1) It is INAB policy that all applicant and accredited testing/calibration laboratories and inspection bodies are required to participate in appropriate PT/EQA/ILCs and achieve a satisfactory performance.

3.2) INAB recommends that proficiency testing scheme providers accredited to ISO/IEC 17043 are used by laboratories and inspection bodies, where possible.

3.3) Laboratories shall develop a documented plan for the level and frequency of participation in PT, over the five-year assessment cycle. The plan shall be regularly reviewed and shall be updated when there are changes in:

3.3.1) Staffing, volume of work
3.3.2) Work activities, extensions to scope
3.3.3) Laboratory equipment, methodologies etc.
3.3.4) Location of testing/calibration, for example site laboratory, main laboratory

3.4) The plan shall include consideration of risks such as 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/EQA/ILC participation for flexible scopes of accreditation is documented in PS11.

3.8) Refer to the appendices I and II for specific PT/EQA/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 ongoing PT/EQA/ILC participation and performance and have a procedure and acceptance criteria in place 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.

3.11) 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, it shall inform INAB and seek voluntary suspension for the test(s) in question (please refer to INAB terms and conditions and INAB regulations).

3.12) If at any time, in the opinion of INAB, the laboratory's performance in proficiency testing/inter-laboratory comparisons 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.

4) 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

5) References

- **ISO/IEC 17025:2017** General requirements for the competence of testing and calibration laboratories.
- **ISO 15189:2012/ISO 15189:2022** 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 – Requirements for the operation of various types of bodies performing inspection.
- **EA-4/18 G: 2021** Guidance on the level and frequency of proficiency testing participation.
- **ILAC-P9:01/2024** ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing.
- **ISO/IEC 17011:2017** Requirements for bodies providing assessment and accreditation of conformity assessment bodies.

6) Contact

For further information about this statement, please contact an assessment manager at the Irish National Accreditation Board.

Phone: +353 1 614 7182

E-mail: inab@inab.ie

Website: www.inab.ie

Appendix I - Medical laboratories (ISO 15189:2022)

Part I: Participation for EQA & ILC for immunohistochemical staining and special stains in histopathology laboratories.

It is INAB policy that a laboratory shall participate in an EQA scheme for its immunohistochemical stains and special histochemical stains. The participation shall reflect the activity in the lab and shall include all relevant automated platforms.

If an EQA scheme does not exist for a particular immunohistochemical stain but the underlying automated technique and staining methodology is covered by an EQA scheme then an EQA for that stain is not always necessary.

The above paragraph does not apply to manual special histochemistry stains, whereby a formal EQA or ILC will continue to be required for each stain on the scope of accreditation.

Policy

- The laboratory must continue to apply for an extension to scope when/if new immunohistochemical 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.
- Participation in a formal EQA is required for all immunohistochemical stains with potential therapeutic implications. However, it is acknowledged that some are more closely linked to a therapeutic option (predictive markers) than others. Such antibodies shall be included in an external EQA scheme and/or an ILC, where EQA does not exist. Accreditation cannot be claimed for such antibodies until successful participation in the EQA has been demonstrated. Examples include hormone receptors, HER 2, CD20, CD117, PDL1, microsatellite instability markers and any immunostain for which the use of a specific targeted therapy is conditional on the results of an immunohistochemical staining.
- In the absence of an appropriate EQA option for individual automated immunohistochemical 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.
    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 from either commercial sources or previous test material.
    4. Maintenance of IQC records and control slides which shall reflect assessment from 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, extent and clinical impact, ensuring involvement of clinical staff.
    6. Records 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 generally available EQA schemes. When an interpretive EQA scheme is available, consultant histopathologists are required to participate. This is applicable to non gynae cytology, screening programmes and subspecialties such as neuro, renal, paediatric, perinatal, etc. These schemes shall be incorporated into the laboratory's EQA participation plan.

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)
- Colorectal screening EQA programme (BowelScreen)

Where an appropriate scheme is not available, participation in programmes such as the National Histopathology Quality Improvement Programme, and use of other QA data to demonstrate reviews / agreements / intradepartmental consultation rates on an individual basis may be acceptable. However this shall be reviewed and justified by the laboratory.

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, the Environmental Protection Agency (EPA).

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 in such a scheme is required once in every accreditation cycle and before initial accreditation can be awarded.

INAB also provides accreditation for *EN 14181 – Stationary source emissions. Quality assurance of automated measuring systems.*

Any testing company carrying out EN 14181 works in Ireland must be ISO 17025 accredited for this test and shall adhere to the EPA PT Scheme on EN 14181, when available.. It will require additional assessment time; please contact your INAB assessment manager for more details.

Accreditation for this standard may be mandatory in other jurisdictions, for example UK/NI. Please contact the relevant competent authority for information on PT participation for this particular standard for more information.