Minimum verification requirements for ISO 17025 & ISO 15189 testing laboratories

PS24

1) Introduction

This policy is to clarify INAB expectations on the minimum verification requirements for applicant and accredited testing laboratories, to allow for consistent implementation and independent assessment.

ISO 15189 (Cl 5.5.1.2) states, "Validated examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use."

ISO 17025 (Cl 5.4.2) states that "The laboratory shall confirm that it can operate standard methods before introducing the tests," i.e. verification process.

2) Definitions

2.1) Validation

confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Examples of when validation is required could include but are not limited to:

- Use of non-standard methods;
- Use of laboratory designed or developed methods;
- Significant modification to validated methods;
- Use of standard methods outside their intended scope e.g. sample types not included in manufacturer's specifications;
- Changes involving new technology; or
- Significant parameter changes e.g. reagents, equipment, time, temperature etc.

2.2) *Verification*

confirmation, through provision of objective evidence, that specified requirements have been fulfilled. However verification is different to validation in that it is the demonstration of the performance characteristics previously found during method validation in the laboratory where it is intended to be used. Verification will demonstrate that a validated method, kit, reagent or equipment which is used without modification, can be satisfactorily performed by the user, and meet defined criteria and end user requirements.

Examples of when verification is required could include but are not limited to:

- Implementation of international, regional or national standard methods;
- Use of manufacturer validated kit, reagent or equipment, used as specified and without deviation.

3) Scope of application of the document

This policy statement applies only to ISO 17025:2005 and ISO 15189:2012 testing laboratories performing tests where a measurement step is required. Where a measurement step is not involved, limits of detection must still be verified.

This policy does not apply to those changes requiring validation, and does not apply to calibration laboratories.

4) Requirements

The laboratory shall ensure the following minimum requirements are documented:

4.1) A verification plan shall be in place for all changes. The plan shall include:

- Clear specification of the planned change in procedure, kit or equipment performance;
- Definition of the criteria for acceptance based on published literature or guidelines;
- Justification for selection of the method, kit or equipment and its suitability for the laboratory's purpose;
- Review of the manufacturer's validation, including consideration of independent review where available, e.g. CE marking, AFNOR etc.;
- Determination of performance characteristics using the sample types for which accreditation is required; and
- Statement of the competence of staff involved in verification process.

4.2) A verification report shall be available. This report shall include objective evidence that the performance claims for the examination procedure have been met. The following items shall be considered in this evaluation, at a minimum:

- Verification of limits of measurement, i.e. upper and lower limits of analytical range;
- Critical limits;
- Independent controls (if available);
- Demonstration of linear range especially when measuring fewer levels than the original validation;
- Demonstration of precision/reproducibility especially with smaller number of repetitions than with the original validation;
- Measurement uncertainty (MU);
- External quality assurance. If not, then alternative as per INAB policy PS1;
- Limitations of method, kit or equipment;
- Method comparison e.g. another, or a previous method used in lab with consideration of slope and correlation, where possible;
- Limit of detection (LOD) / Quantification (LOQ); and
- Appropriate review of the verification results and record of their assessment of fitness for intended use. This shall include clinical involvement, where necessary, for ISO 15189 testing laboratories.

4.3) Implementation / integration of the change in the laboratory quality system. The laboratory shall confirm and document that it has implemented the change in its own quality system. The following items should be considered:

- Test reports;
- New documents/SOPs;
- Internal audit schedule;
- Approved suppliers list;
- Request forms and contracts with customers;
- Training of staff;
- External quality assurance results;
- LIMS/electronic systems updates, if needed; and
- Other aspects as required.

5) References

EN ISO/IEC 17025: "General requirements for the competence of testing and calibration laboratories," 2nd edition, 2005.

EN ISO/IEC 15189: "Medical Laboratories - Requirements for quality and competence," 3rd Edition, 2012.

Official Journal of the European Communities: Council Directive 98/79/EC on in vitro diagnostic medical devices, L331, 1998.

Statutory Instrument No. 304/2001 - European Communities (In Vitro Diagnostic Medical Devices) Regulations, 2001.

INAB PS1 – Policy on proficiency testing.

INAB PS11 - Flexible Scope of Accreditation for ISO 17025 and ISO 15189 Testing Laboratories.

INAB PS15 – Guide to Method Validation for Quantitative Analysis in Chemical Testing Laboratories.

6) Contact

For further information about this statement please contact an accreditation officer at the Irish National Accreditation Board.

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