R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories

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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 laboratory accreditation system. Accreditation is a formal recognition of competence that a laboratory can perform specific tests or calibrations. Accreditation is available to any type of testing or calibration laboratory, 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. Accreditation is available for virtually all types of tests, calibrations, measurements and observations that are reproducible and properly documented.

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
Thermal			

Special programs are developed in response to user needs and may extend across more than one field of testing. If only a few tests from a second field are to be included and all testing is managed in one facility under one management system, these tests may be added to the scope of accreditation in the primary field at no charge for a second field.

Users of accredited laboratories are advised to obtain the Scope(s) of Accreditation from any accredited laboratory or from A2LA. The Scope(s) of Accreditation identifies the specific tests or types of tests or calibration capability for which the laboratory is accredited.

The general requirements (general criteria) for A2LA accreditation are the international standard, ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*.

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

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

a) it is competent to perform specific tests, types of tests, calibrations, or types of calibrations listed on its Scope(s) of Accreditation;
b) its management system addresses and conforms to all elements of ISO/IEC 17025, is documented per ISO/IEC 17025, and is fully operational;
c) it is operating in accordance with its management system; and,
d) it conforms to any additional requirements of A2LA or specific fields or programs necessary to meet user needs.

It is A2LA policy not to accredit or renew accreditation of a laboratory 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:

- Providing independent, world-class accreditation programs that inspire confidence in the quality of services and acceptance of results from accredited organizations.

- 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.

Trace McInturff
Senior Director, Accreditation Services

PART B - CONDITIONS FOR ACCREDITATION

In order to attain and maintain accreditation, laboratories 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 laboratory'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 his/her knowledge and belief. An accredited laboratory's Authorized Representative 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 the *R102 - Conditions for Accreditation*.

PART C - A2LA ACCREDITATION PROCESS

I. Application

A laboratory applies for accreditation by visiting the A2LA website www.A2LA.org and completing appropriate application forms and relevant checklists. All applicants must agree to a set of conditions for accreditation (see Part B of this document), pay the appropriate fees set by A2LA and provide detailed supporting information, including:

- Proposed scope of testing or calibration in terms of field(s) of testing or calibration, testing or calibration technologies, methods and relevant standards, and measurement uncertainty budgets if applicable (always required for calibration and dimensional inspection testing laboratories);
- Quality manual and supporting SOPs;
- Organization structure; and,
- Proficiency testing plan and results.

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 laboratory'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 staff will provide further details as appropriate and on request as to which documents would need to be provided in English.

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 physically separate laboratory (from the main laboratory) that can place their testing or calibration capabilities on the main laboratory's scope (with a footnote to reference their location) as long as the satellite laboratory is:

- in the same field of testing or calibration as the main laboratory;
- operating under the same management system and management as the main laboratory;
- not performing any 'key activities' (i.e. policy formulation, process and/or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessments); and,
- able to have prompt supervisory oversight from the main laboratory, when necessary.

As accreditation is "site specific," only the main laboratory address can be listed in the heading information contained on the Scope of Accreditation. The satellite location(s) address(es) will be listed at the end of the scope content of the main laboratory and will contain all of the scope content that coincides with that satellite location. If there is more than one satellite location, this information is repeated for each separate satellite location. As the satellite location(s) operate under the same management system as the main location, A2LA will assign the same assessor(s) and the satellite assessment(s) will typically occur concurrently with the main location assessment

Field: Any location where testing or calibration takes place as defined in Field Testing/Calibration.

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.

Field Laboratory: A testing or calibration laboratory facility set up in a dedicated location or at

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

a customer's premises, outside of the organization's permanent base or headquarters for the duration of the testing or calibration activities but not for periods expected to exceed three years (e.g. a Construction Materials laboratory set up at an airport construction site, a calibration laboratory under contract set up in support of a customer's manufacturing process). All field laboratories must be identified on the application paperwork, be assessed as part of the permanent laboratory assessment, and be identified on the laboratory's scope of accreditation.

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.

Scopes of Accreditation

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

For testing laboratories, the scope of accreditation is the official listing of the various tests, types of 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, and the specific test methods/specifications/ in-house methods that apply to the accredited tests.

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. If a laboratory requests accreditation to a withdrawn and/or cancelled test method(s), the scope must include the date that these methods were withdrawn or cancelled and include a footnote clarifying that the method itself has been withdrawn and is now considered "historical."

Exclusions to test methods may only be included on a laboratory's scope of accreditation when the test 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 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 types of tests in each of two or more fields of testing will be accredited in each of these fields. However, laboratories seeking accreditation for types of tests primarily in one field of testing, with a few types of tests (*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 and types of 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 activities may be added to a testing Scope of Accreditation under some instances (e.g. in-house calibration laboratory for a branch system), 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. If a laboratory requests accreditation to a withdrawn and/or cancelled method(s), the scope must include the date that these methods were withdrawn or cancelled and include a footnote clarifying that the method itself has been withdrawn and is now considered "historical."

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 wishes 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.

Parameter Based Scopes: If a laboratory requests a "parameter-based" scope because they typically use methods specified by the customer, as much specificity as possible is captured on the scope. This includes the equipment capabilities and at least one method for each technology or parameter listed on the scope in addition to the details of the types of testing requested by the customer and the products/materials on which the testing is done. In addition, wording similar to the following is also listed on the scope: "*Using customer-specified methods directly related to the types of tests listed above.*" As such, the customer-specific methods that are covered under the accreditation are those directly related to the types of tests that the assessor has verified the laboratory is competent to perform. This same procedure can be used when identifying numerous "internal" or "in-house" methods.

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. 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).* 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. The flexible scope option is only available to laboratories accredited in the following fields: calibration, biological, chemical and forensics. For testing laboratories, it is further limited to encompass 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*].

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

II. Assessment Process

The objective of an initial, follow-up, renewal or extraordinary assessment is to establish whether or not a laboratory complies with the A2LA requirements for accreditation and can competently perform the types of tests or calibrations 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 laboratory 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 laboratory fails to undergo its full initial assessment within one year from receipt of the application at A2LA headquarters, the laboratory is prompted by A2LA to take action. If no action is taken within thirty (30) days of that reminder, the laboratory is required to begin the application process again and pay the laboratory accreditation fees in effect at that time. Any fees paid with the initial application are refunded according to the A2LA Refund Policy

Refund Policy: While the A2LA Application Fee is non-refundable, if a laboratory withdraws the application before completion of the initial assessment, it may apply for a refund of up to 50% of the A2LA annual fee(s) and the balance of the unexpended assessor deposit. There will be no refund of annual fees after the assessment has been completed. Refunds of any balance remaining on the assessor deposit will be made at the time of the accreditation decision. Any withdrawal or refund request must be in writing.

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

A. Initial Steps

Once the application information is completed and the appropriate fees are paid, A2LA headquarters staff identifies and tentatively assigns one or more assessors to conduct an initial assessment at the laboratory's site. Assessors are selected based on their testing or calibration expertise so as to be better able to provide guidance to the laboratories. They do not represent their employers (if so affiliated) while conducting assessments for A2LA. The laboratory has the right to ask for another assessor if it objects to the original assignment. A2LA assessors are drawn from industry, academia, government agencies, consultants, and the laboratory 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 laboratory. More than one assessor may be required.

Laboratories 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

laboratory 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 initial and renewal assessments. These documents are intended to ensure that assessments are conducted as uniformly and completely as possible among the assessors and from laboratory to laboratory and to ensure an efficient, value-added service for the customer.

Before an initial assessment is conducted, the assessor team reviews the laboratory-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 laboratory in writing and may ask the laboratory to implement corrective action to fill any documentation gaps required by ISO/IEC 17025 before scheduling the assessment. A pre-assessment visit may be requested by the laboratory 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 tests/calibrations to possibly witness and checks on the availability of the technical personnel who perform the tests/calibrations. An assessment agenda is provided by the assessor.

B. 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 laboratory'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 laboratory 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 laboratory requests a pre-assessment to better prepare for the full initial assessment. In this case, the laboratory 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 program, the laboratory must first apply for accreditation, paying the appropriate fees and assessor deposit. A lead assessor is assigned, with the laboratory's concurrence. If, during the discussions between the laboratory and assessor in preparation for the assessment, the laboratory concludes that it is in its interest to have a pre-assessment, it informs the assessor. The assessor notifies A2LA that the laboratory 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 and assessor deposits. No additional accreditation fees apply. A pre-assessment is generally performed on-site as a truncated version of the full initial assessment but may also be performed remotely in some cases (refer to *A2LA P119 - A2LA Policy on Remote Assessment*).

C. On-Site Assessment

The full initial assessment and renewal assessments generally involve:

- An entry briefing with laboratory management;
- Interviews with technical staff;
- Demonstration of selected tests or calibrations including, as applicable, tests or calibrations at representative field locations;
- Examination of equipment and calibration records;
- Audit of the management system to verify that it is fully operational and that it conforms to all sections of ISO/IEC 17025, including documentation and record review;
- Evaluation of your laboratory's compliance with the A2LA requirements documents including but not limited to:
    - *R102 – Conditions for Accreditation*,
    - *R105 – Requirements When Making Reference to A2LA Accredited Status*,
    - *P102 – A2LA Policy on Metrological Traceability or P113 – A2LA Policy on Measurement Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies*
    - *P103 – Policy on Estimating Measurement Uncertainty for Testing Laboratories*,
    - *R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories*,
    - and the applicable A2LA Technical Advisory Committee (TAC) Consensus Documents (these policy documents can be found on the A2LA website);
- 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 testing or calibration activities, the assessor confirms the depth of technical competency for the laboratory. At a minimum the laboratory must demonstrate that a person has been authorized to perform testing/calibration for each of the tests and/or calibrations 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/calibration 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.

During an on-site assessment, the assessor has the authority to stop the process at any time and consult with A2LA staff and the laboratory'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, or a suspension may be recommended if technical capability is lost (see Section XV Suspension of Accreditation). The assessment can then be rescheduled for a time when the laboratory and assessor feel it is appropriate to proceed.

III. Deficiencies

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

- a laboratory's inability to perform a test, type of test, or calibration for which it seeks accreditation;
- a laboratory's management system does not conform to a clause or section of ISO/IEC 17025, is not adequately documented, or is not completely implemented in accordance with that documentation; or,
- a laboratory does not conform to any additional requirements of A2LA or specific fields of testing or programs 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 laboratory must resolve in order to be accredited, maintain current accreditation or have their accreditation renewed. The assessor holds an exit briefing with the authorized representative (or designee) of the laboratory to review the assessor's findings and any identified deficiencies (deficiency report). The authorized representative of the laboratory (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 laboratory representative concurs that the individual item(s) constitute a deficiency. If the number and/or nature of the deficiencies are deemed by A2LA staff 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 laboratory 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 laboratory 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 laboratory who will check to see if that observation was addressed by the laboratory, resulting in an improvement, or possibly may have progressed into a deficiency.

IV. Corrective Action Process

The laboratory 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 laboratory's cause analysis and a copy of any objective evidence (e.g., calibration certificates, lab 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 laboratory for this time at the prevailing assessor rate. The assessor will discuss the possibility of this review with the laboratory during the exit briefing and obtain the laboratory's concurrence.

When addressing an equipment calibration related deficiency to *P102 - A2LA Policy on Metrological Traceability* or *P113 – A2LA Policy on Measurement Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies*, please note that if the laboratory is using a calibration provider that does not meet *P102* or *P113* to satisfy the deficiency, the laboratory does ***not*** need to immediately re-calibrate the equipment in question using an acceptably accredited calibration source. The laboratory must be able to demonstrate in their corrective action response 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* or *P113 – A2LA Policy on Measurement Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies,* please note that if the laboratory is using a reference material(s) that does not meet *P102* or *P113* to satisfy the deficiency, the laboratory does ***not*** need to immediately purchase a new reference material from a recognized source. The laboratory 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 entirely possible that the laboratory will disagree with the findings that one or more items are deficiencies. In that case, the laboratory is requested to explain in its response why it disagrees with the assessor. The deficiency and laboratory'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.XVII Appeals* for further information on the appeals process.

A new applicant laboratory (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 laboratory that fails to ***resolve*** all its deficiencies within four (4) months of being assessed shall be subject to being reassessed at its expense. A2LA staff has the option to ask for reassessment of a laboratory before an initial accreditation vote is taken based on the number, extent and nature of the deficiencies.

Laboratories 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 or suspension of accreditation). The Accreditation Council panel has the option to require a follow-up assessment of any laboratory (new or renewal) before an affirmative accreditation decision can be rendered. The laboratory is responsible for any costs associated with this follow-up assessment.

V. Accreditation Anniversary Date

The anniversary date of a laboratory'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 date normally remains the same throughout the laboratory's enrollment.

VI. Extensions to the Accreditation Anniversary Date

If a laboratory 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 laboratory submits objective evidence demonstrating that the non-conformances have been addressed. Likewise, extensions are not granted when delays are due to the laboratory'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 laboratory is granted an extension to their accreditation, a revised Certificate and Scope of Accreditation are posted to the A2LA website which reflects 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 considered, upon expiration, laboratories will be removed from the A2LA Accredited list on the A2LA website and placed on a separate website list called "Expired Certificates in Good Standing." Laboratories on this list are currently considered ***not*** accredited but are somewhere in the renewal process.

VII. Proficiency Testing

Proficiency testing is a process for checking actual laboratory testing or calibration performance, usually by means of inter-laboratory 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* and the associated *Annex (R103a)*.

Laboratories are required to participate in proficiency testing programs, where relevant and available, and provide A2LA with the results of their participation within 30 days upon receipt of the results. If the results of the proficiency testing activities include outliers, laboratories are required to provide A2LA with their corrective action measures resolving the non-conformance. It is possible that the assessor involved in the previous assessment may be asked to review the corrective action response to determine if the response is satisfactory. As such, A2LA may invoice the laboratory for this time at the prevailing assessor rate.

VIII. Accreditation Decisions

Before an accreditation decision ballot is sent to Accreditation Council (AC) members, staff shall review the deficiency response, including the laboratory's cause analysis and objective evidence of completed corrective action, for adequacy and completeness. If staff has any doubt about the

adequacy or completeness of any part of the deficiency response, the response is submitted to the assessor(s). Since all deficiencies must be resolved before accreditation can be granted, staff shall ask the laboratory for further written response in those cases where staff recognizes that an affirmative vote is not likely because of incomplete corrective action in response to deficiencies or obvious lack of supporting evidence that corrective action has been completely implemented.

Staff normally selects a panel of between one and three AC members for voting. The panel is chosen so that the full range of the laboratory's testing and/or calibration capabilities is adequately covered by the AC review. Especially in the case of those laboratories seeking (re)accreditation for multiple fields, it may be necessary to select more than three AC members in order to accomplish this. The laboratory is consulted about any potential conflicts of interest with the AC membership prior to sending their package to the AC. If more than three AC members are required to ensure a full review of the laboratory's testing/calibration activities, (re)accreditation may not be granted until all of these 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 laboratories in good standing.

It is the primary responsibility of assessors to judge whether the observed evidence is serious enough to warrant a deficiency. However, the 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 staff will attempt to resolve these differences as they arise, but it remains for the panel to make the initial decision.

Staff shall notify the laboratory asking for further response based on the specific justification for one or more negative votes received from the panel. If further response still does not satisfy the negative voter(s), a follow-up assessment may be proposed or required. If a follow-up assessment is requested by more than one voter, the laboratory is asked to accept a follow-up assessment. The laboratory is responsible for any costs associated with this follow-up assessment. If the laboratory refuses the proposed follow-up assessment, a nine-member Accreditation Council appeals panel is balloted (see Sections XIV Adverse Accreditation Decisions and XVII Appeals Procedures below).

If accreditation is granted, the A2LA staff prepares and forwards a certificate and scope of accreditation to the laboratory for each enrolled field of testing (and special program if appropriate). The laboratory should keep its scope of accreditation available to show clients or potential clients the testing and/or calibration technologies/parameters and methods for which it is accredited. A2LA staff also uses the scopes of accreditation to respond to inquiries and to prepare the A2LA online public directory of accredited laboratories.

IX. Annual Review

Accreditation is granted for two years. However, after the initial year of accreditation, each laboratory 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 laboratory'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 Section XV Suspension of Accreditation).

For subsequent annual reviews occurring after the renewal of accreditation (see Section X Reassessment and Renewal of Accreditation) each laboratory must pay annual fees and submit updated information on its organization, facilities, key personnel and results of any proficiency testing. Objective evidence of completion of the internal audit and management review, in accordance with the laboratory's respective planned intervals, is also required. If the renewal laboratory does not promptly provide complete annual review documentation, if significant changes to the facility or organization have occurred, or if proficiency testing results 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 laboratory's compliance with the accreditation requirements, an appropriate surveillance assessment and payment of the associated assessor fees may be required.

X. Reassessment and Renewal of Accreditation

A2LA conducts a full reassessment of all accredited laboratories at least every two years. Full reassessments are also conducted when evaluations and submissions from the laboratory or its clients raise concerns about ongoing compliance or indicate significant technical changes in the capability of the laboratory have occurred.

Each accredited laboratory 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 laboratory's site must be completed before accreditation is renewed for another two years.

If deficiencies are noted during the renewal assessment, the laboratory is asked to respond in writing to A2LA within 30 days after the assessment describing the corrective action taken. All deficiencies must be resolved before accreditation is renewed for another two years.

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

XI. Extraordinary Assessments

Although rare, A2LA may require laboratories to undergo an extraordinary assessment (also referred to as a "for-cause" assessment) as a result of a complaint(s) or significant changes to the laboratory'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 *II.C. 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 laboratory. 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 SDAS as a result of objective evidence uncovered by the assessment team

during the conducted assessment, the laboratory is responsible to cover any associated costs related to this for-cause assessment.

XII. Adding to the Scope of Accreditation

A laboratory 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 *F108 – Request for Expansion of Scope of Accreditation – Testing* form or the *F112 – Request for Expansion of Scope of Accreditation – Calibration* form. Each request is handled on a case-by-case basis. Unless the previous assessor can verify the competence of the laboratory to perform the additional tests or calibrations, another assessment at the laboratory's site is normally required. If the assessor can recommend a scope addition without an assessment, but this recommendation requires extensive review of supporting documentation requiring more than two hours of time, A2LA may invoice the laboratory for this review time at the prevailing assessor rate. If a laboratory requests multiple scope expansions over the period following its previous assessment and until the assignment of the next assessor, assessor review time beyond the two hours' cumulative gratis time will be invoiced to the laboratory at the prevailing assessor rate. If the additional tests or calibrations involve a new technology, another assessment will be required.

XIII. Laboratory 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 A2LA Headquarters or on the A2LA website, www.A2LA.org. A2LA has also created a guidance document to aid and assist laboratories to implement the R105 requirements, *Guidance for R105 Promoting Accreditation* which can also be found on the A2LA website. Failure to comply with these requirements may result in suspension or withdrawal of a laboratory's accreditation.

XIV. Accreditation Status and Adverse Accreditation Decisions

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

Voluntary Withdrawal – A new applicant laboratory, not yet accredited, or a renewal laboratory, can decide to terminate further accreditation action and voluntarily withdraw from the accreditation program. The laboratory contact must inform A2LA in writing of this request. A2LA does not publicize the fact that a new laboratory had applied and then was withdrawn; however, the voluntary withdrawal status of renewal laboratories is publicized on the A2LA website. If A2LA learns that the accredited laboratory is going or has gone out of business, the laboratory is contacted for further detail and the laboratory'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 laboratory has reached the previously determined expiration date, or up to six months from the date of the action, whichever is longer.

Inactive Status (voluntary) – A laboratory is designated as voluntarily inactive when it has

specifically 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 laboratory must notify A2LA in writing of this desire and undergo a full reassessment, paying all renewal fees and reassessment costs.

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

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

XV. Suspension of Accreditation

Suspension of all or part of a laboratory's accreditation may be a decision made by either the Senior Director Accreditation Services (SDAS) or Accreditation Council panel. The accreditation applicable to a specific laboratory 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 laboratory); 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 laboratory shall immediately be suspended by the Senior Director Accreditation Services (SDAS) if the laboratory or any individual or entity responsibly connected with the laboratory 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 laboratory may appeal the adverse accreditation decision, but the suspension will not be lifted until all court related actions are made final.

When an accredited laboratory is suspended, A2LA shall confirm an official suspension in a certified letter, return receipt requested, (or equivalent means) to the laboratory'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;
- that the suspension, including dates and scopes, will be publicized on the A2LA website;
- that 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 laboratory 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,
- that a further review will be conducted to consider such information and a further written notification will be sent to the laboratory by certified mail, return receipt requested, indicating whether the suspension has been terminated, modified, left in force or converted to a withdrawal 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* and the associated *Annex (R103a).*

XVI. 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 as judged by the Accreditation Council panel;
- When complaints are received relating to one or more of the laboratory's test reports/calibration certificates and investigation reveals serious deficiencies in the management system and/or competence in conducting the specific tests/calibrations;
- If the accreditation rules are changed and the laboratory 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 laboratory;

- If there is evidence of fraudulent behavior, intentional provision of false information or concealed information;
- When such action is necessary to protect the reputation of A2LA; or,
- At the formal request of the laboratory.

When withdrawal of accreditation has been proposed or is being considered, A2LA shall issue a written notice by certified mail:

- That withdrawal is being considered;
- Of the reasons for the proposed withdrawal sufficient to put the laboratory on notice of the cause;
- That within thirty (30) days of receipt of the notice, the laboratory 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; and
- Of the effect of proposed withdrawal, including removing the laboratory'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 laboratory has reached the previously determined expiration date, or up to six months from the date of the action, whichever is longer.

A laboratory may appeal to A2LA against a decision to withdraw or not to award accreditation.

XVII. Appeals

A. Appeal of an Accreditation Decision

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 staff are submitted to the A2LA Quality Council (QC).

A2LA staff shall advise the applicant in writing of its right to challenge an adverse accreditation decision by the initial Accreditation Council panel (see Section VIII Accreditation Decisions) or A2LA Staff.

Any appeal shall be lodged no later than thirty (30) days after notification of the decision by forwarding a certified letter 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 laboratory's accreditation must be agreed upon by two-thirds of the votes received (sum of the affirmative and negative – abstentions are not included). Votes from the nine-member panel of the AC must be received from all members with specific technical background necessary to review the laboratory's scope of accreditation. The decision of the Appeals Panel is communicated in writing to the appellant.

The decision rendered by the Appeals Panel is final and binding.

XVIII. 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 laboratories. 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. 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 laboratory unless required by law or judicial or administrative process or regulation (such as through a properly issued and served subpoena).

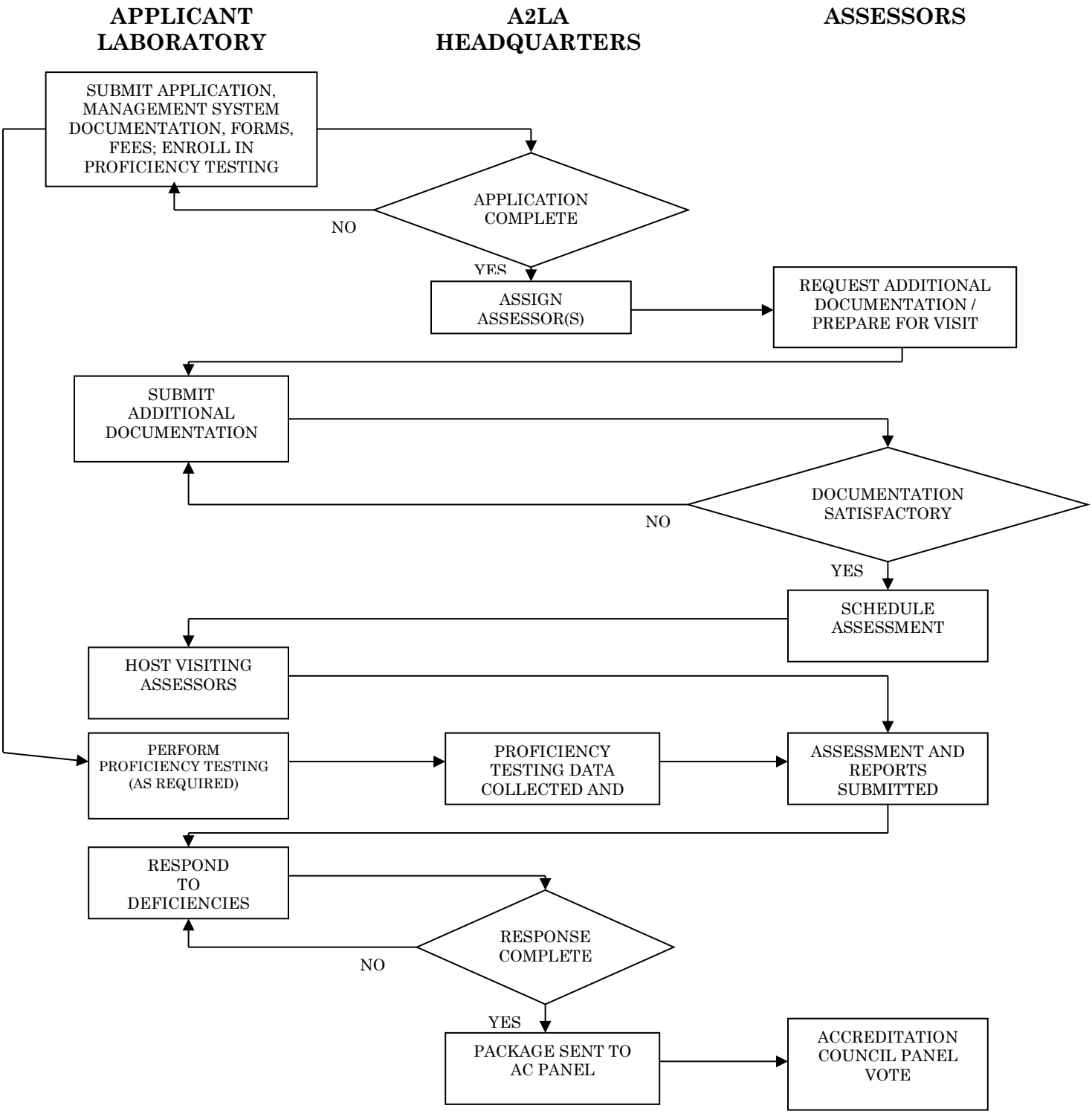
All information provided by applicants in connection with a request for an application package, an application for accreditation, an assessment or proficiency test is confidential. Documents necessary to convey information about accredited laboratories and their scopes of accreditation are not confidential. In response to a question about whether or not a particular laboratory has applied for accreditation, A2LA responds by stating whether or not the laboratory is accredited. Staff neither confirm nor deny whether a laboratory has ever applied for accreditation. If the laboratory itself is saying that it has applied for accreditation, it is the laboratory's responsibility to release the information regarding its applicant status. If a caller states that a laboratory is claiming it applied for accreditation, A2LA staff shall note the name, address and phone number of the laboratory to check whether the laboratory is misleading the client, but staff still will not verify the laboratory's application. Should an applicant laboratory require that staff verify for a potential client that it has applied to A2LA, A2LA staff shall indicate that the laboratory 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 laboratory. However, if an inquiry is made about a laboratory whose accreditation has lapsed but is in the renewal process, A2LA staff can indicate that the laboratory is not now accredited but is in the process of renewal, if that is the case. If the renewal laboratory's accreditation has lapsed with no indication (such as return of renewal forms or payment) that it is pursuing renewal, A2LA staff indicates simply that the laboratory is not accredited.

XIX. 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, 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 Audit & Ethics Committee of the Board and the Senior Director, Accreditation Services 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.

A2LA ACCREDITATION PROCESS



Document Revision History

Date	Description
12/14/2016	• Changed ISO Guide 34 to ISO 17034
12/11/2017	• Part A – removed reference to A2LA Explanations. • Part A – added reference to ISO/IEC 17025:2017, *General Requirements for the Competence of Testing and Calibration Laboratories*. • Part C.I – added a reference to Section 7.2.2.4 of ISO/IEC 17025:2017 for validation data. • Part C.I – Added 'Supporting SOPs' under items needed with the application; Removed option for allowing different standards to be on a single scope. • Part C.II.C and Part C.IV– Added references to *P113 – A2LA Policy on Measurement Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies.* • Part C.IV removed the reference to APLAC MRA. • Part C.V – updated date range for establishing anniversary date for newly accredited laboratories to "45 to 75 days". • Part C.VIII. Updated with revision to AC balloting process.
05/12/18	• Editorial changes. • Updated the Mission statement. • Removed the 50-mile requirement for Satellites. • Added information on Calibration Corporate Scopes. • Changed closing meeting with top management to authorized representative. • Changed appeal process from BOD to Appeal Panel. • Removed appeal process diagram. • Clarified that voluntary withdrawal status is advertised on the A2LA website. • Added "if there is evidence of fraudulent behavior, intentional provision of false information or concealed information" to section XVI. • Clarified voluntary versus enforced inactive status. • Clarified SDAS in consultation with the P/CEO, as necessary. • Updated for the impartiality policy. • Updated the title of ISO/IEC 17011:2017. • Change surveillance visit to assessment. • Changed sign to acknowledge. • Added P/CEO or designee. • Removed "written" from response. • Removed "root" from cause analysis. • Added "typically" in front of F108.
12/07/2018	• Editorial changes. • Removed references to ISO/IEC 17025:2005. • Changed responsible Staff person from P to SDAS. • Added flexibility under I. Application on language. • Added Virtual Site definition. • Added clarification to calibration scopes. • Corrected reference to Corporate Scopes – R238.

	• Clarification under IV Corrective Action Process between 'contested' deficiency and 'appeal'. • Clarified that Extraordinary Assessments are not typical assessments and do not follow a typical assessment process. • Per ISO/IEC 17011:2017 added language under XIV and XVI that withdrawn laboratory's scopes will remain on website for at least 6 months.