FLEXIBLE SCOPE FOR LABORATORIES PERFORMING OFFICIAL PLANT TEST DIAGNOSIS

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INTRODUCTION

The scope of accreditation of a laboratory is the formal and precise statement of the activities which the laboratory is accredited for.

Contains combination of information (scope parameters) concerning the field of activity (e.g. testing, calibration), the product/object tested or calibrated and the methods and procedures used.

The assessment of the scope of accreditation represents the core of the accreditation process and may be defined as the set of operations carried out by the Accreditation Body in order to ensure, with an adequate degree of confidence, that the laboratory has the competence to provide reliable services within the defined scope.

THE FLEXIBLE SCOPE CONCEPT

Accredited laboratories may be allowed to modify their own laboratory-developed methods or to use up-dated versions of standard methods and standards they are accredited for and to introduce similar new methods without having to report to the Accreditation Body in advance, provided that these modifications and up-dated versions or new methods do not incorporate new measurement principles that are not covered by the original description of the scope.

The flexibility of a laboratory in this respect is described by a flexible scope.

Conventionally, the scope of accreditation is described using a fixed list of all methods/ calibration or examination procedures which the laboratory can use when referring to accredited status. This list is usually an annex to the certificate of accreditation and gives the details in the scope of accreditation.

Granting a laboratory a flexible scope provides the possibility of describing major sub disciplines of the laboratory activities in a more general form. The laboratory must anyway retain a current list of methods covered by accreditation including newly modified, introduced or developed methods.

THE FLEXIBLE SCOPE CONCEPT

For the Accreditation Body, it provides a means for better service to the laboratory, less administrative work, more time to concentrate on technical aspects of accreditation, and fewer unexpected surveillance visits for enlarging or modifying the scope of accreditation.

For the laboratory, it allows in-time adaptation of their methods to the needs of new products, manufacturers and conformity procedures, as well as to the technology involved.

The term “flexible scope” is not restricted solely to scopes that are flexible in their entirety. It is also relevant to scopes that include a combination of fixed and flexible methods, or even for primarily fixed scopes that, for example include one or two flexible or generic activities. In some cases it may be best to define the scope by defined activities; in other cases it may be better to use the techniques applied and the (technical) field covered by the body. Sometimes different ways may be combined.

ILAC G18 *(UNDER REVISION)* DOCUMENT/ TYPES OF FLEXIBILITY

Flexible scope can be established based on degrees of freedom for flexibility such as:

- Flexibility concerning object/matrix/sample This means flexibility that allows for changes with respect to various products (e.g. change in matrices) within a product area
- Flexibility concerning parameters/components/analytes This means flexibility that allows for changes with respect to parameters.
- Flexibility concerning the performance of the method This means flexibility that allows for changes in the performance of the method for a given specimen type and a given parameter. This includes for example, the modification of measuring range and uncertainty.
- Flexibility concerning the method This means flexibility which allows adoption of methods that are equivalent to methods already covered by accreditation.

ILAC G18 DOCUMENT /ASSESSMENT OF FLEXIBLE SCOPE

When assessing flexible scopes of accreditation, the focus of the assessment of the laboratory's management system should be on the implementation of the validation and/or verification procedures and the monitoring activities related to their implementation e.g.:

review of requests,

tenders and contracts,

management review,

internal audits,

personnel competence and authorities,

measurement uncertainty estimations,

equipment and measurement traceability,

proficiency testing activities and internal quality control.

Particular attention should also be given to the appropriateness of claims of accreditation status with regard to previously un-assessed activities under the flexible scope of accreditation

EA 2/15 DOCUMENT

CONSTRAINTS

ABs shall retain the right to decide how to define the scope and whether or not to grant a flexible scope to a particular CAB.

ABs shall not allow the principle of flexibility to enable a CAB to move, under accreditation, into a new field of accreditation covered by a different accreditation standard or outside the defined boundaries of the flexible scope without normal full assessment by the AB

EA 2/15 GENERAL CONSIDERATIONS

The differing needs of CABs means that there is no single way of implementing flexible scopes. Instead, it is the responsibility of each CAB to determine exactly what its requirements are, how it can approach this within the framework of the standard used for accreditation, and how it can demonstrate to its AB that this approach is fit for its intended use and capable of being maintained within control.

The technical capability for a CAB to manage itself within a flexible scope becomes the key to introducing flexible scopes. The CAB's design process needs to address how the body determines the input requirements, how it develops the conformity assessment service, how it will verify that it meets the requirements, and how it validates that it has met the requirements.

Accreditation of a flexible scope places more of the responsibility onto the CAB itself for demonstrating that the way that it operates is valid, fit-for-purpose, and is undertaken competently and consistently.

EA 2/15 GENERAL CONSIDERATIONS

CABs will have to devote adequate time to explain to potential customers the boundaries of their accredited scopes, and this may require ABs to spend more time examining contract reviews during assessments. On the other hand, even though it is not the intent of flexible scopes, a CAB may see holding a flexible scope as a overt sign that it is perhaps more competent than a body that operates with a fixed scope.

ABs may, therefore, need to discourage CABs from implying or claiming that a flexible scope implies a greater level of confidence for an accredited activity as there should be no difference in the outcomes of activities specified individually in a scope of accreditation, and the same activities conducted within a flexible scope.

A flexible scope is a reflection of the competence of the CAB, not just technically to carry out activities covered under the accreditation, but also its ability to manage the process of having a flexible scope and its commitment to offer accredited activities within this scope

DISCUSSION

Areas where a flexible scope was given long before the issue was mentioned

Pharmaceutical analysis

Doping control

Pesticides

Horizontal methods

ACCREDITATION PROCEDURE

Prerequisites

Who is reviewing the application

When it is decided that is about a flexible scope?

How to affect the surveillance-re-assessment process

Administrative issues (List of accredited activities. Multi site accreditation)

Other AB policies- PTs, traceability,multi-site procedure

LABORATORY PROCESS DESIGN AND IMPLEMENTATION

Procedure, authorities, responsibilities

Link to personnel's procedure, contract review procedure and other elements of QM system

Technical Files documentation

Review of resources

Review of competence and criteria for selection of personnel

Determination of validation criteria/SOPs/fitness for purpose

Review of needs,relative criteria, regulation, existence of QC schemes

Uncertainty estimation

Use of equipment

LINK TO OTHER POLICIES

Appropriateness of PT schemes

Flexibility of current IQ scheme

Fitness for purpose for RMs- what about traceability?

Commutability of RMs already used

In house RMs

REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Article 37

5. The scope of the accreditation of an official laboratory :

…..c) may be defined in a flexible manner, so as to allow the scope of accreditation to include modified versions of the methods used by the official laboratory when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratory's own validations without a specific assessment by the national accreditation body prior to the use of those modified or new methods…..

But also, some derogations from the condition for mandatory accreditation in article 41 of the regulation

LABORATORIES PERFORMING OFFICIAL PLANT PEST DIAGNOSTICS

Need for flexibility was communicated to EA on 2015 and a discussion paper was sent. ABs representatives in EA/LC TN Food and Feed commented on that.

Main issue concerning the need for flexibility:

Diversity of pests and pest/host matrices and possible combinations and consequences for validation

Are any issues that the flexible scope approach cannot solve?

- **Level of validation**
- **Lack of reference materials**
- **Appropriateness of PTs**
- **Accreditation of diagnosis**

DIVERSITY OF PESTS AND PEST/HOST MATRICES AND POSSIBLE COMBINATIONS AND CONSEQUENCES FOR VALIDATION

The flexible scope accreditation does not mean that a lower level of validation can be accepted. For example, less repetitions for the assessment of performance criteria, or transfer of repeatability and reproducibility of a methodology technique to combinations of analyte/matrix.

The harmonization and the establishment of performance criteria for the validation can be done through other ways.

- **Discussion on the guidance given in specific EPPO standards**
- **Similar approach with other fields**

DIVERSITY OF PESTS AND PEST/HOST MATRICES AND POSSIBLE COMBINATIONS AND CONSEQUENCES FOR VALIDATION

Examples of situations where the need for flexible scope may arise are:

-Optimisation of a given test after validation/verification

-Modification of an existing test to broaden its applicability (e.g. to deal with new matrices) after validation

-Inclusion of a test equivalent to the one that is already covered by accreditation after validation

-application of an already accredited test to a new set of pest/host matrices after validation

Question: Can the flexible scope approach differentiate the requirements of validation in each case?

No, the flexible scope approach only differentiates the way this change of competence is assessed by the AB

NON-AVAILABILITY OF PROFIENCY TESTS, LACK OF RMS

The EPPO considerations related with PTs lack of RMs are equivalent to other type of tests and ABs commented that there is no need to implement a specific approach in the framework of a flexible scope in plant health.

Need to cover for requirements for traceability and appropriate external and internal control are the same for flexible and fixed scope so the discussion should be transferred in another level.

ACCREDITATION OF DIAGNOSIS

In The choice the diagnostic process the diagnostician determines the cause of a disease by selecting the relevant tests and interpetation of the results of these tests

of tests is based on expert judgement and the role of diagnostician puts high demands on his/her expertise and experience. Regarding the diagnostic activity, ABs comments were about:

the need to consider two different cases of "diagnosis":
- Testing for diagnosis purposes : this is the answer to the question "we know the symptom, it is caused by such a pest or not". This is what is currently assessed (laboratory test and concluded)
-"real" diagnosis (diagnosis of unknowns), much more complex and which is based on expertise.This type of diagnosis can not be treated by flexible scopes. Whether is inside or outside the scope of ISO/IEC 17025 it is a discussion need to be made under the concept of opinions and interpretations (EA-INF/13 : 2015 *under revision*) for expertise need to interpret the results and contract review ISO/IEC 17025 requirements for xpertise needed to choose methods appropriate the scope of testing