



*The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 1 of 19

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

**June 2011**

© 2011 by A2LA

All rights reserved. No part of this document may be reproduced in any form or by any means without the prior written permission of A2LA.



## TABLE OF CONTENTS

	<u>Page</u>
<b>Part A - INTRODUCTION</b>	3
<b>Part B - CONDITIONS FOR ACCREDITATION</b>	5
<b>Part C - A2LA ACCREDITATION PROCESS</b>	5
I. Application	5
II. On-site Assessment	6
III. Deficiencies	7
IV. Accreditation Anniversary Date	9
V. Extensions to the Accreditation Anniversary Date	9
VI. Accreditation Decisions	9
VII. Annual Review and Annual PT Report Review	10
VIII. Reassessment and Renewal of Accreditation	11
IX. Extraordinary Assessments	12
X. Adding to the Scope of Accreditation	12
XI. Advertising Policy for Accredited PT Providers	12
XII. Accreditation Status and Adverse Accreditation Decisions	13
XIII. Suspension of Accreditation	13
XIV. Withdrawal of Accreditation (& Inactive Status)	14
XV. Appeals Procedure	15
XVI. Confidentiality Policy	15
XVII. Conflict of Interest Policy	16
 A2LA ACCREDITATION PROCESS DIAGRAM	 17
 A2LA APPEALS PROCESS DIAGRAM	 18
 DOCUMENT REVISION HISTORY	 19



## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 3 of 19

### **PART A**

#### **INTRODUCTION**

The AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA) is a non-profit, non-governmental, public service, membership organization dedicated to operating a nationwide, broad spectrum accreditation system.

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

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

Note that this program applies only to the use of inter-laboratory comparisons for the purpose of proficiency testing (to determine the performance of individual laboratories for specific tests or measurements and to monitor laboratories' continuing performance.) It does not include determining the effectiveness and precision of test methods or determining the characteristics of a material to a particular degree of accuracy, such as in the preparation of reference materials. Please note that A2LA offers a separate accreditation for Reference Material Producers which is based on ISO Guide 34:2009.

It is A2LA policy not to accredit or renew accreditation of a proficiency testing provider that fails to meet the requirements listed in the ***C316-General Checklist: ISO/IEC 17043 Proficiency Testing Provider Accreditation Program, F302-Application for Accreditation: ISO/IEC 17043 Proficiency Testing Providers*** and this document. Proficiency testing providers are also required to meet the A2LA Advertising Policy (P101).

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

A2LA shall ensure that confidentiality is maintained by its employees and its contractors concerning all confidential information with which they become acquainted as a result of their assessments and contacts with proficiency testing providers. Confidential information shall not be released unless authorized by expressed written permission from the proficiency testing providers.



*The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 4 of 19

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.

A handwritten signature in black ink, appearing to read 'Peter Unger', is written over a horizontal line.

Peter S. Unger, A2LA President



## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 5 of 19

### **Part B**

#### **CONDITIONS FOR ACCREDITATION**

In order to attain and maintain accreditation, proficiency testing providers must comply with the Conditions for Accreditation (R102) published by A2LA. This document is available at the A2LA website, [www.A2LA.org](http://www.A2LA.org), or from A2LA Headquarters.

In order to apply, the applicant proficiency testing provider'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.

**Note:** Updates to A2LA policies will be provided to enrolled and accredited organizations via email, whenever possible.

### **Part C**

#### **A2LA ACCREDITATION PROCESS**

##### I. Application

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

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

- Scope of proficiency testing programs, frequency and detailed description of sample/artifact type for each program
- Organization structure
- Collaborators (sub-contractors); and
- PT analyte and sample scoring procedures



## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 6 of 19

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.

Delayed Assessment Policy: If a PT provider fails to undergo its full assessment within one year from receipt of the application at A2LA headquarters, the PT Provider is prompted by A2LA to take action. If no action is taken within thirty (30) days of that reminder, the PT Provider is required to begin the application process again and pay the PT Provider accreditation fees in effect at that time. Any fees paid with the initial application are refunded according to the A2LA Refund Policy.

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

### II. On-site Assessment

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

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

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

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

- An entry briefing with proficiency testing provider management;



## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 7 of 19

- Audit of the management system to verify that it is fully operational and that it conforms to requirements contained in ***C316 - General Checklist: ISO/IEC 17043 Proficiency Testing Provider Accreditation Program***
- Evaluation of your compliance with the A2LA requirements documents ***P101 – Reference to A2LA Accredited Status – A2LA Advertising Policy and P102- A2LA Policy on Measurement Traceability.***
- 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 including:

- A proficiency testing provider's inability to competently provide proficiency testing schemes for which it seeks accreditation;
- A proficiency testing provider's management system does not conform to a clause or section of ISO/IEC 17043, is not adequately documented, or is not completely implemented in accordance with that documentation; or
- A proficiency testing provider does not conform to any additional requirements of A2LA such as the requirements identified in the A2LA Conditions for Accreditation and this requirements document.

At the conclusion of an assessment, the assessor prepares a report of findings, identifying deficiencies which, in the assessor's judgment, the proficiency testing provider must resolve in order to be accredited. The assessor holds an exit meeting, going over the findings and presenting the list of deficiencies (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 American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 8 of 19

Assessors may also write an ‘observation’ when they question the practice or competence of the proficiency testing provider but there is not enough supporting objective evidence to justify a deficiency or the issue cannot be tied to the accreditation requirements. If this occurs, the proficiency testing provider does not have to respond to observations in order for accreditation to be granted.

However, the observations are part of the assessment record and will be followed up by the next assessor to visit the proficiency testing provider who will check to see if that observation was addressed by the proficiency testing provider, resulting in an improvement, or possibly may have progressed into a deficiency.

The proficiency testing provider is requested to respond in writing 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 the proficiency testing provider’s root cause analysis and a copy of any objective evidence (e.g., calibration certificates, revised procedures, records, PT reports, paid invoices, packaging slips and/or training records) to indicate that the corrective actions have been implemented/completed. It is possible that the assessor’s review of the corrective action response may be needed to determine if the response is satisfactory. If this review is expected to take more than one hour’s time, A2LA may invoice the proficiency testing provider for this time at the prevailing assessor rate. The assessor will discuss the possibility of this review with the proficiency testing provider during the exit briefing and obtain the proficiency testing provider’s concurrence.

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

If a new applicant proficiency testing provider fails to respond in writing within four months after the date of the exit briefing, it may be required to submit a new application and be subject to new fees and reassessment should it wish to pursue accreditation after that time.

A new applicant proficiency testing provider that fails to respond to all its deficiencies within six months of being assessed shall be subject to being reassessed at its expense. Even if the proficiency testing provider responds within six months, A2LA staff has the option to ask for reassessment of a proficiency testing provider before an initial accreditation vote is taken based on the amount, extent and nature of the deficiencies.

Proficiency testing providers undergoing renewal assessments shall 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 reassessment of a proficiency testing provider before an affirmative accreditation decision can be rendered.





## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 9 of 19

### IV. Accreditation Anniversary Date

Accreditation is granted for a four-year period. The anniversary date of a proficiency testing provider's accreditation is established 105 to 135 days after the last day of the final on-site assessment before an initial accreditation decision, regardless of the length of time required to correct deficiencies. This date normally remains the same throughout the proficiency testing provider's enrollment.

### V. Extensions to the Accreditation Anniversary Date

If a proficiency testing provider is in their renewal process and is making good faith efforts with A2LA when approaching their accreditation anniversary date, A2LA may extend their accreditation for up to an additional 90 days to complete the renewal of accreditation process. When fundamental nonconformances are identified during an assessment, extensions of accreditation are not considered until the proficiency testing 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 proficiency testing provider is granted an extension to their accreditation, a revised Certificate and Scope of Accreditation are posted to the A2LA website which reflects the extended anniversary date. Hard copies of these documents will be made available only upon request. Upon completion of the renewal process, both documents are reissued, reflecting the renewed anniversary date.

When an extension of accreditation is not considered, upon expiration, proficiency testing providers will be removed from the A2LA Accredited list on the A2LA website and placed on a separate website list called "Organizations in the Renewal Process". Proficiency testing providers on this list are currently considered *not* accredited but are somewhere in renewal process.

### VI. 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



## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 10 of 19

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. Especially in the case of those proficiency testing providers seeking (re)accreditation for proficiency testing schemes covering multiple fields of testing or calibration, it may be necessary to select more than three AC members in order to accomplish this. The proficiency testing provider is consulted about any potential conflicts of interest with the Accreditation Council membership prior to sending their package to the Accreditation Council. At least two affirmative ballots (with no unresolved negative ballots) of the three ballots distributed must be received before accreditation can be granted.

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 XII. Adverse Accreditation Decisions and XV. Appeals Procedures below). If two-thirds of the appeals panel members voting agree to a reassessment, accreditation is denied until a reassessment and satisfactory proficiency testing provider response(s) to all deficiencies are completed.

If accreditation is granted, the A2LA staff prepares and forwards a certificate and scope of accreditation to the proficiency testing provider. The proficiency testing provider should keep its scope of accreditation available to show clients or potential clients the specific proficiency testing programs for which it is accredited. A2LA staff also uses the scopes of accreditation to respond to inquiries and includes these scopes on the A2LA website ([www.A2LA.org](http://www.A2LA.org)).

### VII. Annual Review and Annual PT Report Review

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

After the first, second, and third years of accreditation for each four-year cycle, each proficiency testing provider must pay an **Annual Review Fee** and submit updated information on its



## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 11 of 19

organization, facilities, essential personnel and proficiency testing programs. Objective evidence of completion of the internal audit and management review is also required.

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

- The nature of the samples and the tests/calibrations performed;
- Basic statistical data, including the number of samples (n), mean value, and standard deviation for each analyte/property, and, if possible, summary data for each different method used for each analyte/property;
- Method of publication (e.g. printed report, electronic report, web-based). (A representative sample of PT reports issued since the last A2LA review is provided for review.)

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

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

If the proficiency testing provider does not promptly provide complete requested documentation and reports, or if significant changes to the facility, organization or proficiency testing programs have occurred, a one-day on-site surveillance visit and payment of the associated assessor fees is required.

### VIII. Reassessment and Renewal of Accreditation

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

Each accredited 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 four year period.

If deficiencies are noted during the renewal assessment, the 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 four years.

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



## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011

Page 12 of 19

- 1) If there are no deficiencies, the 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 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 XII. Adverse Accreditation Decisions, XIII. Suspension of Accreditation, and XIV. 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.

### IX. Extraordinary Assessments

Although rare, A2LA may require proficiency testing providers to undergo an extraordinary assessment as a result of complaints or significant changes to the proficiency testing providers management system. Pursuant to the severity of the complaint, this ‘for cause’ assessment may be performed with little or no advance warning.

### X. Adding to the Scope of Accreditation

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

The assessor can recommend a scope addition without an assessment. If this recommendation requires extensive review of supporting documentation requiring more than one hour’s time, A2LA may invoice the proficiency testing provider for this review time at the prevailing assessor rate. If the additional proficiency testing schemes are supported by a new technology not previously evaluated, another assessment is definitely required. Similarly, if a proficiency testing provider relocates, a follow-up assessment is normally warranted.

### XI. Advertising Policy for Accredited PT Providers

For rules on the use of the “A2LA Accredited” symbol, please see the document titled *P101 - Reference to A2LA Accredited Status – A2LA Advertising Policy*.



## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 13 of 19

### XII. Accreditation Status and Adverse Accreditation Decisions

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

**Voluntary Withdrawal** – An applicant proficiency testing provider not yet accredited, or a renewal proficiency testing provider, can decide to terminate further accreditation action and voluntarily withdraw from the accreditation program. The proficiency testing provider contact must inform A2LA in writing of this request. A2LA does not publicize the fact that a new proficiency testing provider had applied and then withdrawn.

**Delinquent** – A proficiency testing provider (newly enrolled or renewal) is classified as delinquent when it has not completed the necessary assessment actions within an acceptable time frame. A proficiency testing provider's delinquent status is not publicized. The proficiency testing provider must undergo a full reassessment, paying only the assessor fees and expenses, before any further accreditation actions can be taken. A new proficiency testing provider's anniversary date is based on the date of this full reassessment (see Section IV above). A renewal proficiency testing provider's anniversary date remains unchanged. Renewal proficiency testing providers also have the option of reapplying as a new proficiency testing provider, undergoing a full assessment, and being assigned a new anniversary date based on that the date of that full assessment.

**Inactive** – A proficiency testing provider is designated as inactive when it has specifically requested in writing that its accreditation be allowed to temporarily expire due to unforeseen circumstances that prevent it from adhering to the A2LA Conditions for Accreditation. To regain accredited status, the Inactive proficiency testing provider must notify A2LA in writing of this desire, agree to undergo a full reassessment, paying all renewal fees and reassessment costs. A proficiency testing 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 proficiency testing provider's site).

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

### XIII. Suspension of Accreditation

Suspension of all or part of a proficiency testing provider's accreditation may be a decision made by either the President or Accreditation Council panel. 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



## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 14 of 19

- 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 on the A2LA website
- That the suspension is for a temporary period to be determined by the time needed to take corrective action;
- That, within thirty (30) days of receipt of the notice, the proficiency testing provider may submit in person, or in writing, information in opposition to the suspension, including any additional information that raises a genuine dispute over material facts;
- that a further review will be conducted to consider such information and a further written notification will be sent to the proficiency testing provider by certified mail, return receipt requested, indicating whether the suspension has been terminated, modified, left in force or converted to a withdrawal of accreditation

#### XIV. Withdrawal of Accreditation

A2LA shall withdraw accreditation for any of the following causes:

- under the relevant provisions for suspension of accreditation;
- if surveillance indicates that deficiencies are of a serious nature as judged by the Accreditation Council panel;
- when complaints are received relating to one or more of the proficiency testing provider's proficiency testing programs and investigation reveals serious deficiencies in the management system and/or competence in operating the proficiency testing program;
- if the system rules are changed and the proficiency testing provider either will not or cannot ensure conformance to the new requirements;
- on any other grounds specifically provided for under these program requirements or formally agreed between A2LA and the proficiency testing provider;
- 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).





## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011

Page 15 of 19

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 name from the A2LA online Directory of accredited organizations and publicizing the action on the A2LA website

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

### XV. Appeals Procedure

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

- 1) Accreditation Council (nine member appeals panel);
- 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.

### XVI. Confidentiality Policy





## *The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 16 of 19

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 proficiency testing providers 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.

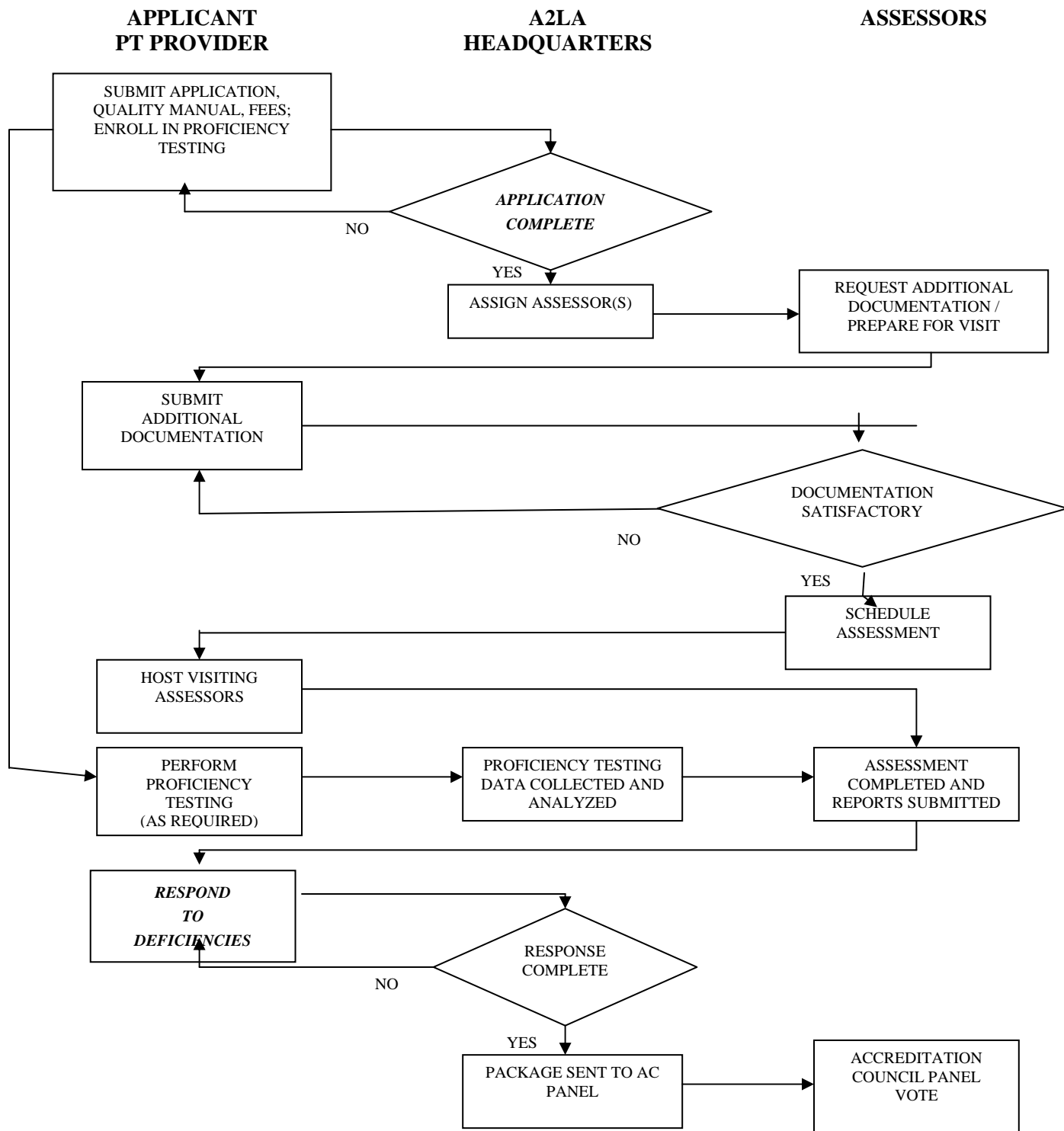
### XVII. Conflict of Interest Policy

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.

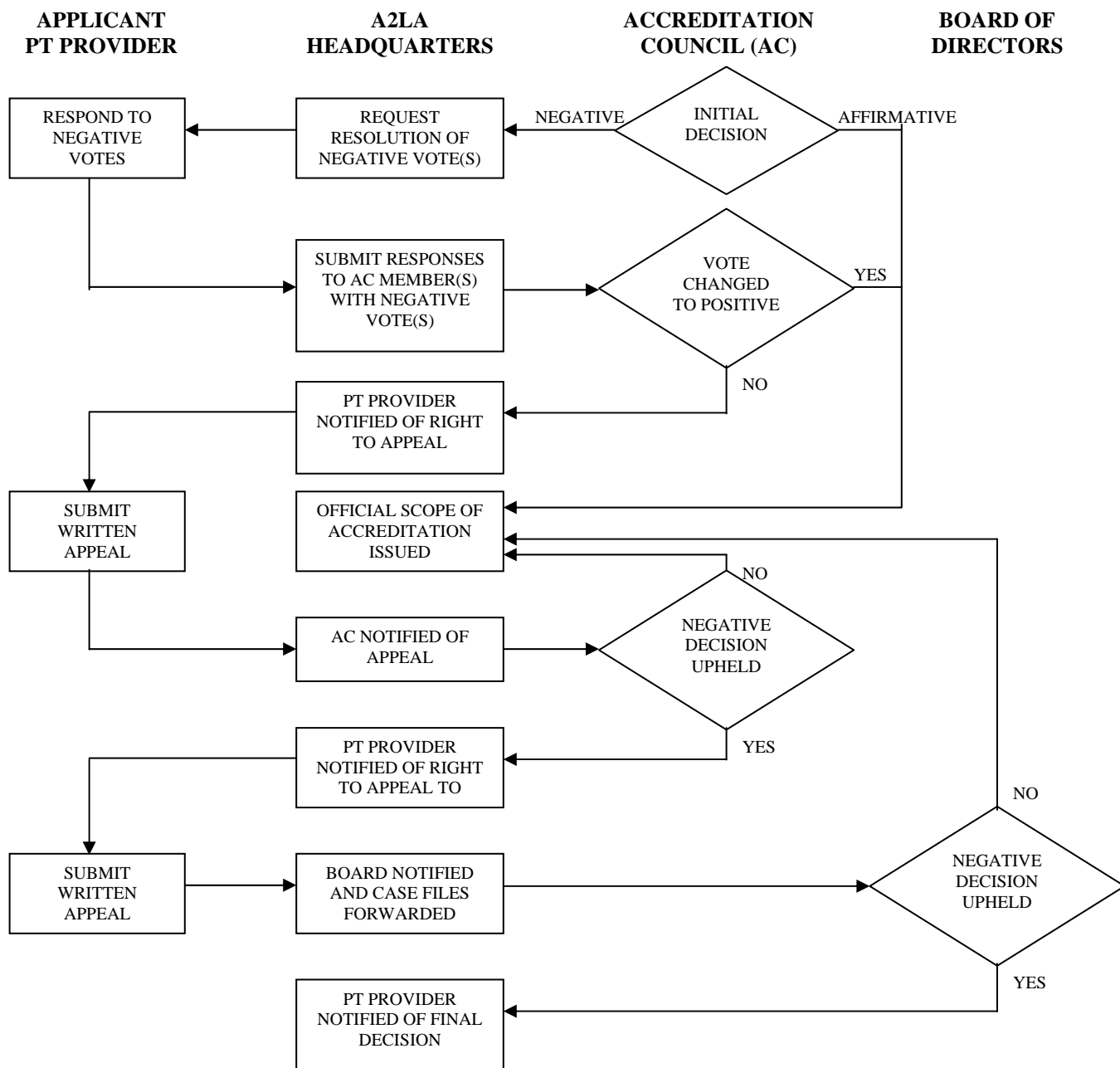


**A2LA ACCREDITATION PROCESS**





### A2LA APPEALS PROCESS DIAGRAM





*The American Association for Laboratory Accreditation*

R302 – General Requirements: Accreditation of  
ISO/IEC 17043 Proficiency Testing Providers

Document Revised:  
June 14, 2011  
Page 19 of 19

**Document Revision History**

Date	Description
March 2006 (Revision of November 1999 version)	Referenced updated <i>Advertising Policy</i> Updated description of application process to include submission of quality manual Updated ISO Standard designations Updated timeframes for responding to deficiencies Clarified Accreditation Council panel selection process and appeals process
May 2006 (Revision of March 2006 version)	Added the requirement for a surveillance assessment at the first year of accreditation Added the requirement for laboratories to submit their root cause analysis along with their objective evidence of deficiency resolution Added a section on assessors writing 'observations' Broke out Corrective Action Process and Extraordinary Assessments into their own sections Requesting an extension to the accreditation anniversary date broken out into its own section and reduced the length of extensions of accreditation to 60 days Changed Title from Procedures Manual.
September 2009 (revision of March 2006 version)	Moved Forward to PART A INTRODUCTION Added Part B Reference to Conditions For Accreditation Clarified Anniversary Date in section IV. Added description of Extensions to Accreditation Anniversary Date Clarified Accreditation Council panel selection process and appeals process Clarified requirement for annual review surveillance assessment Clarified scope additions requirements Removed Ad Policy statements and added reference to P101 A2LA Advertising Policy Clarified language on Adverse Accreditation Decisions Clarified language in appeals procedure Added Appendix I Procedure for Proficiency Testing Oversight
June 1, 2010	Changed to ISO/IEC 17043 from ILAC G-13 Guidelines
June 16, 2010	Added Delayed Assessment and Refund Policies
June 14, 2011	Clarified Section VII on Annual PT Report Review to include detailed information on what summary information must be submitted by the PTP and the possibility of assessor requests for additional information.