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 accreditation system. Accreditation is a formal recognition of competence that an organization can perform specific functions relating to an accreditation standard. Accreditation is available to any type of organization, be it in the private sector (independent or in-house) or in the government sector.

This document sets forth the general requirements for the A2LA accreditation of reference material producers (RMPs) based on the international standard ISO 17034. 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.

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

a) it is competent to produce the reference materials listed on its Scope(s) of Accreditation;
b) its management system addresses and conforms to all elements of ISO17034, is documented per ISO 17034, 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 RMP that fails to meet the above criteria (see Part B, Conditions for Accreditation and Part C, sections on deficiencies, accreditation decisions and types of adverse accreditation decision). 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 inspires 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, reference material producers 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.

Please note that for reference material producers, Section 12 of the R102 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.

To apply, the applicant RMP’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 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 Reference Materials Producer Accreditation Process

I. Application

A reference material producer applies for accreditation by visiting the A2LA website www.A2LA.org and completing the appropriate application forms. The application process involves setting up a user account on our Accreditation Customer Portal. Once a user account is set up all applicants are prompted to agree to the conditions for accreditation (see Part B of this document), pay the appropriate fees set by A2LA, and provide detailed supporting information as requested in the application. This includes information on:

- Scope and types of reference materials produced
- Quality Manual and supporting SOPs
- Organization structure
- Subcontractor Information
- Proficiency testing plan and results
- C307 - General Checklist: ISO 17034 Reference Material Producer Accreditation Program (which contains an area for references to your quality system demonstrating they meet the assessment requirements)

Application materials should be uploaded within the customer portal and will be reviewed by staff upon submission.

II. Scopes of Accreditation

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 17011, APLAC TC008 and IAAC MD 028:

- Specific types of reference materials;
- Clearly identity whether these are CRMs, RMs or both;
- The category and/or subcategory of reference material (including the matrix)
- The property(ies) characterized;
- Ranges of assigned values;
- The characterization technique(s);
- (CRMs) range and uncertainty of property values;
• (CRMs) uncertainty shall be expressed in terms of a best Reference Value Capability which shall include the RMP’s estimate of its least uncertainty of measurement (UCRM) for each property value’s range it reports (APLAC TC008 clause 6.5);
• (CRMs) the uncertainty covered by the Reference Value Capability shall be expressed as the expanded uncertainty having a specific coverage probability (often 95%).

III. Types of Assessments

The objective of an initial, follow-up, renewals or extraordinary assessment is to establish whether or not a reference material producer complies with the A2LA requirements for accreditation and can competently produce the RMs/CRMs 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 reference material producer 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.

There are several types of assessments an organization will undergo as an accredited reference material producer and the purpose of each has been defined as follows:

**Initial Assessment**: An initial assessment represents the first full assessment A2LA performs of a specific location.

**Renewal Assessments**: At the end of the first full accreditation cycle, the organization will undergo an on-site renewal assessment. This assessment will be structured similarly to the initial assessment.

**Surveillance Assessment**: After the initial year of accreditation, the organization must pay annual fees and assessor fees and undergo a surveillance assessment by an assessor, which typically lasts one day on-site. This surveillance assessment is performed to confirm that the 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. Types of Adverse Accreditation Statuses).

**Follow-up Assessment**: If the RMP does not promptly provide complete annual review documentation, if significant changes to the facility or organization have occurred, or if the reference materials produced have had significant issues, a one-day follow-up 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 organization’s compliance with the accreditation requirements, an appropriate follow-up assessment and payment of the associated assessor fees may be required.

**Interim Assessment**: If an organization requests to expand the accredited offerings on the current Scope of Accreditation or add an additional accreditation standard (e.g., ISO/IEC 17025) an interim assessment may be required. Staff will confer with the assessors to make the determination on whether an on-site visit will be required in these cases.

**Extraordinary Assessments**: Although rare, A2LA may require a RMP to undergo an extraordinary assessment (also referred to as a “‘for-cause’” assessment) as a result of a complaint(s) or other reason as deemed appropriate by A2LA. Depending on the severity of the issue, this ‘for-cause’ 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, Section V. 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 organization. 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 organization is responsible to cover any associated costs related to this ‘for-cause’ assessment.

**Pre-Assessment**: 
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 proficiency testing provider’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 proficiency testing provider 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 proficiency testing provider requests a pre-assessment to better prepare for the full initial assessment. In this case, the proficiency testing provider has applied, but is unsure of its documentation or system and wants a pre-assessment performed to identify gaps or problems. The full initial assessment follows later.

To implement the pre-assessment program, the proficiency testing provider must first apply for accreditation. A lead assessor is assigned, with the proficiency testing provider’s concurrence. If, during the discussions between the proficiency testing provider and assessor in preparation for the assessment, the proficiency testing provider concludes that it is in its interest to have a pre-assessment, it informs the assessor. The assessor notifies A2LA that the proficiency testing provider 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 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).

IV. A2LA Assessment Policies

Foreign (Non-English) Language Policy: 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 organization’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 on which documents would need to be provided in English.

Delayed Assessment Policy: If an organization fails to undergo its full assessment within one year from receipt of the application at A2LA headquarters, the RMP is prompted by A2LA to take action. If no action is taken within thirty (30) days of that reminder, the RMP is required to begin the application process again and pay the RMP’s application 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 organization in addition to the assessment fees.

Travel Warning Policy: Organizations located in 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 organization and assessor) insurance coverage (e.g., life, health, kidnapping, etc.) for the assessor or assessment team that will be visiting them.

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 contact with the organization. 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.
organization 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 organization has applied for accreditation, A2LA responds by stating whether or not the organization is accredited. Staff neither confirm nor deny whether an organization has ever applied for accreditation. If the organization itself is saying that it has applied for accreditation, it is the organization's responsibility to release the information regarding its applicant status. If a caller states that an organization is claiming it applied for accreditation, A2LA staff shall note the name, address and phone number of the organization to check whether the organization is misleading the client, but staff still will not verify the organization's application. Should an applicant organization require that staff verify for a potential client that it has applied to A2LA, A2LA staff shall indicate that the organization 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 organization. However, if an inquiry is made about an organization whose accreditation has lapsed but is in the renewal process, A2LA staff can indicate that the organization is not now accredited but is in the process of renewal, if that is the case. If the renewal organization's accreditation has lapsed with no indication (such as return of renewal forms) that it is pursuing renewal, A2LA staff indicates simply that the organization is not accredited.

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, Conformity Assessment –Requirements for accreditation bodies accrediting conformity assessment bodies, 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.

V. Accreditation Cycle
**Initial Accreditation Cycle**: An initial accreditation to ISO 17034 operates on a 2-year cycle.

**Initial Assessment**: The initial assessment consists of a full on-site assessment to establish compliance with ISO 17034. This cycle begins after the conclusion of the initial assessment and after receiving a positive accreditation decision (See section X. Accreditation Decisions).

**Surveillance Assessment**: After the initial year of accreditation, each RMP 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 RMP’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. Types of Adverse Accreditation Statuses).

**Renewal Accreditation Cycle**: A renewal of accreditation to ISO 17034 operates on a 2-year cycle.

**Renewal Assessment**: After the initial accreditation cycle, A2LA conducts a full reassessment of all accredited RMPs at least every two years. Each accredited RMP 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 RMP’s site must be completed before accreditation is renewed for another two years.

**Annual Review**: The annual review initiates (3) months prior to the mid-point in the accreditation cycle. Each RMP 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 RMP’s respective planned intervals, is also required. If the renewal RMP 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.

**VI. Initial Assessment Process**

1. **Completed Application** – All required application materials are submitted.

2. **Assessor Team Selection** – A2LA staff identifies and tentatively assigns one or more assessors to conduct an assessment at the organization. Assessors are selected based on expertise relevant to the references materials being produced. Assessors are under contract with A2LA and do not represent their employers (if so affiliated) while conducting assessments for A2LA. The organization has the right to ask for another assessor if there is a conflict of interest.

3. **Assessment Scheduling**:
   a. Before an initial assessment is conducted, the assessor team reviews the management system documentation and representative technical SOPs in order to prepare for the assessment.
   b. Upon completion of the review, the assessor(s) will provide the results to the reference material producer in writing and will give the opportunity for the organization to address any documentation gaps or items required by ISO 17034 prior to the assessment taking place.
   c. Prior to scheduling the initial assessment, the assessor checks on the availability of the technical personnel who are involved with the production/testing of the RM/CRMs.
   d. An assessment agenda is provided by the assessor.

**VII. On-site Assessment Process**

1. **Opening Meeting** – Entry briefing with reference material producer’s management and review of proposed agenda.
2. Determination of compliance with ISO 17034 quality system requirements - Interviews with staff and audit of the management system to verify that it is fully operational and conforms to requirements contained in C307 – General Checklist: ISO 17034 Reference Material Producer Accreditation Program; Compliance with the R102 – Conditions for Accreditation and R105 – Requirements When Making Reference to A2LA Accredited Status,


4. Assessment Conclusion - A written report of assessor findings and a written exit briefing including the specific written identification of any deficiencies.

Through interviews with technical staff, record review and observations of reference material production and related activities, the assessor confirms the depth of technical competency for the RMP. 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 RMP 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 RMP no longer having the technical competency to perform a given task, etc.). When the essential personnel depart an organization, this will result in the RMP losing the accreditation for those activities the essential personnel was solely responsible. To regain accreditation for those reference materials and related activities, the RMP 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 review, and/or telephone/web interview, as determined by A2LA.

During the full on-site assessment, the assessor has the authority to stop the process at any time and consult with A2LA staff and the RMP’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 full assessment, the visit may be converted to a pre-assessment, or a suspension may be recommended if technical capability is lost (see Section XV. Types of Adverse Accreditation Statuses). The full assessment is can then be rescheduled for a time when the RMP and assessor feel it is appropriate to proceed.

VIII. Deficiencies

During an assessment, assessors may observe deficiencies. A deficiency is any nonconformity to the accreditation requirements such as:

- RMP’s inability to competently provide reference materials for which it seeks accreditation;

- RMP’s management system does not conform to a clause or section of ISO 17034, is not adequately documented, or is not completely implemented in accordance with that documentation; or,

- RMP does not conform to any additional requirements of A2LA or specific programs necessary to meet particular needs.

At the conclusion of an initial or renewal assessment, the assessor prepares a report of findings, identifying deficiencies which, in the assessor’s judgment, the RMP must resolve in order to be accredited, maintain current accreditation, or have their accreditation renewed. The assessor holds an exit meeting, going over the findings and presenting the list of deficiencies (as applicable). At a minimum, the authorized representative should attend the exit meeting, and where practical, top management, technical and quality managers should also attend. The authorized representative of (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 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 of the RMP but there is not enough supporting objective evidence to justify a deficiency, or it cannot be tied to the accreditation requirements. If this occurs, the RMP 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 RMP who will check to see if that observation was addressed, resulting in an improvement, or possibly may have progressed into a deficiency.

IX. Corrective Action Process

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

When addressing an equipment calibration or 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 PTP is using a service provider that does not meet P102 or P113 to satisfy the deficiency, the PTP does not need to immediately re-calibrate the equipment or purchase a new reference material in question from a recognized source. The PTP must be able to demonstrate in their corrective action response that they will use an acceptable source for the next regularly scheduled calibration cycle/during the reference material’s next scheduled purchase, or by its next regularly scheduled A2LA on-site assessment. 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.

It is entirely possible that the RMP will disagree with the findings that one or more items are deficiencies. In that case, the RMP is requested to explain in its response why it disagrees with the assessor. The deficiency and RMP’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 part C, section XVI Appeals for further information on the appeals process.

A new applicant RMP (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 RMP 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 RMP before an initial accreditation vote is taken based on the number, extent and nature of the deficiencies.

RMPs 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 RMP (new or renewal) before an affirmative accreditation decision can be rendered. The RMP is responsible for any costs associated with this follow-up assessment.

X. Accreditation Decisions

Before an accreditation decision ballot is sent to Accreditation Council response, including the RMP’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 RMP 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 RMP’s capabilities is adequately covered by the AC review. Especially in the case of those organizations seeking (re)accreditation for multiple fields, it may be necessary to select more than three AC members in order to accomplish this. The organization is consulted about any potential conflicts of interest with the AC membership prior to sending their package to the AC.

If three or more AC members are required in order to ensure a full review of the RMP’s 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 with less than six cited, non-technical deficiencies), a single AC member can be assigned in order to expedite the decision-making process for organizations 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 or not 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. Staff attempts to resolve these differences as they arise, but it remains for the panel to make the initial decision.

Staff shall notify the RMP 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 be proposed or required. If a follow-up assessment is requested by more than one voter, the RMP is asked to accept a follow-up assessment. The RMP is responsible for any costs associated with this follow-up assessment. If the RMP refuses the proposed follow-up assessment, a nine-member Accreditation Council appeals panel is balloted (see Sections XV. Types of Adverse Accreditation Statuses and XVI. Appeals procedures below).

If accreditation is granted, the A2LA staff prepares and forwards a certificate and scope of accreditation to the RMP for each enrolled reference material. The organization should keep its scope of accreditation available to show clients or potential clients the specific proficiency testing schemes for which it is accredited. A2LA staff also uses the scopes of accreditation to respond to inquiries and to prepare the A2LA online directory.

XI. Accreditation Anniversary Date

The anniversary date of a RMP’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 RMP’s enrollment.

XII. Extensions to the Accreditation Anniversary Date

If a RMP 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 RMP submits objective evidence demonstrating that the non-conformances have been addressed. Likewise, extensions are not granted when delays are due to the RMP’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;
• Closure of all deficiencies beyond 60 days of assessment exit briefing.

When a RMP 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, RMPs 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”. Organizations on this list are currently considered not accredited but are somewhere in renewal process.

XIII. Adding to the Scope of Accreditation

A RMP may request an expansion to its scope of accreditation at any time. Such a request must be submitted to A2LA headquarters. Each request is handled on a case-by-case basis. Unless the previous assessor can reasonably verify the competence of the RMP to perform the new types of reference materials, based solely on documentation provided by the RMP and results of the previous assessment, another on-site assessment 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’ time, A2LA may invoice the RMP for this review time at the prevailing assessor rate. Please note that A2LA, upon consultation with the assessor and organization may allow a remote review of new technologies if all parties have access to technology that can facilitate a thorough review (e.g. video witnessing of the new technology/process). A2LA will have the final say in all approvals regarding the acceptability of remote reviews.

XIV. 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 organizations 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 an organization’s accreditation.

XV. Types of Adverse Accreditation Statuses

There are various levels of status that may be assigned to RMP 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 RMP 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 RMP 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 RMP for no longer than one year, after which time the RMP is removed from the A2LA system and designated as withdrawn.

**Inactive Status (enforced)** – A RMP that has relocated is also 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 RMPs site). In these cases, to regain accredited status, the Inactive RMP must fulfill the requirements of P105 – A2LA Policy on Organization Relocation, and undergo an interim reassessment, paying all interim assessment costs.

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

When an accredited RMP is suspended, A2LA shall confirm an official suspension in a certified letter, return receipt requested, (or equivalent means) to the RMP’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 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 RMP 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;
- That a further review will be conducted to consider such information and a further written notification will be sent to the RMP by certified mail, return receipt requested, indicating whether the suspension has been terminated, modified, left in force or converted to a withdrawal of accreditation.

Organizations under suspension of their A2LA accreditation are listed on the A2LA website.

**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 RMP’s reports 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 provider 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 provider;
• 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; and
• At the formal request of the RMP.

When withdraw of accreditation has been proposed or is being considered, A2LA shall issue a written notice by certified mail, return receipt requested:
• That withdrawal is being considered;
• Of the reasons for the proposed withdrawal sufficient to put the RMP on notice of the cause;
• That within thirty (30) days of receipt of the notice, the RMP 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 RMP’s name from the A2LA online directory and publicizing the action on the A2LA website. 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 RMP has reached the previously determined expiration date, or up to six months from the date of the action, whichever is longer.

XVI. 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 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 X. Accreditation Decisions) or A2LA Staff.

An 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 producer’s accreditation, must be agreed upon by a 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 producer’s scope of accreditation. The decision of the Appeal Panel is communicated in writing to the appellant.

The decision rendered by the Appeals Panel is final and binding.
A2LA ACCREDITATION PROCESS

APPLICANT
RM PRODUCER

SUBMIT APPLICATION, MANAGEMENT SYSTEM DOCUMENTATION, FORMS; ENROLL IN PROFICIENCY TESTING

NO

APPLICATION COMPLETE
YES

ASSIGN ASSESSOR(S)

REQUEST ADDITIONAL DOCUMENTATION / PREPARE FOR VISIT

SUBMIT ADDITIONAL DOCUMENTATION

NO

DOCUMENTATION SATISFACTORY
YES

SCHEDULE ASSESSMENT

HOST VISITING ASSESSORS

PERFORM PROFICIENCY TESTING (AS REQUIRED)

PROFICIENCY TESTING DATA COLLECTED AND ANALYZED

ASSESSMENT COMPLETED AND REPORTS SUBMITTED

RESPOND TO DEFICIENCIES

NO

RESPONSE COMPLETE

YES

PACKAGE SENT TO AC PANEL

ACCREDITATION COUNCIL PANEL VOTE
<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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| 03/05/18   | Referenced that voluntary withdraw renewal organizations will be posted on the A2LA website  
|            | Renamed Withdraw section to “Enforced Withdrawal”                                                                                                                                                    |
|            | Updated for the addition of the 2017 version of ISO/IEC 17025.                                                                                                                                            |
| 05/12/18   | Update appeal process.  
|            | Removed appeal process diagram.  
|            | Added the tax policy.  
|            | Added the mission statement.  
|            | Editorial changes.  
|            | Changed closing meeting with top management to authorized representative.  
|            | Changed appeal process from BOD to Appeal Panel.                                                                                           |
|            | Added QC Panel responsibilities on appeals.  
|            | 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”.  
|            | Clarified voluntary versus enforced inactive status.  
|            | Clarified SDAS in consultation with the P/CEO, as necessary.  
|            | Updated for the impartiality policy.  
|            | Changed to response (removed written).                                                                                                    |
| 08/08/18   | Clarification in Part B that A2LA must be notified when there are changes to subcontractors.                                                                                                              |
| 09/14/18   | Clarification in Part C Section I on the types of application materials that need to be submitted.                                                                                                        |
|            | Clarification in Part C Section I on assessments being conducted in a language other than English.                                                                                                     |
|            | Clarification in Part C Section XI on allowing a remote technical review of new technologies when adding to a scope of accreditation.                                                               |
| 01/10/19   | Significant re-ordering of information to improve end-user readability of this document                                                                                                                      |
|            | Alignment with changes to the R101 for consistency.                                                                                           |
| 01/06/20   | Removed text related to initial invoices for new, renewal, and surveillance assessments                                                                                                                     |
|            | Updated Header/Footer to current version.                                                                                                                                                                |
|            | Updated format and font for consistency.                                                                                                                                                                 |
|            | Added Qualtrax hyperlinks.                                                                                                                                                                             |