INTRODUCTION

A flexible Scope of Accreditation, as described in this policy, is available to laboratories accredited to ISO/IEC 17025. Applications for a flexible Scope of Accreditation will be reviewed on a case-by-case basis, and the final decision on allowing a flexible Scope rests with A2LA. It is also important to note that requirements imposed by regulatory authorities and/or specifiers of accreditation may override A2LA's ability to issue a flexible scope of accreditation.

Calibration scopes of accreditation are most often considered flexible and are enveloped under this policy; therefore F1 – F7 identified below are not applicable as the competence associated with the "flexibility" of a calibration scope is included in the normal assessment and accreditation activities for a calibration laboratory.

While scopes of accreditation for ISO 17034 and ISO/IEC 17043 are not typically considered flexible, there is some flexibility permitted in the following areas. For example, the measurand defined on the scope of accreditation for ISO/IEC 17043 may be defined as a general category or as specific analyte. Similarly, the property/properties characterized for an ISO 17034 scope of accreditation may be defined as a group of chemicals rather than the specific analyte. As such, the scope of accreditation may have some variability in the specificity of these items and the scope of accreditation requested for these applicants will be evaluated to ensure the competency of each organization to provide the proficiency testing schemes or reference materials as they are defined on their scopes of accreditation. This is part of the normal assessment process and does not require any additional information as outlined in this document.

For the applicable testing, a traditional fixed Scope of Accreditation will include the specific test technologies and their associated test methods, standard operating procedures, etc. that a laboratory is accredited to perform. In these cases, a laboratory may only claim that they are accredited to provide results using those methods as defined on the Scope. However, in certain circumstances, this can be considered too restrictive in that it does not readily enable new or modified methods to be added to a laboratory's Scope, even where competence in the general area has previously been demonstrated via on-site assessment.

- An ISO/IEC 17025 Testing flexible Scope of Accreditation allows the laboratory to report these results as being from accredited testing even if the exact tests are not explicitly stated on the Scope of Accreditation but *are performed within boundaries defined on a flexible Scope of Accreditation.* These boundaries on the Scope of Accreditation include the field of testing (chemical, biological, etc.), the materials and products tested, properties or category of properties measured, the type of measurement, and the equipment and/or technology used to perform the measurements.

- For testing laboratories, a traditional, fixed Scope of Accreditation is typically required, but there are some instances where a level of flexibility is warranted due to the circumstances of the laboratory. For example, there are situations that arise when a laboratory requires flexibility in allowing for changes in the matrices within a product area (*flexibility concerning object/matrix/sample)* or with respect to parameters (*flexibility concerning parameters/components/analytes)* due to the unknown nature and variability of samples received on a daily basis The laboratory may not have time to request modification of a method on their Scope or create a new method and request an expansion to their Scope before the customer requires the accredited results to be delivered.

- The amount of time needed to formally make these changes to a Scope of Accreditation may adversely affect the laboratory's ability to comply with tenders and contracts within their customer's timeframe. In

some areas such as research and development, non-routine samples often require the development of a new method created exclusively for these samples that may never be used again. In this case, even if all of the ISO/IEC 17025, requirements are met, the added time and potential expense associated with an assessor's review of the new or modified method may be cost prohibitive and could result in a laboratory's loss of the customer contract.

For the application of calibration, a traditional fixed Scope of Accreditation will include the measurement parameter, the range of measurement, the Calibration Measurement Capability (CMC) uncertainty and the method or procedure used for the CMC. However, the calibration laboratory may define its capability by including the reference standard(s) used rather than a specific method or procedure it if has demonstrated the competency to make the measure with that equipment within the CMC claimed on the scope of accreditation.

- The Scope of Accreditation may be flexible in regard to listing the method or procedure used, as the laboratory's calibration and measurement capabilities are detailed within parameters and ranges listed. The column "Comment" of the scope may identify the type reference standard(s) used to make the measurement in lieu of a method or procedure. The flexibility for calibration scopes of accreditation is limited to listing the method and/or procedure used and can only be applied if the type of referenced standard(s) used are included in the comment section. However, a calibration laboratory may also choose to list the method and/or procedure used in the comment section if so desired. In all cases, the method and/or procedure used is captured in the assessment record and is retained for future reference.

- For additional information on scopes of accreditation, please refer to ILAC G18:12/2021 Guideline for the Formulation of Scopes of Accreditation for Laboratories http://ilac.org/publications-and-resources/ilac-guidance-series/.

This policy outlines the applicability, requirements, and monitoring of organizations that wish to have a flexible Scope of Accreditation.

REQUIREMENTS

The following requirements apply to a laboratory requesting a flexible Scope of Accreditation. The laboratory shall:

(***F1***) Submit a request to A2LA for a flexible Scope of Accreditation containing the following:

- A written explanation of why a fixed Scope is too restrictive for the work currently undertaken such that a flexible scope is justified;

- Identification of authorized personnel with the responsibility for maintaining the flexible Scope process; specifically, those that are assigned to develop and validate new methods (please refer to F4). These personnel are considered to be essential personnel and A2LA must be notified immediately if there are any changes to their status within the organization. If the staff member(s) leave the organization, the organization's flexible Scope may be inactivated or converted to a fixed Scope of Accreditation that lists specific tests/methods until suitably competent individuals have been authorized for assuming responsibility for the flexible Scope process;

- A proposed Testing Scope of Accreditation including the following:

    - All methods, SOPs, etc. that are requested for inclusion on the Scope of Accreditation, if applicable;
    - Field of testing (e.g.., Chemical, Biological);
    - Materials/products tested (e.g., foods, urine, fruit, etc.);
    - Properties or categories of properties measured (e.g., pathogens, drugs of abuse, etc.);

- Category(s) of measurement (i.e., qualitative / quantitative);
- Equipment/technology used to perform the measurement (e.g., atomic absorption, high-performance liquid chromatography, enzyme immunoassay, PCR etc.);
- Tests or types of tests performed and (e.g., toxicity, reactivity analysis etc.); and
- Any other comments/additional information necessary to define the boundaries of the flexible Scope being requested.

- The procedure(s) that cover the review of work related to the flexible Scope process and the associated development and validation of methods used for the work **(see *F3*)**; and

- A listing of the methods developed and validated since the last assessment using the process described above if not already included on the fixed Scope of Accreditation.

The application and supporting information will be reviewed by A2LA staff and a determination on the applicability of and a laboratory's eligibility for a flexible Scope will be made.

(F2) Have previously demonstrated their competence to A2LA by having been first accredited to a fixed Scope of Accreditation for a defined set of published or in house developed methods. As such, a transition to the flexible Scope option in most cases will not occur until at least the surveillance or first reassessment visit;

(F3) Have procedure(s) for how work is reviewed and determined to be within the flexible Scope of Accreditation and for how methods are modified/developed within the flexible Scope. Additionally, the laboratory must demonstrate that it has a management system which will control the flexible Scope so that all tests are carried out in accordance with the requirements for accreditation. It must also provide evidence that it has documented procedures for addressing the addition of new methods developed and a description of what type of records are kept;

(F4) Demonstrate that it has the technical competence and depth of experience to support a flexible Scope. The laboratory shall also provide evidence of those personnel authorized to manage the flexible Scope process and to modify/create and validate the methods related to the flexible Scope. The laboratory must describe the training to be provided in order to ensure that staff is technically competent and knowledgeable of their roles and responsibilities;

(F5) Maintain a list of the modifications and updates of its ISO/IEC 17025 related test methods and/or method development activities (see the master list of flexible Scope changes form).

- The testing laboratory must retain the underlying results and other relevant data (normally in the form of a validation and/or verification report) per ISO/IEC 17025:2017, Section 7.2 and make them available for review upon request at any time;

(F6) For ISO/IEC 17025 test laboratories only: Annually (at the time of the onsite assessment or annual review) or at the request of A2LA provide an updated list of the methods which they have validated since the last assessment and regularly update the Proficiency Testing Plan accordingly to include any relevant and available proficiency testing activities for the newly validated methods. (*NOTE: Some accreditation programs require prior demonstration of proficiency (if available) before accreditation can be conferred and similar participation would be required for laboratories with flexible Scopes)*;

(F7) Ensure that any method modifications do not incorporate new measurement principles that were not previously identified in the Scope of Accreditation. For those method modifications that incorporate new measurement principles not previously evaluated by A2LA, testing laboratories must notify A2LA; reference material producers and/or proficiency testing providers must notify A2LA in writing.

Please note that, for organizations with a flexible Scope, additional on-site assessment time will likely be necessary to accommodate a review of all the elements related to this policy. The time onsite will also increase if

the organization has been very active in using its flexible Scope of Accreditation and has utilized a number of ISO/IEC 17025 related modified/laboratory developed methods.

A2LA reserves the right to suspend a flexible Scope if the laboratory is found at any time to be in non-compliance with the requirements of this policy.

If you have any questions about this policy, please contact A2LA at 301 644 3248.

DOCUMENT REVISION HISTORY

Date	Description
10/12/23	➢ Updated reference from ILAC G18:04/2010 to G18:12/2021 ➢ Removed reference to F108 in F7 ➢ Minor grammar updates throughout

Master list (Labs) of flexible scope changes for any particular year

Test/ Assay Name	Specimen Type	Measurement Technique	PT or IQC/ frequency	Aim of Analysis	Equipment	SOP	Description of change / date
Example: Pesticides	**fruits**	**Spectroscopy**	**Each batch**	**Screen/ Confirmatory**	**GCMS/MS**		**Enter details of the change examples could possibly be the following:**
							Change of range
							Change of kit
							Addition of new test
							Change of dilution in test method
							Upgrade of equipment