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A012



Management of fixed and flexible accreditation scopes

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1. Introduction

The aim of this appendix is to outline OLAS' policy for defining fixed and flexible accreditation scopes of laboratories accredited against ISO/IEC 17025 or ISO 15189 in accordance with the applicable standards and guidelines. The present document also defines the procedure applied by OLAS to manage auditing of fixed and flexible scopes, and provides sample drafts of such accreditation scopes.

2. Definitions

Laboratory:

Body which carries out clinical biology tests, calibrations or analyses.

Accreditation scope:

Description of the activities for which a body is accredited.

The description of the scope must be clear and unequivocal and wholly unambiguous, so as to provide a credible reference for the body's capabilities.

Depending on the needs of the laboratory, the accreditation scope may be of two types:

- Fixed scope:

Accreditation scope whereby the object submitted for testing/analysis/calibration, the characteristic or the property being measured and the method used (recognised or designed by the laboratory) may not be modified without a prior audit.

- Flexible scope:

In order to meet market requirements, the laboratory may be required to adapt or draw up new methods to analyse other objects or properties. Such modifications should be possible without prior audit. The laboratory's flexible accreditation scope shall allow for these modifications.

Recognised or reference method: ISO/IEC 17025 (§ 7.2.1 ~~5.4.2~~)

These methods are generally accepted by the relevant technical sector. They cover methods which are:

- Published in international, regional or national standards;
- Published by renowned technical organisations;
- Published in scientific texts or specialised journals;
- Described by manufacturer of the equipment or of the analysis kits and which formally recognised (certification from a recognised organisation, CE marking for clinical biology laboratories etc.);
- Imposed by the legislator within the framework of a regulation.

Internal method:

Method implemented by a laboratory for its own use or in order to meet client needs. This method may be derived from the modification of a recognised method or may be designed in its entirety by the laboratory.

Verification:


Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

NOTE 1 The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

NOTE 2 The activities carried out for verification are sometimes called a qualification process.

NOTE 3 The word "verified" is used to designate the corresponding status.

(ISO 9000:2015)

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~~Appendix A011 – Guide to check and validating testing and calibration methods in accordance with ISO/IEC 17025~~

~~Verification by the laboratory of its capacity to implement a recognised method.~~

Validation:

Confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

NOTE 1 The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

NOTE 2 The word “validated” is used to designate the corresponding status.

NOTE 3 The use conditions for validation can be real or simulated.

(ISO 9000:2015)

~~The laboratory shall validate non standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified the non-standard methods derived from the modification of a recognised method (used outside their expected application), or designed in their entirety by the laboratory, to confirm that they are suitable for the expected purpose. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory must record the results obtained, the operating procedure used for the validation, as well as a declaration concerning the suitability of the method for the intended use.~~

(ISO/IEC 17025 § ~~7.2.2.1~~ 5.4.5.1 and 5.4.5.2)

Measurement principle: derived from the VIM (2.4)



Physical, chemical or biological phenomenon which serves as a basis for testing, analysis or calibration.

Testing, analysis or calibration method: derived from the VIM (2.5)

Generic description of a logical organisation of operations used in testing, analysis or calibration.

3. References

- ISO/IEC 17025: General requirements for the competence of calibration and testing laboratories.
- ISO 15189: Medical laboratories. Specific requirements for quality and competence.
- EA-2/15: EA requirement for the accreditation of flexible scope.
- EA-4/02: Expression of the uncertainty of measurement in calibration.
- EA-4/17: EA Position Paper on the description of accreditation scopes of medical laboratories.
- ILAC-G18: 04/2010 Guideline for the Formulation of accreditation scopes for Laboratories.
- Appendix A011 - Guidelines for checking and validating test, ~~and calibration~~ and medical biology methods according to ISO/IEC 17025 and ISO 15189. (OLAS document)

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4. Policy

In accordance with standards ISO/IEC 17025, ISO 15189 and documents EA-2/15, EA-4/17 and ILAC-G18, OLAS applies a policy of promoting fixed and flexible scopes to laboratories to enable them to adapt quickly to the needs of the market. The fixed or flexible scope of a laboratory shall not depend on the number of people or on the extent of the accreditation scope. Each laboratory shall be responsible for the content of its accreditation scope, regardless of whether it is fixed or flexible.

~~Methods (fixed and flexible scopes):~~

~~In accordance with the requirements of the applicable standards and guidelines, accredited laboratories may use recognised methods, non-standard methods which are the product of adapted recognised methods, or methods that have been entirely designed by the laboratory. Their accreditation scope shall be defined according to the choices made to meet their needs.~~

4.1 Fixed accreditation scope:

Laboratories with a fixed accreditation scope may not amend this scope without first notifying OLAS. An application for extension must be made for all amendments to the accreditation scope (see *F001B - Accreditation application for laboratories*). A fixed scope can include standard and/or non-standard methods.

4.2 Flexible accreditation scope:

The flexibility of the accreditation scope does not depend on whether or not the methods used are standardised. It consists in the fact that laboratories with a flexible accreditation scope may amend this scope to meet the needs of the market or of a client, without having first to report to OLAS, and based on their own validation. Such amendments may only be made under certain conditions and must be validated by OLAS during the next surveillance or renewal audit. The degrees of freedom of the flexible scope may involve one or more of the following parameters:

- 1) Objects submitted for testing/analysis/calibration (e.g. extending research on the cadmium content of fruit to research on the cadmium content of cereals);
- 2) Characteristics or properties measured (e.g. extending the determination of the content of chromium in water to include other metals);
- 3) The method used for the testing, analysis or calibration (e.g. modifying a recognised method or designing a new method, replacing one method with another equivalent method which is already covered by the accreditation).

Appendix 3 gives more details concerning flexibility with regard to testing methods.

- 4) Performance of the method (e.g. variation in the performance of the method for one kind of object and one given parameter - modifying the scope of the measure and the uncertainty).

Be careful: Even with a flexible scope, the introduction of a new measurement principle or a new technical domain, which is not part of the original accreditation scope, is not allowed. In

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this case, the laboratory has to submit an application for scope extension to OLAS, in order that it may be covered by accreditation.

An accreditation scope may include both a fixed and a flexible part. OLAS is responsible for the expression of the accreditation scope and the acceptance of an application for a flexible accreditation scope. This type of application shall only be accepted after an audit has established the competence of a laboratory to manage this flexibility (e.g. staff competence, documented procedures etc.).

In order to display the granted flexibility, flexible scopes may be described in more general terms (see appendix 2). In addition, an explanation of flexibility is added below the scope, such as:

“The laboratory is proven competent to implement new test methods, objects submitted for testing and characteristics or properties measured. The possibility of introducing new methods does not include the introduction of new measurement principles.

The present scope is not exhaustive. An updated list of all objects submitted for testing, characteristics or properties measured and test methods under accreditation is available from the laboratory on request.”

5. Procedure for management of accreditation scopes

5.1 Processing of accreditation applications

5.1.1 Application for accreditation in fixed and flexible scopes:

A laboratory applying for a fixed or flexible accreditation scope must fill out the application form *F001B*, and return it to OLAS at the address indicated on the form. If a laboratory is applying for a flexible accreditation scope, it must clearly indicate this in its draft accreditation scope, which is available in the application form *F001B*.

In order for an accreditation to be granted, extended or renewed, the laboratory must send its draft fixed or flexible accreditation scope to OLAS using the form *F001B*. The draft scope shall list the fields in which the laboratory wishes to be accredited.

The accreditation scope drawn up by the laboratory includes the following parameters:

- The technical field (e.g. electricity, chemistry, mechanics, haematology);
- The objects submitted for testing/analysis/calibration (e.g. products, materials, samples, dies, equipment);
- The characteristics or the properties measured (e.g. voltage, nitrate content, determination of analyte concentration);
- The measurement principle (potentiometry, infra-red, colorimetry) and equipment (e.g. potentiometer, HPLC, optical microscope);
- The testing, analysis or calibration methods (e.g. recognised methods, methods designed in-house or methods adapted from recognised methods).

The accreditation scope may also, if applicable, refer to:

- The measurement range;

- The uncertainty of the measurement associated with the result or the Calibration and Measurement Capability (CMC).

After checking the draft scope, OLAS shall select a team which includes a lead assessor and competent auditors/technical experts to cover the accreditation scope proposed by the laboratory, in accordance with procedure *P002 - Performing audits and definitions*.

5.1.2 Switch from a fixed to a flexible scope:

A laboratory that has already a fixed scope accreditation, and that wishes to introduce some flexibility into its accreditation, has to make an application to OLAS using form *F001B* to identify the relevant activities. The progression from a fixed to a flexible scope is carried out using a surveillance or renewal audit, during which staff competence and the process for validating methods shall be checked.

5.2 Changes in the accreditation scope between two OLAS assessments:

<u>Change type</u>	<u>Fixed scope</u>	<u>Flexible scope</u>
<u>Evolution of a method</u>	<u>Allowed</u>	<u>Allowed</u>
<u>Change of an automated analyser (identical measurement principle)</u>	<u>Allowed</u>	<u>Allowed</u>
<u>Adding a new matrix</u>	<u>Not allowed</u>	<u>Possible (depending on the degrees of freedom granted)</u>
<u>Adding a new parameter</u>	<u>Not allowed</u>	<u>Possible (depending on the degrees of freedom granted)</u>
<u>Adding a new method</u>	<u>Not allowed</u>	<u>Possible (depending on the degrees of freedom granted)</u>
<u>Adding a new measurement principle</u>	<u>Not allowed</u>	<u>Not allowed</u>
<u>Adding a new technical domain</u>	<u>Not allowed</u>	<u>Not allowed</u>

5.2.1 Evolution of a method

In case of an accreditation according to standardised methods, the accreditation scope shall not mention the date of publication of the relevant standard. Generally speaking, the laboratory must implement the most recent version, except where a client has made an explicit request to the contrary.

When the modifications to the new version are insignificant with regard to the measurement principle, the laboratory must document the measures taken to handle the progression to the new version. This documentation shall be subject to specific examination during the following audit.

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Where the implementation of the new version of a standardised method involves significant modifications to the measurement principles, the laboratory must inform OLAS. An additional audit must be organised before this new method can be introduced in the laboratory's accreditation scope.

Case of laboratories which use extraction, purification or analysis kits, whether for manual methods or automatic equipment:

Where a laboratory replaces an analysis kit with another (evolution/ improvement of the method or use of an equivalent kit from another supplier), the laboratory must check the new kit. The laboratory must inform OLAS each time a kit is replaced. During the following audit, the technical auditor shall check the new method implemented by the laboratory.

5.2.2 Change of an automated analyser

Where the laboratory replaces an automated analyser with equipment that uses the same measurement principle, it must check the coherence of the results obtained compared to those obtained using the old equipment before the new automated analyser can be used to carry out analyses under accreditation. The result of the check is sent to OLAS, which forwards it to a technical auditor for approval based on a documentary audit. If the check is accepted by the auditor, the laboratory shall be authorised to publish the results obtained with the new automated analyser under accreditation. The conclusions of this assessment are recorded on the form F003Q – audit F003Q – documentary audit in order to validate a change of equipment.

Where the laboratory replaces an automated analyser with equipment that uses a different measurement principle, it must conduct a full check of the equipment and the associated methods before the new automated analyser can be used to carry out analyses under accreditation. The result of the check shall then be sent to OLAS, and OLAS shall then arrange an on-site audit, to verify whether the accreditation may be maintained.

5.3 Performing accreditation audits

5.3.1 Laboratory with a fixed accreditation scope:

The fixed scope accreditation of a laboratory is handled under procedure *P002 - Performing audits and definition*.



5.3.2 Laboratory with a flexible accreditation scope:

The flexible scope accreditation of a laboratory is also handled under procedure *P002 - Performing audits and definition*. Introducing flexibility into operation of the laboratory shall, however, require more in-depth checking of certain aspects.

List of accredited activities

When a laboratory, which is accredited according to a flexible scope, modifies its scope, it has to update in parallel the objects, characteristics and methods listed in the detailed accreditation scope that it manages.

This detailed scope, which shall be available to OLAS as well as any other interested party, shall take into account:

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- Updates of recognised methods;
- Modified and developed methods;
- Modified or developed methods which have been recently introduced.

Modified accreditation scopes will be updated on the OLAS website after the next audit.

Contract review

In case of a flexible scope, the contract review procedure shall detail how it processes a request which is within the boundaries of its flexible scope, but where the activity has not been undertaken before (i.e. not on the list). In such cases the laboratory needs to ensure the following:



- It informs the customer that it will not be able to issue a report/certificate under accreditation until the activities have been established and authorised within its system under its flexible scope process
- It informs the customer of the appropriate implications (e.g. turnaround time, price, etc)
- It has access to all necessary resources and other means required for the completion of the specific requested activity
- It has suitably qualified personnel for the completion of the specific activity and its validation or verification.
- The necessary validation or verification has been carried out
- Updating of the List is made only after appropriate technical activities have been properly performed as per the design and implementation process and duly authorised by the laboratory
- All premises of the laboratory involved in the additional conformity assessment activity have been previously declared to OLAS. An additional conformity assessment activity shall not be included in the list if it involves new premises of the laboratory that have not been previously assessed by OLAS.

Design and implementation process

The laboratory shall have a documented design and implementation process which needs to ensure the following:

- How it determines the input requirements
- How it develops the conformity assessment activity
- How it will verify/validate that it meets the requirements
- The responsibilities for the management of the flexible scope and for each set of activities
- The contract review process confirms and informs the customer/enquirer that a request is within the boundaries of its flexible scope
- Information on what is covered by accreditation is transparent and accurate

Should the validation process of an activity result in the conclusion that the laboratory is not capable of issuing valid reports/certificates, the laboratory must ensure that an analysis of the cause is carried out and that adequate corrective action is taken. Such actions will include:

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- To inform its customer that while the analysis and any consequent actions are being progressed, the laboratory will not be able to issue accredited reports/certificates and the reasons for this
- The revision of the relevant procedures or methods should the reason be specific technical problems for this particular activity, in order to resolve the problem identified and to ensure it does not happen again in the future
- Redefinition of the boundaries within which the scope is flexible. In this case, the laboratory shall inform OLAS in order to review whether the way that the accreditation scope is described must be modified


For this reason, the auditing team must:

- ~~Meet the staffs who carry out modifications and developments and who validate the methods, in order to assess their competence, roles and responsibilities. All the stages of method development and validation must be assessed before the laboratory can be accredited;~~
- ~~Before the laboratory is accredited, check that the procedures and recording system setting out the processes for modifying, developing and validating the methods are properly implemented. The list of "flexible" activities, as well as the management of how it is updated shall also be checked by the auditing team;~~
- ~~Check that the recordings and the data in the verification and validation files are available for consultation during audits. The same shall apply for the recordings of the periodical reviews of the methods modified and developed by the laboratory.~~

~~Checking and Validation of methods~~

~~Where the laboratory uses recognised methods, its capacity to implement these methods must be checked. If the laboratory uses methods that have been modified or developed in-house, they must, prior to accreditation, be validated before being added to the accreditation scope. The checking and validation process is set out in *Appendix A011* of OLAS. In particular, where a laboratory modifies or develops new methods, the audit must demonstrate that they have at their disposal:~~

- ~~A commitment from management to provide the resources necessary to manage the flexible scope;~~
- ~~Trained, qualified and experienced staff who are able to demonstrate their technical competence to modify, develop and validate methods;~~
- ~~A description of the roles and responsibilities of the people authorised to modify, develop and validate methods. A periodical review of the modified and developed methods must also be factored in;~~
- ~~Documented procedures which describe the process for modifying, developing and validating the methods referenced in the accreditation scope. Checking of additional methods shall also be taken into account in these procedures;~~
- ~~A recording system outlining the internal and external audit processes for modifying, developing and checking these methods. This documentary system must also take into account the updated activities list, outlined below;~~

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Handling of flexible accreditation scopes

5.3.3 Assessment of parameters added in the context of the flexible scope:

Laboratories have to send their detailed accreditation scope, including the updated list of objects, characteristics and methods, to OLAS during the preparation phase of any upcoming audit via the form F045 – Assessment preparation – laboratories. Parameters added during the year, within the context of the flexible scope, have to be assessed during the next audit. However, if the concerned domain is not planned to be assessed during the next surveillance, OLAS may plan a document audit rather than an on-site audit, depending on the extent and the complexity of the modifications.

Appendix 1: Sample draft of fixed scopes

Accreditation in accordance with standard ISO/IEC 17025 - Testing laboratory

General field: environment, health and hygiene			
Technical field: chemistry			
Objects submitted for testing (e.g. products, materials, samples, matrices, equipment)	Characteristics or properties measured	Measurement principle and equipment (e.g. manual or automatic measurement)	test methods (e.g. published, adapted, checked internally)
water: potable water, surface water, drinking water, underground water, wastewater	pH	potentiometry	ISO 10523
water: potable water, surface water, drinking water, underground water, wastewater	carbonate hardness (total and composite alkalinity)	titimetric analysis	ISO 9963-1

Accreditation in accordance with standard ISO/IEC 17025 - Calibration laboratory

General field: Calibration				
Technical field: Electricity				
Objects submitted for calibration	Characteristics or properties measured	Calibration methods (e.g. published, adapted, checked internally)	Measurement range	Calibration and Measurement Capability (CMC) Expanded uncertainty (k=2)
Voltmeters	Direct current potential difference	Comparison with the comparator f = 45–60 Hz	0 mV–320 mV	$60 \cdot 10^{-6} \cdot U + 9.6 \mu V$ U = Value measured
Ammeters	Alternative current carrying capacity	Comparison with the comparator f = 45–60 Hz	0–320 μA	$0.14 \cdot 10^{-3} \cdot I + 54 \text{ nA}$ I = Value measured

Accreditation in accordance with standard ISO 15189 - Medical laboratory

General field: Clinical biology			
Technical field: biochemistry			
Objects submitted for analysis (e.g. products, materials, samples, matrices, equipment)	Characteristics or properties measured	Measurement principle and equipment (e.g. manual or automatic measurement)	test methods (e.g. published, adapted, checked internally)
Blood and blood products or urine	Uric acid	Colorimetry ABBOTT C16000 (automated method)	Corresponding kit
Urine	Albumin	Immunoturbidimetry ABBOTT C16000 (automated method)	Corresponding kit

Appendix 2: Sample draft of flexible scopes

Accreditation in accordance with standard ISO/IEC 17025 - Testing laboratory

General field: environment, health and hygiene			
Technical field: chemistry			
Objects submitted for testing (e.g. products, materials, samples, matrices, equipment)	Characteristics or properties measured	Measurement principle and equipment (e.g. manual or automatic measurement)	test methods (e.g. published, adapted, checked internally)
Drinks	Determination of the Acesulfame K, aspartame and sodium salt saccharin content	HPLC – FLD	LMBG 00.00-28

The laboratory is considered capable of realising tests on several types of drinks in the field described in the accreditation scope. The laboratory is responsible for the management of the list of drinks it is analysing within the framework of this accreditation.

General field: environment, health and hygiene			
Technical field: chemistry			
Objects submitted for testing (e.g. products, materials, samples, matrices, equipment)	Characteristics or properties measured	Measurement principle and equipment (e.g. manual or automatic measurement)	test methods (e.g. published, adapted, checked internally)
water: potable water, surface water, drinking water, underground water, wastewater	Assay of total elements	Assay of elements chosen by ICP-OES	ISO 11885

The laboratory is considered capable of analysing the components defined in the standard referenced in the accreditation scope. The laboratory is responsible for the management of the list of elements it analyses.

General field: environment, health and hygiene			
Technical field: chemistry			
Objects submitted for testing (e.g. products, materials, samples, matrices, equipment)	Characteristics or properties measured	Measurement principle and equipment (e.g. manual or automatic measurement)	
water: potable water, surface water, drinking water, underground water, wastewater	carbonate hardness (total and composite alkalinity)	titimetric analysis	

The laboratory is deemed competent at adapting and implementing recognised methods as well as methods designed by it. The laboratory is responsible for the validation of the methods it implements. The laboratory is also responsible for the management of the list of methods it uses.

Accreditation in accordance with standard ISO 15189 - Medical laboratory

General field: medical			
Technical field: Biochemistry			
Objects submitted for analysis (e.g. products, materials, samples, matrices, equipment)	Characteristics or properties measured	Measurement principle and equipment (e.g. manual or automatic measurement)	analysis methods (e.g. published, adapted, checked internally)
EDTA peripheral blood	Identification of a membrane antigen	Flow cytometry FACSCALIBUR	immunological method

The laboratory is considered competent to adapt and implement recognised methods or non-standard methods (which are the product of recognised methods which have been modified or designed by the laboratory). The laboratory is responsible for the validation of the methods it implements. The laboratory is also responsible for the management of the list of methods it uses.

The accreditation scopes outlined above are general scopes with no detail as regards the objects, properties or testing methods for the performance of which the laboratory is recognised as competent.

The laboratory must document a detailed accreditation scope covering all of the parameters for which it has been considered competent. This accreditation scope must be made available (and must remain available) to OLAS.

Appendix 3: Flexibility at the level of methods

Flexibility at the level of methods allows the introduction of new methods in the accreditation scope, provided that they belong to a measurement principle for which the laboratory is:

- already accredited **and**
- accredited according to a flexible scope.

Examples of methods grouped in different measurement principles:

Measurement principle	Test methods
ELISA and related immunoassays	ELISA, ELISA – DOT, CMIA, RIA, FEIA, CLIA, ELFA.
Light microscopy	Bright field microscopy after staining, Phase-contrast microscopy, Thick film microscopy.
Flow cytometry	Cell count and classification, Cell count after staining with a specific fluorochrome, Immunophenotyping.
Agglutination tests	Treponema pallidum particle agglutination assay, VDRL flocculation test, Waller-Rose test, Latex agglutination test, Slide agglutination test.
Antimicrobial susceptibility test	Broth dilution tests, Liquid medium micro-method, Solid media methods, Disk diffusion test, E-test.
Real-time PCR	TaqMan method, SYBR Green method, “molecular beacon” method.