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1- Object : this document is aims to:

- Present ALGERAC's policy regarding the definitions of fixed and flexible accreditation scopes for testing and calibration laboratories.
- Define the evaluation modalities for fixed and flexible scopes.

2- Scope:

This document applies to laboratories, accredited or applicant for accreditation, according to ISO/IEC 17025 standard.

Also concerned with the application of this document are ALGERAC's technical structure personnel, and ALGERAC's assessors, experts and committee members.

3- References

- ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories,
- ISO/IEC 17011: Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies
- EA-2/15: EA requirements for the accreditation of flexible scopes,
- ILAC-G18:4 Guidelines for the formulation of accreditation scopes for laboratories.

4. Definitions:

4.1 Accreditation scope:

Specific conformity assessment subject activities for which accreditation is requested, or has been granted.

Depending on the needs of the laboratory, accreditation scope may be fixed or flexible:

- ✓ **Fixed scope:** an accreditation scope for which the item subject to testing/analysis/calibration, the characteristic measured or sought after as well as the method (recognized or non-recognized with the current version) can in no way be modified without prior evaluation by ALGERAC.

- ✓ **Flexible scope:** an accreditation scope which is established in such a way that it is possible for laboratories to modify the methodology and other parameters consistent with their competence as attested by ALGERAC.



4.2 *Known or reference methods: those refer to the methods described below:*

- methods published in international, regional, or national standards,
- methods published by renowned technical bodies,
- methods published in scientific publications (texts, specialized scientific journals, volumes),
- methods provided by the equipment or analysis kit manufacturer, and recognized by a third party (certified by a recognised body, or CE-mark),
- Methods imposed, described, or referenced in a regulatory text.

4.3 **Non-recognised methods:**

Methods implemented and intended to be used by the laboratory, or meeting customers' needs. Those methods may be the result of the modification of a recognized method (standardized method used outside its scope of application, a recognized method which is adapted, supplier's instructions that are not recognized by a third party), or entirely developed by the laboratory. Within the accreditation scope, those methods are referred to as « **internal methods** ».

4.4 Adopting a method: implementing and applying a recognized method without modifying it.

4.5 Adapting a method: modifying a method with the aim of meeting a laboratory's or customer's needs.

4.6 Developing a method: : Designing a new method.

4.7 Validating a method : Ensuring the specified requirements are good for a determined use of the method.

5. **Policy:**

As required by the standard ISO/IEC 17025, and by EA-2/15 and ILAC G18 documents, ALGERAC's policy is based on choosing fixed scopes and flexible scopes when dealing with laboratories in order to make it possible for them to adapt to their customers' needs and the market development.

No matter which scope the laboratory may choose (fixed or flexible), the latter is responsible for the content of its accreditation scope.

5.1 **Method implementation requirements:**

- Prior to using a recognised method, the laboratory shall make sure it masters it in its own environment with regard to criteria and allowable limits it has previously set.
- The lab shall validate a non-recognised method prior to using it.

I. **Management and formulation of scopes for testing and calibration laboratories**

- 1- **Fixed scope:** for this kind of scope, the laboratory seeks accreditation for a defined list of activities associated to methods (recognised and/or non-recognised previously validated by the laboratory).

Laboratories accredited to fixed scopes are **not allowed to change their accreditation scope without previously notifying ALGERAC about it**. Any change in the scope shall be the subject of a request for an extension.



Referencing a recognised method: this is done through the identification of its version accompanied with the following indication :

« Fixed scope : the laboratory is acknowledged as technically competent to carry out the recognised methods which are described in the accreditation scope by strictly complying with them.»

Non-recognised methods: referencing of the internal method (example : operating mode) is done through the identification of its version accompanied with the following indication :

« Fixed scope : the laboratory is acknowledged as technically competent to carry out testings/calibrations/samplings by strictly complying with the methods cited in the accreditation scope. No technical changes can be made to the method.»

Applying for this scope: the laboratory shall provide ALGERAC with the elements supporting the validation of the non-recognised method in order to have its request processed prior to on-site assessment.

2- Flexible scope: Laboratories accredited to flexible scope are allowed to change their accreditation scope to meet the market's or customers' needs without having to previously report this to ALGERAC, and on the basis of their own validation. Those changes are possible under some conditions, and shall be subject to ALGERAC's approval during the following surveillance or renewal assessment.

The degree of freedom of a flexible scope is defined according to the following types :

- *Adopting successive reviews of recognised methods (Flexibility A),*
- *adopting new recognised methods, or using new non-recognised methods (Flexibility B),*

Hence, when a laboratory designs its scope project, it behoves to it to define the desired type of flexibility by having the possibility to choose several types within the same accreditation scope (fixed and/or Flexible A and/or Flexible B).

2.1 Flexible A scope: The laboratory may routinely take ownership of the successive reviews of a recognised method and apply them under accreditation without assessment nor a previous decision made by ALGERAC as long as the method content remains in adequacy with the scope descriptions ;

Reviews made to the recognised methods described in the accreditation scope shall not lead to new competences (to comply with the method principle) for which the laboratory has not been initially evaluated.

The references of the recognized methods provide no review indication.

The scope, which is formulated in the technical annex of the accreditation certificate of the laboratory, is accompanied with the following note:



« **Flexible Scope A: the laboratory is acknowledged as competent to carry out testings/calibrations/samplings, by complying with the referenced methods and their later reviews.** »

So as to be accredited according to this type of scope, the laboratory shall have a documented procedure which clearly defines the different steps to follow and the associated responsibilities, as long as it identifies the review of a recognized method in its accreditation scope until the use of the revised method, under accreditation, is allowed.

It shall consider the records of each step carried out in this procedure.

During the following assessments (depending on the accreditation cycle), the assessing team examine the conditions in which the review of the method of the accreditation scope has been allowed under accreditation.

The assessing team shall, as well, examine the following:

- ✓ Watch and confirmation aspects with regard to the mastery of the methods prior to being allowed to be used under accreditation
- ✓ The internal audit plan and management review covering this process.

2.2 Flexible scope B: The laboratory requests being accredited for a defined competence area which it undertakes using **recognized or non-recognized methods**, but without establishing a detailed list of those methods.

The laboratory has the right to adopt equivalent standards, or extend its accredited activity to new standards established after accreditation has been awarded, while remaining in adequacy with its scope of accreditation.

Such flexibility of scope includes the possibility to develop methods, adapt existing methods, or adopt new non-recognized methods and use them under accreditation without previous evaluation by ALGERAC, as long as evidence that they are validated and mastered can be provided.

For a calibration laboratory, Flexible scope B can as well be applied to method performance (type of object subject to calibration, measuring and uncertainty scope), if the laboratory has a process in place to apply it to the performance of the method covered by the scope of accreditation.

For this type of flexibility, the scope expressed in the technical annex of the accreditation certificate of the laboratory is accompanied with the following note:

« **Flexible scope B : the laboratory is acknowledged as competent, in the area covered by the accreditation scope, to adopt any recognized method and to develop or implement any other method, the validation of which it shall ensure.** »

To apply for this type of flexibility, **the laboratory shall have a documented procedure** which specifies the steps to follow right from the moment when it identifies a recognized method which is likely to be included into its accreditation scope until the method in question is allowed to be used under accreditation; **it shall, as well, have a documented procedure** which specifies the design and the validation of the methods, needs identification until the use under accreditation of the method, developed or implemented, is allowed.

It shall have defined the associated responsibilities, and scheduled to keep records of the application of these previous measures.



In preparation of the on-site evaluations of the accreditation cycle and upon ALGERAC's request, the laboratory shall establish a report of the methods it has adopted and/or developed since the previous visit.

During the evaluations of the accreditation cycle, the evaluating team shall examine the following :

- ✓ The conditions under which the use under accreditation of the method has been allowed (examination and evaluation of the records corresponding to the validation, use review and authorization).
- ✓ The internal audit plan and management review, and ensuring they cover these processes.
- ✓ The clarity of information conveyed to laboratory's customers with regard to the offering of the accredited services.

II. Obligations linked to flexible scope

The laboratory has the responsibility to implement an organization and controls which will ensure that the introduction of new methods (or new method versions) in its flexible scope is mastered.

In case it turns out that the laboratory has failed to meet its obligations, ALGERAC shall make a decision adapted to the extent and seriousness of the situation.

This depends on the nature, implications, and frequency of non-conformities and may consist of actions such as :

- ✓ reduction of the type of flexibility (reformulating the accreditation scope) ;
- ✓ Suspension of accreditation for the activity scope concerned with non-conformities (see PRO 23: Procedure of suspension, reduction, and withdrawal of an accreditation);
- ✓ Complete suspension of the accreditation awarded (see PRO 23)

The decision may include the reminder of testing/calibration reports duly issued with reference to accreditation, and/or explicit information on the affected customers.

Moreover, the laboratory has the duty to keep the detailed scope updated in real time, and convey it to ALGERAC following each development.

III. Publication of scopes

Accreditation certificate refers to the technical annex which details the laboratory's accreditation scope by specifying the flexibility type.

The current version is accessible on ALGERAC's website ([www .algerac.dz](http://www.algerac.dz)).

General Director

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IV. Annex

Example of formulating fixed and flexible accreditation scope for testing laboratories.

I. Fixed scope

Example 1: Testing laboratory/Civil engineering area

Area:Civil engineering/Geomaterials			
Testings on materials « concrete and ciment »			
Object	Measured or sought characteristics	Method principle	Method reference
Hardened concrete test tube	Resistance to compression	Measuring of resistance in compression of a test tube subject to an increasing load until breakage.	NF EN 12390-3 : 2012
Ciment	Determining the setting time	Measuring with a Vicat tester of a needle penetrating ciment paste of standardised consistency.	NF EN 196-3+A1 : 2009

Fixed scope: «The laboratory is acknowledged as competent to carry out the recognized methods described in the accreditation scope by strictly complying with them.»



Example 2: testing laboratory/Materials engineering area

Materials engineering area / Metallurgy			
Chemical testings on metallic materials			
Object	Measured or sought characteristics	Method principle	Method reference
Brass alloy	Determining the percentage(%) of chemical elements	Optical emission spectroscopy	Supplier's method
Weakly alloyed steels	Determining the percentage(%) of chemical elements	Optical emission spectroscopy	Supplier's method

Fixed scope : « The laboratory is acknowledged as competent to carry out testing in by strictly complying with the methods mentioned in the accreditation scope. Technical changes are not allowed to be made to the method.»



II. Flexible scope:

➤ Flexible scope A

Example 1: Testing laboratory/Agricultural science area

Agricultural science area / Phytotechnical			
Physical and physiological testings			
Object	Measured or sought characteristics	Method principle	Method reference
Self-pollinated cereals seeds	Species purity	Seed sorting and species identifying	ISTA standards Chapter 3
Self-pollinated cereals seeds	Reduced and limited count	Identifying and counting seeds of other species in the sample	ISTA standards Chapter 4

« The laboratory is acknowledged as competent to carry out testing by complying with the referenced methods and their later changes.»



Example 2: Testing laboratory/Petrochemical area

Petrochemical area / Petroleum refining			
Physiochemical analysis of petroleum products			
<i>Object</i>	<i>Measured or sought characteristics</i>	<i>Method principle</i>	<i>Method reference</i>
Commercial gasoil	Pensky-Martens flash point (°C)	Measuring the lowest temperature at which vapor emitted from a product contained in a closed cup and gradually heated ignites in presence of flame .	ASTM D93
Commercial gasoil	Volume fraction of a product distilled at a given temperature (% V/V at °C)	. Distillation at atmospheric pressure of a test sample	ASTM D86

« *The laboratory is acknowledged as technically competent to carry out testing by complying with the referenced methods and their later changes.*»



➤ Flexible scope B

Example: Testing laboratory/Veterinary science area

Veterinary science area/ Zoonoses			
Animal immunoserology testings			
Object	Measured or sought characteristics	Method principle	Method reference
Sérum Serum	Anticorps dirigés contre le virus de l'Influenza Antibodies to influenza virus	HI-test	- Internal method XX 01 - (Kit providerXX)
Serum	Antibodies to infectious bovine rhinotracheitis virus	ELISA	- Internal method XX 03 - provider XXXX)

Flexible scope (B) : « The laboratory is acknowledged technically competent to adopt any recognised method in the area covered by accreditation scope, and develop any other method the validation of which it shall ensure. The exhaustive list of the methods proposed under accreditation is updated by the laboratory.»



Example of formulating fixed and flexible accreditation scopes for calibration laboratories

Example of fixed scope

<i>Item subject to calibration</i>	<i>Measurand</i>	<i>Measuring range</i>	<i>MCC (Measuring and calibration capacity) (k=2)</i>	<i>Measuring principle Method reference</i>	<i>Means of calibration(equipment, measuring standard)</i>	<i>Laboratory (L) and/or on-site performance (S)</i>
Analog manometer	<i>Pressure</i>	<i>0,2MPa to 5,5MPa</i>	$\pm 1,2 \cdot 10^{-4} \cdot Pr + 8 Pa$	<i>Calibration by comparison (DKD-R 6-1) / 2014</i>	<i>Pressure compensator</i>	<i>L</i>

Fixed scope : « The laboratory is acknowledged as competent to carry out testing in by strictly complying with the methods mentioned in the accreditation scope. Technical changes are not allowed to be made to the method.



Example of flexible scope

<i>Item subject to calibration</i>	<i>Measurand</i>	<i>Measuring range</i>	<i>MCC (Measuring and calibration capacity) (k=2)</i>	<i>Measuring principle méthode Method reference</i>	<i>Means of calibration, measuring standard)</i>	<i>Laboratory (L) and/or on-site performance (S)</i>
<i>Analog manometer</i>	<i>Pressure</i>	<i>5kPa to 65kPa</i>	$\pm 27 \text{ Pa}$	<i>Calibration by comparison (DKD-R 6-1) / 2014</i>	<i>Pressure compensator</i>	<i>L</i>
<i>Digital pressure gauge</i>	<i>Pressure</i>	<i>0,2MPa to 5,5MPa</i>	$\pm 1,2 \cdot 10^{-4} \cdot Pr + 8 \text{ Pa}$	<i>Calibration by comparison (DKD-R 6-1) / 2014</i>	<i>Pressure compensator</i>	<i>L</i>