R101 - General Requirements: Accreditation of Conformity Assessment Bodies

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PART A - INTRODUCTION

The AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA) is a non-profit, non-governmental, public service, membership organization dedicated to operating a nationwide, broad spectrum conformity assessment accreditation system. Accreditation is a third-party attestation related to a Conformity Assessment Body (CAB), conveying formal demonstration of its competency, consistent operation and impartiality in performing specific conformity assessment activities. Accreditation is available to any type of CAB, be it in the private sector (independent or in-house) or in the government sector.

A2LA was formed in 1978 as a practical and efficient organization to develop and manage a system to verify and recognize competent laboratories. Today, accreditation is available for virtually all types of tests, calibrations, measurements, inspections, certifications, and observations that are reproducible and properly documented. The general requirements (general criteria) for A2LA accreditation is the applicable international standard:

- For testing and calibration laboratories: ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories, and
    - Annex A: Additional Requirements for ISO/IEC 17025 Laboratories;
- For clinical testing laboratories: ISO 15189, Medical laboratories, Requirements for quality and competence, and
    - Annex B: Additional Requirements for ISO 15189 Laboratories;
- For inspection bodies: ISO/IEC 17020, Requirements for the operation of various types of bodies performing inspection, and
    - Annex C: Additional Requirements for ISO/IEC 17020 Inspection Bodies;
- For reference material producers: ISO 17034, General requirements for the competence of reference material producers, and
    - Annex D: Additional Requirements for ISO 17034 Reference Material Producers;
- For proficiency testing providers: ISO/IEC 17043, General requirements for the competency of proficiency testing providers, and
    - Annex E: Additional Requirements for ISO/IEC 17043 Proficiency Testing Providers;
- For product certification bodies: ISO/IEC 17065, Requirements for bodies certifying products, processes and services, and
    - Annex F: Additional Requirements for ISO/IEC 17065 Certification Bodies;
- For biobanks: ISO 20387, General requirements for biobanking, and
    - Annex G: Additional Requirements for ISO 20387 Biobanks.

Additional program requirements (specific criteria) for specific fields (e.g. calibration, environmental testing, Forensic Inspection etc.) or specific programs which are necessary to meet particular user needs (e.g. Veterinary Laboratory Accreditation Program, FedRAMP, FCC TCB etc.) complement these general requirements in particular areas.

In effect, A2LA accreditation attests that a CAB has demonstrated:

a) it is competent to perform specific conformity assessment activities listed on its Scope(s) of Accreditation;
b) its management system is documented, fully operational and addresses and conforms to all elements of the applicable accreditation scheme (e.g. ISO/IEC 17020, 17025 etc.) and any additional international, A2LA, and/or field specific requirements (e.g. ILAC, IAF, A2LA, and/or regulatory policies); and,
c) it is operating in accordance with its management system.

It is A2LA policy not to accredit or renew accreditation of a CAB that fails to meet the above criteria (see Part B, Conditions for Accreditation and Part C, Accreditation Process, sections on deficiencies, accreditation decisions and suspension or withdrawal of accreditation). In general, A2LA endeavors to follow the procedures outlined herein for assessing applicants, though special circumstances may arise that warrant different procedures at A2LA's sole discretion, as will be discussed with applicants when such circumstances arise.

In keeping with our mission, our staff, assessors and committees are committed to:

- Embodying the highest integrity and expertise to create trust, safety, and quality throughout the world.

- Providing excellence in accreditation and the highest level of customer service and support to our valued accredited conformity assessment bodies, applicants and stakeholders relying on accreditation.

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Trace McInturff, Vice President, Accreditation Services

PART B - CONDITIONS FOR ACCREDITATION

In order to attain and maintain accreditation, CABs must comply with the *Conditions for Accreditation (R102)* published by A2LA. This document is available at the A2LA website, www.A2LA.org, or from A2LA Headquarters.

To apply, the applicant CAB's Authorized Representative must agree to the conditions for accreditation and must attest that all statements made on the application are correct to the best of their knowledge and belief. An accredited CAB's Authorized Representative holds binding authority for the organization and is responsible for ensuring that all of the relevant conditions for accreditation are met. During on-site assessment(s), the assessor will examine records and documentation to verify compliance with *R102 - Conditions for Accreditation*.

PART C - A2LA ACCREDITATION PROCESS

1. Application

A CAB applies for accreditation by visiting the A2LA website, www.A2LA.org, and completing the appropriate application forms and relevant checklists. All applicants must agree to a set of conditions for accreditation (see Part B of this document), and provide detailed supporting information, including (but not limited to):

- Proposed scope of accreditation (see annexes of this document for details specific to each accreditation scheme);
- Management system documentation and supporting SOPs;
- Completed General Checklist for the accreditation scheme(s) being applied for (see annexes of this document for corresponding checklists and accreditation schemes);
- Organization structure;
- Proficiency testing plan and results (where relevant); and,
- Any other application requirements in the applicable annex of this document.

In most cases, all documentation must be provided in English and the assessment conducted in English. An appropriate English translation of pertinent documentation must be provided as well as a translator, if needed, to facilitate the assessment. If A2LA has an appropriate and available assessor(s) that can communicate in the CAB's native language, A2LA will make efforts to assign the assessor to alleviate the need for some translation. Please note, however, that some documents (e.g. corrective action responses, etc.) must be provided in English. A2LA will provide further details as appropriate, and on request, as to which documents would need to be provided in English.

Notwithstanding anything herein to the contrary, a CAB (or any individual or entity associated with or reasonably connected with the CAB as determined in A2LA's sole discretion) may not apply for or resubmit an application for accreditation for a period of six (6) months following an enforced withdrawal of accreditation for fraudulent activities.

Regardless of the cause for enforced withdraw, A2LA, prior to accepting an application for accreditation, may:

- refuse an application from a previously enforced withdrawal of a CAB;
- request additional application information above and beyond the normal application materials and/or inquire about resolution of the issue given rise to the enforced withdrawal. (e.g., full corrective action response, organizational changes made, etc.);
- review CAB records dated before the application submittal date (i.e., back to the previous accreditation period); and,
- impose additional accreditation conditions and administration fees.

These and any additional items are imposed in order to restore confidence with the applicant organization.

Scopes of Accreditation

The scope of accreditation is the fundamental document attesting to the organization's competence to perform the conformity assessment activities for which it is accredited.

The content of scopes of accreditation is dependent upon the accreditation scheme the CAB is accredited to. See the annexes to this document for more details on scopes for each scheme.

Users of accredited CABs are advised to obtain the Scope(s) of Accreditation from any accredited CAB or from A2LA. The A2LA Certificates that accompany the Scopes of Accreditations are intended for display purposes. All active A2LA scopes and certificates can also be found on the A2LA website, www.A2LA.org.

2. Assessment Process

The objective of an initial, surveillance, follow-up, interim, renewal or extraordinary assessment is to establish whether or not a CAB complies with the A2LA requirements for accreditation and can competently perform the activities for which accreditation is sought. However, when accreditation is required to demonstrate compliance with additional criteria which may be imposed by other authorities, such as in the case of U.S. EPA, the A2LA assessment will include such additional criteria. Assessors may also provide information, based on observations or in response to questions, in order to help the CAB improve its performance. Assessors are restricted from providing consultation as this is not permitted under ISO/IEC 17011 *Conformity Assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*, the standard A2LA operates and adheres to.

Delayed Assessment Policy: If a CAB fails to undergo its full initial assessment within one year from receipt of the application at A2LA headquarters, the CAB is prompted by A2LA to take action. If no action is taken within thirty (30) days of that reminder, the CAB is typically required to begin the application process again and pay the accreditation fees in effect at that time.

Tax Policy: Any tax imposed by the jurisdiction where the assessment takes place or where fees are imposed is to be paid by the CAB in addition to the assessment fees.

2.1. Initial Steps

Once the application information is completed, A2LA identifies and tentatively assigns one or more assessors to conduct an initial assessment at the CAB's site. Assessors are selected based on their technical expertise as it related to the proposed Scope(s) of Accreditation. They do not represent their employers (if so affiliated) while conducting assessments for A2LA. The CAB has the right to ask for another assessor if it objects to the original assignment due to conflict of interest or perceived lack of technical expertise. A2LA assessors are drawn from industry, academia, government agencies, consultants, and the conformity assessment community. Assessors

work under contract to A2LA. Assessments may last from one to several days depending on the extent of the desired scope and the size of CAB. More than one assessor may be required.

CABs in those countries for which the U.S. Department of State has issued a travel warning may be required to provide (at their expense and for an amount to be agreed upon between the CAB and assessor) insurance coverage (e.g., life, health, kidnapping, etc.) for the assessor or assessment team that will be visiting them.

Assessors are given an assessor instruction manual (AIM) and checklists to follow in performing assessments. These documents are intended to ensure that assessments are conducted as uniformly and completely as possible among the assessors and from CAB to CAB, and to ensure an efficient, value-added service for the customer.

Before an initial assessment is conducted, the assessor team reviews the CAB-provided management system documentation and representative technical SOPs in order to prepare for the assessment. The management system and related documentation must be reviewed by the assessment team before the assessment can begin. This review is done ideally before the assessment is scheduled. Upon review of submitted documentation, the assessor(s) will provide the document review results to the CAB in writing and may ask the CAB to implement corrective action to fill any documentation gaps required by the applicable accreditation scheme(s) before scheduling the assessment. A pre-assessment visit may be requested by the CAB or suggested by the assessor as an option at this point to enhance the success of the full assessment.

Prior to scheduling the initial assessment, the assessor reviews the draft scope(s) to determine the activities to possibly witness and checks on the availability of the technical personnel who perform those conformity assessment activities. An assessment agenda is provided by the assessor.

2.2. Pre-Assessment (when requested)

A2LA assessors are permitted to conduct pre-assessments. There are two situations when a pre-assessment may be conducted:

1. When the lead assessor finds major gaps in the CAB's management system documentation or begins the assessment and finds a large number of nonconformances. In this case, the assessor identifies the nonconformances and suggests to the CAB that a full initial assessment should wait until the issues have been addressed. This first identification of the nonconformances would be considered a pre-assessment; or

2. When a CAB requests a pre-assessment to better prepare for the full initial assessment. In this case, the CAB has applied but is unsure of its documentation or system and wants someone to perform a pre-assessment to identify problems. The full initial assessment follows later.

To implement the pre-assessment, the CAB must first apply for accreditation. A lead assessor is assigned, with the CAB's concurrence. If, during the discussions between the CAB and assessor in preparation for the assessment, the CAB concludes that it is in its interest to have a pre-assessment, it informs the assessor. The assessor notifies A2LA that the CAB wants a pre-assessment. The daily rate of the pre-assessment is the same as the regular assessment rate and will be invoiced separately from other assessment fees. No additional accreditation fees apply. A pre-assessment is generally performed remotely, when possible (refer to *A2LA P119 - A2LA Policy on Remote Assessment*).

2.3. On-Site Assessment

Full initial and renewal assessments generally involve:

- An entry briefing with CAB management;
- Interviews with technical (and administrative, as determined by A2LA) staff;
- Demonstration of selected conformity assessment activities, and as determined by A2LA, demonstration of these activities at representative field locations;
- Examination of equipment and calibration records, and the CAB facilities;
- Audit of the management system to verify that it is fully operational and that it conforms to all sections of the relevant accreditation scheme(s), including documentation and record review;
- Evaluation of the CAB's compliance with the applicable A2LA requirements documents including but not limited to (see Annexes of this document for additional A2LA requirements):
    - *R102 – Conditions for Accreditation*;
    - *R105 – Requirements When Making Reference to A2LA Accredited Status*;
    - *P102 – A2LA Policy on Metrological Traceability* (if applicable);
    - *P103 – Policy on Estimating Measurement Uncertainty for Testing Laboratories* (if applicable); and,
    - *R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories* (if applicable).
- A written report of assessor findings; and,
- An exit briefing including the specific written identification of any deficiencies.

Through interviews with technical staff, record review, and observations of technical activities, the assessor confirms the depth of technical competency for the CAB. In some cases, at the discretion of A2LA management, remote assessment techniques may be used in full or in part. At a minimum the CAB must demonstrate that a person has been authorized to perform each of the conformity assessment activities that the CAB is seeking accreditation for. If it is determined that there is only one person authorized for a given activity, this person is identified as essential personnel in the assessor deliverables to A2LA. The CAB is then responsible for informing A2LA whenever the status of the essential personnel changes (e.g. cross-training of additional individuals such that the essential person is no longer the only person technically competent to perform a given task(s), departure of the essential personnel resulting in the CAB no longer having the technical competency to perform a given task, etc.). An essential personnel departing a CAB will result in the CAB losing accreditation for those activities the essential personnel was solely responsible. To regain accreditation for those activities, the CAB would be required to provide objective evidence they have authorized applicable staff to perform such activities. This can be achieved via on-site or remote assessment, record review, and/or telephone/web interview, as determined by A2LA.

During an assessment, the assessor has the authority to stop the process at any time and consult with A2LA and the CAB's authorized representative to determine if the assessment should proceed. In cases where the number of significant deficiencies affects the ability to successfully complete the assessment, the visit may be converted to a pre-assessment (initial assessment only), or a suspension may be recommended (renewal assessment) if technical capability is lost (see Part C.14 Suspension of Accreditation). The assessment can then be rescheduled for a time when the CAB and assessor feel it is appropriate to proceed.

3. Deficiencies

During an assessment, assessors may identify deficiencies. A deficiency is any nonconformity to accreditation requirements including:

- a CAB's inability to perform a conformity assessment activity for which it seeks accreditation;
- a CAB's management system does not conform to a clause or section of the applicable accreditation scheme(s), is not adequately documented, or is not completely implemented in accordance with that documentation; or,
- a CAB does not conform to any additional requirements of A2LA necessary to meet particular needs.

At the conclusion of an initial or renewal assessment, the assessor prepares a final written report of findings, identifying deficiencies which, in the assessor's judgment, the CAB must resolve in order to gain accreditation, maintain current accreditation or have their accreditation renewed. The assessor holds an exit briefing with the authorized representative (or designee) of the CAB to review the assessor's findings and any identified deficiencies (deficiency report) and describe the deficiency resolution process. The authorized representative of the CAB (or designee) is asked to acknowledge the deficiency report to attest that the deficiency report has been reviewed with the assessor. The acknowledgement does not imply that the CAB representative concurs that the individual item(s) constitute a deficiency. If the number and/or nature of the deficiencies are deemed by A2LA as extreme, A2LA may require a follow-up assessment be conducted to ensure that appropriate corrective actions have been implemented.

Assessors may also write an "observation" when they question the practice or competence of the CAB but there is not enough supporting objective evidence to justify a deficiency, or the issue cannot be tied to the accreditation requirements. If this occurs, the CAB does not have to respond to observations for accreditation to be granted. However, the observations are part of the assessment record and will be followed up by the next assessor to visit the CAB who will check to see if that observation was addressed by the CAB, resulting in an improvement, or possibly may have progressed into a deficiency. The CAB also has the right to decline the writing of observations, this option will be discussed during the opening meeting.

4. Corrective Action Process

The CAB is requested to respond, in writing, within one month (30 days) after the date of the exit briefing or after other notice of deficiency detailing either its corrective action or why it does not believe that a deficiency exists. The corrective action response must include the CAB's cause analysis and a copy of any objective evidence (e.g., calibration certificates, revised procedures, paid invoices, packaging slips and/or training records) to indicate that the corrective actions have been implemented/completed. It is possible that the assessor's review of the corrective action response may be needed to determine if the response is satisfactory. If this review is expected to take more than two hours of time, A2LA may invoice the CAB for this time at the prevailing assessor rate. The assessor will discuss the possibility of this review with the CAB during the exit briefing and obtain the CAB's concurrence.

When addressing an equipment calibration related deficiency to *P102 - A2LA Policy on Metrological Traceability*, please note that if the CAB is using a calibration provider that does not meet *P102* to satisfy the deficiency, the CAB does ***not*** need to immediately re-calibrate the equipment in question using an acceptably accredited calibration source. The CAB must be able to demonstrate in their corrective action response the traceability of the current calibration and that they will use an acceptable source of calibration *for the next regularly scheduled calibration cycle*. An acceptable source is a calibration laboratory accredited by A2LA or one of our mutual recognition partners. We invite your attention to our website, www.A2LA.org, for a listing of our partners.

When addressing a reference material related deficiency to *P102 - A2LA Policy on Metrological Traceability*, please note that if the CAB is using a reference material(s) that does not meet *P102* to satisfy the deficiency, the CAB does ***not*** need to immediately purchase a new reference material from a recognized source. The CAB must demonstrate in its corrective action response that it will purchase acceptable reference materials *on its next scheduled purchase or by its next regularly scheduled A2LA renewal assessment, whichever is sooner*. An acceptable source is a reference material producer accredited by A2LA or one of our mutual recognition partners that are recognized for reference material producer accreditation.

It is possible that the CAB will disagree with the findings that are presented by the assessor as deficiencies. In that case, the CAB is requested to explain in its response why it disagrees with the assessor. The deficiency and CAB's explanation will be classified as a contested deficiency and provided to the Accreditation Council for a decision on validity. A contested deficiency should not be confused with an accreditation decision appeal – please refer to section *C.6. Appeals* for further information on the appeals process.

A new applicant CAB (i.e. one undergoing initial assessment) must ***respond*** in writing within 30 days of the exit briefing and ***resolve*** all deficiencies within four (4) months of the exit briefing. A new applicant CAB that fails to ***resolve*** all its deficiencies within four (4) months of being assessed may be subject to being reassessed at its expense. A2LA has the option to ask for reassessment of a CAB before an initial accreditation vote is taken based on the number, extent and nature of the deficiencies.

CABs undergoing a renewal assessment must ***respond*** in writing within 30 days of the exit briefing and ***resolve*** all deficiencies within 60 days of the exit briefing. Failure to meet these deadlines may result in adverse accreditation action (e.g. a "follow-up" assessment, reassessment, or suspension of accreditation). The Accreditation Council also has the option to require a follow-up assessment of any CAB (new or renewal) before an affirmative accreditation decision can be rendered. The CAB is responsible for any costs associated with this follow-up assessment.

5. Accreditation Anniversary Date

The anniversary date of a CAB's accreditation is established 45 to 75 days after the last day of the final assessment before an initial accreditation decision, regardless of the length of time required to correct deficiencies. This anniversary date normally remains the same throughout the CAB's enrollment.

6. Extensions to the Accreditation Anniversary Date

If a CAB is in their renewal process and is making good faith efforts with A2LA when approaching their accreditation anniversary date, A2LA may extend their accreditation for up to an additional 90 days to complete the renewal of accreditation process. When fundamental non-conformances are identified during an assessment, extensions of accreditation are not considered until the CAB submits objective evidence demonstrating that the non-conformances have been addressed. Likewise, extensions are not granted when delays are due to the CAB's failure to respond to requests within established deadlines including:

- receipt of complete renewal application after imposed due date;
- assessment not performed within assessor availability;
- receipt of response to assessor deficiency report beyond 30 days of assessment exit briefing; or,
- closure of all deficiencies beyond 60 days of assessment exit briefing.

When a CAB is granted an extension to their accreditation, a revised Certificate and Scope of Accreditation are posted to the A2LA website reflecting the extended anniversary date. Hard copies of these documents will be made available only upon request. Upon completion of the renewal process, both documents are reissued, reflecting the renewed anniversary date.

When an extension of accreditation is not granted, upon expiration, CABs will be removed from the A2LA Accredited list on the A2LA website.

7. Accreditation Decisions

Before an accreditation decision ballot is sent to the Accreditation Council (AC), A2LA shall review the deficiency response, including the CAB's cause analysis and objective evidence of completed corrective action, for adequacy and completeness. If A2LA has any doubt about the adequacy or completeness of any part of the deficiency response, the response is submitted to the assessor(s) for review. Since all deficiencies must be resolved before an accreditation decision can be made, A2LA shall ask the CAB for further written response in those cases where A2LA recognizes that an affirmative vote is not likely due to incomplete corrective action in response to deficiencies or obvious lack of supporting objective evidence that corrective action has been completely implemented.

A2LA normally selects a panel of between one and three AC members for voting. The panel is chosen so that the full range of the CAB's capabilities are adequately covered by the AC review. Especially in the case of those CABs seeking (re)accreditation for multiple fields or areas, it may be necessary to select more than three AC members to accomplish this. The CAB is consulted about any potential conflicts of interest with the AC membership prior to sending their package to the AC. Accreditation may not be granted until all votes have been received and any negative votes resolved. In some instances, (typically packages of a non-technical nature with less than six cited deficiencies), a single AC member can be assigned to expedite the decision-making process for CABs in good standing.

It is the primary responsibility of assessors to evaluate whether the observed evidence is serious enough to warrant a deficiency. However, the AC panel members that are asked to vote on an accreditation decision are required to make a judgment whether deficiencies still exist based on information contained in the ballot package. Accordingly, panel members can differ with assessor judgments, based upon their interpretation of the criteria for the specific case under question and the supporting evidence available whether a deficiency does or does not exist. A2LA will attempt to resolve these differences as they arise, but it remains for the panel to make the decision.

A2LA shall notify the CAB asking for further response based on the specific justification for any negative votes received from the AC panel. If further response still does not satisfy the negative voter(s), a follow-up assessment may be proposed or required. The CAB is responsible for any costs associated with this follow-up assessment. If the CAB refuses the proposed follow-up assessment, or if the CAB does not agree with the initial AC decision, a nine-member Accreditation Council appeals panel is balloted (see Part C.13 Adverse Accreditation Decisions and Part C.16 Appeals Procedures below).

If the accreditation decision is positive, A2LA prepares and forwards a certificate and scope of accreditation to the CAB for each enrolled field and subfield of accreditation (and special program if appropriate). The CAB should direct clients or potential clients to their listing in the A2LA online directory to show the conformity assessment activities for which it is accredited. A2LA will post all valid scopes of accreditation to the online directory, and use the scopes of accreditation to respond to inquiries.

8. Annual Review

Accreditation is granted for two years (except PTPs, seen Annex E). However, after the initial year of accreditation, each CAB must pay annual fees (including any applicable program surcharge fees) and assessor fees and undergo a one-day surveillance assessment by an assessor. This surveillance assessment is performed to confirm that the CAB's management system and technical capabilities remain in compliance with the accreditation requirements. Failure to complete the surveillance assessment within the designated timeframe may result in adverse accreditation action (see Part C.14 Suspension of Accreditation).

For subsequent annual reviews occurring after the renewal of accreditation (see Part C.9 Reassessment and Renewal of Accreditation) each CAB must pay annual fees and submit updated information on its organization, facilities, key personnel and (if applicable) results of any proficiency testing (see annexes for additional Annual Review requirements for each accreditation scheme). Objective evidence of completion of the internal audit and management review, in accordance with the CAB's respective plans and procedures, is also required. If the renewal CAB does not promptly provide complete annual review documentation, if significant changes to the facility or organization have occurred, or if CAB performance results (e.g. proficiency testing results, complaints received against the CAB, previous assessment results etc.) have been consistently poor, a one-day surveillance assessment (and payment of the associated assessor fees) or an adverse accreditation action may be required. Furthermore, if significant problems were noted during the last on-site assessment that warrant follow-up or if significant issues have arisen since the last on-site assessment that could call into question the CAB's compliance with the accreditation requirements, an appropriate surveillance assessment and payment of the associated assessor fees may be required.

9. Reassessment and Renewal of Accreditation

A2LA conducts a full reassessment of all accredited CABs every two years (except PTPs, which are assessed at least every four years). Full reassessments are also conducted when evaluations and submissions from the CAB or its clients raise concerns about ongoing compliance or indicate significant technical changes in the capability of the CAB have occurred.

Each accredited CAB is provided with a renewal application six (6) months in advance of the expiration date of its accreditation to allow sufficient time to complete the renewal process. A successful reassessment at the CAB's site(s) must be completed before accreditation is renewed for another two years.

If deficiencies are noted during the renewal assessment, the CAB is asked to respond in writing to A2LA within 30 days after the assessment describing the corrective action taken. All deficiencies must be resolved, as described in section C.4 Corrective Action Process, before accreditation is renewed for another two years.

In cases where significant deficiencies are identified in a renewal assessment, the CAB may be required to undergo a surveillance assessment in conjunction with the next annual review to verify continued implementation of corrective actions (see Part C.8 Annual Review).

10. Extraordinary Assessments

Although rare, A2LA may require CABs to undergo an extraordinary assessment (also referred to as a "for-cause" assessment) as a result of a complaint(s) from any party or significant changes to the CAB's management system. Depending on the severity of the complaint or changes, this assessment may be performed with little or no advance warning. A for-cause assessment typically does not follow the assessment process as indicated in part *C.2.3 On-Site Assessment* above. A2LA staff, accompanied with the assigned technical assessor, will provide a detailed memorandum to the Authorized Representative identifying the reason for the assessment and any additional guidelines surrounding the assessment upon arrival at the CAB. Failure to allow the A2LA assessment team to enter the facility and/or gather necessary and applicable evidence may be grounds for suspension. If reasons for the for-cause assessment are determined to be justified or substantiated by the VPAS as a result of objective evidence uncovered by the assessment team during the conducted assessment, the CAB is responsible to cover all associated costs related to this for-cause assessment.

11. Adding to the Scope of Accreditation

A CAB may request an expansion to its scope of accreditation at any time. If a request is made at a time in which an assessor will not be on-site (e.g. surveillance, renewal assessment), the request must be submitted in writing to A2LA headquarters typically using the A2LA *Customer Portal (once logged in, click on the scope expansion tab).* Each request is handled on a case-by-case basis; a further assessment may be required.

12. Reference to A2LA Accredited Status

The requirements pertaining to the use of the "A2LA Accredited" symbol and to any other reference to A2LA accreditation are outlined in the document titled *R105 – Requirements When Making Reference to A2LA Accredited Status*. The document is available from the A2LA Customer Portal or on the A2LA website, www.A2LA.org. A2LA has also created a guidance document to aid and assist CABs to implement the R105 requirements, *G125 – A2LA Promotion of Accreditation Information* which can also be found on the A2LA website. Failure to comply with these requirements may result in suspension or withdrawal of a CAB's accreditation.

13. Accreditation Status and Adverse Accreditation Decisions

There are various levels of status that may be assigned to CABs that cannot uphold the requirements for initial or continued accreditation:

Voluntary Withdrawal – An applicant CAB, not yet accredited, or a renewal CAB, can decide to terminate further accreditation action and voluntarily withdraw from the accreditation program. The CAB's authorized representative must inform A2LA in writing of this request. A2LA does not publicize the fact that a new CAB had applied and then was withdrawn; however, the voluntary withdrawal status of renewal CABs is publicized on the A2LA website. If A2LA learns that the accredited CAB is going or has gone out of business, the CAB is contacted for further detail and the CAB's accreditation is voluntarily withdrawn. In accordance with ISO/IEC 17011:2017, clause 8.2.2, the publication of voluntary withdrawal status, including dates and scopes, will remain on the A2LA website until the CAB has reached the previously determined expiration date, or up to six months from the date of the action, whichever is longer.

Inactive– A CAB is designated as inactive when it has requested in writing that its accreditation be allowed to temporarily expire due to unforeseen circumstances that prevent it from adhering to the A2LA Conditions for Accreditation. To regain accredited status, the Inactive CAB must notify A2LA in writing of this desire and typically undergo a full reassessment, paying all renewal fees and reassessment costs.

The Inactive status is publicized on the A2LA website and can typically be given to a CAB for no longer than one year, after which time the CAB is removed from the A2LA system and designated as withdrawn.

A CAB that has relocated may, on a case-by-case basis, be designated as inactive until its ability to perform the activities on its scope at the new location has been confirmed (e.g. by a visit to the CAB's site). In these cases, to regain accredited status, the Inactive CAB must fulfill the requirements of *P105 – A2LA Policy on Organization Relocation* and may be required to undergo an interim reassessment, paying all interim assessment costs.

14. Suspension of Accreditation

Suspension of all or part of a CAB's accreditation may be a decision made by either the Vice President, Accreditation Services (VPAS) or Accreditation Council panel. The accreditation applicable to a specific CAB may be suspended upon adequate evidence of:

- Non-compliance with the requirements of a nature not requiring immediate withdrawal (e.g. identification of significant deficiencies during an assessment);
- Failure to provide full corrective action responses resulting from deficiencies cited during surveillance, renewal, follow-up, or extraordinary assessments within the specified timeframe;
- Improper use of the "A2LA Accredited" symbol (e.g., misleading prints or advertisements that are not resolved by suitable retractions and appropriate remedial measures by the CAB); and,
- Other departures from the requirements of the A2LA accreditation program (e.g., failure to pay the required fees, submit annual review information within 60 calendar days after it is due, or complete a surveillance assessment within the designated time frame or non-compliance with *R102 – Conditions for Accreditation*).

The accreditation of a CAB shall immediately be suspended by the VPAS if the CAB or any individual or entity responsibly connected with the CAB is indicted for, convicted of, or has committed acts which would: under United States federal or state law, constitute a felony or misdemeanor involving misstatements, fraud, or a bribe-related offense; or reflect adversely on the business integrity of the applicant or A2LA. A CAB may appeal the adverse accreditation decision, but the suspension will not be lifted until all court related actions are made final.

When an accredited CAB is suspended, A2LA shall confirm an official suspension via formal written notification to the CAB's authorized representative, stating:

- The noncompliance(s) that has been identified;
- The rationale for imposing the suspension;
- The conditions under which the suspension will be lifted;
- The suspension, including dates and scopes, will be publicized on the A2LA website;
- The suspension is for a temporary period to be determined by the time needed to take corrective action;
- That, within thirty (30) days of receipt of the notice, the CAB may submit in person, or in writing, information in opposition to the suspension, including any additional information that raises a genuine dispute over material facts; and,
- A further review will be conducted to consider such information and a further formal written notification will be sent to the CAB, indicating whether the suspension has been terminated, modified, left in force or converted to a withdrawal of accreditation.

The suspension status is publicized on the A2LA website.

15. Enforced Withdrawal of Accreditation

A2LA shall withdraw accreditation for any of the following causes:

- Under the relevant provisions for suspension of accreditation;
- If surveillance or reassessment indicates that deficiencies are of a serious nature;
- When complaints are received relating to one or more of the CAB's reports/certificates and investigation reveals serious deficiencies in the management system and/or competence in conducting the specific conformity assessment activities;
- If the accreditation rules are changed and the CAB either will not or cannot ensure conformance to the new requirements;
- On any other grounds specifically provided for under these program requirements or formally agreed between A2LA and the CAB;
- If there is evidence of fraudulent behavior, intentional provision of false information or concealed information; or,
- When such action is necessary to protect the reputation of A2LA.

When withdrawal of accreditation has been proposed or is being considered, A2LA shall issue a formal written notice identifying:

- That withdrawal is being considered, or in the case of fraud that withdrawal has occurred;
- The reasons for the withdrawal sufficient to put the CAB on notice of the cause;
- Except in cases of fraud, that within thirty (30) days of receipt of the notice, the CAB may submit in person, or in writing, information in opposition to the withdrawal, including any additional information that raises a genuine dispute over material facts. In the event of fraud, the CAB's accreditation shall be immediately withdrawn without further action on the part of the CAB or A2LA; and,
- The effect of proposed withdrawal, including removing the CAB's name from the A2LA on-line directory and publicizing the action on the A2LA website, along with dates and scopes. In accordance with ISO/IEC 17011:2017, clause 8.2.2, the publication of enforced withdrawal status, including dates and scopes, will remain on the A2LA website until the CAB has reached the previously determined expiration date, or up to six months from the date of the action, whichever is longer.

Except in cases of fraud, a CAB may appeal to A2LA against a decision to withdraw or not to award accreditation.

The withdrawal status is publicized on the A2LA website.

16. Appeals

An appeal can be made to the Appeals Panel. The Appeals Panel consists of two bodies:

1) Appeals on accreditation decisions made by the Accreditation Council (AC) are submitted to a nine-member panel of the AC;
2) Appeals on adverse accreditation decisions made by A2LA are submitted to the A2LA Quality Council (QC).

A2LA shall advise the applicant in writing of its right to challenge an adverse accreditation decision by the initial Accreditation Council panel (see Part C.7 Accreditation Decisions) or A2LA.

Any appeal shall be lodged no later than thirty (30) days after notification of the decision, by submitting formal written notification to A2LA for timely consideration by the Appeals Panel.

Any decision from the Appeals Panel which would deny or withdraw all or a portion of a CAB's accreditation must be agreed upon by two-thirds of the votes received (sum of the affirmative and negative – abstentions are not included). At least one member of the AC appeals panel that are technical experts in the field(s) of accreditation or in the regulatory requirements related to the appellant CAB (other than the original AC members balloted) shall be included in the nine-member appeal panel. The decision of the Appeals Panel is communicated in writing to the appellant. The decision rendered by the Appeals Panel is final and binding.

17. Confidentiality Policy

A2LA is responsible for seeing that confidentiality is maintained by its employees, assessors and Accreditation Council members concerning all confidential information with which they become acquainted as a result of their contacts with CABs. Such information is examined by a small group of A2LA staff, assessors, and Accreditation Council and external bodies as needed for recognition of the program. All are made aware of its confidentiality and are required to sign the A2LA *A132 – Code of Conduct and Business Ethics* policy. The Association agrees to hold all disclosed confidential or proprietary information or trade secrets in trust and confidence. The information shall be used only for accreditation purposes, and shall not be used for any other purpose, nor shall it be disclosed to any third party without written consent of the applicant CAB unless required by law or judicial or administrative process or regulation (such as through a properly issued and served subpoena).

All information provided by applicants in connection with a request for an application package, an application for accreditation, an assessment or proficiency test is confidential. Documents necessary to convey information about accredited CABs and their scopes of accreditation are not confidential. In response to a question about whether or not a particular CAB has applied for accreditation, A2LA responds by stating whether or not the CAB is accredited. A2LA neither confirms nor denies whether a CAB has ever applied for accreditation. If the CAB itself is saying that it has applied for accreditation, it is the CAB's responsibility to release the information regarding its applicant status. If a caller states that a CAB is claiming it applied for accreditation, A2LA shall note the name, address and phone number of the CAB to check whether the CAB is misleading the client, but A2LA still will not verify the CAB's application. Should an applicant CAB require that A2LA verify for a potential client that it has applied to A2LA, A2LA shall indicate that the CAB has applied only if the applicant makes such a request to A2LA in writing or designates on the application for accreditation that A2LA is authorized to release information regarding the applicant's status.

Accreditation status is public information and A2LA reserves the right to inform anyone of changes to the accreditation status of any CAB. However, if an inquiry is made about a CAB whose accreditation has lapsed but is in the renewal process, A2LA can indicate that the CAB is not now accredited but is in the process of renewal, if that is the case. If the renewal CAB's accreditation has lapsed with no indication (such as return of renewal forms) that it is pursuing renewal, A2LA indicates simply that the CAB is not accredited.

18. Impartiality Policy

Since its inception, A2LA has had a policy that actual or apparent conflicts of interest must be avoided as mandated by normal business ethics. Consistent with the principles set forth in ISO/IEC 17011, A2LA believes that it is vital that its accreditation services be impartial and objective, and uninfluenced by the private interests of individuals acting for A2LA. Accordingly, any person directly involved in actions relating to the A2LA accreditation process shall avoid direct participation in A2LA actions that could compromise impartiality. The VPAS or designee shall, as promptly as possible, take all possible means to prevent or overcome any such actions that may conceivably be in violation of this policy.

19. Quality Policy

It is A2LA's policy to operate a comprehensive accreditation system for laboratories, inspection bodies, proficiency testing providers, reference material producers, product certifiers, biobanks, and related programs associated with accreditation in accordance with nationally and internationally accepted standards. In pursuing this policy, A2LA is committed to:

- Achieving customer satisfaction through meeting the needs of accredited bodies and their users;
- Improving the quality of accredited bodies and the data they produce; and,
- Increasing acceptance of accredited data to facilitate trade.

Annex A: Additional Requirements for ISO/IEC 17025 Laboratories

In addition to the above requirements, conformity assessment bodies seeking accreditation to ISO/IEC 17025, are required to meet the following additional requirements. The section numbers given below correspond to the section numbers in the main body of this document. If a number is skipped in the annex, there are no additional requirements for that section.

PART A – INTRODUCTION

The accreditation of laboratories is offered in the field of calibration and the following fields of testing:

Acoustics/Vibration	Biological	Chemical	Construction Material
Electrical	Environmental	Forensics	Geotechnical
Information Technology	Mechanical	Nondestructive	Sustainable Energy
Sampling	Thermal		

Special programs are developed in response to user needs and may extend across more than one field of testing.

All laboratories seeking accreditation in the calibration field will be required to undergo an assessment to A2LA's *R205 - Specific Requirements - Calibration Laboratory Accreditation Program*.

PART C – ACCREDITATION PROCESS

Laboratory Types and Related Definitions

Accreditation is site specific and is available for testing laboratories (tests) and calibration laboratories (calibrations). A2LA has defined the following laboratory types as follows:

Main Laboratory: A laboratory (organization) that maintains a single location only.

Permanent Laboratory: A laboratory erected on a fixed location. This is the laboratory location (address) denoted on the scope of accreditation.

Branch Laboratory [multi-location system]: A laboratory within a system that consists of two or more laboratories owned and operated by the same organization, utilizing the same management system and managed by a Corporate Representative [see *P106 - Branch System Policy* for more information].

Satellite Laboratory: A laboratory(ies) owned (or under contract with) and operated by the same organization as the Main Laboratory, utilizing the same management system, that does not conduct any Key Functions (see definition below) under its accreditation activities, and is managed by the same management as the Main Laboratory. [see *P120 – Policy on Satellite Laboratories* for more information].

Key Function(s): Primary functions conducted by the Main Laboratory, including policy formulation, process and/or procedure development, contract review, reporting of final results, planning conformity assessments, review, approval and decision on the results of conformity assessments.

Virtual Site: An online environment allowing persons to execute processes (e.g. in a cloud environment). (see *P119 – A2LA Policy on Conducting Remote Assessments* for more information)

Field Testing/Calibration: Testing/Calibration performed by staff of a laboratory or organization outside of the premises or grounds on which the permanent laboratory or the organization's permanent base or headquarters is located. Field testing/calibration may include sampling where it forms part of the documented calibration or test procedure. Accreditation for stand-alone sampling is also offered.

Field Tests or Calibrations are normally performed under two categories:

- Field tests or calibrations performed by staff sent out in the field by an accredited, permanent laboratory. This includes in-situ testing[1].
- Field tests or calibrations performed in the field by organizations that do not have a permanent laboratory.

Mobile Laboratory: Fully equipped, self-contained, transportable testing or calibration laboratory capable of performing tests or calibrations under controlled environmental conditions. A mobile laboratory may be a main or branch laboratory and is subject to the same accreditation requirements. The scope will identify the laboratory as a mobile laboratory and the fixed business address of the operator of the mobile laboratory shall be included on the scope.

To be considered for accreditation, the laboratory must have a mobile laboratory available and be included in the assessment, and the mobile technical capabilities must be fully available for evaluation and delineated on the scope of accreditation for the laboratory. Once a laboratory with mobile capabilities is accredited, there is not a requirement to assess additional mobile units if the technical capabilities being considered under accreditation is within the current scope of accreditation. If additional technical capabilities are added, an on-site assessment may be warranted.

For renewal assessments, when possible, a different mobile laboratory than the one previously assessed shall be made available for the assessment.

Campus Laboratory: A laboratory that performs accredited activities that are situated in several different buildings throughout the campus.

Sampling Laboratory: A stand-alone sampling organization (SASO) that conducts sampling associated with subsequent testing.

Scopes:

For testing laboratories, the scope of accreditation is the official listing of the various tests and/or technologies that the testing laboratory has been deemed competent to perform under the A2LA Accreditation. The testing scope identifies, wherever possible, the materials and/or products on which the testing is being performed; the component/parameter or characteristics tested; and where appropriate, the techniques, methods and/or equipment used.

The testing scope of accreditation is normally identified in terms of standard test methods prepared by international, national, and professional standards writing bodies. If a laboratory desires accreditation for a superseded version of a standard test method, the date, edition, version, etc. used is identified in its scope of accreditation. When the date, edition, version, etc. is not identified in the scope of accreditation, laboratories may use the version that immediately precedes the current version for a period of one year from the date of publication of the standard test method. Test methods currently under revision or in "draft" status may not be listed on a scope of accreditation.

Exclusions (i.e., not performing the entire test) to test methods may only be included on a laboratory's scope of

[1] In-situ: Testing or calibration of a device or system performed at the place of its installation.

accreditation when the test method contains multiple methods or method options (various techniques embedded within the technical requirement to perform the measurement) and the laboratory is only capable of performing a portion of these methods or method options. The scope must indicate these "exclusions" or "inclusion" of the actual tests the lab is capable of performing. When a test method does not contain multiple methods or method options, the laboratory must be able to demonstrate full competency to meet all of the technical requirements in the method. In the cases where a laboratory is not capable of meeting the technical requirements, the laboratory may write and validate their own internal procedure (see below).

Laboratories seeking accreditation for many tests or in each of two or more fields of testing will be accredited in each of these fields. However, laboratories seeking accreditation for tests primarily in one field of testing, with a few tests (i.e., *typically no more than 5*) from a second field, may include those tests from the second field on the scope of the primary field, although the laboratory will be assessed in all areas. In either case, all tests for which the laboratory applies and is found competent to perform will be included on its scope of accreditation. Note: A limited number of calibration parameters may be added to a testing Scope of Accreditation under some instances, but these will be determined on a case-by-case basis.

Likewise, for calibration laboratories, a traditional 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.

In general, calibration capability cannot be derived from scope parameters. In some cases, a laboratory's capability will be described in terms of types of measurements, techniques, or other descriptive text when it is not appropriate or practical to identify specific calibrations (see *G118 – Guidance for Defining the Scope of Accreditation for Calibration Laboratories*).

When calibration scopes of accreditation identify standard measurement methods prepared by international, national, and professional standards writing bodies, the calibration laboratory shall be able to demonstrate full competency to meet all of the technical requirements in the standard measurement method. Exclusions to measurement methods may only be included on a laboratory's scope of accreditation when the measurement method contains multiple methods or method options, and the laboratory is only capable of performing a portion of these methods or method options. The scope must indicate these "exclusions." When a measurement method does not contain multiple methods or method options, the laboratory shall be able to demonstrate full competency to meet all of the technical requirements in the method. In the cases where a laboratory is not capable of meeting all the technical requirements of the standard measurement method, the laboratory shall not include it on the scope of accreditation.

If a calibration laboratory desires accreditation for a superseded version of a standard measurement method, the date, edition, version, etc. used is identified in its scope of accreditation. When the date, edition, version, etc. is not identified in the scope of accreditation, laboratories may use the version that immediately precedes the current version for a period of one year from the date of publication of the standard measurement method.

Accreditation of non-standard tests and calibrations which the assessor is permitted to examine in detail may be granted and shall be referenced in the scope by unambiguous identification. A2LA reserves the right to refuse to consider accreditation for proprietary tests or calibrations, without prejudice, if there is not sufficient accessibility to the method, records, equipment and/or facilities.

If a laboratory is pursuing accreditation for the use of its own methods, then it must provide the following information to the assessor(s) before assessment:

- Origin of method;
- Comparison with the standard methods they replace including any departures from the standard (if applicable);
- Reasons for and effects of departures; and,
- Validation data per ISO/IEC 17025.

Flexible Scopes: There are circumstances in which a laboratory must perform testing or calibration activities in which it cannot identify either standard test or measurement methods prepared by national, international or professional standards writing bodies, or in-house developed non-standard methods on their fixed scope of accreditation, or because they typically use specifications/methods identified by the customer rather than a standard method. For testing laboratories these situations usually arise when the 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).* It should be noted that "Parameter Based Scopes" are considered a flexible Scope when a testing laboratory is performing a test method that is not listed on the scope and the A2LA *P112 – Flexible Scope Policy* shall apply.

For calibration laboratories, listing of a calibration or measurement method or procedure is most often considered flexible and included within the normal assessment and accreditation activity of the laboratory; however, there is no flexibility in listing the measurement parameter, the range of measurement, or the CMC. In the case of biological, chemical and forensics testing, the flexible scope option is limited to only those activities related to chemical, biochemical and molecular biology testing. *This option will be reviewed on a case-by-case basis, and the final decision on allowing the flexible scope option rests with A2LA* [see A2LA *P112 – Flexible Scope Policy).*

Calibration Corporate Scope: In some cases, accredited calibration laboratories within branch systems not only operate under a single corporate quality management system, but also have similar parameters, ranges, and CMC uncertainties on their Scopes of Accreditation. The corporation may also manage the calibration of their reference standards and/or measuring and test equipment (M&TE) company-wide rather than individually by facility, resulting in the need for a Corporate Scope of Accreditation. In these situations, the corporation may elect to combine their Scopes into a single document covering all of their technical capabilities.

These requirements are applicable to *calibration* laboratories only accredited to ISO/IEC 17025 by A2LA and that also maintain a branch system of laboratories (see *P106 - Branch System Policy* for more information on operating a branch system). This policy is in addition to *R205 - Specific Requirements: Calibration Laboratory Accreditation Program* [see A2LA *R238 - Specific Requirements - Calibration Corporate Scopes of Accreditation*].

14. Suspension of Accreditation

In some fields of testing, calibration or special programs, failure to meet the criteria for acceptable proficiency test results can result in automatic suspension of accreditation for the test(s) and/or calibration(s) under question (not the entire scope). These are identified in the specific requirements for those fields or in the *R103 - General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories*.

19. Proficency Testing (PT)

Proficiency testing is a process for checking actual laboratory testing (or calibration) performance, usually by means of interlaboratory data comparisons. For many tests and calibrations, results from proficiency testing are very good indicators of competence. Proficiency testing programs may take many forms and standards for satisfactory performance can vary depending on the field. For details on the requirements for proficiency testing, please refer to the *R103 General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories*.

Laboratories are required to participate in proficiency testing programs, where appropriate and available. If the results of the proficiency testing activities include outliers, laboratories are required to initiate their corrective action process for resolving the non-conformance.

A2LA may confer with assessors to discuss the results of such studies and assessors may be instructed to review all data associated with these studies during each assessment. Additional charges for assessor review of this data and/or corrective actions may apply.

Annex B: Additional Requirements for ISO 15189 Laboratories

In addition to the above requirements, conformity assessment bodies seeking accreditation to ISO 15189, are required to meet the following additional requirements. The section numbers given below correspond to the section numbers in the main body of this document. If a number is skipped in the annex, there are no additional requirements for that section.

PART A – INTRODUCTION

The A2LA ISO 15189 accreditation program offers accreditation on human specimens in the following Specialties and Subspecialties:

- Histocompatibility
- Microbiology
  - Bacteriology
  - Mycobacteriology
  - Mycology
  - Parasitology
  - Virology
- Diagnostic Immunology
  - Syphilis Serology
  - General Immunology
- Chemistry
  - Routine Chemistry
  - Urinalysis
  - Endocrinology
  - Toxicology
- Hematology
- Immunohematology
  - ABO/Rh Group
  - Antibody Transfusion
  - Antibody Non-Transfusion
  - Compatibility Testing
- Pathology
  - Histopathology
  - Oral Pathology
  - Cytology
- Radiobioassay
- Cytogenetics
- Flow Cytometry*
- Molecular Pathology*

*A2LA recognizes that Molecular Pathology testing and Flow Cytometry testing may be considered by a laboratory to apply to a different Specialty or Subspecialty than how they are categorized here. The laboratory can decide, with the assessor's input, how best to describe Molecular Pathology and Flow Cytometry on their scope of accreditation.

The A2LA clinical testing accreditation program, (as described in Part C of this document), ensures the competence and reliability of clinical testing laboratories:

a) To protect all individuals served by laboratories against substandard testing of specimens;
b) To safeguard the general public against health and safety hazards that might result from laboratory activities; and,
c) To motivate laboratories to comply with these accreditation requirements so that they can provide accurate and reliable test results.

All clinical testing laboratories are not alike and do not offer the same combinations of testing in the same facility configuration and staff organization. A2LA can customize the assessment process to match a laboratory's combination of specialties and subspecialties, whether a single application for multiple sites within a hospital campus and under a common director or multiple applications for laboratory sites within the same physical location.

PART C – ACCREDITATION PROCESS

1. Application

Part C.1 of this document details the general requirements for the application for accreditation. Additionally, ISO 15189 CABs are required to submit Key staff qualifications (including copies of verifiable credentialing documents).

Laboratory Types and Related Definitions

A2LA has defined the following clinical laboratory types as follows:

Main Laboratory: A clinical laboratory (organization) that maintains a single location only.

Permanent Laboratory: A clinical laboratory erected on a fixed location. This is the laboratory location (address) denoted on the clinical scope of accreditation.

Branch Laboratory [multi-location system]: A clinical laboratory within a system that consists of two or more laboratories owned and operated by the same organization, utilizing the same management system and managed by a Corporate Representative [see *P106 – Policy on Branch Systems* for more information].

Satellite Laboratory: A laboratory(ies) owned (or under contract with) and operated by the same organization as the Main Laboratory, utilizing the same management system, that does not conduct any Key Functions (see definition below) under its accreditation activities, and is managed by the same management as the Main Laboratory. [see *P120 – Policy on Satellite Laboratories* for more information].

Key Function(s): Primary functions conducted by the Main Laboratory, including policy formulation, process and/or procedure development, contract review, reporting of final results, planning conformity assessments, review, approval and decision on the results of conformity assessments.

Mobile Laboratory: Fully equipped, self-contained, transportable clinical testing laboratory capable of performing clinical tests under controlled environmental conditions. A mobile laboratory may be a main or branch laboratory and is subject to the same accreditation requirements. The scope will identify the laboratory as a mobile laboratory and the fixed business address of the operator of the mobile laboratory shall be included on the scope.

To be considered for accreditation, the laboratory must have a mobile laboratory available and be included in the assessment, and the mobile technical capabilities must be fully available for evaluation and delineated on the scope of accreditation for the laboratory. Once a laboratory with mobile capabilities is accredited, there is not a requirement to assess additional mobile units if the technical capabilities being considered under accreditation is within the current scope of accreditation. If additional technical capabilities are added, an assessment may be warranted.

For renewal assessments, when possible, a different mobile laboratory than the one previously assessed shall be made available for the assessment.

Point of Care Testing: A2LA will accredit for Point of Care Testing (POCT) as part of the assessment of the applicant clinical laboratory, if requested by the laboratory. The POCT requirements are based on ISO 22870:2016 – *Point of Care Testing (POCT) – Requirements for quality and competence* and the ISO 15189:2012 or the ISO 15189: 2022 (including annex A) standard. Point of care testing is defined as tests done at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside of the physical facilities of the clinical laboratory. A sampling of the applicant laboratory's POCT services is assessed, if the clinical laboratory requests accreditation for POCT.

Specimen Collection Sites: Any specimen collection sites that support the activities of the applicant laboratory are assessed as part of the accreditation process for the laboratory. A sampling plan is used to ensure that all collection sites are eventually assessed over a span of accreditation periods. A specimen collection assessor checklist (available as part of the application process) is used to assess specimen collection sites.

In order to use both the assessor's and the laboratory staff time effectively, A2LA requires that the following information be accessible and retrievable at the time of the onsite visit:

- Standard operating procedures with all test procedures (package inserts and supplemental information, as necessary);
- Records of tests referred to other laboratories;
- Management system assessment plans and records: policies and procedures directed towards monitoring, assessing and correcting identified problems;
- Records that support personnel qualifications, training, experience, competency assessment, responsibilities and authority;
- Records that support validation of test methods;
- Documentation of ongoing assessment activities including corrective action effectiveness reviews, policy and procedure revisions made to prevent recurrence of a problem, discussion of assessment reviews with staff;
- Patient test records including requisitions, instrument printouts and test reports;
- Quality Control records: with remedial actions, calibration and calibration verification, statistical limits, instrument maintenance and function checks;
- Access to any specimen collection sites that A2LA may wish to assess as part of the accreditation process;
- Proficiency testing (PT) reports including the test runs and results, printouts, report forms, reviews, attestation signatures, and performance summary data; and,
- Accommodation records: facility (environmental monitoring, water system, etc.) and Laboratory Information Management System (LIMS).

All testing is subject to full assessment by A2LA assessors.

If a clinical laboratory is pursuing accreditation for the use of its own methods (i.e., laboratory-developed methods and/or modified FDA-approved tests), then it must provide the following information to the assessor(s) before the assessment:

- Origin of method;
- Comparison with the standard methods they replace including any departures from the standard (if applicable);
- Reasons for and effects of departures; and,
- Validation data (per ISO 15189).

Where an A2LA accreditation requirement states "laboratory management" this means the same thing as "the Laboratory Director" or designee. A2LA requires the Laboratory Director to sign the Conditions for Accreditation attestation in the Application for A2LA Accreditation for Clinical Laboratories. The clinical laboratory's director has overall responsibility for all accreditation requirements. In addition to the responsibilities outlined in ISO 15189, the Laboratory Director is also responsible for ensuring that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-examination, examination and post examination processes.

Scope of Accreditation

The scope of accreditation is the fundamental document attesting to the organization's competence to perform test as indicated on the scope of accreditation.

The scope of accreditation is the official listing of the various specialties, subspecialties, tests, and analytes that the clinical testing laboratory has been deemed competent to perform under the A2LA accreditation. The testing scope identifies, wherever possible, the matrices on which the testing is being performed, and the specific test methods that apply to the accredited tests.

Accreditation of non-standard tests which the assessor is permitted to examine in detail may be granted and shall be referenced in the scope by unambiguous identification. A2LA reserves the right to refuse to consider accreditation for proprietary tests, without prejudice, if there is not sufficient accessibility to the method, records, equipment and/or facilities.

2. Assessment Process

2.3 On-site Assessment

In addition to the list given in C.2 above, the full initial and renewal assessment of a CAB seeking accreditation to ISO 15189 will also involve:

- Observation of staff performing assigned tasks in all three areas of the workflow process (pre- examination, examination, and post examination);
- Examination of test records, supplies, reagents, and PT records;
- Evaluation of the laboratory's compliance with the A2LA requirements document including but not limited to:
    - *P102 – A2LA Policy on Metrological Traceability,*
    - *P903 - Policy on Estimating Uncertainty of Measurement for ISO 15189 Testing Labs*,
    - *R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories*;

Through interviews with technical staff, record review, and observations of testing activities, the assessor confirms the depth of technical competency for the clinical laboratory. At a minimum the laboratory must demonstrate that a person has been authorized to perform testing for each of the tests the laboratory is seeking accreditation. If it is determined that there is only one person authorized for a given activity, this person is identified as essential personnel in the assessor deliverables to A2LA. The laboratory is then responsible for informing A2LA whenever the status of the essential personnel changes (e.g. cross-training of additional individuals such that the essential person is no longer the only person technically competent to perform a given task(s), departure of the essential personnel resulting in the laboratory no longer having the technical competency to perform a given task, etc.). When the essential personnel departs a laboratory this will result in the laboratory losing the accreditation for those activities the essential personnel was solely responsible. To regain accreditation for those testing activities, the laboratory would be required to provide objective evidence they have authorized applicable staff to perform such activities. This can be achieved via on-site or remote assessment, record review, and/or telephone/web interview, as determined by A2LA.

The assessor is looking for effective processes (pre-examination, examination, and post examination) that function well together. The assessor will also look at the processes that the laboratory uses to detect, prevent and control non-conformances and assure quality testing and services. The assessor focuses on the effectiveness of the management system in all aspects of the clinical laboratory.

4. Corrective Action Process

In addition to the requirements given in C.4 above, the corrective action response must also detail any corrective actions taken for patients found to have been affected, or have the potential of being affected, by the deficient practice.

20. Proficency Testing (PT)

Proficiency testing is a process for checking actual laboratory testing performance, usually by means of inter- laboratory test data comparisons. For many tests, results from proficiency testing are very good indicators of competence. Proficiency testing programs may take many forms and standards for satisfactory performance can vary depending on the specialty/subspecialty of clinical testing. For details on the requirements for proficiency testing, please refer to the *R103 General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories*. Please note *R103 General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories* includes the PT requirements for ISO 15189 laboratories.

Laboratories are required to participate in proficiency testing programs, where appropriate and available. If the results of the proficiency testing activities include outliers, laboratories are required to initiate their corrective action process for resolving the non-conformance.

A2LA may confer with assessors to discuss the results of such studies and assessors may be instructed to review all data associated with these studies during each assessment. Additional charges for assessor review of this data and/or corrective actions may apply.

Annex C: Additional Requirements for ISO/IEC 17020 Inspection Bodies

In addition to the above requirements, conformity assessment bodies seeking accreditation to ISO/IEC 17020, are required to meet the following additional requirements. The section numbers given below correspond to the section numbers in the main body of this document. If a number is skipped in the annex, there are no additional requirements for that section.

PART A – INTRODUCTION

A2LA acknowledges that some user organizations may choose to accept only inspections conducted by Type A (third party or independent) bodies. It is up to such organizations to decide which accredited inspection bodies they will accept.

A2LA's official application of the Standard is consistent with the current version of ILAC-P15- Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies. (ILAC-P15 may be obtained free of charge in the documents section of the ILAC web site WWW.ILAC.ORG). Additional criteria needed to clarify proficiency testing requirements for inspection bodies are included within this document. When tests and measurements are involved as part of the inspection process and measurement traceability is required, A2LA's *P102 - A2LA Policy on Metrological Traceability* applies.

PART C – ACCREDITATION PROCESS

1. Application

Accreditation is available for any type of inspection body. Typically, the scope of accreditation is identified in terms of standard inspection methods prepared by national, international, and professional standards writing bodies.

Inspection Body Structure

Locations of offices where key activities take place will require separate scopes of accreditation and need to be assessed on the two-year cycle. Key activities include:

- Policy formulation and approval;
- Development and approval of processes and procedures necessary for the operation of the inspection body, including requirements for selection and authorization of inspectors;
- Review of contractual arrangements;
- Development, evaluation and maintenance of the Inspection processes; and,
- Development and approval of policies, processes and procedures for the resolution of appeals and complaints received from all parties about the inspection process and criteria, including the final decision.

Accreditation of main locations may cover additional locations on the same scope of accreditation where the following are true:

- All inspections are in the same field;
- All inspectors operate under the same management system and management as the main inspection body. Inspectors need to be trained on the management system and included on the organizational chart;
- All 'key activities' (i.e. policy formulation, process and/or procedure development, process of

initial selection of inspectors) and, as appropriate, contract review, occur at the main location;
- All inspectors are able to have prompt supervisory oversight from the main location, when necessary;
- All inspectors must be included in the inspector witnessing plan as detailed in section VIII; and,
- Inspection records from all field inspectors can be accessed by management.

The additional locations shall be recorded on the Scope of Accreditation. Deviations from the above requirements will be reviewed on a case-by-case basis.

Branch Inspection Body: An inspection body system that consists of two or more locations owned and operated by the same parent organization but cannot meet the requirements stated above. These types of organizations will require separate scopes for each location.

Virtual Site: An online environment allowing persons to execute the conformity assessment activities in a virtual environment (e.g. in a cloud environment).

Scopes of Accreditation

The scope of accreditation is the fundamental document attesting to the organization's competence to perform the listed inspections.

The scope of accreditation is the official listing of the inspections or types of inspections that the inspection body has been deemed competent to perform along with the level of independence at the organizational level or by type of inspection, if it varies, under the A2LA Accreditation. The scope identifies the products, process, service or installation on which the inspections are being performed, the inspection requirements, and technologies/methods/specifications/in-house methods that apply to the accredited inspections.

The scope of accreditation can be identified in terms of standard methods prepared by international, national, and professional standards writing bodies or internally developed inspection procedures. If an inspection body desires accreditation for a superseded version of a standard method, the date of the version used is identified in its scope of accreditation. When the date, edition, version, etc. is not identified in the scope of accreditation, inspection bodies may use the version that immediately precedes the current version for a period of one year from the date of publication of the standard method.

Accreditation of non-standard inspection methods, which the assessor is permitted to examine in detail, may be granted and shall be referenced on the scope by unambiguous identification. A2LA reserves the right to refuse to consider accreditation for proprietary methods, without prejudice, if there is not sufficient accessibility to the method, records, equipment, facilities and/or witnessing of the inspection. If the inspection body is using non- standard methods, such methods must be appropriate and fully documented per the requirements per sections 7.1.1, 7.1.2 and 7.1.3 of ISO/IEC 17020 and ILAC P15.

Users of accredited inspection bodies are advised to obtain the Scope(s) of Accreditation from any accredited inspection body or from A2LA. The A2LA Certificates that accompany the Scopes of Accreditation are intended for display purposes.

3. Assessment Process

An assessment will be conducted at the main inspection body facility.

When the intended scope of accreditation will be covering inspections that occur at additional locations, the addresses and a listing of inspectors at each location is required to be submitted as part of the application. A decision regarding the on-site assessment of inspection body additional locations will be

made on a case-by-case basis. A2LA management will make the ultimate decision as to locations that need to be visited.

The most critical contribution to inspection decisions is the inspector; as such it follows that inspectors must also be witnessed performing inspections. The witnessing of inspectors needs to be such that the effectiveness of systems can be verified, and the competence of individual inspectors can be confirmed. Some of the considerations in determining the amount of witnessing include:

- Scope of accreditation requested;
- The extent to which inspectors are required to exercise professional judgment;
- Total number of inspectors;
- Frequency of each type of inspection;
- Number of locations of the inspection body;
- Past history of performance during (re)assessment;
- Personnel certification or other formal qualifications held by inspectors;
- The training system of the inspection body;
- Effectiveness of internal monitoring of inspectors;
- Organizational stability and risk awareness of the inspection body; and,
- Any statutory requirements.

During renewal assessments, effort should be made to interview or review records of different personnel than were interviewed previously. If the appropriate number of personnel are not available for witnessing during the onsite assessment, an interim assessment may be required to ensure appropriate coverage of qualified inspectors.

20. Proficency Testing (PT)

PT Participation:
Proficiency testing is typically associated with laboratory accreditation and is defined as a process for checking actual laboratory testing performance, usually by means of interlaboratory test data comparisons. For many tests and calibrations, results from proficiency testing are very good indicators of competence. However, in some instances proficiency testing may be relevant to inspection bodies. Records of these activities shall be available at the inspection body's facility. For specific information about relevant PT please see the specific program requirements documents that pertain to your inspection body.

Failure to participate, patterns of erratic results, successive failures, or other poor performance in required proficiency testing programs may result in revocation of accreditation for affected parameters and/or a required on-site surveillance visit by an A2LA assessor. The inspection body's scope of accreditation found on the A2LA web site will be revised to reflect any revocations. Failure to meet minimum participation requirements or to respond to A2LA requests for information may result in an adverse accreditation action.

A2LA considers a result outside of three standard deviations of the mean of results to be an outlying result and requires a corrective action response. Any results that are evaluated as "unacceptable" by the PT scheme provider, using its stated evaluation protocol, also require a corrective action response.

Remedial Actions:
If unacceptable results are received on a formal proficiency testing program (e.g., CTS), the inspection body must enroll for the same analysis in the next available proficiency-testing round and demonstrate acceptable performance. Failure to successfully analyze the sample in this "remedial" round will result in immediate revocation of the inspections concerned from the inspection body's Scope of Accreditation. Accreditation will be reinstated only upon demonstration of acceptable performance on a future proficiency testing round.

It is understood that proficiency-testing samples are occasionally not completely compatible with the materials and methods used by an inspection body. In these cases, an inspection body can decline to participate in a specific round of proficiency testing and justify their decision to A2LA.

21. Witnessing of Inspectors by the Inspection Body

ISO/IEC 17020:2012 clauses 6.1.8 and 6.1.9 state the following:

"6.1.8 Personnel familiar with the inspection methods and procedures shall monitor all inspectors and other personnel involved in inspection activities for satisfactory performance. Results of monitoring shall be used as a means of identifying training needs (see 6.1.7).

NOTE Monitoring can include a combination of techniques, such as on-site observations, report reviews, interviews, simulated inspections and other techniques to assess performance, and will depend on the nature of inspection activities.

6.1.9 Each inspector shall be observed on-site, unless there is sufficient supporting evidence that the inspector is continuing to perform competently.

NOTE It is expected that on-site observations are performed in a way that minimizes the disturbance of the inspections, especially from the client's viewpoint."

IB1 Requirement:

Therefore, A2LA requires that Inspection Bodies have suitably implemented these requirements and have a documented plan of how they intend to witness all inspectors performing all major types of inspections on their scope of accreditation (for which they are authorized) over a four-year period (IB1). The plan must detail the frequency of witnessing, and detail how all inspectors will be witnessed performing each type of inspection (and if necessary, on specific types of products). The documented witnessing plan along with the documented results of the witnessing will be reviewed at each on-site assessment and during annual review submissions to A2LA.

Additional guidance and recommended practices on inspector monitoring is provided in ILAC P15.

Annex D: Additional Requirements for ISO 17034 Reference Material Producers

In addition to the above requirements, conformity assessment bodies seeking accreditation to ISO 17034, are required to meet the following additional requirements. The section numbers given below correspond to the section numbers in the main body of this document. If a number is skipped in the annex, there are no additional requirements for that section.

PART A – INTRODUCTION

The ***A2LA Accreditation Program for Reference Material Producers*** is primarily designed for reference material producers who wish to demonstrate their competence by formal compliance with a set of internationally acceptable requirements for producing reference materials.

PART B – CONDITIONS FOR ACCREDITATION

Please note that for reference material producers, Section 12 of A2LA's *R102 – Conditions for Accreditation* includes the need to inform A2LA headquarters within 30 days, in writing, of any changes to subcontractors. The information provided shall contain enough detail to establish competency of subcontractor to provide the requested materials or services.

PART C - A2LA ACCREDITATION PROCESS

Part C.1 of this document details the general requirements for the application for accreditation. Additionally, ISO 17034 CABs are required to submit information on the subcontractors they utilize as part of their application.

2. Assessment Process

The scope of accreditation is the fundamental document attesting to the organization's competence to produce reference materials (RMs) and/or certified reference materials (CRMs). For reference material producers, the scope of accreditation contains the official listing of the RMs and/or CRMs covered under the A2LA Accreditation. At a minimum A2LA must include the following information on the scope of accreditation in order to meet minimum requirements for ISO/IEC 17011:

- Specific types of reference materials, clearly identifying whether these are CRMs, RMs or both;
- The RM and/or CRM matrix or artefact;
- The property(ies) characterized; and,
- The approach used to assign the property values.

Annex E: Additional Requirements for ISO/IEC 17043 Proficiency Testing Providers

In addition to the above requirements, conformity assessment bodies seeking accreditation to ISO/IEC 17043, are required to meet the following additional requirements. The section numbers given below correspond to the section numbers in the main body of this document. If a number is skipped in the annex, there are no additional requirements for that section.

PART A – INTRODUCTION

The program will also provide users of proficiency testing programs (laboratories, accreditation bodies such as A2LA, technical assessors, etc.) increased confidence that the programs being relied upon are being operated competently in accordance with specified technical and management system requirements.

Note that this program applies only to the use of inter-laboratory comparisons for the purpose of proficiency testing (to determine the performance of individual laboratories for specific tests or measurements and to monitor laboratories' continuing performance.) It does not include determining the effectiveness and precision of test methods or determining the characteristics of a material to a particular degree of accuracy, such as in the preparation of reference materials. Please note that A2LA offers a separate accreditation for Reference Material Producers which is based on ISO 17034.

Proficiency testing programs are used by A2LA as part of the laboratory accreditation assessment process to determine the ability of laboratories to perform competently tests or calibrations for which accreditation is held. Proficiency testing programs are also used to monitor accredited laboratories' continuing performance. A2LA recommends that wherever possible, A2LA-accredited testing and calibration laboratories use ***accredited*** *proficiency testing (PT) providers* to meet the ISO/IEC 17025 requirements for participation in proficiency testing.

A2LA shall not administer any ongoing, commercial proficiency testing programs while carrying out this PT accreditation program. A2LA does reserve the right to utilize artifacts or reference materials to conduct measurement audits with individual laboratories as needed for the effective assessment of an organization's technical competence.

1. Application

Part C.1 of this document requires all applicant and renewal CABs to submit a proposed scope of accreditation with their application for accreditation. Additionally, PTPs are requested to submit the following with their proposed scope of accreditation:

- Proficiency testing schemes,
- Detailed description of sample/artifact type for each program/scheme, and,
- The measurand(s) or characteristic(s) to be identified, measured, or tested.

PART B – CONDITIONS FOR ACCREDITATION

Please note that for Proficiency Testing Providers, Section 12 of A2LA's *R102 – Conditions for Accreditation* includes the need to inform A2LA headquarters within 30 days, in writing, of any changes to subcontractors. The information provided shall contain enough detail to establish competency of subcontractor to provide the requested materials or services.

3. Deficiencies

Assessors may also write deficiencies during the annual reviews if there is supporting evidence to justify non-compliance to ISO/IEC 17043 and A2LA specific requirements.

4. Corrective Action Process

A proficiency testing provider that is undergoing an annual review and had a deficiency cited during this review, will be required to respond in writing within 30 days of when you were notified of the finding(s) and resolve all deficiencies within 60 days of the notification from A2LA.

5. Accreditation Anniversary Date

Accreditation is granted for a four-year period. The anniversary date of a proficiency testing provider's accreditation is established 45 to 75 days after the last day of the final on-site assessment before an initial accreditation decision, regardless of the length of time required to correct deficiencies. This date normally remains the same throughout the proficiency testing provider's enrollment.

8. Annual Review and Annual PT Report Review

Accreditation is valid for four years. However, after the initial year of accreditation the Proficiency Testing Provider must pay annual fees and assessor fees and undergo a one-day surveillance assessment by an assessor. This surveillance assessment is performed to confirm that the proficiency testing provider's management system and technical capabilities remain in compliance with the accreditation requirements. Failure to complete the surveillance assessment within the designated time frame may result in adverse accreditation action (see Part C.13, Accreditation Status and Adverse Accreditation Decisions).

After the first, second, and third years of accreditation for each four-year cycle, each proficiency testing provider must pay an **Annual Review Fee** and submit updated information on its organization, facilities, essential personnel, subcontractor information and proficiency testing programs. Objective evidence of completion of the internal audit and management review is also required.

In addition, after each year of accreditation, each proficiency testing provider must also pay an **Annual PT Report Review Fee** to cover the cost of a technical assessor's (statistician) review of the list of all proficiency testing programs that were conducted since the last A2LA review, including the following summary information for each program:

- The nature of the samples and the tests/calibrations performed;
- Basic statistical data, including the number of samples (n), mean value, and standard deviation for each analyte/property, and, if possible, summary data for each different method used for each analyte/property; and,
- Method of publication (e.g. printed report, electronic report, web-based). (A representative sample of PT reports issued since the last A2LA review is provided for review.)

The technical assessor (statistician) may request additional reports from the proficiency testing provider and the number sampled will depend on the number and types of reports issued by the accredited PT provider since the last A2LA review. The statistician may also cite deficiencies if they find areas of non-compliance to ISO/IEC 17043 and/or any additional A2LA requirements. The deficiencies are to be resolved within 60 days before accreditation reaffirmation can be granted. If the resolution of the finding(s) are not resolved in a timely manner, this may warrant suspension of accreditation.

Total charges for the annual PT report review are not to exceed one 8-hour review day per year unless significant technical issues reveal the need for further review. There are no additional assessor expenses (such as travel) associated with the review. For details on the fees currently in effect, please review the application form.

If the proficiency testing provider does not promptly provide complete requested documentation and reports, or if significant changes to the facility, organization or proficiency testing programs have occurred, a one-day on-site surveillance assessment and payment of the associated assessor fees is required.

Annex F: Additional Requirements for ISO/IEC 17065 Certification Bodies

In addition to the above requirements, conformity assessment bodies seeking accreditation to ISO/IEC 17065, are required to meet the following additional requirements. The section numbers given below correspond to the section numbers in the main body of this document. If a number is skipped in the annex, there are no additional requirements for that section.

PART A – INTRODUCTION

A2LA recognizes the very close relationship between certification, testing and inspection, yet understands that certification includes a variety of activities not covered in testing laboratory or inspection body accreditation alone. Certification includes products (e.g. services, software, hardware, and processed materials), as well as processes and services, including the examination of test reports for compliance with specified criteria – both domestic and international. A product certification body (PCB) which is engaged in testing, inspection, measurement or sampling work may apply for accreditation for this work concurrently with its application for accreditation of its certification activities.

Accreditation is based on the assessment of performance of a product certification body including (as appropriate) procedures, staff competence, inspection, review of product/process/service acceptability, and reporting. It is available to all Conformity Assessment Bodies (CABs) providing certification. A2LA welcomes applications for the accreditation of all types of product certifications, provided they fall within A2LA's scope of activities. The following are examples of work for which accreditation may be sought:

Appliances	Marine products
Automotive lifting devices	Personal protective and safety equipment
Bottled water and packaged ice	Plastic piping systems and components
Building products	Plumbing products
Building and institutional furniture	Recreational clothing
Class II biohazard cabinetry	Occupational health and safety/personal protective clothing
Drinking water additives	Sanitation products
Drinking water treatment units	Sealed insulating glass
Electric appliances and accessories	Software
Electrical products	Solar energy
Fenestration products	Swimming pools, spas and components
Food service equipment	Telecommunications
Gas appliances and accessories	Treated wood
Gas and oil products	Wastewater treatment units
Waste water treatment	Windows and doors
Manufactured products and recreational vehicle plumbing products	Wood Products

PART C - A2LA ACCREDITATION PROCESS

1. Application

Part C.1 of this document details the general requirements for the application for accreditation. Additionally, ISO/IEC 17065 CABs are required to submit copies of all certification schemes as well as provide evidence of compliance with any relevant program requirements for all certification scheme(s).

Product certification attests that a product meets specified standards, especially for quality or safety and health issues. For product certification bodies accredited by A2LA, the scope of accreditation is normally identified in terms of a certification scheme(s) and specification(s) used to certify a product/process/service.

Certification Scheme Review Requirements

When a product certification body applies for accreditation operating a scheme which is not operated by any other current A2LA-accredited product certifiers, A2LA is required to review the certification scheme and supporting requirements to determine if the scheme is suitable to assess to, while also confirming A2LA has the appropriate assessors and experts available to facilitate an adequate assessment of the scheme. This review may take a few hours or a few days, depending on the length and difficulty of the scheme's contents, and any need to research the technical background of the certification steps that are to be performed by the product certification body.

A2LA will give the applicant written notice of the receipt of the application and certification scheme and will periodically update the applicant with the status of the scheme review, including requesting additional information as necessary. At the end of this review process, A2LA will give written notice to the applicant on the conclusion of whether the application can be fully accepted, and the product certification body assessed.

If A2LA determines that it is NOT able to accredit the applicant product certification body, A2LA is not permitted to fully discard all application information but will respect all application information confidentiality within the requirements we as an accreditation body must follow.

Multiple Certification Schemes

Organizations may apply for accreditation to multiple certification schemes. However, when the certification schemes are unrelated (e.g. Telecommunication and WaterSense) or are developed for different, specific regulators/specifiers in a given industry, the product certification body will be required to maintain separate scopes of accreditation for each certification program/scheme.

If you are applying for more than one certification program/scheme, a separate application must be completed for each certification program/scheme. Product certification bodies that have applied or hold multiple accreditations will be eligible to receive a fee discount.

The conditions for receiving the fee discount when applying for multiple certification programs are as follows:

All applications, renewal of accreditation and annual review processes must be coordinated through one central person, the Corporate Representative:

- All fee payments and invoices must be coordinated through the Corporate Representative;
- All certification programs/schemes must operate under the same management system; and,
- Product certification bodies accredited to multiple certification programs/schemes will be assigned related certificate numbers (e.g., 301.01, 301.02, 301.03, etc.).

Scopes of Accreditation

In order to facilitate the assessment process, and to ensure consistency among Scopes of Accreditation of product certification bodies accredited by A2LA, all Scopes of Accreditation for accredited product certification bodies must meet the following requirements:

- All scopes must be in a three (3) column format, with those columns being:
    - **Certification Scheme** – this is the formal name of the certification scheme or system being operated by the accredited product certification body.
    - **Product Type / Category** – this is the description of the category or type of product (or products) the accredited product certification body is competent to certify.
    - **Standards / Requirements** – this is the documented set of requirements that the product (or products) is verified as complying with by the accredited product certification body.

Examples from a small number of certification areas follow:

Certification Scheme	Product Type / Category	Standards / Requirements
Federal Communication Commission (FCC) - TCB Roles and Responsibilities[1]	Unlicensed Radio Frequency Devices (Scope A)	Scope A1, A2, A3, A4 of the *FCC TCB Roles and Responsibilities*
	Licensed Radio Frequency Devices (Scope B)	Scope B1, B2, B3, B4 of the *FCC TCB Roles and Responsibilities*
	Telephone Terminal Equipment (Scope C)	Scope C1 of the *FCC TCB Roles and Responsibilities*

Certification Scheme	Product Type / Category	Standards / Requirements
EPA ENERGY STAR	Residential Ventilating Fans (*excluding certification of Luminaires*)	ENERGY STAR Program Requirements for Residential Ventilating Fans (ver. A)
Company X Certified Ratings Program	Fans	Company X Publication 1, Certification Program Manual; Company X Publication 2 – Product Rating Manual for Fan Air Performance; Company X Publication 3 – Product Rating Manual for Fan Sound Performance

Certification Scheme	Product Type / Category	Standards / Requirements
EPA ENERGY STAR	Telephony	ENERGY STAR Program Requirements Product Specification for Telephony (ver. X)
	Audio/Video Equipment	ENERGY STAR Program Requirements Product Specification for Audio/Video (ver. Y)

2. Assessment Process

2.3 On-site Assessment

In addition to the list given in C.2 above, the full initial and renewal assessment of a CAB seeking accreditation to ISO/IEC 17065 will also involve:

- Observing witness assessments or other off-site activities as required by the certification scheme(s).

In instances where the certification scheme requires some form of witnessing or other off-site certification activity (e.g. inspection, auditing, etc.), the certification body must have a legally enforceable arrangement (e.g. contract) with their clients that commits the clients to provide, on request, access to A2LA's assessment team to assess the certification body's performance carrying out its certification activities.

8. Annual Review

In addition to the requirements given in C.8 above, certification bodies are also required to submit objective evidence of completion of surveillance activities in accordance with the certification scheme or program, or the organization's respective planned intervals when the scheme and program are silent.

12. Reference to A2LA Accredited Status

Per IAF Resolution 2018-13, all IAF accreditation body members shall have legally enforceable arrangements with their accredited CABs for product certification that prevents the CAB from issuing non-accredited certifications in scopes for which they are accredited. This requires that all CABs under this program must include the A2LA accredited symbol and/or make reference to the accreditation status of the CAB including the identification of the accreditation body (A2LA). Exceptions to this requirement can be requested with justification by the CAB to A2LA and will be reviewed on a case-by-case basis. However, even if an exception is granted, the certification will still be considered accredited and will still need to meet all requirements of ISO/IEC 17065 and the applicable certification scheme.

13. Accreditation Status and Adverse Accreditation Decisions

When a product certification body's A2LA accreditation has lapsed or been removed for any reason (i.e. Inactive, Voluntary or Enforced Withdrawal or Suspension), the certification body shall have provisions in place to provide its customers with information on the withdrawal of its accreditation, and the consequences of that withdrawal to its customers.

Annex G: Additional Requirements for ISO 20387 Biobanks

In addition to the above requirements, conformity assessment bodies seeking accreditation to ISO 20387, are required to meet the following additional requirements. The section numbers given below correspond to the section numbers in the main body of this document. If a number is skipped in the annex, there are no additional requirements for that section.

PART B – CONDITIONS FOR ACCREDITATION

Please note that for Biobanks, Section 12 of A2LA's *R102 – Conditions for Accreditation* includes the need to inform A2LA headquarters within 30 days, in writing, of any changes to subcontractors. The information provided shall contain enough detail to establish competency of subcontractor to provide the requested materials or services.

PART C - A2LA ACCREDITATION PROCESS

1. Application

Part C.1 of this document details the general requirements for the application for accreditation. Additionally, ISO 20387 CABs are required to submit the following:

- List of Equipment per Section 6.5.4 and 6.5.5 of ISO 20387; and,
- Technical Staff Matrix for Accreditation – ISO 20387

Scopes of Accreditation

The scope of accreditation is the fundamental document attesting to the organization's competence to provide the Biobanking activities indicated on the scope of accreditation. At a minimum A2LA must include the following information on the scope of accreditation in order to meet ISO/IEC 17011:

Minimum Required Information

Scopes of accreditation for Biobanks must include:

- Type of materials stored by the Biobank (human, animal, environmental, see table below for examples of categories);
- Activities performed by the Biobank must include at least acquisition and storage, and at least one other activity, per ISO 20387 clause 3.6 (collection, preparation, preservation, testing, analysing, and/or distribution);
- Storage conditions; and,
- Methods/Standard Operating Procedures.

Human Repositories*	**Animal/Environmental Repositories***
Clinical Trials	Animal Specimens
Disease Based	Environmental Specimens
Cord Blood	Biodiversity
Population-Based	Micro-Organism Culture Collection
Pediatric	Plant-Seed Repository

*Note: ISO 20387 does not apply to biological material intended for food/feed production and/or therapeutic use.

20. Proficiency Testing

Proficiency testing is a process for checking Biobanking performance, usually by means of inter-laboratory data comparisons. Proficiency testing programs may take many forms, and standards for satisfactory performance can vary depending on the field. For Biobanks performing testing and/or analysing, the requirements in *R103 General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories* apply. More details on the requirements for proficiency testing can be found within the associated *G133 – A2LA Guide for Establishing Proficiency Testing Plans*.

DOCUMENT REVISION HISTORY

Date	Description
09/08/22	➢ Part C.1 – added "where relevant" for PT plan and result submission ➢ Part C.1 – under "Scopes of Accreditation", removed reference to in-house calibrations being added on to testing scopes, and changed the term calibration "activities" to "parameters" ➢ Part C.1 – under "Scopes of Accreditation", added language to disallow publication of scopes of accreditation with "draft" test methods listed ➢ Part C.2.2 – added reference to initial invoices for pre-assessments ➢ Part C.12 – removed links to obsolete scope expansion forms and replaced with link to Customer Portal for requests ➢ Part C.14 – under Inactive Status, added "typically" to allow flexibility on the one-year term ➢ Part C.20 – added biobank reference to the Quality Policy
01/16/24	➢ Renamed document from "R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories" to "R101 – General Requirements: Accreditation of Conformity Assessment Bodies" ➢ Complete re-write of document to be general to all accredited customers under the ILAC/IAF umbrella rather than specific to ISO/IEC 17025 ➢ Part C2.2 – Revised preferred assessment technique for pre-assessments from on-site to remote ➢ Annex A, Part C – Removed definition for "Parameter Based Scopes" and enveloped it into the definition for "Flexible Scopes" ➢ Annex A and B – Removed definition of a field laboratory ➢ Added annexes to cover additional requirements specific to each accreditation scheme
02/16/24	➢ Updated Mission statement in Part A