Policy Statement on scope format for testing laboratories accredited to ISO 15189

PS35

1) Purpose

The purpose of this policy is to give guidance to applicant and accredited testing laboratories regarding their scope of accreditation.

2) Introduction

2.1. The definitive statement of the accreditation status of a testing laboratory is the certificate of accreditation and the associated scope of accreditation.

2.2. The certificate of accreditation includes the laboratory details, INAB registration number, standard to which the CAB is accredited, and the award date and expiry date of certificate of accreditation.

2.3. The scope of accreditation defines the measurement capabilities, ranges and boundaries of the testing activities for which the organisation holds accreditation. It is therefore important that the scope of accreditation is presented in a manner that is scientifically meaningful and presents unambiguous information in a manner that will be readily understood by the target audience.

2.4. This policy provides guidance on the format, presentation and content of scopes for laboratories accredited to ISO 15189. Use of this guidance will assist in ensuring consistency of scopes for any potential users of the service. Refer also to CRM-FS 14.

2.5. It is INAB policy that normally both the laboratory procedure and the standard (national or international) on which it is based shall be included on the scope.

2.6. Where the laboratory procedure is carried out in all respects as detailed in a standard method, and the standard method is applicable to the matrix being analysed, then only the standard need be listed on the scope.

2.7. The term 'based on' a standard method may be used if there are minor modifications made by the laboratory to the standard method. However critical steps in the standard method shall be included, for example, sample preparation, incubation temperatures, technical specifications in the method etc. If critical steps are not followed, then it is an in-house method with additional details described on scope.

2.8. The term 'based on' a standard method may be used if there are minor modifications made by the laboratory to the standard method and providing that:

2.8.1. The principle of the method/technique shall remain unchanged (pre-enrichment, selective enrichment, GC-MS etc.).

2.8.2. Critical steps shall be included. For example, sample preparation steps, incubation temperatures and times. This applies also in the case of pooled samples, if the sample preparation is outside the manufacturer's instructions then 2.8.4 shall apply.

2.8.3. Components, such as media and reagents, if specified in the standard method, shall be included, for example primers, probes, media broth.

2.8.4. If any of the above sub-clauses 2.8.1 to 2.8.3 are not followed, then it is an in-house method with additional details described on the scope. A full validation will be required in these cases. The term 'based on' cannot be used in these instances.

2.9. The extent of deviation between the in-house method and standard, and any potential impact on the result of the test, shall be documented and available for review by the INAB assessment team

2.10. Evidence shall be available to the INAB assessment team to demonstrate that the laboratory's customers have been informed of any significant deviation from the standard method, the extent of deviation and potential impact on the result of the test.

2.11. Where the method has been developed and validated by the laboratory/company and is not based on published international or national standards, this shall be referred to as an "In-house test procedure". This includes test methods based on academic research publications and company-specific procedures.

3) Scopes

3.1. The first page of a scope of accreditation for permanent laboratories normally contains the following details:

- Name of the accredited organisation.
- Contact details, including name, telephone and email address and web site details.
- Statements to the effect that the organisation is accredited to ISO/IEC 15189 and that testing is performed at the given address(es) only.
- The INAB accreditation symbol and the organisation's registration number.
- Sites from which accredited services are delivered (Refer also to P7 and PS19).

4) Classifications and column headings

4.1. INAB scopes of accreditation are published for each accredited body and contain information relevant to the accreditation standard. The scopes are intended to provide as much useful information as possible to the end user of the accredited service.

4.2. INAB has developed a classification system for each field which is summarised in the table below. All classification systems are available on the INAB website. Each test area is further subdivided into two further levels of sub-classifications ('sub-scope') which encompass all types of test within the field.

4.3. When applying for an extension to scope, the appropriate classification must be selected for each scope element. Your INAB assessment manager, in conjunction with the technical assessor, will be able to advise you on appropriate sub-category to choose.

CLASSIFICATION	DETAIL	INAB REFERENCE GUIDE (AVAILABLE ON INAB WEBSITE AND CRM)
Medical testing laboratories	Microbiology and Virology	ST6CRM
ISO15189	Blood Transfusion science	
	Haematology	
	Immunology	
	Histopathology	
	Chemical Pathology	
	Genetics	
	Assisted reproduction	
	Audiology	

4.4. Each accredited test method shall be listed on the scope and in the INAB CRM as an individual scope element.

4.5. Each scope element includes five to seven fields which are free-text and must be completed by the laboratory.

4.6. The column headers vary depending on classification and will include elements of this list;

- Test /Assay

- Specimen type
- Technique
- Equipment
- Range of measurement
- Method (CE / non CE / In house developed / based on standard method)
- SOP

4.7. At application stage you will be prompted to complete the appropriate fields.

4.8. **For Test / Assay;**

- Please use the full name of the test / assay and an abbreviation (if one exists). For example Full Blood Count (FBC), Prothrombin Time (PT).
- The National IT system catalogue naming convention is to be used. If this is not available (in the case of private laboratories, then use the full name of the test / assay.
- If a profile is generally requested by users, name of profile shall be stated. If tests in the profile are assayed in one closed system (e.g. FBC), names of individual tests reported to be listed as well as the profile name (all to be included in one entry, not as individual scope items). If tests can be ordered separately, these should be entered on scope as individual items (e.g. for liver function test profile, individual assays should be entered as separate scope items).

4.9. **For specimen type;**

- A combination of the body fluid / sample type, together with the anticoagulant type shall be used. For example, blood in EDTA, blood in Sodium citrate.
- All sample types, combinations with anticoagulants, that are accredited should be listed.

4.10. **For technique;**

- This refers to the general test method used (eg ELISA, HPLC, compression).
- Principle of measurement shall be documented in all cases (fluorescent flow cytometry, turbidometric, chromogenic)
- For assays involving screening under the microscope, the term microscopy shall suffice.

4.11. **Equipment;**

- This refers to the actual test equipment used. Both make and model shall be listed. It is not intended to apply to peripheral laboratory equipment (e.g. pipettes, balances, incubators) or equipment used in pre-examination processes (e.g. tissue processors, centrifuges, sample transfer equipment/robotics).
- If a commercially available test kit is used the kit name shall also be listed under equipment.
- In the case of manual assays it is sufficient to enter in 'manual method'.

4.12. **For range of measurement;**

- The validated range of measurement (in SI units) must be included (where appropriate). This will only be included for quantitative and semi-quantitative methods.

4.13. **For method (CE / non-CE / In house developed/based on standard method)**

- Use 'CE' where all equipment and reagents (or test kit) is CE marked and used exactly as directed in the manufacturers' instructions.
- Use 'in house developed' where some deviation from 'instructions for use' (IFU) is in use but all reagents are CE marked (e.g. using serum instead of Lithium Heparin, counterstaining Kleihauer kit with Haematoxylin, etc.). See also 2.7 above.

- The publication date of the relevant reference standard method must be included, where available.
- If using kits from another supplier in an open system, where reagents from another supplier are specifically 'allowed', the term CE can be used, otherwise 'In house developed' shall be used.
- For tests that require manual interpretation, these can be designated as 'CE' if reagents/equipment used in preparation are CE marked
- If a commercially available kit is used the manufacturer and kit name shall also be listed.

4.14. **Std. Ref. and SOP**

- Std. Ref refers to the standard reference test method on which the SOP is based (national or international standards or guidelines)
- SOP refers to the laboratory's own Standard Operating Procedure or test method.
- Both shall be listed on the scope where applicable.

5) Symbols and Units

5.1 It is recommended that only units of the SI and those units recognised for use with the SI should be used to express the ranges of measurement. Nevertheless, other commonly used units may be used where considered necessary for the intended audience. For example, the term "ppm" (part per million) is frequently used by manufacturers of test and measurement equipment to specify the performance of their products. Terms like this may be used where they are in common use and understood by the users of such equipment, providing their use does not introduce any ambiguity in the capability that is being described.

5.2 The dash (-) should not be used to indicate a range of values, due to ambiguity with the negative operator (minus sign). The word "to" should be used instead. Example:
Correct: 0.8 g/ml to 1.0 g/ml
Incorrect: 0.8 g/ml - 1.0 g/ml

5.3 There is a space between the numerical value and unit symbol, even when the value is used in an adjectival sense, except in the case of superscript1 units for plane angle. Examples:
Correct: 100 °C, Incorrect: 100°C
Correct: 0.25 %, Incorrect: 0.25%

5.4 In cases where a number is not used as part of an expression, there is no space between mathematical operators (such as "+" or "-" signs) and the associated number.
Correct: -20 °C
Incorrect: - 20 °C

6) Binomial Nomenclature

6.1 Formatting of text related to binomial nomenclature of organisms: Although the name of the organism should be italicised or underlined, INAB's CRM cannot currently handle this formatting. However, the following rules should still be followed:

6.2 The genus is capitalized but the species is not (for example, "Staphylococcus aureus").

6.3 After the full genus name is given, it can be written as "S. aureus", as long as there are no other genera in the scope that start with the same letter, otherwise it should be, for example, "Staph. aureus" and "Sal. typhimurium".

6.4 The abbreviation "sp." may be used when the actual specifies name cannot or need not be specified. The abbreviation "spp." (plural) indicates multiple species in same genus.

[1] Subscripts and superscripts, as well as Greek characters such as µ can be entered by using the Insert Symbol/Special Characters function in Microsoft Word or Excel.

7) Status and Implementation

This policy is mandatory and applicable from date of issue.

8) Contact

For further information about this statement please contact your INAB assessment manager at
The Irish National Accreditation Board.
Phone: 01 6147182
E-mail: inab@inab.ie
Website: www.inab.ie