

Flexible Scope of Accreditation for Chemical Testing Laboratories

PS11

1) Introduction

The accreditation of laboratories is based on a defined scope of accreditation which is clear and unambiguous, and provides the laboratory and other interested parties with a detailed list of the tests for which the laboratory has been accredited.

Currently the scope of accreditation provides a precise description of the specific tests for which the laboratory is deemed competent and requires an evaluation of the laboratory's competence for each new test that is added to the scope.

Nevertheless, in recent times, it has become desirable to establish mechanisms which permit laboratories to extend the range of their scope on the basis that their competence in the development and validation of tests has already been evaluated.

This document sets out INAB policy for defining the scope of accredited tests in a more flexible way. In no way does it open the possibility of issuing indefinite or diffuse scopes of accreditation.

Before requesting accreditation to a flexible scope, laboratories will be required to carry out an analysis to determine that they specifically require it. The additional effort to develop, implement and maintain an extended management system that a flexible scope requires will only be beneficial in those cases where the necessity for such flexibility has been clearly established.

2) Overview

Flexible scopes allow a laboratory to undertake certain tests and to claim accreditation for these tests even though those tests may not be explicitly stated on their scope of accreditation.

The system is based on a document, the List of Additionally Accredited Tests (LAAT) which is used in conjunction with the laboratory's Scope of Accreditation. Additional tests for which the laboratory claims accreditation via its flexible scope, since the last INAB surveillance visit, are listed within a defined classification (P9) category. For testing laboratories, the matrix, parameters tested, reporting range, analytical technique and method are recorded in this document. The LAAT is controlled and updated by the laboratory.

This policy statement describes how the Laboratory's management system should control and demonstrate that tests added to the LAAT are validated and approved according to a predefined system and also establishes how INAB evaluates laboratories that wish to have a flexible scope of Accreditation.

The laboratory will be required to demonstrate:

That a fixed scope is too restrictive for the work they are currently undertaking and that a flexible scope is justified.

That it has a management system which will control the flexible scope so that all tests are carried out in accordance with the requirements of accreditation.

That it has the technical competence and depth of experience to support the granting of a flexible scope.

3) Scope

This policy statement applies only to chemical testing laboratories accredited for testing that require a flexible scope of accreditation. This policy does not apply to calibration, biological or medical laboratories.

In cases where there are specific and/or additional requirements laid down by authorities (in directives, standards, etc.), these requirements shall be followed.

4) Objective

The objective of this document is to describe the requirements that testing laboratories shall meet to justify and implement a flexible scope of accreditation. This form of accreditation is also described in European co-operation for Accreditation guideline EA-2/05 and International Laboratory Accreditation Cooperation guideline ILAC-G18.

5) Definition of scope parameters

A laboratory's scope of accreditation is shown in the laboratory's schedule of accreditation and refers to the items listed below.

5.1) Materials/products tested

This is the material or product (types of matrices) on which a test method is undertaken and a list of these materials is identified in the INAB publication P9, *Classification System for Testing and Calibration Laboratories*.

Examples of product groups are 'Water' (group classification 766 in P9) and 'Food' (751). Examples of specific materials are 'Trade Wastes' (766.05) and 'Meat and Meat products' (751.04).

5.2) Test type/property measured/range of measurement

This is the measured parameter/property of materials that includes the range of measurement over which accreditation is awarded. Examples are chromium content (0.1 to 10 µg/ml) and pH (1 to 12).

5.3) Standard specification

This is the procedure used in the testing/analysis. The method may be a regional/sectoral or national or international standard method, or a method developed in the laboratory (in-house method).

5.4) Measurement techniques used

These are the measurement techniques underlying the performance of the test. Examples are: gravimetry, atomic absorption, and high-pressure liquid chromatography.

6) Non-flexible and flexible scope

6.1) Non-flexible scope of accreditation

In the case of a non-flexible accreditation scope, all the sub-elements listed in clause 5 above are fixed and can only be changed on application to and with prior approval by INAB. However, ongoing updating of methods is allowed if these changes do not significantly affect the test result.

6.2) Flexible scope of accreditation

Flexible scope of accreditation means that a laboratory may claim accreditation for changes made to its scope of accreditation without prior approval by INAB. The changes may be permanent or may apply to a single task.

Extension of a laboratory's accreditation to include flexible scope of accreditation can only take place based on a method previously assessed and accredited by INAB. The use of flexibility requires the laboratory to perform validation with respect to each of the categories where a change occurs.

6.3) Categories of Flexible Scope

Flexibility may only cover the following categories:

6.3.1 Flexibility for materials/products tested

This means flexibility that allows for changes in the specific products or materials tested within a product group (e.g. change in matrices, or categories listed in P9), if this can be done by using the same testing techniques for the test parameters (properties/analytical parameters) for which the laboratory is already accredited.

6.3.2 Flexibility concerning test parameters

This means flexibility that allows for changes in the testing field with respect to test parameters (properties/analytical parameters/accredited range) if this can be done by using testing techniques and test types for which the laboratory is already accredited.

6.3.3 Flexibility concerning the performance of the method

This means flexibility that allows for changes in the performance of a particular method for a test of a specific product or material (as listed in P9) and a given test parameter (property/analytical parameter) if this can be

done by using the same testing technique for which the laboratory is already accredited. (e.g. change in sample preparation, clean - up procedure)

7) Requirements for laboratories with flexible scope of accreditation

To develop new or modified methods, a thorough technical understanding of the methods and techniques to be used is needed. This understanding can be achieved by taking part in relevant research or development projects, participating in method development projects or by having broad experience in the relevant testing field.

In addition to the general requirements for accredited testing, the laboratory shall extend and adapt its management system to take into account the size and complexity of the test category or categories (6.3.1 above) for which it intends to gain accreditation. The laboratory shall prove adequate reliability of its technical capacity to carry out tests within the full category, complying at all times with all the requirements of ISO/IEC 17025 and INAB Regulations.

Flexible accreditation scope can be achieved, at the earliest, in connection with the first reassessment visit (i.e. four or five years after initial accreditation).

7.1) The laboratory management system must comply with the following requirements in order to qualify for a flexible scope of accreditation:

- a) Management of the laboratory shall authorise technically competent individuals and assign key responsibilities in the management of the system, including the development and revision of testing methods, validation of methods, and authorisation to approve implementation of new or revised methods. These individuals shall be approved by INAB and all changes of the above key people shall be notified to INAB.
- b) The laboratory shall establish a validation strategy suitable to the extent and technical nature of the category or categories for which it requires a flexible scope of accreditation.

The laboratory shall establish the criteria for the acceptance of validation results, confirm that the method is suitable for the intended purpose, and document how it will inform the client of the results of the validation.

NOTE:

The above strategy may consist of a general validation procedure together with more detailed validation procedures for specific classification groups or parameters.

The laboratory could define, for example, different test categories, and establish different degrees of validation. In some cases, the validation would initially be more extensive in order to determine the characteristics of the method and it could require different degrees of partial validation should a new product be added to a group of products that have already been validated. Similarly, the extension of the analytical range of a method might require less extensive validation than was initially required.

7.2) There must be one person with overall responsibility for each individual validation job. The person in charge shall have documented experience of independent method development within the subject area in question and have theoretical and practical competence such that the individual concerned:

- a) can assess the suitability of the method, including fitness in relation to the customer's needs
- b) can draw up a specific validation plan
- c) can assess the performance of the method and draw up budgets for uncertainty of measurement.

Validation plans must be drawn up for any method change implemented within the flexible accreditation scope. Results from validation and verification shall be documented in a report. The report shall be certified by the party responsible for the validation.

7.3) The laboratory must record any changes within the flexible accreditation scope (a form of logbook). These records shall be comprehensive so that they allow internal and external audits to 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 show that all the actions required by the laboratory prior to approval were effectively put in place before the issue of test report(s).

The laboratory's records shall at a minimum cover,

- a) evidence of the activities carried out for the revision, adaptation and extension of the testing methods included in the flexible scope
- b) what the change entails
- c) whether the change is permanent
- d) from what date the change applies
- e) where appropriate, what job the change applies to, if it is not permanent
- f) the validation report
- g) name and position of the employee responsible for the validation
- h) evidence of authorisation to implement the tests
- i) staff training for key personnel

7.4) The procedure for the processing of requests, tenders and contracts shall contain the features applicable to a flexible scope of accreditation. In those cases where the laboratory has no established routine for the requested test the laboratory shall inform its client 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 validation procedures.

Accreditation for a flexible scope within any particular category implies a commitment by the laboratory to offer accredited tests within the extent of the category listed in the laboratory's scope. Therefore, generalised issue of unaccredited test reports within its scope may bring into question the laboratory's ability to provide this type of service.

7.5) The laboratory must establish a protocol describing the procedures to be followed on receipt of applications for tests that are within the range of the laboratory's flexible scope, but not previously carried out by the laboratory. Such procedure must ensure the laboratory complies with the following minimum requirements before it can claim accreditation for the test.

- a) All the necessary reference material, equipment and other means required for the completion of the specific requested test are available to the laboratory.
- b) Suitably qualified and experienced personnel are available for completion of the specific test(s).
- c) Responsibilities are assigned for each of the set activities.
- d) The necessary validation activities are carried out according to the procedures established by the laboratory.
- e) The relevant test procedure(s) are approved.
- f) The implementation of the new test(s) is authorised.

7.6) Should the validation process result in the conclusion that the laboratory is not capable of issuing accredited test reports, the laboratory must conduct a cause analysis and investigation and ensure that adequate corrective action is taken. Such actions shall include:

- a) Informing its client that while this investigation and any consequent actions are in progress, the laboratory will not be able to issue accredited reports for this test.
- b) Revision of the relevant procedures or method, should the reason be identified as a specific technical problem associated with the particular test.
- c) Maintaining a record of the occurrence of the problem and the details and conclusions of the investigation which the laboratory has carried out.

7.7) The quality assurance program for the test(s) must include both internal and external activities that represent all the individual tests included in the flexible scope of Accreditation.

- a) **Internal audits** of the system implemented to ensure the fulfilment of the requirements of this procedure, the implementation records and its effectiveness.

Procedures and plans of action for method development, revision and new development of test methods and associated responsibilities and risks must be continuously incorporated in the laboratory's internal audit.

- b) **Management reviews**, including the suitability and effectiveness of the system established to control the flexible scope.

8) Application for Flexible Scope

Only laboratories complying with the conditions established in clause 7 of this document and those fulfilling the following requirements within the testing category for which they seek accreditation, may qualify for a flexible scope of accreditation.

- a) The laboratory must have extensive experience in performance of specific tests that are sufficiently representative of the testing category for which they seek accreditation.
- b) The laboratory must have adequate experience in the development and validation of testing methods.
- c) The laboratory must be able to show acceptable results in its internal and external quality assurance control and in INAB assessments.
- d) The laboratory must have the specific measurement equipment in order to operate within the full testing category for which they seek accreditation.

9) Preliminary Evaluation Process

A laboratory that considers that it fulfils the requirements of clauses 7 and 8 above and wishes to apply for a scope of accreditation must present INAB with documentation to demonstrate the following:

- a) The laboratory's experience and competence in the testing category for which it intends to apply for accreditation, including a summary of the laboratory's previous experience in terms of the development and validation of testing methods within the proposed testing category. This summary should include a list of the products (matrices) and tests within the category applied for, that have been validated by the laboratory.
- b) The laboratory's experience in carrying out specific tests within the testing category for which a flexible scope of accreditation is being sought and indication of the annual number of analysed samples for each specific test.
- c) The internal and external quality assurance programmes carried out and planned for the specific tests within the category, including a record of the laboratory's performance in relevant proficiency testing schemes.

- d) A document setting out the laboratories justification of their requirement for a flexible scope of accreditation. This document must clearly show that the laboratory's fixed scope of accreditation is too rigid to effectively service the needs of the laboratory and its customers in the category in which a flexible scope of accreditation is sought and that these needs would be better served by a flexible scope of accreditation.

INAB will evaluate the documentation submitted and determine whether the classification category for which accreditation is being sought complies with the provisions of this document, whether in this case a flexible scope of accreditation best suits the needs of the laboratory and its clients and whether the laboratory's experience is adequate and sufficiently representative for the defined classification.

If at this stage, the laboratory's application is not accepted by INAB, it will be informed so that it can pursue its application for specific tests following the normal application procedure for extension to scope.

10) Application

If the laboratory's preliminary evaluation is successful, it will be informed by INAB and must complete the relevant application form for an extension of scope and accompany it with the following documentation:

- a) Documents describing the protocol of the laboratory for dealing with requests for tests that are within the category of the proposed flexible scope, but which have not previously been carried out by the laboratory.
- b) The validation protocol for the test category applied for and the associated validation procedures.
- c) The proposed test procedures
- d) The list of key personnel authorised to carry out the development, validation, revision, extension and authorisation of testing methods.

The application documents should reach INAB at least 3 months prior to the proposed visit date, which may or may not be a scheduled surveillance visit.

An examination of all the technical documentation provided, including those listed above, will be carried out before the assessment visit. Revisions or clarifications will be requested by INAB as deemed necessary.

11) Assessment Visit

INAB's assessment must be expected to require extra time for laboratories with flexible scope of accreditation. In the case of all regular visits, and when considered necessary, INAB will assess the laboratory's competence relative to the flexible scope.

During the visit, INAB will monitor the following activities:

The implementation of the management system.

The competence of the individuals who are responsible for the validation of methods implemented under flexible scope, including interview and CV reviews.

Specific examples of the tests carried out by the laboratory, both routinely and infrequently in each test category for which the laboratory has applied for a flexible scope. The selection criteria for the tests may depend on the level of complexity of the test technique, the frequency of use of the specific testing method, etc.

INAB will give the laboratory advance notice of the specific tests which will be examined. This notice will be given via the visit plan, which will be sent to the laboratory at least 2 weeks prior to the date of the arranged visit.

12) Presentation of Flexible Scopes of accreditation

Flexible Scopes of accreditation are presented in a similar fashion to that used for fixed scopes with the additional requirement that reference is made to the laboratories List of Additionally Accredited Tests (LAAT). An example of Laboratory's scope of accreditation which includes a flexible element for the analysis of trace metals in foods by HGA atomic absorption spectroscopy is shown below.

SCOPE OF ACCREDITATION

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
751 Foods* .01 Cereals and bakery products .02 Nuts and nut products, snacks .08 Fruit, jams and other fruit products	Lead 0.1 to 2 mg/Kg Cadmium 0.01 to 1 mg/Kg	In-house method 165H Atomic absorption, HGA
766 Waters .01 Waters for potable and domestic purposes	Ammonia 0.025 to 0.80 mg/l NH ₄ Nitrite 0.02 to 0.50 mg/l NO ₂ Nitrate 5 to 20 mg/l NO ₃	In-house method 105B Absorption Spectroscopy

***Flexible scope**

Additional foods may be added and ranges extended in accordance with the laboratory's approved and documented procedures. For details refer to the laboratory's List of Additionally Accredited Tests, available from the laboratory.

12.1) List of Additionally Accredited Tests (LAAT)

The LAAT is a document, controlled by the laboratory, which lists the additional tests for which the laboratory claims accreditation, but have not yet been added to the laboratory's scope of accreditation.

The LAAT is publicly available from the laboratory and has a similar format to the laboratory's published scope of accreditation. The LAAT contains the following:

Name and address of laboratory

Laboratory INAB registration number

Title: List of Additionally Accredited Tests (LAAT)

Reference to the current Edition of the INAB Schedule of Accreditation

The revision number of the LAAT

The matrices and INAB classification numbers (ref. P9) for which the laboratory has been authorised to apply a flexible scope of accreditation.

The group of tests or properties measured (e.g. trace metals, pesticides), and the list of additional tests within each group for which the laboratory claims accreditation via its scope.

The date on which the test, extension to range, material or product was added to the LAAT

The testing technique for each group of tests or property measured and reference to each corresponding test method.

Measurement ranges and/or limits of detection, whichever is applicable.

An example of a laboratory's LAAT showing an extension to the range for lead and the addition of Dairy Products to the LAAT is shown overleaf.

Testing Laboratory
123 Test Lane
Dublin

INAB REG No 999T

LIST OF ADDITIONALLY ACCREDITED TESTS

The accredited tests shown below are in addition to the Laboratory's published Scope of Accreditation, Edition 14, dated 17-5-2005.

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
751 Foods .01 Cereals and bakery products .02 Nuts and nut products, snacks .08 Fruit, jams and other fruit products	Lead 0.1 to 10 mg/Kg Extension of range (20/09/2005).	In-house method 165H Atomic absorption, HGA
751 Foods .03 Dairy products (added 06/10/2005)	Lead 0.1 to 2 mg/Kg Cadmium 0.01 to 1mg/Kg	In-house method 165H Atomic absorption, HGA

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13) Maintenance of accreditation

During surveillance visits the implementation and effectiveness of the controls established by the laboratory for the management of the flexible scope will be examined. The laboratory must provide evidence of maintaining technical competence and use of the established management system.

In addition to the requirements of PS 10, the laboratory must forward the following documentation to INAB 6 weeks prior to a proposed assessment or surveillance visit:

The LAAT

Full validation reports for all test or method changes made under the laboratory's flexible scope of accreditation since the last assessment or surveillance visit.

A summary document, in spreadsheet format, showing the extent of the validation performed for each method change. This document should record, at least:

- The method title and reference number.
- The date the change was authorised.
- The name, signature and title of the person authorising the change.
- A brief description of the change (e.g. "Cu added", "Range extended")

Which of the following method performance characteristics were or were not addressed in relation to the method change or modification:

- Repeatability
- Reproducibility
- Linearity
- Limit of detection or quantification
- Trueness
- Robustness
- Sensitivity
- Selectivity

In case where a particular performance characteristic listed above is not addressed, a justification for this exclusion must be given.

The approach to controlling a flexible scope of accreditation places the main responsibility for making and justifying decisions relating to the inclusion of new tests on the LAAT with the laboratory.

If INAB are satisfied that all additional tests have been added to the LAAT following appropriate validation and with proper implementation of the Laboratory's management procedures these tests are then added to the Laboratory's Schedule of Accreditation.

If it is discovered that a laboratory has not maintained its management system, or that controls have not been effectively implemented resulting in the inappropriate authorisation of tests, sanctions may be imposed on the laboratory by INAB. These sanctions may include:

The suspension of a specific testing activity or area from a scope of accreditation.

The revocation of the laboratory's authority to operate a flexible scope

The suspension of all accredited testing activities.

Any other measures INAB deems appropriate

14) References

- 14.1) EN ISO/IEC 17025: "General requirements for the competence of testing and calibration laboratories", 2nd edition, 2005.
- 14.2) EA-2/05: "The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing", EA, European co-operation for Accreditation, August 2001 rev. 02.
- 14.3) ILAC-G18: 2002: "The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing", ILAC, International Laboratory Accreditation Cooperation.

15) Contact

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

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