Flexible scope of accreditation for ISO 17025 and ISO 15189 test laboratories

PS11

1 Introduction

Laboratories are accredited based on a defined scope of accreditation. This scope document provides the laboratory and other interested parties with a detailed list of the tests and/or examinations for which the laboratory has been accredited.
Any changes/additions to this scope normally require an INAB evaluation before the change is implemented and the results are reported as accredited.
This flexible scope policy defines the INAB process in place to allow laboratories to report as accredited, within defined criteria, results of tests and/or examinations not currently in their defined scope of accreditation. This could be completed without prior approval from INAB.
The use of a flexible scope will not reduce the validation/verification requirements for the laboratory in any way.

2 Scope of application of the document

This policy statement applies only to ISO 17025 and ISO 15189 testing laboratories.

The policy does not apply to:

- Testing subcontracted by the laboratory;
- Calibration laboratories;
- Testing laboratories that may be relocating equipment or facilities;
- Accreditation of opinions and interpretations.

3 Definition of scope parameters

A laboratory's scope of accreditation consists of the following parameters:

a) INAB scope element/classification system
This refers to the classification system for all testing and calibration laboratories as available in the CRM portal document library.

b) Materials/products/specimens tested
This is the material/product or specimen (types of matrices) to which a test method is applied.

c) Test/property measured/range of measurement
This is the measured parameter/property of materials tested and may include the range of measurement over which accreditation is awarded.

d) Method principle/techniques used
This is the technique underlying the performance of the test/examination. Examples are: atomic absorption, high-pressure liquid chromatography, enzyme immunoassay, microscopy, PCR, cultural enumeration and detection techniques, etc.

e) Equipment (may not be specified on all scopes)
This describes the type of equipment, name of the equipment and supplier, and kit and reagent information where applicable.

f) SOP/standard specification
This is a reference to the laboratory procedure used in the testing/examination. The SOP may be based on a regional/sectoral, national or international standard method, or a method developed in the laboratory (in-house method).

g) Location
The location where the testing occurs (See CRM-FS-14).

4 Flexible Scope

It is INAB policy to award flexible scope in one/some/all of the following categories only:

- Range of measurement may be extended for the test
- New parameters/tests may be added
- New matrices may be added
- Changes to equipment/kits where the underlying methodology does not change

5 Validation/Verification of Changes

The laboratory shall have a process in place to determine whether a validation or verification process for the changes should be completed for any flexible scope changes, taking into account any regulatory requirements that may apply also to the testing.
In either case the requirements in the appendices of this document will apply.

6 Flexible scope

1. Flexible scope of accreditation means that a laboratory may claim accreditation for testing not currently included in the defined scope of accreditation, without prior approval by INAB.
   This may lead to a permanent change in the defined scope of the laboratory or it may apply to a single task or event. (For example temporary equipment in use, analysis in connection with a particular outbreak posing a public health risk etc.).
2. *A testing laboratory may use a flexible scope when the particular change needed:*
   a) Utilises a technique that has been previously assessed and accredited by INAB and is included in the laboratory's current scope of accreditation;
   b) Is within the same scope classification, scientific discipline and utilises the same technique (see 3 (d));
   c) Ensures the use of kits and/or equipment within the manufacturer's instructions (where applicable).
3. *The following points shall be read in conjunction with point 2 and shall apply to all relevant types of test laboratories.*
   a) The term 'technique' as referred to in section 3 (definition of scope parameters) encompasses all parts of the process including sample preparation, extraction,

analysis and detection. A significant change in any part of the process is considered a change in 'technique' and requires an extension to scope application to INAB;

b) It is unlikely that a change in organism could be considered under flexible scope as there is normally significant changes to conditions of the test, detection techniques etc. Changes within species of organisms / strains of viruses could be considered as part of flexible scope. Please contact your INAB assessment manager if you wish to clarify any particular proposed changes;

c) Initial accreditation for testing Category 3 organisms are excluded from the flexible scope and would require an INAB assessment. Please see PS3 (Example *E. coli* 0157);

d) For ISO 15189 histopathology laboratories, the addition of any special stains or specialist areas requires an extension to scope application to INAB;

e) Flexible scope does not apply when a change from manual to automated systems is proposed, even if the underlying technique is unchanged;

f) Flexible scope will apply to equipment upgrades only if there is no change to the underlying measurement/detection technique;

g) For blood transfusion laboratories, this testing is governed by EU directives and agreements with the Health Protection Regulatory Authority (HPRA). These laboratories may operate flexibility in cases of changing kits, sample and matrix types, ranges where appropriate. Addition of new tests is not permitted (category 2);

h) Techniques such as next generation sequencing/whole genome sequencing are excluded from flexible scope at present;

i) CE marked/kit-based methods, used within the manufacturer's specifications and without variation, in the area of PCR testing may be included as part of the flexible scope system. In-house developed methods in the area of PCR testing shall not be part of a flexible scope system;

j) Where tests have been suspended (either voluntarily by the CAB or by INAB), they cannot be reinstated using flexible scope. INAB needs to be satisfied that the conditions leading to suspension have been adequately addressed to reinstate the test to the scope. The normal extension to scope process applies.

k) In the case of PCR testing, the following also applies:
   - Addition of strains of the same organism is permitted using the flexible scope providing there is no change to the technique.
   - If a lab is accredited for commercial kits it may add on another commercial kit for another organism, providing there is no change to technique.
   - Change from qualitative to quantitative techniques is not permitted for an existing accredited method, even if underlying technique is the same.
   - Additional sample matrices can be added providing they are within manufacturers' specifications.

7 Requirements for laboratories applying for a flexible scope of accreditation

1. Flexible scope of accreditation can be applied for as an extension to scope request, at the earliest following the laboratory's first successful surveillance visit after the laboratory's initial award of accreditation in a particular scientific discipline. Please use the extension to scope form process through CRM.
2. In its application, the laboratory shall detail the departments/scientific disciplines in which flexible scope is being applied. It may apply for a single discipline (e.g. chemistry only), technique (e.g. mass spectrometry only), change in range of measurement only, change of matrix only, etc. It may also apply for the entire suite of accredited testing.

3. The laboratory shall designate the person(s) with responsibility for the flexible scope system. These individuals are considered key personnel and any changes shall be notified to INAB, as they occur. A deputy shall be designated for this key role also.
4. The laboratory shall also document the process to be followed on receipt of applications for tests/examinations that are within the range of the laboratory's flexible scope, but not previously carried out by the laboratory. Minimum requirements for this documented process are defined in Appendix A.
5. The laboratory shall document the validation/verification process, suitable to the extent and technical nature of the categories for which it requires a flexible scope. Requirements for this documented process are defined in Appendix B, as it applies to flexible scope.
6. The records associated with Appendices A and B shall be sufficiently detailed so as to allow internal and external audits evaluate the process that has been followed and the decision taken, including cases where a test could not be approved as accredited. These records must provide evidence that all the actions required by the laboratory prior to approval were effectively completed before the issue of an accredited test report. Please note: validation/ verification can be concurrent with testing, provided it is completed before the test report is issued. The potential risk of this may be assessed individually by each laboratory.
7. Additional tests/examinations for which the laboratory claims accreditation via its flexible scope, since the last INAB surveillance visit, shall be listed in a document held by the laboratory. This document will be the '**List of flexible scope changes**' for a particular time period: e.g. 2015. This list is controlled and updated by the laboratory on an ongoing basis and shall be submitted by the laboratory prior to each assessment visit. Minimum requirements for such a template are in Appendix C.
   The list shall be made publicly available.
8. The flexible scope system shall be subject to internal audit by the laboratory and shall also be reviewed as part of the laboratory's management review. These records will be reviewed at INAB assessments.

8 Application process for a flexible scope

1. CRM-FS-20 describes the process to follow when applying for an extension for flexible scope through the CRM. A minimum of six months' notice is required for INAB to organise such an assessment.
2. In addition to completion of this form, laboratories are also requested to provide the following information with the application:
   a) A description of the reason and justification for applying for a flexible scope;
   b) A list of the person(s) responsible for the flexible scope system within the laboratory and a brief description of their competence and experience;
   c) The documented process that the lab will follow on receipt of applications for tests within the flexible scope (Appendix A);
   d) The documented process that the lab will follow on receipt of applications for tests within the flexible scope;
   e) A practical example of an extension to scope under the flexible scope system, for each technical area for which flexible scope is sought;
   f) Records of the laboratory's own internal audit completed as evidence of conformity with this policy document.

9 Initial assessment visit for flexible scope

1. The initial assessment of flexible scope will be an on-site visit which will be completed as part of a scheduled surveillance visit to allow input from the technical assessors. Additional time for the lead assessor (minimum of 0.5 days) will be required for this initial assessment

on site. Thereafter, assessment of the flexible scope system and 'List of flexible scope changes' will be incorporated into the normal surveillance activities of INAB. Please also see 8.1.

2. Requirements outlined in appendices will be assessed, at minimum, during this visit.
3. The INAB assessment manager will update the scope of accreditation for the laboratory indicating the areas in which flexible scope of accreditation has been awarded. The flexible scope is defined according to the notes below. These notes shall be displayed at the end of the scope document for reference and used throughout to define where flexible scope has been awarded on a test/technique basis.

   The note to be inserted to the last page of the scope document is as follows:

   The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.
   Note 1 - Range may be extended for the test
   Note 2 – New parameters/tests may be added
   Note 3 – New matrices may be added
   Note 4 – Changes to equipment/kits where the underlying methodology does not change
   For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.
4. The INAB team, as per the normal process, may recommend award of accreditation for a flexible scope and this will be presented to the INAB manager for decision.

10 Maintenance of accreditation

1. At each surveillance visit, the implementation and effectiveness of the controls established by the laboratory for the management of the flexible scope will be examined. If a laboratory has made significant use of their flexible scope between INAB visits, additional time may be needed by the assessment team to evaluate these changes. This will be decided on a case by case basis with the assessment manager.
2. The laboratory shall refer to INAB policy statement PS10 for documentation to be supplied to INAB in advance of a surveillance visit, in relation to their flexible scope system. Prior to the annual surveillance visit, the laboratory shall submit an application in CRM titled "List of flexible scope changes_Reg No_Year". This will be assessed during the visit.
3. If INAB is satisfied that the flexible scope system in the laboratory has managed the changes effectively then the tests/examinations outlined in the list of flexible scope changes are then added to the laboratory's fixed scope of accreditation.
4. INAB reserves the right to revoke the laboratory's authority to operate a flexible scope, should it be discovered that the laboratory has not maintained its management system, or that controls have not been effectively implemented resulting in the inappropriate authorisation of tests/examinations as accredited. Should this occur, the laboratory is required to inform its clients (including any relevant regulatory authorities) that the laboratory no longer operates a flexible scope of accreditation.

11 References

- EN ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories", December 2017.
- EN ISO 15189, "Medical Laboratories - Particular requirements for quality and competence", 3rd Edition 2012.
- EA-2/15, "EA requirements for the Accreditation of Flexible Scopes".

- EA-4/17, "EA Position Paper on the description of scopes of accreditation of medical laboratories".
- EA-2/05, “The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing.”
- ILAC-G18: 04/2010, “The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing”.
- PS1, INAB Policy on Proficiency Testing.
- PS15, Guide to Method Validation for Quantitative Analysis in Chemical Testing Laboratories.
- PS24, Minimum verification requirements for Verification for ISO17025 and ISO15189 accredited laboratories.

12 Implementation

From date of publication.

13 Contact

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

Appendix A - Minimum requirements for the documented process to be followed within the laboratory on receipt of applications for tests/examinations that are within the range of the laboratory's flexible scope.

This documented process shall ensure the following items are clearly defined and recorded:

I. The responsibility for the flexible scope system within the laboratory.
II. Identification of suitably qualified and experienced personnel to complete verification/validation and testing.
III. Confirmation that suitable equipment, equipment capacity and consumables are available for completion of the specific test(s). (Subcontracting is not permitted)
IV. The final authorisation for the decision on whether the new test or change in test method can be added to the list of flexible scope changes.
V. If a particular test / change in test method is requested by a client, they, when appropriate, shall be informed of the following:
    a. The implications (e.g. turnaround time, price, etc.) of the request for this test
    b. That there is a possibility that the laboratory will not be able to issue accredited test results depending on the outcome of the verification/ validation procedures.

Appendix B - Minimum requirements for a documented validation/verification process suitable to the extent and technical nature of the categories for which the laboratory holds a flexible scope.

i. Should the validation/verification process result in the conclusion that the laboratory is not in a position to issue accredited test reports, the laboratory must conduct an investigation to ensure that adequate corrective action is taken, where deemed necessary by the laboratory. Further corrective action may not be required in instances where the laboratory has decided not to progress and the client is satisfied with such an outcome.

ii. The validation/verification process may consist of a general procedure together with more detailed procedures for specific classification groups or parameters.

iii. The laboratory could establish different degrees of validation/verification. The process may be more extensive in the case of a new matrix added to an existing suite, or an upgraded piece of equipment, while it would be less extensive in the extension of the analytical range of an already accredited method.

iv. Successful participation in proficiency testing (PT) scheme(s) is normally required during validation/verification of a change in method, test parameter, etc. If a PT is unavailable then the requirements of PS1 shall apply.

v. The laboratory shall document when it would/would not consider it necessary to demonstrate successful participation in an appropriate PT scheme before reporting a result as accredited. This shall be assessed by the INAB team during the initial assessment for flexible scope.

vi. Significant changes will require a successful PT result before reporting a result as accredited. Examples include:
    a. Upgrade/change of equipment
    b. Additional test/examination

vii. However, results from PT participation may not be required in some instances, before test results are reported as accredited. Examples include:
    a. Change in range, kit change, reagent change
    b. Sample dilution/concentration steps
    c. Additional sample matrix where the PT for a particular test is independent of the matrix. Note: where there is a specific PT for matrices available, then the laboratory should participate before the testing is reported as accredited.

Appendix C - List of flexible scope changes for any particular year

INAB scope classification		Test/assay name	Specimen type	Technique	Equipment	SOP	Description of change and date
							Enter details of the change. Possible examples below:
							Change of range
							Change of kit
							Addition of new test
							Change of dilution in test method
							Upgrade of equipment