Policy Statement on Scope Format for Testing Laboratories accredited to ISO/IEC 17025

PS34

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 testing laboratories accredited to ISO 17025. 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 is 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 and providing that:

- 2.7.1 The principle of the method/technique shall remain unchanged (pre-enrichment, selective enrichment, GC-MS etc.).
- 2.7.2 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 2.7.4 shall apply.
- 2.7.3 Components, such as media and reagents, if specified in the standard method, shall be included, for example primers, probes, media broth.
- 2.7.4 If any of the above sub-clauses 2.7.1 to 2.7.3 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 and reference to any ISO method shall not be permitted.

2.8. 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

2.9. There shall be evidence available to the INAB assessment team 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.

2.10. 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.

2.11. Where applicable legislation mandates validation according to a particular procedure or standard, the laboratory shall follow it without exception.

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 17025 and that testing is performed at the given address(es) only.
- The INAB accreditation symbol and the organisation's accreditation number.
- Sites from which accredited services are delivered (Refer also to P07 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)
Class-AcoVib	Acoustic and vibration testing	ST1-CRM
Class-BiolVet	Biological and veterinary testing	ST2-CRM
Class-Chem	Chemical testing	ST3-CRM
Class-Const	Construction materials testing	ST4-CRM
Class-Elect	Electrical testing	ST17-CRM
Class-For	Forensic testing	ST14-CRM
Class-HTH	Heat, temperature and humidity testing	ST10-CRM
Class-LabNB	Laboratory testing for notification	ST22-CRM
Class-Mech	Mechanical testing	ST5-CRM
Class-NDT	Non-destructive testing	ST18-CRM
Class-Opt	Optical testing	ST16-CRM
Class-Rad	Radiometry testing	ST19-CRM

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 five to seven of this list;

- Test Name

- Analyte
- Parameter
- Product tested
- Matrix
- Range of Measurement
- Equipment
- Technique
- Standard Reference
- SOP
- Measurement Units (e.g. Amp, V, Hz) (electrical testing only)

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

4.8 Tests/scope elements are grouped on the published scope of accreditation according to classification number. Within each group they are listed alphabetically according to test name.

4.9 The validated range of measurement (in SI units) must be included (where appropriate).

4.10 Where the same test procedure is applicable to multiple analytes or sample matrices, each analyte and/or matrix should be listed as a separate scope element. Any deviation from this shall be agreed with assessment manager and documented in the CAB file.

4.11 'Technique' refers to the general test method used (eg ELISA, HPLC, compression).

4.12 'Equipment' 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).

4.13 If a commercially available kit is used the manufacturer and kit name shall also be listed.

4.14 The publication date of the relevant reference standard method must be included.

4.15 SOP refers to the laboratory Standard Operating Procedure or test method (see 2.6 – 2.10).

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" (parts 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 Unit symbols are unaltered in the plural:
Correct: l = 75 cm
Incorrect: l = 75 cms

5.3 Unit symbols (or names) are not modified by the addition of subscripts or other information. The following form, for example, is used instead.
Correct: Vmax = 1000 V
Incorrect: V = 1000 Vmax

5.4 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.
Correct: 0.8 g/ml to 1.0 g/ml
Incorrect: 0.8 g/ml - 1.0 g/ml

5.5 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 superscript[1] units for plane angle. Examples:
Correct: a 25 kg mass, Incorrect: a 25-kg mass
Correct: 100 mV, Incorrect: 100mV
Correct: an angle of 2˚ 3' 4", Incorrect: an angle of 2 ˚ 3' 4"

[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.

Correct: 100 °C, Incorrect: 100°C
Correct: 0.25 %, Incorrect: 0.25%

5.6 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
Correct: -100 mV to +100 mV, Incorrect: - 100 mV to + 100 mV
NOTE: the absence of a “+” or “-” sign implies that the value is positive, however the use of the “+” sign is encouraged where negative values are also included, as in the second example above.
However, if the number and symbol are part of an expression (e.g. a + b), then spaces should be used.

6) Binomial Nomenclature

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:

6.1 The genus is capitalized but the species is not (for example, “Staphylococcus aureus”).

6.2 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”.

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

7) Status and Implementation

This policy is mandatory and applicable from date of issue.

8) Contact

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

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