

**R303 – SPECIFIC REQUIREMENTS:
NELAC PROFICIENCY TESTING PROVIDER
ACCREDITATION PROGRAM**

August 2005

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FOREWORD

The AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA) is a non-profit, non-governmental, public service, membership organization dedicated to operating a nationwide, broad spectrum laboratory accreditation system using as a basis for accreditation, “General requirements for the competence of calibration and testing laboratories” (ISO/IEC 17025:1999).

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 National Environmental Laboratory Accreditation Conference (NELAC) accredited laboratories. The ***A2LA Accreditation Program for NELAC 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 NELAC standard, Chapter 2.

A2LA’s accreditation program for NELAC 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 ***ILAC-G13: 2000 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing***. These requirements are based upon ISO Guide 43-1(1997) and on the relevant elements of ISO/IEC 17025:1999 applicable to characterization, homogeneity, and stability testing of proficiency testing materials. Also, specific assessment requirements to be accredited as a NELAC PT provider, as listed in the criteria established in the NELAC Standards Chapter 2, Section 2.1 and Appendix A.2, include:

- ISO Guide 34: 2000 General Requirements for the Competence of Reference Material Producers
- NELAC Chapter 2: 2003 Proficiency Testing (and associated appendices)
- ISO/IEC 17025: 1999 General Requirements for the Competence of Testing and Calibration Laboratories
- Relevant sections of the NELAC Chapter 5 (2003) and
- the EPA National Standards for Water Proficiency Testing Studies, Criteria Document 1998.

Specific checklists have been created covering the aforementioned requirements. It is A2LA policy not to accredit or renew accreditation of a NELAC proficiency testing provider that fails to meet the requirements listed in the *Assessor Checklists*, the *Application Form*, and in this *Requirements Document*.

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 NELAC proficiency testing providers. Confidential information shall not be released unless authorized by expressed written permission from the NELAC 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 a laboratory’s technical competence.

_Peter S. Unger, A2LA President

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PART A
A2LA ACCREDITATION PROCESS

I. Application

A commercial proficiency testing provider applies for accreditation by obtaining the application package from A2LA headquarters, 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. All applicants must agree to the Conditions for Accreditation (see Application), pay the appropriate fees, 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; and
- Collaborators (sub-contractors)
- PT analyte and sample scoring procedures

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 will usually be required.

Assessors are given an assessor guide 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 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 quality 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 reports;
- A written report of assessor findings; and
- An exit meeting, including the specific written identification of any deficiencies.

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 operate the proficiency testing 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 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 (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 proficiency testing provider (or designee) is asked to sign the deficiency report to attest that the deficiency report has been reviewed with the assessor. The signature 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.

The proficiency testing provider is requested to respond within one month 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 reports) to indicate that the corrective actions have been implemented/completed.

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.

Applicants 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 applicant (new or renewal) before an affirmative accreditation decision can be rendered.

IV. Accreditation Anniversary Date

NELAC PT provider accreditation is granted for a two-year period. All applicant PT Providers meeting the A2LA timelines established in the A2LA Timetable for the Accreditation of Proficiency Testing Providers to the A2LA NELAC PTPA/PTOB Requirements (August 5, 2005), and successfully meeting the requirements for accreditation will be accredited in the first class of A2LA NELAC PT Providers.

V. 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 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 selects a "Panel of Three" from the Accreditation Council members for voting. The "Panel of Three" 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. 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.

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 written response based on the specific justification for one or more negative votes received from the panel. If further written 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 XI. Adverse Accreditation Decisions and XIV. 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 NELAC proficiency testing provider. The NELAC 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 include these scopes on the A2LA website (www.A2LA.org).

VI. Annual Review and On-Going Monitoring

Accreditation is valid for two years. However, at the midpoint of accreditation for each two-year cycle, each NELAC proficiency testing provider must pay an **Annual Review Fee** and submit updated information on its organization, facilities, and proficiency testing programs. Objective evidence of completion of the internal audit and management review is also required.

The ongoing monitoring of the accredited proficiency testing providers will be based upon the requirements established in NELAC Chapter 2 Appendix D.4:

- Referee laboratories will be utilized to verify the concentration of analyses in randomly selected proficiency testing provider samples. Accredited laboratories will be used in support of this role.
- 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 D.4 (b). This will entail the proficiency testing provider submitting reports and 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 A, 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 NELAC 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 visit and payment of the associated assessor fees is required.

VII. Reassessment and Renewal of Accreditation

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

Each accredited NELAC proficiency testing 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 NELAC proficiency testing 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.

The renewal decision process is similar to the initial decision process (see section V. Accreditation Decisions), except as follows:

- 1) If there are no deficiencies, renewal is automatically processed without an Accreditation Council panel vote.
- 2) If there are only a few deficiencies of a minor nature (i.e., non-compliance does not directly affect the integrity of the proficiency testing program that is accredited) and there is sufficient objective evidence that the deficiencies have been resolved, the President may elect to renew accreditation without an Accreditation Council panel vote.
- 3) If there are major deficiencies (i.e., non-compliance directly affects the integrity of proficiency testing programs), the staff advises the NELAC proficiency testing provider of the required time-frame (normally 30 days) in which to resolve all deficiencies or be subject to further actions leading to suspension or withdrawal of accreditation (see sections XI. Adverse Accreditation Decisions, XII. Suspension of Accreditation, and XIII. Withdrawal of Accreditation). Several related minor deficiencies or repeat deficiencies from previous assessments may also be considered a major deficiency. In these cases, a ballot of the Accreditation Council panel is conducted using the same voting procedure as for initial accreditation decisions.

VIII. Adding to the Scope of Accreditation

An A2LA-accredited NELAC 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 addition 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.

IX. Advertising Policy for Accredited PT Providers

A2LA-accredited PT providers are strongly recommended to use the “A2LA-accredited” symbol to demonstrate their third party recognition of technical competence. “A2LA-accredited PT provider” symbol sheets are sent to all accredited PT providers, and an electronic version is available upon request.



However, since A2LA PT provider accreditations are issued for a number of different types of PT programs, it is the ethical responsibility of accredited PT providers to describe their accredited status in a manner that does not imply accreditation in areas that are outside their actual scope of accreditation. This may be accomplished through adherence to the following guidelines:

- Where the A2LA name and/or symbol are used on general literature such as letterhead and advertisements; it shall always be accompanied by at least the word "accredited".
- While there are no restrictions on the size and color of the “A2LA-accredited” symbol reproduction, the symbol must maintain its form.
- The “A2LA-accredited” symbol may be generated electronically provided that the prescribed formats and forms are retained.
- When promoting or providing proof of accreditation, accredited PT providers should use the scope(s) of accreditation, as this document details the specific PT programs which are accredited. The certificate should be used for display purposes and may also accompany the scope.
- Where the “A2LA-accredited” symbol is used to endorse PT reports, it shall always be accompanied by the A2LA certificate number(s). The following conditions also apply:
 - The “A2LA-accredited” symbol may be displayed on all PT reports, which contain **exclusively** results from PT programs that have been carried out within the accredited scope of the PT provider concerned.
 - Non-accredited PT programs may be reported in PT reports that include the A2LA symbol provided these results are unambiguously identified as non-accredited. This may be done by placing an asterisk after each program along with a footnote stating: "This PT program is not covered by our current A2LA accreditation".

- When the A2LA name and/or symbol is used on a business solicitation document such as a proposal or quotation form, the PT provider has the responsibility to distinguish between those proposed PT programs that fall within the PT provider's scope of accreditation and those that do not. This can be done by attaching a copy of its current A2LA Scope of Accreditation sheet and Supplement to the Scope, if appropriate, or by noting which PT programs are non-accredited.
- The "A2LA-accredited" symbol and/or reference to the PT provider's accreditation may be made in advertisements provided the requirements of this document are strictly followed.
- The "A2LA-accredited" symbol shall not be displayed on business cards.
- The "A2LA-accredited" symbol shall not be displayed on a test item or product or used to imply product certification. If the "A2LA-accredited" symbol is used in literature relating to a product, the symbol must appear directly adjacent to the reference to the accredited PT provider and it must be clearly stated that inclusion of the symbol does not imply certification/approval of the products.
- Upon suspension or termination of accreditation, a PT provider must immediately cease to issue PT reports displaying the logo and shall cease publishing documents containing the symbol.
- An accredited PT provider owns the right to release A2LA assessor reports and deficiency reports as long as the reports are reproduced in whole and not in part. A2LA holds this assessment information in confidence unless specifically requested in writing by the accredited PT provider to release this information to another party.

Note: Every circumstance where the principle of accurate representation applies cannot be anticipated and dealt with in this document. Therefore, it is the responsibility of the accredited PT provider not to misrepresent its accredited status under any circumstances. If there are questions, the PT provider should submit intended uses of the symbol, draft advertisements, and/or any other accreditation claims to A2LA Headquarters for advance approval.

X. Misuse of the A2LA Accreditation Symbol

A2LA provides guidance to accredited proficiency testing providers on the use of its accreditation symbol. Incorrect references to A2LA or misleading use of the accreditation symbol found in advertisement, catalogs, etc. shall be dealt with by suitable actions that could include corrective action (such as suspension and subsequent withdrawal of accreditation), legal action, and possibly publication of the transgression.

XI. Adverse Accreditation Decisions

Any decision from an appeals vote that would deny or withdraw a NELAC proficiency testing provider's complete accreditation, must be agreed upon by a two-thirds vote of the sum of affirmative and negative votes from a nine-member appeals panel of the Accreditation Council.

Suspension actions of all or part of a proficiency testing provider's accreditation may be taken by the President. Suspension actions by the President are generally taken based on failure to comply with the Conditions for Accreditation.

See the following sections on XII. Suspension of Accreditation, XIII. Withdrawal of Accreditation and XIV. Appeals Procedures for further details.

XII. Suspension of Accreditation

The accreditation applicable to a specific proficiency testing 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 proficiency testing 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).

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 cause;
- the conditions under which the suspension will be lifted;
- that the suspension will be publicized in the A2LA Newsletter and on the Worldwide Web;
- 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

XIII. 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 quality 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;
- 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 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 scope from the A2LA website and publicizing the action in the A2LA Newsletter and on the Worldwide Web.

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

Inactive Status – A PT provider may also be temporarily classified as inactive. An Inactive PT provider is one that has specifically requested in writing that their accreditation be allowed to temporarily expire due to unforeseen circumstances that prevent them from adhering to the A2LA Conditions for Accreditation.

To regain their accredited status, the Inactive PT provider must notify A2LA in writing of this desire, agree to undergo a full reassessment, paying all renewal fees and reassessment costs.

The Inactive status can be given to a PT provider for no longer than one year, after which time the laboratory is removed from A2LA records and designated as "Lapsed". If they decide to re-enroll after this time, they are treated as a new PT provider, paying all new fees in effect at that time.

XIV. Appeals Procedure

There are two possible levels that an appeal can reach before being resolved:

- 1) Accreditation Council;
- 2) Board of Directors

The A2LA staff shall advise the applicant in writing of its right to challenge an adverse accreditation decision by the Accreditation Council panel. The appeals policy, including an applicant's right to a hearing, are contained in the A2LA Bylaws.

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 of the Accreditation Council.

The decision of the Accreditation Council's appeals group is communicated in writing to the appellant.

If the decision is not favorable to the appellant, the appellant may lodge a further appeal within thirty (30) days of notification by forwarding a certified letter to A2LA for timely consideration by the Board of Directors. This letter shall include appropriate substantiation for the appeal. This letter will be promptly transmitted to the members of the Board of Directors, except to those Board of Directors members that have a conflict of interest.

The decision of the Board of Directors shall be final and is communicated in writing to the appellant.

A2LA will also alert NELAC to any change in the status of the NELAC PT provider's A2LA accreditation.

XV. 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 laboratories 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, unless otherwise advised by the applicant, A2LA simply responds by saying that the proficiency testing provider is not accredited. Staff should 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 is misleading the client but staff still will not verify the proficiency testing provider's application. Should the proficiency testing 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 proficiency testing provider makes such a request to A2LA in writing.

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.

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

XVI. Conflict of Interest 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 involve an actual or apparent conflict of interest.

The Chairman of the Board and the President 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.