R302 - GENERAL REQUIREMENTS:
ACCREDITATION OF ISO/IEC 17043
PROFICIENCY TESTING PROVIDERS

2018

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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 accreditation system.

This document sets forth the general requirements for the A2LA accreditation of proficiency testing providers. The A2LA Accreditation Program for Providers of Proficiency Testing Programs is primarily designed for proficiency testing providers who wish to demonstrate their competence by formal compliance with a set of internationally-acceptable requirements for the planning and implementation of proficiency testing programs. The program will also provide users of proficiency testing programs (laboratories, accreditation bodies such as A2LA, technical assessors, etc.) increased confidence that the programs being relied upon are being operated competently in accordance with specified technical and management system requirements.

The specific assessment requirements for this program are listed in C316-General Checklist: ISO/IEC 17043 Proficiency Testing Provider Accreditation Program and are based on the requirements contained in the ISO/IEC 17043 Conformity assessment-General Requirements for Proficiency Testing.

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

It is A2LA policy not to accredit or renew accreditation of a proficiency testing provider that fails to meet the requirements listed in the C316-General Checklist: ISO/IEC 17043 Proficiency Testing Provider Accreditation Program, F302-Application for Accreditation: ISO/IEC 17043 Proficiency Testing Providers and this document. Proficiency testing providers are also required to meet A2LA R105 – Requirements When Making Reference to A2LA Accredited Status.

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

A2LA shall ensure that confidentiality is maintained by its employees and its contractors concerning all confidential information with which they become acquainted as a result of their assessments and contacts with proficiency testing providers. Confidential information shall not be released unless authorized by expressed written permission from the proficiency testing providers.
A2LA shall not administer any ongoing, commercial proficiency testing programs while carrying out this PT accreditation program. A2LA does reserve the right to utilize artifacts or reference materials to conduct measurement audits with individual laboratories as needed for the effective assessment of an organization’s technical competence.

Lonnie Spires, A2LA President and CEO
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 Proficiency Testing Providers, 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.

In order to apply, the applicant reference material producer’s Authorized Representative and Authorized Deputy 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 reference material producer’s Authorized Representative is responsible for ensuring that all of the relevant conditions for accreditation are met. During the on-site assessment, the assessor will examine records and documentation to verify compliance with the Conditions for Accreditation.

Part C - A2LA ACCREDITATION PROCESS

I. Application

A proficiency testing provider applies for accreditation by obtaining the application package from A2LA headquarters, then completing and submitting the appropriate application pages and C316-General Checklist: ISO/IEC 17043 Proficiency Testing Provider Accreditation Program (which contains the specific assessment requirements) and a copy of the proficiency testing provider’s quality manual and related SOPs.

All applicants must agree to the Conditions for Accreditation (see PART B of this document); pay the appropriate fees set by the A2LA President and CEO, and provide detailed supporting information as requested in the application. This includes information on:

- Scope of proficiency testing programs, frequency and detailed description of sample/artifact type for each program;
- Organization structure;
- Subcontractors; and
- PT analyte and sample scoring procedures.

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.

The specific assessment requirements for this program are ISO/IEC 17043, “Conformity Assessment – General Requirements for Proficiency Testing”. ISO/IEC 17043 sets out the general
requirements in accordance with which a proficiency testing provider has to demonstrate that it operates, if it is to be recognized as competent to carry out proficiency testing activities.

Delayed Assessment Policy: If a PT provider fails to undergo its full assessment within one year from receipt of the application at A2LA headquarters, the PT Provider is prompted by A2LA to take action. If no action is taken within thirty (30) days of that reminder, the PT Provider is required to begin the application process again and pay the PT Provider 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 PT Provider withdraws the application before completion of the 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.

II. On-site Assessment

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 on-site assessment. Assessors are selected on the basis of their technical and statistical expertise so as to be better able to provide guidance to the proficiency testing providers. They do not represent their employers (if so affiliated) while conducting assessments for A2LA. The proficiency testing provider has the right to ask for another assessor if it objects to the original assignment. A2LA assessors are drawn from the ranks of the recently retired, consultants, industry, academia, government agencies, and from the proficiency testing provider and testing laboratory communities. Assessors work under contract to A2LA. Assessments may last from one to several days. More than one assessor may be required.

Assessors are provided assessor standard operating procedure to follow and checklists to complete in performing an assessment. These documents are intended to ensure that assessments are conducted as uniformly and completely as possible among the assessors and from proficiency testing provider to proficiency testing provider.

The quality manual and related documentation must be reviewed by the assessment team before the on-site assessment can begin. This review is done ideally before the assessment is scheduled. Upon review of submitted documentation, the assessor(s) may ask the proficiency testing provider to implement corrective action to fill any documentation gaps before scheduling the assessment. A pre-assessment visit may be requested by the proficiency testing provider as an option at this point to enhance the success of the full assessment.

Prior to scheduling the full assessment, the assessor provides an assessment agenda. The full assessment generally involves:

- An entry briefing with proficiency testing provider management;
Audit of the management system to verify that it is fully operational and that it conforms to requirements contained in **C316 - General Checklist: ISO/IEC 17043 Proficiency Testing Provider Accreditation Program**


Interviews with technical and administrative staff as appropriate to verify compliance;

Examination of facilities and published PT reports;

A written report of assessor findings; and

An exit meeting, including the specific written identification of any deficiencies.

During interviews with technical staff, record review and observations of proficiency testing schemes and related activities, the assessor confirms the depth of technical competency for the proficiency testing provider. At a minimum the proficiency testing provider must demonstrate that a person has been authorized to perform testing/calibration for each proficiency testing scheme (if applicable) in which the organization is seeking accreditation. If it is determined that there is only one person authorized for a given activity, this person is identified as an essential personnel on the assessor report. The proficiency testing provider 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 proficiency testing provider no longer having the technical competency to perform a given task, etc.). When the essential personnel depart an organization this will result in the proficiency testing provider losing the accreditation for those activities the essential personnel was solely responsible. To regain accreditation for those proficiency testing schemes and related activities, the proficiency testing provider would be required to provide objective evidence they have authorized applicable staff to perform such activities. This can be achieved via on-site assessment, record review, and/or telephone/web interview, as determined by A2LA.

During the full assessment, the assessor has the authority to stop the process at any time and consult with A2LA staff and the proficiency testing provider’s management to determine if the assessment should proceed. In cases where the number of significant deficiencies affects the ability to successfully complete a full assessment, the visit may be converted to a pre-assessment, or a suspension may be recommended if technical capability is lost (see Section XIV Suspension of Accreditation). The full assessment is then rescheduled when the organization and assessor feel it is appropriate to proceed.

### III. Deficiencies

During the assessment, assessors may observe deficiencies. A deficiency is any nonconformity to the accreditation requirements including:
• A proficiency testing provider’s inability to competently provide proficiency testing schemes for which it seeks accreditation;

• A proficiency testing provider’s management system does not conform to a clause or section of ISO/IEC 17043, is not adequately documented, or is not completely implemented in accordance with that documentation; or

• A proficiency testing provider does not conform to any additional requirements of A2LA such as the requirements identified in the A2LA Conditions for Accreditation and this requirements document.

At the conclusion of an assessment, the assessor prepares a report of findings, identifying deficiencies which, in the assessor’s judgment, the proficiency testing provider must resolve in order to be accredited. 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, authorized representative, technical and quality managers should also attend. The authorized representative of the proficiency testing provider (or designee) is asked to attest that the deficiency report has been reviewed with the assessor. The attestation does not imply that the proficiency testing provider representative concurs that the individual item(s) constitute a deficiency. All assessment records are forwarded to A2LA for review and processing. A2LA staff has the option of requiring a follow-up on-site assessment based on the number and nature of the deficiencies cited.

Assessors may also write an ‘observation’ when they question the practice or competence of the proficiency testing provider 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 proficiency testing provider does not have to respond to observations in order 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 proficiency testing provider who will check to see if that observation was addressed by the proficiency testing provider, resulting in an improvement, or possibly may have progressed into a deficiency.

IV. Corrective Action Process

The proficiency testing provider is requested to respond in writing within one month (30 days) after the date of the exit briefing detailing either its corrective action or why it does not believe that a deficiency exists. The corrective action response must include the proficiency testing provider’s cause analysis and a copy of any objective evidence (e.g., calibration certificates, revised procedures, records, PT reports, 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 one hour’s time, A2LA may invoice the proficiency testing provider for this time at the prevailing assessor rate. The assessor will discuss the possibility of this review with the proficiency testing provider during the exit briefing and obtain the proficiency testing provider’s concurrence.
It is entirely possible that the proficiency testing provider will disagree with the findings that one or more items are deficiencies. In that case, the proficiency testing provider is requested to explain in its response why it disagrees with the assessor.

A new proficiency testing provider applicant (i.e. 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 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 proficiency testing provider before an initial accreditation vote is taken based on the number, extent and nature of the deficiencies.

Renewal proficiency testing provider 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. reassessment or suspension of accreditation). The Accreditation Council panel also has the option to require a follow-up assessment of any organization (new or renewal) before an affirmative accreditation decision can be rendered. The proficiency testing provider is responsible for any costs associated with this ‘follow-up’ assessment.

V. Accreditation Anniversary Date

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

VI. Extensions to the Accreditation Anniversary Date

If a proficiency testing provider 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 proficiency testing provider submits objective evidence demonstrating that the non-conformances have been addressed. Likewise, extensions are not granted when delays are due to the proficiency testing provider's failure to respond to requests within established deadlines:

- 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 proficiency testing provider 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, proficiency testing providers will be removed from the A2LA Accredited list on the A2LA website and placed on a separate website list called “Organizations in the Renewal Process”. Proficiency testing providers on this list are currently considered not accredited but are somewhere in renewal process.

VII. Accreditation Decisions

Before an accreditation decision ballot is sent to Accreditation Council members, staff shall review the deficiency response, including 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 proficiency testing provider for further 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 three from the Accreditation Council members for voting. The selection takes into account as much as possible each member's technical expertise with the proficiency testing provider programs for which accreditation is being sought. Especially in the case of those proficiency testing providers seeking (re)accreditation for proficiency testing schemes covering multiple fields of testing or calibration, it may be necessary to select more than three AC members in order to accomplish this.

The proficiency testing provider is consulted about any potential conflicts of interest with the Accreditation Council membership prior to sending their package to the Accreditation Council. At least two affirmative ballots (with no unresolved negative ballots) of the three ballots distributed must be received before accreditation can be granted. In some instances, (typically packages of a non-technical nature with less than six cited deficiencies), a single AC member can be assigned in order to expedite the decision making process for CABs 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 proficiency testing provider 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 reassessment may be proposed or required. If a reassessment is requested by more than one voter, the proficiency testing provider is asked to accept a reassessment. If the proficiency testing provider refuses the proposed reassessment, a nine (9) member Accreditation Council appeals panel is balloted (see sections on XIII. Adverse Accreditation Decisions and XVI. Appeals Procedures below). If two-thirds of the appeals panel members voting agree to a reassessment, accreditation is denied until a reassessment and satisfactory proficiency testing provider response(s) to all deficiencies are completed.
If accreditation is granted, the A2LA staff prepares and forwards a certificate and scope of accreditation to the proficiency testing provider. The proficiency testing provider should keep its scope of accreditation available to show clients or potential clients the specific proficiency testing programs for which it is accredited. A2LA staff also uses the scopes of accreditation to respond to inquiries and to prepare the A2LA online directory.

VIII. Annual Review and Annual PT Report Review

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

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

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

- The nature of the samples and the tests/calibrations performed;

- Basic statistical data, including the number of samples (n), mean value, and standard deviation for each analyte/property, and, if possible, summary data for each different method used for each analyte/property;

- Method of publication (e.g. printed report, electronic report, web-based). (A representative sample of PT reports issued since the last A2LA review is provided for review.)

The technical assessor (statistician) may request additional reports from the proficiency testing provider and the number sampled will depend on the number and types of reports issued by the accredited PT provider since the last A2LA review.

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

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

IX. Reassessment and Renewal of Accreditation

A2LA conducts a full on-site reassessment of all accredited proficiency testing providers at least once every four years. Reassessments are also conducted when evaluations and submissions from the proficiency testing providers or its clients indicate significant changes in the capability of the proficiency testing providers have occurred.

Each accredited proficiency testing providers is sent a renewal application, well in advance of the expiration date of its accreditation, to allow sufficient time to complete the renewal process. A successful reassessment at the organization’s site must be completed before accreditation is extended for another two years.

If deficiencies are noted during the renewal assessment, the proficiency testing providers is asked to write to A2LA within 30 days after the assessment stating the corrective action taken. All deficiencies must be resolved before accreditation is renewed for another two years (see section III).

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

X. Extraordinary Assessments

Although rare, A2LA may require proficiency testing providers to undergo an extraordinary assessment as a result of complaints or significant changes to the proficiency testing providers’ management system. Pursuant to the severity of the complaint, this ‘for cause’ assessment may be performed with little or no advance warning. If reasons for the “for cause assessment” are determined to be justified or substantiated during the conducted assessment, the proficiency testing provider is responsible to cover any associated costs.

XI. Adding to the Scope of Accreditation

An A2LA-accredited proficiency testing provider may request an expansion to its scope of accreditation at any time. Such a request must be submitted in writing to A2LA headquarters. Each request is handled on a case-by-case basis. Unless the previous assessor can reasonably verify the competence of the proficiency testing provider to competently operate additional proficiency testing programs based solely on documentation provided by the proficiency testing provider and results of the previous assessment, another on-site assessment is normally required.

The assessor can recommend a scope addition without an assessment. If this recommendation requires extensive review of supporting documentation requiring more than one hour’s time, A2LA may invoice the proficiency testing provider for this review time at the prevailing assessor rate. If the additional proficiency testing schemes are supported by a new technology not previously evaluated, another assessment is definitely required.
XII. Proficiency Testing Providers 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. Failure to comply with these requirements may result in suspension or revocation of a proficiency testing provider’s accreditation.

XIII. Accreditation Status and Adverse Accreditation Decisions

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

**Voluntary Withdrawal** – A new applicant proficiency testing provider, not yet accredited, or a renewal organization, can decide to terminate further accreditation action and voluntarily withdraw from the accreditation program. The proficiency testing provider contact must inform A2LA in writing of this request. A2LA does not publicize the fact that a new proficiency testing provider had applied and then withdrawn; however, the voluntary withdrawal status of renewal organizations are publicized on the A2LA website. If A2LA learns that the accredited proficiency testing provider is going, or has gone out of business, the proficiency testing provider is contacted for further detail and the lab’s accreditation is voluntarily withdrawn.

**Inactive Status (voluntary)** – A proficiency testing provider is designated as 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 lab must notify A2LA in writing of this desire, agree to 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 proficiency testing provider for no longer than one year, after which time the proficiency testing provider is removed from the A2LA system and designated as withdrawn.

**Inactive Status (enforced)** - A proficiency testing provider 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 proficiency testing provider’s site).

XIV. Suspension of Accreditation

Suspension of all or part of a proficiency testing provider’s accreditation may be a decision made by either the Senior Director Accreditation Services (SDAS) in consultation with the President & CEO (P/CEO), where necessary, 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 or follow up assessments within the specified timeframe;

• improper use of the “A2LA Accredited” symbol (e.g., misleading prints or advertisements are not solved by suitable retractions and appropriate remedial measures by the proficiency testing provider); 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 proficiency testing provider shall immediately be suspended by the the Senior Director Accreditation Services (SDAS) in consultation with the President & CEO (P/CEO), where necessary, if the proficiency testing provider or any individual or entity responsibly connected with the proficiency testing provider 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 proficiency testing provider may appeal the adverse accreditation decision but the suspension will not be lifted until all court related actions are made final.

When an accredited proficiency testing provider is suspended, A2LA shall confirm an official suspension in a certified letter, return receipt requested, (or equivalent means) to the proficiency testing provider'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 proficiency testing provider 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 proficiency testing provider by certified mail, return receipt requested, indicating whether the suspension has been terminated, modified, left in force or converted to a withdrawal of accreditation.

The Suspended status is publicized on the A2LA website.
XV. Enforced Withdrawal of Accreditation

A2LA shall withdraw accreditation for any of the following causes:

- under the relevant provisions for suspension of accreditation;
- if surveillance 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 proficiency testing provider's proficiency testing programs and investigation reveals serious deficiencies in the management system and/or competence in operating the proficiency testing program;
- if the system rules are changed and the proficiency testing 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 proficiency testing 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 proficiency testing provider (See also Inactive Status below).

When it is proposed to enforce withdraw accreditation, 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 proficiency testing provider on notice of the cause;
- that within thirty (30) days of receipt of the notice, the proficiency testing provider 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 proficiency testing provider's name from the A2LA online Directory of accredited organizations and publicizing the action on the A2LA website.

A proficiency testing provider may appeal to A2LA against a decision to withdraw or not to award accreditation. The status of organizations that undergo the enforced withdrawal process are published on the A2LA website.

XVI. 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 VII 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 laboratory'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 laboratory'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.

**XVII. 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 reference material producer. 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 proficiency testing provider 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 proficiency testing provider and their scopes of accreditation are not confidential. In response to a question about whether or not a particular proficiency testing provider has applied for accreditation, A2LA simply responds by saying that the proficiency testing provider is not accredited. Staff neither confirm nor deny whether a proficiency testing provider has ever applied for accreditation. If the proficiency testing provider itself is saying that it has applied for accreditation, it is the proficiency testing provider's responsibility to release the information regarding its applicant status. If the caller says that the proficiency testing provider claims it applied, staff shall take the name, address and phone number of the proficiency testing provider to check to see if the proficiency testing provider's procedure is misleading the client but staff still will not verify the proficiency testing provider's application. Should an applicant proficiency testing provider require that staff verify for a potential client that it has applied to A2LA, staff shall indicate that it 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 proficiency testing provider. However, if an inquiry is made about a proficiency testing provider whose accreditation has lapsed but is in the renewal process, staff can indicate that the proficiency testing provider is not now accredited but is in the process of renewal, if that is the case. If the renewal proficiency testing provider’s accreditation has lapsed with no indication (return of renewal forms or payment) of pursuit of renewal, staff indicates simply that the proficiency testing provider is not accredited.

XVIII. 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 President 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

APPLICANT
PT PROVIDER

<table>
<thead>
<tr>
<th>SUBMIT APPLICATION, MANAGEMENT SYSTEM DOCUMENTATION, FORMS, FEES; ENROLL IN PROFICIENCY TESTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPLICATION COMPLETE</td>
</tr>
<tr>
<td>NO</td>
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<tr>
<td>YES</td>
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| A2LA HEADQUARTERS |

<table>
<thead>
<tr>
<th>REQUEST ADDITIONAL DOCUMENTATION / PREPARE FOR VISIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSIGN ASSessor(s)</td>
</tr>
<tr>
<td>APPLICATION COMPLETE</td>
</tr>
<tr>
<td>NO</td>
</tr>
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<td>YES</td>
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</table>

| ASSESSORS |

<table>
<thead>
<tr>
<th>SUBMIT ADDITIONAL DOCUMENTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
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<table>
<thead>
<tr>
<th>DOCUMENTATION SATISFACTORY</th>
</tr>
</thead>
<tbody>
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| HOST VISITING ASSESSORS |

<table>
<thead>
<tr>
<th>PERFORM PROFICIENCY TESTING (AS REQUIRED)</th>
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</thead>
<tbody>
<tr>
<td>NO</td>
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<table>
<thead>
<tr>
<th>PROFICIENCY TESTING DATA COLLECTED AND ASSESSMENT COMPLETED AND REPORTS</th>
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<tbody>
<tr>
<td>NO</td>
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<table>
<thead>
<tr>
<th>RESPONSE TO DEFICIENCIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
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<table>
<thead>
<tr>
<th>RESPONSE COMPLETE</th>
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<tr>
<td>NO</td>
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<table>
<thead>
<tr>
<th>PACKAGE SENT TO AC PANEL</th>
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<tbody>
<tr>
<td>NO</td>
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<td>YES</td>
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<table>
<thead>
<tr>
<th>ACCREDITATION COUNCIL PANEL VOTE</th>
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</thead>
<tbody>
<tr>
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<td>YES</td>
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## Document Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>12/28/16</td>
<td>Editorial changes including updating reference to Guide 34 to ISO 17034 and adding A2LA P113. Added option to send assessment package to one AC member when there are less than six non-technical deficiencies.</td>
</tr>
<tr>
<td>11/21/2017</td>
<td>Changed date range for newly accredited CABs from 105-135 to 45-75 days, clarified process for selecting AC members. Also updated document to current formatting requirements for program general requirement documents.</td>
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</tbody>
</table>
| 05/12/18   | - Updated appeals process to reference appeals panel instead of BOD  
- Referenced that voluntary withdraw renewal organizations will be posted on the A2LA website  
- Renamed Withdraw section to “Enforced Withdrawal”  
- Removed appeals process diagram.  
- Editorial changes.  
- 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”.  
- Clarified voluntary versus enforced inactive status.  
- Clarified SDAS in consultation with the P/CEO, as necessary.  
- Updated for the impartiality policy.  
- Changed quality manual to management system documentation and added forms.  
- Change surveillance visit to assessment.  
- Added P/CEO or designee.  
- Removed “written” from response.  
- Removed “root” from cause analysis. |
| 8/8/18     | - Clarification in Part B that A2LA must be notified when there are changes to subcontractors.  
- Editorial Changes. |