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R303 - General Requirements:
**TNI Proficiency Testing and SSAS Provider
Accreditation Program**
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 that want to be recognized to provide proficiency testing samples to The NELAC Institute (TNI) accredited laboratories. The ***A2LA Accreditation Program for TNI 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 along with the specific requirements of the TNI EL-V3: 2009 standard

A2LA's accreditation program for TNI Proficiency Testing Providers covers the following matrices: potable water, non-potable water, soil, chemical materials, tissues, air emissions, microbiology, radiochemistry and environmental toxicology.

The baseline requirements for this program are the ***ISO/IEC 17043 Conformity Assessment-General requirements for proficiency testing***. Also, specific assessment requirements to be accredited as a TNI PT provider, as listed in the criteria established in the TNI EL-V3: 2009 include:

- ISO Guide 34 General Requirements for the Competence of Reference Material Producers
- ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories

Specific checklist ***C317-Specific Checklist ISO/IEC 17043, TNI EL-V3, ISO/IEC 17025 and ISO Guide 34 Proficiency Testing Provider Accreditation Program*** has been created covering the aforementioned requirements. It is A2LA policy not to accredit or renew accreditation of a TNI proficiency testing provider that fails to meet the requirements listed in the ***Assessor Checklist C317***, and in this ***Requirements Document***.

This document also sets forth the general requirements for the A2LA accreditation of Stationary Source Audit Sample providers (SSAS Providers) that want to be recognized to provide audit samples.

The baseline requirements for the SSAS program are the ***ISO/IEC 17043 Conformity assessment-General requirements for proficiency testing***. Also, specific assessment requirements to be accredited as a TNI SSAS provider, as listed in the criteria established in the TNI Standards Volume 1, Module 1 include:

- TNI Volume 1, Module 1 and appendices;
- ISO Guide 34 Requirements pertinent to the provider's manufacturing system;

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- And ISO/IEC 17025 Requirements for the testing facilities used to support the verification, homogeneity, and stability testing.

A specific checklist *C315 - Specific Checklist - TNI SSAS Provider Accreditation Program* has been created to cover the A2LA TNI SSAS Accreditation Program.

Providers seeking accreditation for the aforementioned programs are also required to meet *R105 – Requirements When Making Reference to A2LA Accredited Status* and *P113 – A2LA Policy on Measurement Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies*

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 TNI proficiency testing and SSAS providers. Confidential information shall not be released unless authorized by expressed written permission from the TNI proficiency testing and SSAS providers. A2LA shall not administer any ongoing, commercial proficiency testing programs while carrying out this 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 a laboratory’s technical competence.

In effect, A2LA accreditation attests that a proficiency testing provider has demonstrated:

- it is competent to perform the specific proficiency testing schemes listed on its Scope(s) of Accreditation;
- its management system addresses and conforms to all elements of the applicable requirements described in this section, is documented per those requirements, and is fully operational;
- it is operating in accordance with its management system; and
- it conforms to any additional requirements of A2LA or specific fields or programs necessary to meet particular user needs.

In keeping with our mission:

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

Our staff, assessors and committees are committed to providing the 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.



Lonnie Spires, A2LA President and CEO

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PART B - CONDITIONS FOR ACCREDITATION

In order to attain and maintain accreditation, accredited organizations must comply with the *Conditions for Accreditation (R102)* published by A2LA.

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'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 proficiency testing provider'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 conduct personnel interviews, evaluate procedures, and examine records and documentation to verify compliance with the Conditions for Accreditation.

PART C - A2LA ACCREDITATION PROCESS

I. Application

A proficiency testing and SSAS provider applies for accreditation by obtaining the application package from A2LA headquarters or the A2LA website www.A2LA.org, then completing and submitting the appropriate application pages, the assessor checklists, (which contains the specific assessment requirements) and the quality manual and related SOPs that are referenced in the completed checklists to A2LA. All applicants must agree to the Conditions for Accreditation (see Part B of this document), pay the appropriate fees as 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 and SSAS programs, frequency and detailed description of sample/artifact type for each program
- Organization structure; and
- Collaborators (subcontractors)
- PT and SSAS 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.

II. Assessment Process

The objective of an assessment is to establish whether or not a proficiency testing provider complies with the A2LA requirements for accreditation and can competently perform proficiency

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testing schemes 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 proficiency testing provider improve its performance. Assessors are restricted from providing consultation as this is not permitted under ISO/IEC 17011 *Conformity Assessment-General requirements for accreditation bodies accrediting conformity assessment bodies*, the standard A2LA operates and adheres to.

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

A. Initial Steps

Once the application information is completed and the appropriate fees are paid, A2LA headquarters staff identifies and tentatively assigns one or more assessors to conduct an 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 and SSAS providers. They do not represent their employers (if so affiliated) while conducting assessments for A2LA. The proficiency testing and SSAS 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 will usually be required.

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

Assessors are given assessor standard operating procedures and checklists to follow 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 provider to 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.

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Upon review of submitted documentation, the assessor(s) may ask the proficiency testing and SSAS 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 and SSAS provider as an option at this point to enhance the success of the full assessment.

Prior to scheduling the full assessment, the assessor reviews the draft scope(s) to check on the availability of the technical personnel who conduct the proficiency testing schemes. An assessment agenda is provided by the assessor.

B. Pre-Assessment (when requested)

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

1. When the lead assessor finds major gaps in the quality manual, or actually begins the assessment and finds a large number of problems. In this case, the assessor identifies them and suggests to the proficiency testing provider that a full assessment should wait until the problems have been addressed. This first identification of the problems would be considered a pre-assessment; or
2. When a proficiency testing provider requests a pre-assessment to better prepare for the full assessment. In this case, the proficiency testing provider has applied, but is unsure of its documentation or system and wants someone to perform a pre-assessment to identify problems. The full assessment follows later.

To implement the pre-assessment program, the proficiency testing provider must first apply for accreditation, paying the appropriate fees and assessor deposit. 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 can be deducted from any assessor deposits held on account at A2LA. No additional accreditation fees apply. Please note, however, that careful attention to the requirements should preclude the need for a pre-assessment.

C. On-Site Assessment

The full assessment generally involves:

- An entry briefing with proficiency testing and SSAS provider management;
- Audit of the management system to verify that it is fully operational and that it conforms to the requirements contained in the assessor checklists;
- Interviews with technical and administrative staff as appropriate to verify compliance;
- Examination of facilities and published PT and SSAS reports;
- Evaluation of compliance with the A2LA requirements documents *R105 – Requirements When Making Reference to A2LA Accredited Status*, *P113 - A2LA Policy on Measurement*

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Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies, P103 – Policy on Estimating Measurement Uncertainty for Testing Laboratories, and R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories (these requirements documents can be found on the A2LA website);

- A written report of assessor findings; and
- An exit meeting, including the specific written identification of any deficiencies.

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 authorized representative 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 XV Suspension of Accreditation). The full assessment is then rescheduled when the proficiency testing provider and assessor feel it is appropriate to proceed.

The objective of an assessment is to establish whether or not a proficiency testing and SSAS provider complies with the A2LA requirements for accreditation and can competently operate the proficiency testing and/or SSAS programs for which accreditation is being sought.

III. Deficiencies

During the assessment, assessors may observe deficiencies. A deficiency is any nonconformity to the accreditation requirements contained in the assessor checklists.

At the conclusion of an assessment, the assessor prepares a report of findings, identifying deficiencies that, in the assessor's judgment, the provider must resolve in order to be accredited. The assessor holds an exit meeting with the authorized representative (or deputy representative), going over the findings and presenting the list of deficiencies (deficiency report). 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 the provider (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 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.

The provider is required to respond within 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 a copy of any objective evidence (e.g., procedures, records, PT and/or SSAS reports) to indicate that the corrective actions have been implemented/completed.

It is entirely possible that the provider will disagree with the findings that one or more items are deficiencies. In that case, the provider is requested to explain in its response why it disagrees with the assessor.

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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 root cause analysis and a copy of any objective evidence (e.g., calibration certificates, proficiency testing provider's 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 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.

When addressing a deficiency to the A2LA traceability policy, please note that if the proficiency testing provider is using a calibration provider that does *not* meet the A2LA Traceability Policy, to satisfy the deficiency the proficiency testing provider does *not* need to immediately re-calibrate the equipment in question using an acceptably accredited calibration source. The proficiency testing provider must be able to demonstrate in their corrective action response that they will use an acceptable source of calibration *for the next regularly scheduled calibration cycle*. An acceptable source is a calibration proficiency testing provider 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 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 applicant proficiency testing provider (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 the proficiency testing provider before an initial accreditation vote is taken based on the number, extent and nature of the deficiencies.

Renewal proficiency testing providers 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 proficiency testing provider (new or renewal) before an affirmative accreditation decision can be rendered.

V. Accreditation Anniversary Date

TNI PT provider and/or SSAS accreditation is granted for a two-year period. The anniversary date of a provider's accreditation is established 45 to 75 days after the last day of the final assessment

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before an initial accreditation decision, regardless of the length of time required to correct deficiencies. This date normally remains the same throughout the provider's enrollment.

VI. Extensions to the Accreditation Anniversary Date

If a 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 nonconformances are identified during an assessment, extensions of accreditation are not considered until the provider submits objective evidence demonstrating that the nonconformances 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 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, 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". 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 provider 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 three from the Accreditation Council members for voting. The panel of three selections takes into account as much as possible each member's technical expertise with the provider programs for which accreditation is being sought. Especially in the case of those providers seeking (re)accreditation for proficiency testing and/or SSAS 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 provider is consulted about any potential conflicts of interest with the Accreditation Council membership prior to sending their package to the Accreditation Council. At

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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 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 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 provider is asked to accept a reassessment. If the provider refuses the proposed reassessment, a nine (9) member Accreditation Council appeals panel is balloted (see the section on XVII. Appeals Procedures below). If two-thirds of the appeals panel members voting agree to a reassessment, accreditation is denied until a reassessment and satisfactory 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 provider. The provider should keep its scope of accreditation available to show clients or potential clients the specific proficiency testing and/or SSAS programs for which it is accredited. A2LA staff also uses the scopes of accreditation to respond to inquiries and to include these scopes on the A2LA website (www.A2LA.org).

VIII. Annual Review and On-Going Monitoring

Accreditation is valid for two years. However, after the initial year of accreditation, each 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 provider's management system and technical capabilities remain in compliance with the accreditation requirements. At the midpoint of accreditation for each two-year cycle, each provider must pay an **Annual Review Fee** and submit updated information on its organization, facilities, and proficiency testing, subcontractor information, and/or SSAS programs. Objective evidence of completion of the internal audit and management review is also required.

For those PT schemes that fall outside the TNI program, a list of all PT programs conducted since the last A2LA review, including the following summary information for each program is also required to be provided to A2LA:

- The nature of samples and the tests performed
- Basic statistical data, including 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

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- 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.

A. TNI Proficiency Testing Provider Ongoing-Monitoring

The ongoing monitoring of the accredited proficiency testing providers is required per Section 4.0 of TNI EL-V3:2009, and conducted per Section 6.3 of TNI EL-V4.

- Use of a referee laboratory will be on an as needed basis pursuant to Appendix I, Section IV Part c.
- A2LA will employ the services of an expert statistician for the statistical monitoring of the proficiency testing provider’s study data as outlined in Appendix I. This will entail the proficiency testing provider submitting summary raw data to the statistician for review. A2LA will use a database in support of this responsibility for efficiency. One statistician and an apprentice will be utilized to ensure uniformity in the reviews.
- Biennial on-site assessments will be a feature as described in Part C, Section II.
- On-site assessments will also be conducted “for cause”. This may be due to complaints received by the PTPA/PTOB, relocation of the applicant, expansion of the applicant’s scope or results of the ongoing monitoring that may indicate anything other than acceptable performance of the proficiency testing provider.

If the TNI 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.

B. SSAS Providers Ongoing-Monitoring

Annually, A2LA will conduct ongoing monitoring of all accredited SSAS providers. This will a review of SSAS verification and SSAS data to assure that every SSAS meets the criteria defined in TNI Standard Volume 1, Module 1 and also include:

- Assurance that concentrations are distributed throughout the specified analyte ranges;
- Confirmation of the required number of analytes included in groups;
- Approval of documentation for any change in the initial assigned value;
- Confirmation of the correct calculation of assigned values and acceptance limits as appropriate per analyte;
- Verification of the prepared or assigned value;
- Appropriate homogeneity testing;
- Appropriate stability testing; and

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- Investigating any situation where the SSAS provider’s overall or analyte pass/fail rate is statistically different from the national average at a 95% level, as determined by appropriate statistical techniques.

IX. Use of Referee Laboratory

A2LA may use an accredited reference laboratory to verify the assigned values of the concentrations when monitoring indicates that the SSAS provider’s SSAS is of unacceptable quality. In determining unacceptable quality, the same acceptance criteria that were used in the manufacture of the SSAS shall be used. For example, one standard deviation for verification or the approved criteria for homogeneity and stability.

A2LA shall provide each SSAS with a report describing the results of any required referee analysis.

The monitoring shall also provide verification of the SSAS provider’s adherence to the appropriate standards for the following:

- Correct and complete analyte lists as per SSAS provider accreditation
- A process for handling complaints;
- Compliance with defined nomenclature (codes) for methods, analytes and technologies;
- Timeliness of reports to customers, regulatory agencies, and to A2LA.

Based upon the results of the ongoing monitoring, A2LA may determine that the SSAS provider’s accreditation status should be suspended or withdrawn.

X. Reassessment and Renewal of Accreditation

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

Each accredited provider is sent a renewal questionnaire, well in advance of the expiration date of its accreditation, to allow sufficient time to complete the renewal process. A successful on-site reassessment must be completed before accreditation is extended for another two-year period.

If deficiencies are noted during the renewal assessment, the provider 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.

XI. Adding to the Scope of Accreditation

An A2LA-accredited 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 provider to competently operate addition proficiency testing and/or SSAS programs based solely on documentation provided by the provider and results of the previous assessment, another on-site assessment is normally required. If the assessor can recommend a scope addition without an

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assessment, but this recommendation requires extensive review of supporting documentation requiring more than one hour's time, A2LA may invoice the provider for this review time at the prevailing assessor rate. If the additional proficiency testing and/or SSAS schemes are supported by a new technology not previously evaluated, another assessment is definitely required. Similarly, if a proficiency testing provider relocates, a follow-up assessment is normally warranted.

XII. 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 provider's management system. Pursuant to the severity of the complaint, this 'for cause' assessment may be performed with little or no advance warning.

XIII. Advertising Requirements for Accredited Providers

For rules on the use of the "A2LA Accredited" symbol, please see the document titled *R105 – Requirements When Making Reference to A2LA Accredited Status*.

XIV. Accreditation Status and Adverse Accreditation Decisions

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

Voluntary Withdrawal – An applicant provider not yet accredited, or a renewal provider, can decide to terminate further accreditation action and voluntarily withdraw from the accreditation program. The provider contact must inform A2LA in writing of this request. A2LA does not publicize the fact that a new provider had applied and then was withdrawn, however, the voluntary withdrawal status of renewal laboratories are publicized on the A2LA website.

Inactive Status (voluntary) – A provider 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 provider must notify A2LA in writing of this desire, agrees to undergo a full reassessment, paying all renewal fees and reassessment costs.

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

Inactive Status (enforced) - A provider that has relocated is also designated as inactive until its ability to provide proficiency testing schemes on its scope at the new location has been confirmed (e.g. by a visit to the provider's site). In these cases, to regain accredited status, the Inactive lab must fulfill the requirements of [P105](#) – *A2LA Policy on Organization Relocation*, and agree to undergo an interim reassessment, paying all interim assessment costs.

XV. Suspension of Accreditation

Suspension of all or part of a provider's accreditation may be a decision made by either the Senior Director Accreditation Services (SDAS) in consultation with, where necessary, the President &

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CEO (P/CEO) or Accreditation Council panel. The accreditation applicable to a specific provider may be suspended upon adequate evidence of:

- Non-compliance with the requirements of a nature not requiring immediate withdrawal;
- Improper use of the accreditation symbol (e.g., misleading prints or advertisements are not solved by suitable retractions and appropriate remedial measures by the provider); and
- Other deviations from the requirements of the A2LA accreditation program (e.g., failure to pay the required fee or to submit annual review information within 60 calendar days after it is due).

The accreditation of a provider shall immediately be suspended by the Senior Director Accreditation Services (SDAS) in consultation with, where necessary, the President & CEO (P/CEO), if the provider or any individual or entity responsibly connected with the 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 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 provider is suspended, A2LA shall confirm an official suspension in a certified letter, return receipt requested, (or equivalent means) to the provider's authorized representative, stating:

- The cause;
- 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 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 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.

XVI. Enforced Withdrawal of Accreditation

A2LA shall withdraw accreditation for any of the following causes:

- Under the relevant provisions for suspension of accreditation;

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- 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 provider's proficiency testing programs and investigation reveals serious deficiencies in the management system and/or competence in operating the program;
- If the system 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 provider (See also Inactive Status below).

When it is proposed to enforce withdrawal of 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 provider on notice of the cause;
- That within thirty (30) days of receipt of the notice, the 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 provider's name from the A2LA on-line directory of accredited organizations and publicizing the action in the A2LA website.

A proficiency testing provider may appeal to A2LA against a decision to withdraw or not to award accreditation.

XVII. Appeals

A. Appeal of an Accreditation Decision

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

- 1) Appeals on accreditation decisions made by the Accreditation Council (AC), are submitted to a nine-member panel of the AC;

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2) Appeals on adverse accreditation decisions made by A2LA staff are submitted to the A2LA Quality Council (QC).

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

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 provider'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 provider's scope of accreditation. The decision of the Appeal Panel is communicated in writing to the appellant.

All unresolved conflicts on technical matters between the PT providers and A2LA will be submitted to the TNI PT Executive Committee. All other decisions rendered by the Appeals Panel is final and binding.

XVIII. Confidentiality Policy

All information provided by applicants in connection with a request for an application package, an application for accreditation, or an assessment is confidential. 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. Such information shall not be released unless the applicant provides A2LA permission in writing to do so.

Documents necessary to convey information about accredited providers and their scopes of accreditation are not confidential.

In response to a question about whether or not a particular provider has applied for accreditation, unless otherwise advised by the applicant, A2LA simply responds by saying that the provider is not accredited. Staff should neither confirm nor deny whether a provider has ever applied for accreditation. If the provider itself is saying that it has applied for accreditation, it is the provider's responsibility to release the information regarding its applicant status. If the caller says that the provider claims it applied, staff shall take the name, address and phone number of the provider to check to see if the provider is misleading the client but staff still will not verify the provider's application. Should the provider insist that staff verify for a potential client that it has applied to A2LA; staff shall indicate that it has applied only if the provider makes such a request to A2LA in writing.

If an inquiry is made about a provider whose accreditation has lapsed but is in the renewal process, staff can indicate that the provider is not now accredited but is in the process of renewal, if that is the case. If the renewal provider's accreditation has lapsed with no indication (return of renewal forms or payment) of pursuit of renewal, staff indicates simply that the provider is not accredited.

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If A2LA finds that a provider is misrepresenting its applicant or accredited status, staff shall treat such information like a complaint by first informing the A2LA President & CEO. The President & CEO shall determine the appropriate action that would usually involve contacting the provider directly about the alleged misrepresentation.

XIX. Impartiality Policy

Since its inception, A2LA has had a policy that actual or apparent conflicts of interest must be avoided as mandated by normal business ethics. 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 may could compromise impartiality.

The Audit & Ethics Committee of the Board and the President & CEO 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.

Appendix I

Procedure for Proficiency Test Provider Oversight

Scope and Purpose

This standard operating procedure covers the reviews and statistical analyses that will be used for oversight of PT programs conducted according to requirements of The NELAC Institute (TNI) Proficiency Testing Provider accreditation program.

The procedures below describe reviews that will be performed as part of routine oversight activities. These analyses use office review of documents, automated database checks, and routine statistical procedures. Statistical procedures are performed using the open-source software “R” and, as noted, coded into the database software. The procedures will be applied to all water analytes in the chemical and microbiology fields, and to soil analytes in the chemical and radiological areas. As needed, procedures will be extended appropriately for air and Whole Effluent Toxicity (WET) testing and Stationary Source Audit Samples (SSAS).

Instructions incorporated within the database, describes the data that are to be submitted by PT providers. This includes summarized participant data and data for Verification, Homogeneity, and Stability testing that are to be submitted after the close of each study, and information on problems encountered in each quarter (to be submitted every three months).

Note 1: oversight will not include supplemental PT, also called “quick turnaround” or “corrective action” PT. This exemption is because those studies are conducted with previous lots of material that have been shown to be stable. Each provider’s procedures for assuring stability and protecting confidentiality are reviewed in the on-site assessment.

Note 2: all data will be submitted at the close of a study, within 1 week of the final report to

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participants and accrediting bodies.

I. Office Review of PT Operations

Many oversight functions are performed by manual review of records submitted by the PT providers. Appropriate records should be sent to A2LA within 30 days of the action. In all cases, review will result in following step IV below regarding consultation with the appropriate PT provider (PTP):

- a) Changes in ownership, management, or physical location;
- b) Ongoing function of the providers quality management system (internal audits and management reviews);
- c) Unresolved PTP customer complaints;
- d) Complaints from PTP customers and Accrediting Bodies (AB);
- e) Review cases of changed assigned value;
- f) Management of referee lab testing - contract appropriate laboratory and send reports to the appropriate PT provider.

II. Automated Database review

Automatic review of the activities listed below will be performed within the database system. A2LA will review all indicators from these automated analyses, and follow the procedure under step IV on possible violation of suitability criteria.

- a) Studies open for 45 calendar days, reports to labs within 21 calendar days – conducted by counting days between closing date and opening date (45) and report date (21);
- b) Complete lists of analytes - conducted by comparing to PTP Scope;
- c) Concentrations within regulated ranges – compare with TNI Fields of Proficiency testing (FoPT) tables;
- d) Minimum numbers of analytes in groups – compare with TNI rules;
- e) Correct composition of qualitative microbiology sets;
- f) Correct calculation of acceptance ranges – use TNI FoPT tables;
- g) Correct verification of assigned value – verification mean within 1SD of assigned value;
- h) Correct verification of homogeneity* - use $S_s/\text{Eval Interval} < .25$;
- i) Correct verification of stability* - use Pre-Post / Eval Interval $< .20$.

* Different procedures for each provider

The oversight database generates a report on the result of every check listed above. This report is sent automatically to the appropriate PTP, A2LA administration, and to the A2LA analyst or staff member. The PTP is expected to review the report and take the appropriate action for every flag in the report. This response does not need to be sent to A2LA unless the review leads to a change in an assigned value or any participant evaluation. These responses will be reviewed during the biennial on-site assessment, and can also be reviewed, on demand at any time for questions about a particular dataset. An A2LA analyst will investigate, as appropriate, any dataset that is flagged as grossly violating multiple sections of the screen. This review will include visual review for flags that indicate a major failure of a study, or unexpected problems with format or database operation. Any concerns will be discussed with the appropriate PTP (see step IV).

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III. Data Review and Statistical Analyses

The analyses in this section are based on data submitted electronically. These analyses require some manual review and statistical analysis. The reviews described in this section will be conducted as needed.

A. Objective: Assure provider offers analyte concentrations across the full range.

Process: Examine the regulated ranges for each analyte. Test for a uniform distribution across quadrants.

Statistical procedure: Use the most recent 12-20 samples for that analyte in that program (use no fewer than 12 studies for this analysis).

1. Using the TNI FoPT table range for determining the test range, divide the test range into four levels, equally spaced (linearly or logarithmically as appropriate).
2. Create a tabular presentation with analytes as rows (ordered by group) and four concentration levels as columns. Place in the cells the count of sample assigned values (out of the last 12-20) that fell into that range.
3. Conduct a Chi-square test (3 degrees of freedom, and Expected counts = 3 to 5 for each quadrant).
4. Test at $\alpha < .05$; and
5. Indicate any statistically significant result

*Note - Section B, which follows below, has been suspended as another Proficiency Testing Provider Accreditor (PTPA) has been approved by TNI. It is currently not possible to calculate the national average as a database has not been implemented that will allow data from all accredited proficiency testing providers to be compared from each PTPA. Section B will be reinstated when it is again possible to collect and analyze such data from all accredited providers and if deemed necessary.

B. Objective: Assure the consistency of unacceptable rates in programs from different Providers

Background: The regulatory requirement is to check for PT providers that have unacceptable rates statistically significantly different than the national average at the 95% level of significance. This implies that for every analyte, there is a single “national average” or norm. Therefore, every provider is to be compared against the same criteria, as opposed to comparing every provider against the combined unacceptable rates of other providers, which would be a more sensitive test for aberrant unacceptable rates.

Experience shows that unacceptable rates can vary greatly across studies, for the same analyte. Rates of 0% are not uncommon, and rates can be 20% or more, especially in small groups. Therefore, it may be difficult to identify clearly different rates for a particular provider. Nevertheless, this analysis is important for the credibility of the PTPA system. The regulatory concern is that proficiency testing providers will provide unethical assistance to assist laboratories achieve acceptable results, such as consultation, excess volume of test material, or “QC samples” from similar previous rounds where correct concentrations are known; the concern here is for significantly and consistently low rates of unacceptable results. Similarly, the concern of laboratories is that a PTP will provide unrepresentative, inhomogeneous, or unstable samples, and

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thereby increase the laboratory's likelihood of receiving an unacceptable result unfairly; the concern here is for significantly high rates of unacceptable results.

Process: This analysis will be conducted separately for every analyte. In some cases it may be conducted by analyte group, when analytes in the same group show consistently similar distributions of unacceptable rates. Calculate national average unacceptable rates by examining data from all providers. Compare every provider's unacceptable rate for that analyte with the distribution of unacceptable rates nationally investigate significant differences (high and low). When reasonable, combine results by analyte group and do the same comparison.

This includes all quantitative microbiology samples, with the log-transformed results treated the same as other quantitative analytes, and all radiological chemistry analytes. This procedure also applies to qualitative microbiology results, where for each organism the review will cover false positive and false negative rates.

Statistical Procedures:

The following analyses will be conducted on an as needed basis and will be for each analyte separately:

1. Calculate rates of unacceptable results (high and low combined) for the current shipment and combined with the previous 3 shipments from every provider.
2. Review any combined rate that is < 0.5% (.005);
3. Calculate the unacceptable rate for all providers combined
4. Calculate a z score for every provider's unacceptable rate compared with this overall rate. In this calculation, treat the overall average as fixed (0 SE), and use the Binomial SE for the provider's rate.
5. Flag any $z \geq 2.0$ or $z \leq -2.0$

The following analyses will be conducted as needed, for every analyte group:

- i. Combine counts of numbers of results and numbers of unacceptable results for each analyte group;
- ii. Review any combined rate that is less than 0.5% (.005)
- iii. Calculate the overall rate for all PT providers
- iv. Calculate a z score for the difference between every provider's rate compared with the overall rate. In this calculation, treat the overall average as fixed (0 SE), and use the Binomial SE for the provider's rate.
- v. Flag any $z > 2.0$ or $z < -2.0$

Analyses C and D are run on an as-needed basis only.

C. Objective: Assure the consistency of sample recovery and group agreement with published TNI acceptance criteria in programs from different providers

Process: Examine group means and standard deviations vs. expected means and SD's. The main components of this analysis are regression analysis of observed compared to expected results and the visual analysis of residuals. Compare also the recovery rates compared to 100%. This analysis does not apply to quantitative microbiology or soils, where recovery cannot be calculated or anticipated in advance based on past experience.

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Analyses are conducted semi-annually, based on the most recent 3 years of results, and are conducted separately for each analyte.

Statistical Procedure:

1. Calculate the simple linear regression* of observed means (dependent variable) vs. expected means (independent variable);
2. Calculate the simple linear regression of observed standard deviation (dependent variable) vs. expected standard deviation (independent variable);
3. Test each regression for slope $\neq 1.0$ and for intercept $\neq 0.0$ at $\alpha < .05$;
4. Conduct analysis separately for every provider; if one or two providers are significantly different, examine each significant provider in detail.
5. If three or more providers have significant differences, conduct a review of the regression equations – combine results from all providers and re-calculate regression a b c d coefficients per the defined field of proficiency testing (FoPT) procedure (study D, below);
6. Conduct analyses steps 1-5 again with revised coefficients. Calculate percentage recovery as the participant mean divided by the manufactured (assigned) value, multiplied by 100%.
7. Plot percentage recovery vs. concentration.
8. Examine plots for individual manufacturers to check for differences.

* These regressions will change as the database grows. Initially the procedure will follow the TNI FoPT Committee protocol, but as soon as sufficient data are available, other techniques will be used such as weighting data points for uncertainty and nonlinear models.

D. Objective: Update TNI PT regressions (optional, as needed)

Process: Use the TNI PT Board SOP for conducting regression analysis on group means and standard deviations. This is done bi-annually for all analytes, or on demand from the TNI PT Board or the TNI PT Expert Committee. It also can be initiated by findings in analysis C above, if there are concerns about the validity of current evaluation criteria. Quantitative microbiology can be treated like soils, with regressions for SD only. Note that the actual data used in this analysis will not be distributed outside A2LA or the database vendor. If the regression data points (or residuals) are requested by TNI, only the assigned values, means, and SDs will be shared, not the number of results that determined the means and SDs.

Statistical procedure:

1. Assemble the most recent 3 years of results from all approved PT providers (for each study: provider assigned value, group bi-weight mean, group bi-weight SD, and the number of results).
2. Run 1st pass regressions*, remove studies $> 2SE$ from line;
3. Review ranges, remove extreme studies;
4. Re-run regressions, remove studies where for the SD regression, the SD $> 0.5SE$ from line;
5. Re-run regressions, check for acceptable number of results and R-square.
6. Contact PT providers to check for impact on unacceptable rates, if there is a suggestion that coefficients will be revised.

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* These regressions will change as the database grows. Initially the procedure will follow the TNI PT Board SOP, but as soon as sufficient data are available, other techniques will be used such as weighting data points for uncertainty and nonlinear models.

IV. Review of possible unsatisfactory PT provider performance

In all cases where an analysis suggests that a study or a PT provider may have failed to meet requirements:

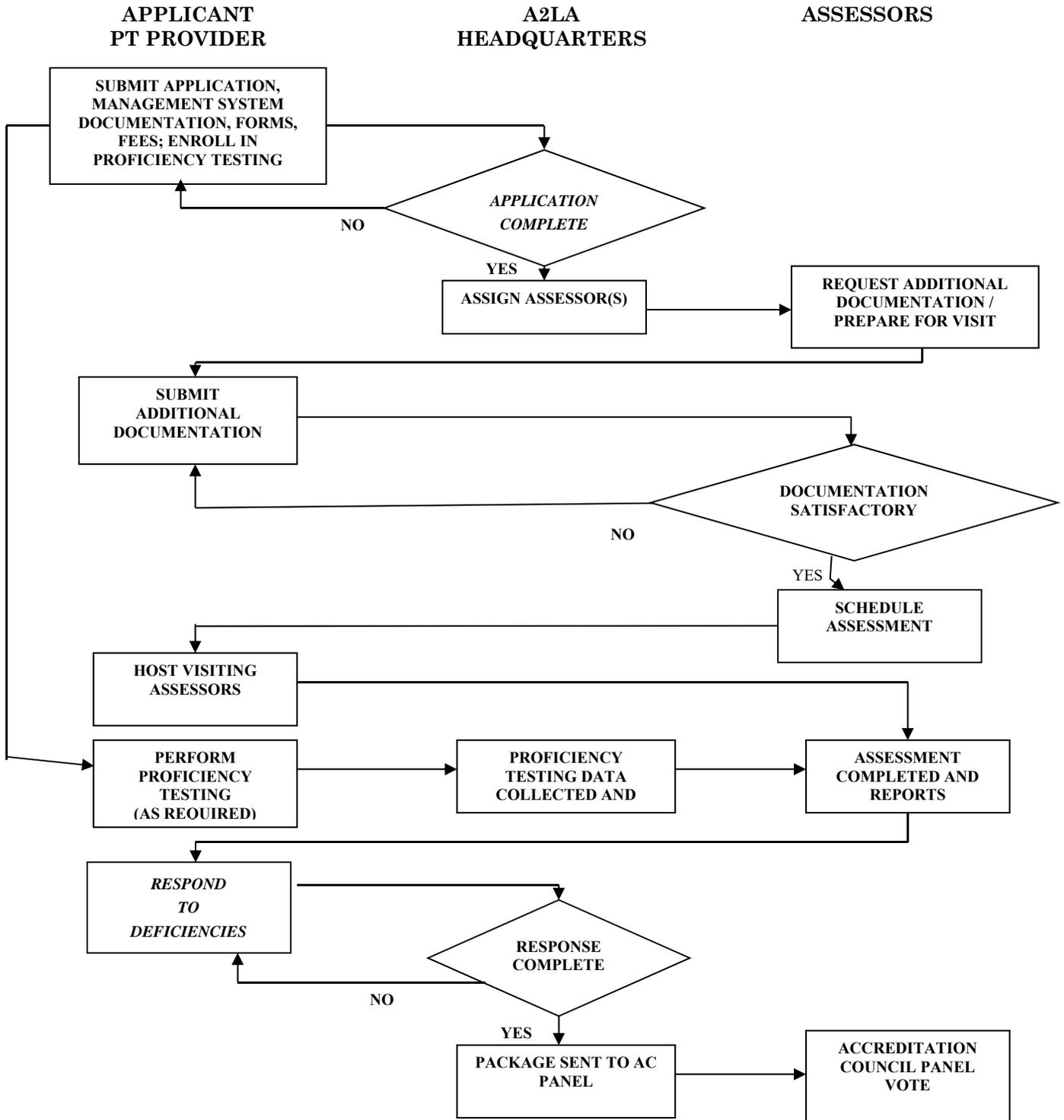
- a) Assemble all relevant data and discuss with the indicated PT provider. The response from the PT provider will be considered before any further action results from the indications.
- b) When an analysis suggests a trend or long-term potential concern (e.g., the full range of concentrations has not been used for an analyte):
 - i. Discuss the findings with the provider and possible reasons for the finding.
 - ii. Discuss with the provider a plan for addressing the concern.
- c) When an analysis suggests that a study lot may have been unacceptable or inappropriate (based, for example, on high unacceptable rates or a changed assigned value from the provider):
 - i. Discuss the findings with the provider and possible reasons for the finding.
 - ii. Review individual laboratory results (could be conducted by the provider).
 - iii. If this review does not lead to a resolution of the concern, then designate a 3rd-party accredited laboratory to process 3 randomly selected samples from the lot in question.
 - iv. Review the results and determine whether to declare a study invalid or to suggest other appropriate action. The criteria for acceptance of the referee laboratory results are the same as the verification requirements used by a PT provider for that type of sample.
 - v. Send a report of the results of referee analysis to the PT provider, within 10 days of receipt.

V. Records of Oversight Reviews

The analyst will create a record for every completed review, with written notes on all anomalies that were checked manually.

A2LA will accumulate records from all reviews for each PTP and will invoice all providers on a quarterly basis.

A2LA ACCREDITATION PROCESS



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Document Revision History

Date	Description
11/15/17	Editorial change to update A2LA's President and CEO and to reflect current policy documents.
05/12/18	<ul style="list-style-type: none"> • Editorial changes. • Updated to authorized representative. • Changed to response for section VIII (removed written). • Change visit to assessment for section IX. • 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" to section XVI. • Clarified voluntary versus enforced inactive status. • Clarified SDAS in consultation with the P/CEO, as necessary. • Updated for the impartiality policy. • Added P/CEO or designee. • Added suspension in regards to fraud etc.
8/1/18	<ul style="list-style-type: none"> • Clarification in Part B that A2LA must be notified when there are changes to subcontractors. • Editorial Changes.