ETHIOPIAN ACCREDITATION SERVICE	**Guidance on the Application of Flexible Scopes for Laboratory Accreditation**	**Copy No.** **Page 1 of 14** **Document No. GD07/02** **Rev No. 1.3** **Effective date 2023-02-07**

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1. Purpose

The purpose of this guideline is to establish EAS's policy, process and guidance on assessment and accreditation of laboratories wishing to implement and maintain a management system capable of controlling a flexible scope of accreditation within the boundaries of ISO/IEC 17025 and ISO 15189 as outlined in ILAC G18.

For the purposes of this document the phrase 'flexible scope' is used throughout and refers to a scope which is flexible within pre-determined boundaries and where the laboratory has a management system capable of effectively validating the application of the method or technique to be used within different parameters, for instance on a different matrix, substrate, product, etc. within a short period of time.

2. Scope

This guidance 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 include one or two flexible or generic methods.

2. References

ISO/IEC 17011:2017 Conformity Assessment – Requirements for accreditation bodies accrediting conformity assessment bodies;

ILAC G18**,** Guideline for the Formulation of Scopes of Accreditation for Laboratories

3. Overview

3.1. There are certain laboratories such as contract test laboratories and possibly Research & Development laboratories where the need arises where the laboratory needs to modify a method or the application of the method in while at the same time maintaining accreditation status in order to satisfy customer requirements. Although applications for an extension to fixed scopes can be made at any time throughout the assessment cycle, the timescales involved may actually prevent tenders or contracts being met within a client's timeframe. The concept of flexible scopes was therefore introduced by ILAC to allow those laboratories that have the necessary resources to effectively re-validate a method within specified boundaries in order to meet their customer requirements. Such arrangements would by their very nature be geared towards high-value requirements since the application of such resources to re-validate a method for a specific customer

or contract would need to be cost effective for the laboratory.

3.2. Flexible scopes of accreditation can allow a laboratory to undertake certain tests/calibrations, and to report the results as accredited, even though they may not be explicitly stated on their accreditation scope. This may involve the:

a) inclusion of new or amended tests in accordance with a method described by a standard or well validated
b) modification of existing methods to broaden their applicability, e.g. to deal with new materials tested or properties measured, etc; and
c) Inclusion of newly revised or technically equivalent standard methods that are already covered by accreditation
d) Change in confidence level (uncertainty)

3.3. Accreditation of a flexible scope places more of the responsibility onto the laboratory itself for demonstrating that valid, fit-for-purpose tests are undertaken competently and consistently. However, this does not mean that a laboratory can then undertake any test that is requested of it by a client. The boundaries within which the scope is flexible must be clearly defined, with the laboratory demonstrating to EAS that it has the knowledge, experience, competence and resources to work within the full range of its flexible scope, as well as possessing suitable laboratory environments and equipment. These boundaries should be set with respect to the range of the:

a) materials/products tested;
b) field of test,
c) properties/parameters measured;
d) Measurement being performed;
e) equipment/techniques used and
f) uncertainty

3.4. Where a laboratory wishes to apply for a flexible scope of accreditation it must demonstrate that it has a management system in place that can control its proposed approach whilst continuing to comply with the requirements of ISO/IEC 17025 / ISO 15189. This shall include, but not be limited to, clear policy statements within its quality documentation and processes for functions such as method validation/acceptance, competence of key and technical personnel, record keeping and reporting.

4. Applicability

Flexible scopes of accreditation are applicable to a wide range of different laboratories, primarily in testing but also, in some instances, in calibration. The differing needs of these laboratories means that there is no single way of implementing flexible scopes. Instead it is the responsibility of each laboratory to determine exactly what its requirements are, how it can approach this within the framework of ISO/IEC 17025 / ISO 15189, and how it demonstrates to EAS that this approach is fit for its intended use and capable of being maintained within control.

5. Approaches to Flexible scope

Some common approaches are presented below, but this does not necessarily preclude other approaches from being adopted if their suitability and effectiveness can be demonstrated to the satisfaction of EAS.

5.1. Flexibility concerning parameters/ Components/ analyst

5.1.1. This means flexibility that allows for changes with respect to parameters. Example: Extension of cadmium determination in food to other trace metals by atomic absorption spectrophotometer.

5.2. Flexible concerning object/matrix/sample

5.2.1 This shows flexibility that allows for changes with respect to various products. Example: Change in matrix covers using atomic absorption spectroscopy extended from determination of cadmium in fruits, jams, and other fruit products for the determination of cadmium from cereals, bakery products.

5.3. Flexible concerning performance of the method

6.3.1 This means flexibility that allows for changes in the performance of the method in the give specimen type and a given parameter. Example: Modification of measuring range and uncertainty

5.4. Flexible concerning the Method

5.4.1 This means flexible which allows adoption of methods that are equivalent to method already covered by accreditation.

6. Assessments of Scope

This assessment applies for fixed and flexible scope.

6.1. Staff competency

Evaluation of the technical competence at all hierarchical levels and for all functions of a laboratory is one of the core responsibilities of Accreditation Bodies when assessing laboratories' competence. The competence of staff can be obtained and demonstrated in various ways such as:

- ✓ General knowledge in the domain which the clients of the laboratory are working in.
- ✓ Knowledge about risks the clients are dealing with and how they intend to use the results.
- ✓ Knowledge about the procedures applied, about their reliability, including the associated uncertainties. The individual components contributing to the uncertainty of these procedures.
- ✓ Formal education and the years of experience in the respective field.
- ✓ Training courses in the past years and the effect of these training courses.
- ✓ Cooperation with scientific organisations, standardisation organisations, national and international organisations contributing to the development of the techniques and application of conformity assessments' procedures and its use in the field.
- ✓ Internal learning and improvement processes due to audits, reviews, cooperation with clients.

When a laboratory develops a new or a modified method special attention must be given to the competence of the staff. The staffs who undertake development and modification of methods shall have the necessary technical understanding of the test method and the technology used. They shall be able to judge the suitability of methods and the quality of the results obtained. This competence can be obtained and demonstrated in various ways such as:

- ✓ Formal education and training received,
- ✓ Experience within the field,
- ✓ Participation in research or development projects,
- ✓ Participation in standardisation committees,
- ✓ Participation in scientific or authoritative committees.

Accreditation Bodies should assess staff who are authorised to develop and validate methods in order to assess them for this capability. The evaluation should be more comprehensive if the laboratory operates a flexible scope and should include documented evidence that the laboratory operates all steps involved in the development and operation of methods within the flexible scope.

6.2. Modification of Methods

6.2.1. Accreditation to a fixed scope is generally sufficient in meeting the needs of

laboratories that undertake routine analysis of specified test and/or calibration items. The methods covered by the accreditation will have been validated to cover the full range of items processed by the laboratories. However, although some laboratories have methods/techniques that they routinely use, they may not always know what the application of these will be in advance. For instance, a customer might request that a method be used on a new material/product or for a new measurand that has not previously been included within the validation process. In these circumstances, as long as the request falls within the agreed boundaries of a flexible scope, a laboratory can implement a process of review/development and validation of an existing accredited method. This should follow a predefined protocol in order to demonstrate that the method is fit for purpose for the new application.

6.2.2. Examples of this type of approach are chemistry laboratories that may have a standard method for analyzing a couple of pesticides in soil but are requested to analyze for a new pesticide for which the method has not previously been validated. Alternatively, a physical testing laboratory accredited for testing the temperature and pressure resistance of pipes might be requested to carry out similar tests on the fittings that connect the sections of pipe together.

6.3. **Development of new methods**

6.3.1. In certain areas, such as research and development, laboratories are provided with samples that are not routine. In these instances, the laboratory may be required to develop a new method specifically for these samples, one that may never be used again. In this instance it may not be cost effective to apply for an extension to scope on each occasion,

6.3.2. In order to be able to develop a new method under existing accreditation a laboratory must already have demonstrated to EAS that it is competent to test each of the key components involved (including test item preparation as well as testing). In addition to this it needs to demonstrate that it has the technical competence required to design and validate a method that is fit-for-purpose. The laboratory can achieve this by documenting a generic process to be followed when developing and validating new methods, enabling EAS to ensure that all relevant issues will be covered on an ongoing basis. The laboratory will also need to have experienced staff who have a

thorough technical understanding of the testing procedures and technologies applied and are competent to review the validation data prior to authorizing the method for use; such personnel should be authorized to perform this role by management.

6.4. **Inclusion of technically equivalent standard methods**

In some sectors laboratories specialize in certain tests in accordance with standard methods specified by the client. Under a fixed scope of accreditation the laboratory would need to demonstrate competence to undertake each specific standard method. However, in some cases the client may request the test to be conducted to a national, or similar, standard that has not been specifically accredited by EAS although, with the possible exception of one or more minor differences in parameters such as time, temperature, pressure, etc, it may be regarded as technically equivalent to the method that has been accredited. Where such occurrences arise, as long as the laboratory has undertaken a formal review of the new standard method against their existing accredited method to determine the key differences and to ensure that these are within the boundaries of its flexible scope, then these can be authorized by the laboratory for use. EAS must have confidence in the laboratory's capability to conduct these standard methods having previously determined the competence and capability required by the laboratory to conduct similar methods.

6.5. **Inclusion of revised standard methods**

This approach is similar to 6.4. above , although it is more concerned with laboratories working within a sector (e.g. EMC testing) where standard methods are continually being updated. In order for laboratories operating within such environments to demonstrate ongoing competence to EAS they need to be able to demonstrate that the revisions remain within their specified competence and capabilities. Therefore, laboratories will need to have a formal process in place to review the revised standard, determine the changes and, if they fall within the boundaries of their flexible scope, authorize the revised standard for use.

8. Key Requirements for flexible scope

8.1. All laboratories seeking accreditation for a flexible scope of accreditation must be able to demonstrate compliance with the following key requirements:

a) new methods, or modifications/updates of existing ones, shall not incorporate new measurement principles that are not included within the agreed boundaries of the flexible scope of accreditation. For such an addition the laboratory will need to apply to EAS following the normal route for an extension to scope;
b) laboratories applying for a flexible scope must demonstrate their technical capability to validate these methods in accordance with Section 7.2 of ISO/IEC 17025:2017
c) the lab shall have a process how to act when using a method covered by the flexible scope. The process shall address the input requirements, the present capabilities of the lab regarding equipment, space and staff, ways of verification and validation how the requirements are met and methods of quality control to assure the stability of newly introduced methods;
d) laboratory management must authorize appropriate personnel as competent to take responsibility for key tasks including the development/review, validation and the authorization of modified or new methods for inclusion within the system. Any changes to these key posts shall be notified to EAS in accordance to the *Accreditation Agreement.*
e) the process for development/review and accepting/authorizing methods under a flexible scope must be incorporated into the internal audit program. Application of the flexible scope process must be fed into the predetermined management reviews;
f) all requests, tenders and contracts must be carefully reviewed to determine the requirements of the client and whether the required parameters fall within the agreed boundaries of the laboratory's flexible scope of accreditation. The client should be clearly informed whether or not the laboratory is capable of undertaking the work within its flexible scope, and whether the results can be reported as accredited;
g) the laboratory must maintain a record system that can demonstrate how a method was developed/modified and accepted, the justification for any modifications, and who was responsible for each key activity. The information recorded should be sufficient to allow audits to clearly follow the events leading to the introduction of each new and/or modified method;
h) all reports and certificates that bear results derived from a flexible scope of accreditation must clearly indicate the method used, and whether this is within the boundaries of the flexible scope of accreditation. Attention should also be given to any reporting requirements placed on the laboratory, either by the method or by the client;

i) the laboratory shall keep an updated list of accredited test/calibration methods, including newly modified, introduced or developed methods, available for review by EAS. The list has to be approved by the lab management after each change.

9. Application for Accreditation on flexible scope

9.1. Applicant laboratories, applying for accreditation of testing/calibration for the first time, should clearly state in the application form if they would also like their management system to be assessed for the purposes of controlling a flexible scope of accreditation. The application form should clearly define the testing/calibration activities and areas that are proposed for inclusion within the boundaries of the flexible approach.

9.2. A laboratory that is already accredited for testing/calibration can apply to EAS to modify its accreditation from a fixed to a flexible scope at any time. The application must clearly define the accredited testing/calibration activities and areas that are proposed for inclusion within the boundaries of the flexible approach. Such applications shall be processed by EAS following the normal route for extensions of scope.

9.3. Prior to offering accreditation for a flexible scope EAS must have a high degree of confidence that the staff are technically competent and that the management system controlling certain key processes (e.g. development, review, validation, authorization, quality assurance, traceability, performance in PTs etc) is both robust and effective. For an existing accredited laboratory EAS will have prior knowledge of its competence and ability to maintain its system. For an applicant laboratory EAS will not have any previous knowledge and therefore will have to adopt an assessment approach that will allow confidence to be established.

10. Preparation of Assessment of flexible scope

10.1. When receiving an application for flexible scope EAS will:-

- ✓ request from the CAB a definition of the content and the limits of the flexible scope and how the lab will manage the flexible scope
- ✓ Check for the availability of the required resources for such assessments
- ✓ make quotations for flexible scope according to the complexity of its activities.
- ✓ Plan the assessment and follow up activities taking into account risk assessment,

complexity of flexible scope, performance in PTs, compliance with reporting duties of the lab, training of the lab's staff and their understanding of underlying principles of the flexible methods they apply, existence of working instructions,

- ✓ Check for assessor competence for assessing flexible scope and give training if needed
- ✓ Prepare a draft of the future accreditation certificate
- ✓ Define the requirements for ongoing proof of competence of the lab

11. Assessment of Applicant

11.1. It should be noted that the very nature of a flexible scope of accreditation requires that the laboratory will undergo extensive assessment of its capability to react to customer requests in the future. Therefore, the resources and responsiveness of the laboratory and its systems will need to be adequately robust and sufficiently documented and practicable to be applied as, and when, needed in order to provide confidence in its ability to review, validate and adapt quality assurance practices, within the boundaries of the flexible scope, to any new application.

11.2. The assessment of an applicant laboratory shall include the:

a) competence and capability to perform each technique included within the boundaries of the flexible scope of accreditation;

b) management system and controls implemented by the laboratory for the purpose of maintaining a flexible scope of accreditation;

c) process of reviewing, validating, participating in PTs, approving and authorizing new and/or modified methods for use within the boundaries of the flexible scope of accreditation.

11.3. The laboratory's documented quality system must clearly state whether it maintains a flexible scope of accreditation and if so, specify the areas of activity and the limits within which it operates. The process of modifying, adding, reviewing and authorizing methods must be documented.

11.4. The laboratory must submit all relevant documentation to EAS for review according to EAS's procedure P07 giving proof of the special requirements set out under §6 of this document and record about the activities in the flexible scope.

11.5. To assess the laboratory's competence to operate under a flexible scope of accreditation EAS shall use the following assessment techniques as appropriate:

a) examination of the effective implementation of the procedures and practices;

b) examination of the adequacy of the competence criteria for all key laboratory personnel;
c) capability of method development, validation and documentation;
d) examination of the adequacy of mechanisms in place to determine and monitor the competence of laboratory personnel;
e) interview of nominated key laboratory personnel to verify qualifications, experience, technical knowledge and training;
f) examination of laboratory records that define and justify the basis upon which new/modified methods have been developed and implemented;
g) use of other assessment techniques, as appropriate
h) Performance in PT activities

11.6. Following grant of accreditation of a flexible scope, records of the first methods authorized by the laboratory under its flexible scope may be requested by EAS in order to confirm the satisfactory functioning of the relevant management controls.

12. Monitoring

12.1. The implementation and effectiveness of a laboratory's management system in controlling its flexible scope of accreditation shall be monitored as part of the normal assessment cycle. Sufficient time shall be allowed at future follow-up and re-assessment visits to assess the continuing effectiveness of the management system. This shall include the examination of laboratory records relating to decisions on new and/or modified methods since the last assessment visit, on a sampling basis, as appropriate. The time required for these follow up activities will depend upon the approach taken, the technical area(s) involved, the risk to humans and environment of faulty results and the number and complexity of new/modified methods included. In some circumstances this may require an additional visit or suited follow up activities or visits, to be made to a laboratory's premises; this shall be agreed during the initial assessment stage.

12.2. Between scheduled visits EAS may randomly select a method introduced via the flexible scope process and request that the laboratory submits for assessment the relevant records relating to its validation/authorization for review.

13. Accreditation

13.1. EAS Scope of Accreditation shall define the boundaries of the flexible scope within which the laboratory can operate. The general format of the schedule will be the same as that used for fixed scopes of accreditation, with the exception that the areas of flexibility shall be clearly identified. The actual way in which the flexibility is presented will vary depending upon the type of flexible scope operated by the laboratory, but this should be agreed between EAS and the laboratory management taking into account the guidance provided in GD07/01 "*Guidance on the description of fixed scopes in laboratories*".

13.2. The scope of accreditation may use footnotes, reference to documented laboratory-developed methods and procedures, or clarifying statements, etc as appropriate. However, in all cases the scope should provide sufficient detail to enable the laboratory, customer and EAS to determine whether a new activity can be included within the laboratory's scope of accreditation.

13.3. If the conduct of a new or revised method is to become routine within a laboratory then it may be specifically included within the scope of accreditation. Depending upon the needs of the laboratory the schedule shall be updated at predetermined intervals, as agreed with EAS. However, EAS retains the right to refuse the inclusion of a new or modified standard if there are doubts about it falls within the boundaries of the laboratory's flexible scope.

13.4. If it is discovered that a laboratory has not maintained its management system, and that the controls have not been effectively implemented resulting in the inappropriate authorization of modified or new methods, then appropriate actions will be taken by EAS upon that laboratory. They will depend upon the nature, implications and frequency of the non-conformance, but may include:

a) suspension of a specific testing/calibration activity or area from the flexible scope;
b) revocation of the laboratory's ability to operate a flexible scope of accreditation;
c) total suspension of all accredited testing/calibration activities.

In addition, the laboratory is required to write to all clients that have been directly affected by any tests/calibrations in question to notify them that the previous reports were outside the

laboratory's scope of accreditation. This notification must also clearly state the reason why this has occurred and include any further actions that may be necessary as a result.

Revision No.	Date approved	Revision History
1	2018-08-16	This document was revised because of the new standard ISO/IEC 17011:2017
1.1	2021-05-17	Separate Purpose and Scope Clause 4 Applicability, included ISO 15189 New added Clause 5.1-6.2
1.2	2022-05-10	• The document is revised due to the name Ethiopian National Accreditation Office (ENAO) change to Ethiopian Accreditation Service (EAS) and new logo developed.
1.3	2023-072-07	• Correction done on page 1 that, this document was prepared by Meseret Tessema replaced by Zewdu Ayele (new quality manager). • Former director general was resigned and replaced by Mrs. Meseret Tessema.