




**R101 -  
General  
Requirements:  
Accreditation  
of ISO/IEC 17025 Laboratories**

**August 2010**


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	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 2 of 23

## Table of Contents

<b>PART A.....</b>	<b>3</b>
<b>PART B.....</b>	<b>5</b>
<b>CONDITIONS FOR ACCREDITATION.....</b>	<b>5</b>
<b>PART C.....</b>	<b>5</b>
<b>A2LA ACCREDITATION PROCESS .....</b>	<b>5</b>
I.    APPLICATION .....	5
II.   ASSESSMENT PROCESS .....	8
III.  DEFICIENCIES .....	10
IV.  CORRECTIVE ACTION PROCESS .....	10
V.   ACCREDITATION ANNIVERSARY DATE.....	11
VI.  EXTENSIONS TO THE ACCREDITATION ANNIVERSARY DATE.....	11
VII.  PROFICIENCY TESTING .....	12
VIII. ACCREDITATION DECISIONS.....	12
IX.  ANNUAL REVIEW .....	13
X.   REASSESSMENT AND RENEWAL OF ACCREDITATION.....	13
XI.  EXTRAORDINARY ASSESSMENTS.....	14
XII.  ADDING TO THE SCOPE OF ACCREDITATION.....	14
XIII. LABORATORY REFERENCE TO A2LA ACCREDITED STATUS.....	14
XIV.  ACCREDITATION STATUS AND ADVERSE ACCREDITATION DECISIONS.....	14
XV.  SUSPENSION OF ACCREDITATION .....	15
XVI.  WITHDRAWAL OF ACCREDITATION .....	16
XVII. APPEALS PROCEDURE .....	17
XVIII. CONFIDENTIALITY POLICY .....	17
XIX.  CONFLICT OF INTEREST POLICY .....	18
<b>A2LA ACCREDITATION PROCESS .....</b>	<b>19</b>
<b>A2LA APPEALS PROCESS DIAGRAM.....</b>	<b>20</b>
<b>DOCUMENT REVISION HISTORY .....</b>	<b>21</b>

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 3 of 23

## 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 laboratory accreditation system. Accreditation is defined as a formal recognition of competence that a laboratory can perform specific tests or calibrations. Accreditation is available to any type of testing or calibration laboratory, be it in the private sector (independent or in-house) or in the government sector.

A2LA was formed in 1978, as a practical and efficient organization to develop and manage a system to verify and recognize competent laboratories. Accreditation is available for virtually all types of tests, calibrations, measurements and observations that are reproducible and properly documented.

The accreditation of laboratories is offered in the field of calibration and the following fields of testing:

Acoustics and Vibration	Biological	Chemical	Construction Materials
Electrical	Environmental	Forensics	Geotechnical
Information Technology	Mechanical	Nondestructive	Thermal

Special programs are developed in response to user needs and may cut across more than one field of testing. If only a few tests from a second field are to be included and all testing is managed in one facility under one management system, these tests may be added to the scope of accreditation in the primary field at no charge for a second field. If there are two managers of equivalent status responsible for the testing in each field, accreditation will be necessary in both fields.


Users of accredited laboratories are advised to obtain the Scope(s) of Accreditation from any accredited laboratory or from A2LA. The Scope(s) of Accreditation identifies the specific tests or types of tests or calibration capability for which the laboratory is accredited.

The general requirements (general criteria) for A2LA accreditation are the international standard, ISO/IEC 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories*. A2LA's official applications of the ISO/IEC 17025 requirements are contained on the A2LA website ([www.A2LA.org](http://www.A2LA.org)) under the section titled, "A2LA Additional ISO/IEC 17025 Requirements", and are updated frequently. It is expected that laboratories will implement the requirements of the standard in accordance with the applications listed there. Otherwise, areas of non-conformance will be identified by the assessor during the on-site assessment.

Additional program requirements (specific criteria) for specific fields (e.g. calibration, environmental testing) or specific programs which are necessary to meet particular user needs (e.g. Automotive EMC Laboratory Accreditation Program) complement these general requirements in particular areas.

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


- a) it is competent to perform specific tests, types of tests, calibrations, or types of calibrations listed on its Scope(s) of Accreditation;
- b) its management system addresses and conforms to all elements of ISO/IEC 17025, is documented per ISO/IEC 17025, and is fully operational;
- c) it is operating in accordance with its management system; and

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 4 of 23

- d) it conforms to any additional requirements of A2LA or specific fields or programs necessary to meet particular user needs.

It is A2LA policy not to accredit or renew accreditation of a laboratory that fails to meet the above criteria (see Part B, Conditions for Accreditation and Part C, Accreditation Process, sections on deficiencies, accreditation decisions and suspension or withdrawal of accreditation).

  
President & CEO

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 5 of 23

## PART B

### CONDITIONS FOR ACCREDITATION

In order to attain and maintain accreditation, laboratories 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 laboratory'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 laboratory's Authorized Representative is responsible for ensuring that all of the relevant conditions for accreditation are met. During the on-site assessment, the assessor will examine records and documentation to verify compliance with the Conditions for Accreditation.

## PART C

### A2LA ACCREDITATION PROCESS

#### I. Application

A laboratory applies for accreditation by obtaining the application package (available from A2LA headquarters or the A2LA website [www.A2LA.org](http://www.A2LA.org)) and completing appropriate application sheets and relevant checklists. All applicants must agree to a set of conditions for accreditation (see Part B of this document), pay the appropriate fees set by the A2LA President & CEO, and provide detailed supporting information, including:

- Proposed scope of testing or calibration in terms of field(s) of testing or calibration, testing or calibration technologies, methods and relevant standards, and measurement uncertainty budgets if applicable (always required for calibration and dimensional inspection testing laboratories);
- Quality manual;
- Organization structure; and
- Proficiency testing results.


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.

Accreditation is site specific and is available for testing laboratories (tests) and calibration laboratories (calibrations). A2LA has defined the following laboratory types as follows:

**Main Laboratory:** A laboratory (organization) that maintains a single location only.

**Permanent Laboratory:** A laboratory erected on a fixed location. This is the laboratory location (address) denoted on the scope of accreditation.

**Branch Laboratory** [multi-location system]: A laboratory system that consists of two or more laboratories owned and operated by the same organization, utilizing the same management system and managed by a

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 6 of 23

Corporate Representative [see [P106 - Branch System Policy](#) for more information].

**Satellite Laboratory:** A branch laboratory that is allowed to place their testing or calibration on the main laboratory's scope (with a footnote to reference their location) as long as the satellite laboratory is in close proximity to the main laboratory (usually within 50 miles, unless special exception is granted by A2LA management), operates under the same management system as the main laboratory, can have prompt supervisory oversight from the main laboratory, when necessary, and is willing to share the same A2LA contact that represents the main laboratory.

As accreditation is 'site specific', only the main laboratory address can be listed in the heading information contained on the Scope of Accreditation. The satellite location(s) address(es) will be listed at the end of the scope content of the main laboratory and will contain all of the scope content that coincides with that satellite location. If there is more than one satellite location, this information is repeated for each separate satellite location. As the satellite location(s) operate under the same management system as the main location, A2LA will assign the same assessor(s) and the satellite assessment(s) will occur concurrently with the main location assessment

**Field:** Any location where testing or calibration takes place as defined in Field Testing/Calibration.

**Field Testing/Calibration:** Testing/Calibration performed by staff of a laboratory or organization outside of the premises or grounds on which the permanent laboratory or the organization's permanent base or headquarters is located. Field testing/calibration may include sampling where it forms part of the documented calibration or test procedure. Accreditation for sampling alone is also offered.

Field Tests or Calibrations are normally performed under two categories:


- Field tests or calibrations performed by staff sent out in the field by an accredited, permanent laboratory. This includes in-situ testing<sup>1</sup>.
- Field tests or calibrations performed in the field by organizations that do not have a permanent laboratory.

**Field Laboratory:** A testing or calibration laboratory facility set up in a dedicated location or at a customer's premises, outside of the organization's permanent base or headquarters for the duration of the testing or calibration activities but not for periods expected to exceed three years (e.g. a Construction Materials laboratory set up at an airport construction site, a calibration laboratory under contract set up in support of a customer's manufacturing process). All field laboratories must be identified on the application paperwork, be assessed as part of the permanent laboratory assessment, and be identified on the laboratory's scope of accreditation.

**Mobile Laboratory:** Fully equipped, self-contained, transportable testing or calibration laboratory capable of performing tests or calibrations under controlled environmental conditions. (Note: Mobile laboratories are subject to the same terms of accreditation as a field laboratory. Mobile laboratories left at one location for three years or more will be subject to the same terms of accreditation as a permanent laboratory.)

For tests, the scope of accreditation is normally identified in terms of standard test methods prepared by national, international, and professional standards writing bodies. If a laboratory desires accreditation only for a superseded version of a standard test method, the date of the version used is identified in its scope of

<sup>1</sup> In-situ: Testing or calibration of a device or system performed at the place of its installation.

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 7 of 23

accreditation. When the date is not identified in the scope of accreditation, laboratories are expected to be competent in the use of the current version within one year of the date of publication of the standard test method. If a laboratory requests accreditation to a withdrawn and/or cancelled test method(s), the scope must include the date that these methods were withdrawn or cancelled and include a footnote clarifying that the method itself has been withdrawn and is now considered “historical”.

Exclusions to test methods may only be included on a laboratory’s scope of accreditation when the test method contains multiple methods or method options and the laboratory is only capable of performing a portion of these methods or method options. The scope must indicate these ‘exclusions’. When a test method does not contain multiple methods or method options, the laboratory must be able to demonstrate full competency to meet all of the technical requirements in the method. In the cases where a laboratory is not capable of meeting the technical requirements, the laboratory may write and validate their own internal procedure (see below).

If you seek accreditation for many tests or types of tests in each of two or more fields of testing, your laboratory will be accredited in each of these fields. However, if you seek accreditation for types of tests primarily in one field of testing, with a few tests (*typically no more than 5*) from a second field, your laboratory may include those tests from the second field on the scope of the primary field, although you will be assessed in all areas. In either case all tests and types of tests for which you apply and are found competent to perform will be included in your scope of accreditation.


For calibrations, the scope of accreditation is described typically in terms of the measurement parameter, range of measurement and Calibration and Measurement Capability (CMC). In general, calibration capability may not be derived from scope parameters. In some cases, a laboratory's capability will be described in terms of types of tests, testing technologies, or other descriptive text when it is not appropriate or practical to identify specific tests or calibrations. (see R218 – Applications for Calibration Scopes of Accreditation and R218a – Annex A: General and Specific Editorial Considerations for more information).

Accreditation of non-standard tests and calibrations which the assessor is permitted to examine in detail may be granted and shall be referenced in the scope by unambiguous identification. A2LA reserves the right to refuse to consider accreditation for proprietary tests or calibrations, without prejudice, if there is not sufficient accessibility to the method, records, equipment and/or facilities.

If a laboratory wishes accreditation for the use of its own methods, then it must provide the following information to the assessor(s) before assessment:

- Origin of method;
- Comparison with the standard methods they replace including any departures from the standard (if applicable);
- Reasons for and effects of departures;
- Validation data (per Section 5.4.5 of ISO/IEC 17025).

Parameter Based Scopes: If a laboratory requests a ‘parameter-based’ scope because they typically use methods specified by the customer, as much specificity as possible is captured on the scope. This includes the equipment capabilities and at least one method for each technology or parameter listed on the scope in addition to the details of the types of testing requested by the customer and the products/materials on which the testing is done. In addition, wording similar to the following is also listed on the scope: *“Using customer-specified methods directly related to the types of tests listed above.”* As such, the customer-specific methods that are covered under the accreditation are those directly related to the types of tests that the assessor has verified the laboratory is competent to perform. This same procedure can be used when identifying numerous “internal” or

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 8 of 23

“in-house” methods.

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

The objective of an assessment is to establish whether or not a laboratory complies with the A2LA requirements for accreditation and can competently perform the types of tests or calibrations 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 advice, based on observations or in response to questions, in order to help the laboratory improve its performance.


### **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 assessment at the laboratory’s site. Assessors are selected on the basis of their testing or calibration expertise so as to be better able to provide guidance to the laboratories. They do not represent their employers (if so affiliated) while conducting assessments for A2LA. The laboratory has the right to ask for another assessor if it objects to the original assignment. A2LA assessors are drawn from industry, academia, government agencies, consultants, and from the laboratory community. Assessors work under contract to A2LA. Assessments may last from one to several days depending on the extent of the desired scope and the size of laboratory. More than one assessor may be required.

Laboratories 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 lab and assessor) insurance coverage (e.g., life, health, kidnapping, etc.) for the assessor or assessment team that will be visiting them.

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 laboratory to laboratory.

Before the assessment is conducted, the assessor team requests copies of quality documentation and representative technical SOPs in order to prepare for the assessment. The quality manual and related documentation must be reviewed by the assessor team before the assessment can begin. This review is done ideally before the assessment is scheduled. Upon review of submitted documentation, the assessor(s) will

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010
		Page 9 of 23

provide the document review results to the laboratory in writing, and may ask the laboratory to implement corrective action to fill any documentation gaps required by ISO/IEC 17025 before scheduling the assessment. A pre-assessment visit may be requested by the laboratory or suggested by the assessor 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 determine the tests to possibly witness and checks on the availability of the technical personnel who perform the tests. 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 laboratory 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 laboratory 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 laboratory requests a pre-assessment to better prepare for the final assessment. In this case, the laboratory 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 laboratory must first apply for accreditation, paying the appropriate fees and assessor deposit. A lead assessor is assigned, with the laboratory's concurrence. If, during the discussions between the laboratory and assessor in preparation for the assessment, the laboratory concludes that it is in its interest to have a pre-assessment, it informs the assessor. The assessor notifies A2LA that the laboratory 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. 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 laboratory management;
- Interviews with technical staff;
- Demonstration of selected tests or calibrations including, as applicable, tests or calibrations at representative field locations;
- Examination of equipment and calibration records;
- Audit of the management system to verify that it is fully operational and that it conforms to all sections of ISO/IEC 17025, including documentation;
- Evaluation of your laboratory's compliance with the A2LA requirements documents P101 – Reference to A2LA Accredited Status – A2LA Advertising Policy, P102 – A2LA Policy on Measurement Traceability, 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 briefing including the specific written identification of any deficiencies.

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 10 of 23

During the full assessment, the assessor has the authority to stop the process at any time and consult with A2LA staff and the laboratory's management to determine if the assessment should proceed. In cases where the number of significant nonconformances 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). The full assessment is then rescheduled when the laboratory and assessor feel it is appropriate to proceed.

### III. Deficiencies

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


- a laboratory's inability to perform a test, type of test, or calibration for which it seeks accreditation;
- a laboratory's management system does not conform to a clause or section of ISO/IEC 17025, is not adequately documented, or is not completely implemented in accordance with that documentation; or
- a laboratory does not conform to any additional requirements of A2LA or specific fields of testing or programs necessary to meet particular needs.

At the conclusion of an assessment, the assessor prepares a report of findings, identifying deficiencies which, in the assessor's judgment, the laboratory must resolve in order to be accredited. The assessor holds an exit briefing with top management of the laboratory, going over the findings and presenting the list of deficiencies (deficiency report). The authorized representative of the laboratory (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 laboratory representative concurs that the individual item(s) constitute a deficiency.

Assessors may also write an 'observation' when they question the practice or competence of the laboratory 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 laboratory 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 laboratory who will check to see if that observation was addressed by the laboratory, resulting in an improvement, or possibly may have progressed into a deficiency.

### IV. Corrective Action Process

The laboratory 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 laboratory's root cause analysis and a copy of any objective evidence (e.g., calibration certificates, lab 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 one hour's time, A2LA may invoice the laboratory for this time at the prevailing assessor rate. The assessor will discuss the possibility of this review with the laboratory during the exit briefing and obtain the laboratory's concurrence.

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 11 of 23

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

If a new applicant laboratory (i.e. initial assessment) 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 laboratory that fails to **resolve** all its deficiencies within six months of being assessed shall be subject to being reassessed at its expense. Even if the laboratory responds within six months, A2LA staff has the option to ask for reassessment of a laboratory before an initial accreditation vote is taken based on the number, extent and nature of the deficiencies. Renewal laboratories 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 laboratory (new or renewal) before an affirmative accreditation decision can be rendered.

#### V. Accreditation Anniversary Date

The anniversary date of a laboratory's accreditation is established 105 to 135 days after the last day of the final assessment before an initial accreditation decision, regardless of the length of time required to correct deficiencies. This date normally remains the same throughout the laboratory's enrollment.

#### VI. Extensions to the Accreditation Anniversary Date

If a laboratory 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 laboratory submits objective evidence demonstrating that the nonconformances have been addressed. Likewise, extensions are not granted when delays are due to the laboratory'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 laboratory 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, laboratories will be removed from the A2LA Accredited list on the A2LA website and placed on a separate website list called "Expired Certificates in Good Standing". Laboratories on this list are currently considered **not** accredited but are somewhere in renewal process.

#### VII. Proficiency Testing

Proficiency testing is a process for checking actual laboratory testing performance, usually by means of interlaboratory test data comparisons. For many tests and calibrations, results from proficiency testing are very

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 12 of 23

good indicators of competence. Proficiency testing programs may take many forms and standards for satisfactory performance can vary depending on the field. For details on the requirements for proficiency testing, please refer to the *R103 General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories* and the associated *Annex (R103a)*.

Laboratories are required to participate in proficiency testing programs, where relevant and available, and provide A2LA with the results of their participation in a timely manner. If the results of the proficiency testing activities include outliers, laboratories are required to provide A2LA with their corrective action measures resolving the non-conformance. It is possible that the assessor involved in the previous assessment may be asked to review the corrective action response to determine if the response is satisfactory. As such, A2LA may invoice the laboratory for this time at the prevailing assessor rate.


### VIII. Accreditation Decisions

Before an accreditation decision ballot is sent to Accreditation Council members, staff shall review the deficiency response, including the laboratory’s root cause analysis and objective evidence of completed corrective action, for adequacy and completeness. If staff has any doubt about the adequacy or completeness of any part of the deficiency response, the response is submitted to the assessor(s). Since all deficiencies must be resolved before accreditation can be granted, staff shall ask the laboratory 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 at least three Accreditation Council members for voting. The panel is chosen so that the full range of the laboratory’s testing and/or calibration capabilities is adequately covered by the Accreditation Council review. Especially in the case of those laboratories seeking (re)accreditation for multiple fields, it may be necessary to select more than three AC members in order to accomplish this. The laboratory is consulted about any potential conflicts of interest with the Accreditation Council membership prior to sending their package to the Accreditation Council. Generally, at least two affirmative ballots (with no unresolved negative ballots) of the three ballots distributed must be received before accreditation can be granted. If three or more AC members are required in order to ensure a full review of the laboratory’s testing/calibration activities, (re)accreditation may not be granted until all of these votes have been received and any negative votes resolved.

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 laboratory 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 laboratory is asked to accept a reassessment. If the laboratory refuses the proposed reassessment, a nine-member Accreditation Council appeals panel is balloted (see Sections XIV. Adverse Accreditation Decisions and XVII. Appeals Procedures below).

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 13 of 23

If accreditation is granted, the A2LA staff prepares and forwards a certificate and scope of accreditation to the laboratory for each enrolled field of testing (and special program if appropriate). The laboratory should keep its scope of accreditation available to show clients or potential clients the testing technologies and test methods for which it is accredited. A2LA staff also uses the scopes of accreditation to respond to inquiries and to prepare the A2LA online directory.

#### IX. Annual Review

Accreditation is granted for two years. However, after the initial year of accreditation, each laboratory 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 laboratory's management system and technical capabilities remain in compliance with the accreditation requirements. Failure to complete the surveillance assessment within the designated time frame may result in adverse accreditation action (see Section XV).

For subsequent annual reviews occurring after the renewal of accreditation (see Section X) each laboratory must pay annual fees and submit updating information on its organization, facilities, key personnel and results of any proficiency testing. Objective evidence of completion of the internal audit and management review is also required. If the renewal laboratory does not promptly provide complete annual review documentation, significant changes to the facility or organization have occurred, or proficiency testing results have been consistently poor, a one-day surveillance visit and payment of the associated assessor fees is required. Furthermore, if significant problems were noted during the last on-site assessment that warrant follow-up or if significant issues have arisen since the last on-site assessment that could call into question the laboratory's compliance with the accreditation requirements, an appropriate surveillance visit and payment of the associated assessor fees may be required.

#### X. Reassessment and Renewal of Accreditation


A2LA conducts a full reassessment of all accredited laboratories at least every two years. Reassessments are also conducted when evaluations and submissions from the laboratory or its clients indicate significant technical changes in the capability of the laboratory have occurred.

Each accredited laboratory 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 reassessment at the laboratory's site must be completed before accreditation is renewed for another two years.

If deficiencies are noted during the renewal assessment, the laboratory 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 VIII. 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., the non-compliances do not directly affect the integrity of calibration or test results) 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.

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010
		Page 14 of 23

- 3) If there are major deficiencies (i.e., the non-compliances directly affect the integrity of calibration or test results), the staff advises the laboratory 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 XIV. Adverse Accreditation Decisions, XV. Suspension of Accreditation, and XVI. 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.

In cases where significant deficiencies are identified in a renewal assessment, the laboratory may be required to undergo a surveillance assessment in conjunction with the next annual review to verify continued implementation of corrective actions (see Section IX above).

#### XI. Extraordinary Assessments

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

#### XII. Adding to the Scope of Accreditation

A laboratory 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 verify the competence of the laboratory to perform the additional tests or calibrations, another assessment at the laboratory's site is normally required. If the assessor can recommend a scope addition without an assessment, but this recommendation requires extensive review of supporting documentation requiring more than two hour's time, A2LA may invoice the laboratory for this review time at the prevailing assessor rate. If the additional tests or calibrations involve a new technology, another assessment is definitely required. Similarly, if a laboratory relocates, a follow-up assessment is normally warranted.


#### XIII. Laboratory Reference to A2LA Accredited Status

The requirements pertaining to the use of the "A2LA Accredited" symbol and to any other reference to A2LA accreditation are outlined in the document titled *P101 - Reference to A2LA Accredited Status – A2LA Advertising Policy*. The policy is available from A2LA Headquarters or on the A2LA website, [www.A2LA.org](http://www.A2LA.org). Failure to comply with these requirements may result in suspension or revocation of a laboratory's accreditation.

#### XIV. Accreditation Status and Adverse Accreditation Decisions

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

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

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010
		Page 15 of 23

Inactive – A laboratory is designated as inactive when it has specifically requested in writing that its accreditation be allowed to temporarily expire due to unforeseen circumstances that prevent it from adhering to the A2LA Conditions for Accreditation. To regain accredited status, the Inactive lab must notify A2LA in writing of this desire, agree to undergo a full reassessment, paying all renewal fees and reassessment costs. A laboratory that has relocated is also designated as inactive until its ability to perform the tests and/or calibrations on its scope at the new location has been confirmed (e.g. by a visit to the laboratory’s site).

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

#### XV. Suspension of Accreditation


Suspension of all or part of a laboratory's accreditation may be a decision made by either the President or Accreditation Council panel. The accreditation applicable to a specific laboratory may be suspended upon adequate evidence of:

- non-compliance with the requirements of a nature not requiring immediate withdrawal (e.g. identification of significant deficiencies during an assessment);
- improper use of the “A2LA Accredited” symbol (e.g., misleading prints or advertisements are not solved by suitable retractions and appropriate remedial measures by the laboratory); and
- other departures from the requirements of the A2LA accreditation program (e.g., failure to pay the required fees, submit annual review information within 60 calendar days after it is due, or complete a surveillance assessment within the designated time frame).

The accreditation of a laboratory shall immediately be suspended by the President if the laboratory or any individual or entity responsibly connected with the laboratory 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 laboratory may appeal the adverse accreditation decision but the suspension will not be lifted until all court related actions are made final.

When an accredited laboratory is suspended, A2LA shall confirm an official suspension in a certified letter, return receipt requested, (or equivalent means) to the laboratory'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 laboratory 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;

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 16 of 23

- that a further review will be conducted to consider such information and a further written notification will be sent to the laboratory by certified mail, return receipt requested, indicating whether the suspension has been terminated, modified, left in force or converted to a withdrawal of accreditation.

In some fields of testing or special programs, failure to meet with the criteria for acceptable proficiency test results can result in automatic suspension of accreditation for the test(s) under question (not the entire scope). These are identified in the specific requirements for those fields or in the *R103 - General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories* and the associated *Annex (R103a)*.

#### XVI. Withdrawal of Accreditation


A2LA shall withdraw accreditation for any of the following causes:

- under the relevant provisions for suspension of accreditation;
- if surveillance or reassessment indicates that deficiencies are of a serious nature as judged by the Accreditation Council panel;
- when complaints are received relating to one or more of the laboratory's test reports/calibration certificates and investigation reveals serious deficiencies in the management system and/or competence in conducting the specific tests/calibrations;
- if the system rules are changed and the laboratory 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 laboratory;
- when such action is necessary to protect the reputation of A2LA; and
- at the formal request of the laboratory.

When it is proposed to withdraw accreditation, A2LA shall issue a written notice by certified mail:

- that withdrawal is being considered;
- of the reasons for the proposed withdrawal sufficient to put the laboratory on notice of the cause;
- that within thirty (30) days of receipt of the notice, the laboratory 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 laboratory's name from the A2LA on-line directory and publicizing the action on the A2LA website.

A laboratory may appeal to A2LA against a decision to withdraw or not to award accreditation.

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 17 of 23

## XVII. 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 President or initial Accreditation Council panel (see Section VIII). The appeals policy, including an applicant's right to a hearing, is 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 nine-member appeals panel of the Accreditation Council.


Any decision from an appeals vote which would deny or withdraw a laboratory's complete accreditation, must be agreed upon by a two-thirds of the (sum of the affirmative and negative – abstentions are not included) votes received from the nine-member appeals panel of the Accreditation Council. Votes must be received from all members with specific technical background necessary to review the laboratory's scope of accreditation. 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 and appropriate background documentation will be promptly transmitted to the members of the Board of Directors appeals group, the composition of which to be determined by the Board Chairman taking into account any conflict-of-interest considerations and the nature of the appeal. The decision of the Board of Directors shall be final and binding, except that any court having jurisdiction may set aside such decision when bias, fraud or misconduct of the Board has been determined, and is communicated in writing to the appellant.

## XVIII. Confidentiality Policy

A2LA is responsible for seeing that confidentiality is maintained by its employees, assessors and Accreditation Council members concerning all confidential information with which they become acquainted as a result of their contacts with laboratories. Such information is examined by a small group of A2LA staff, assessors, and Accreditation Council and external bodies as needed for recognition of the program. All are made aware of its confidentiality. The Association agrees to hold all disclosed confidential or proprietary information or trade secrets in trust and confidence. The information shall be used only for accreditation purposes, and shall not be used for any other purpose, nor shall it be disclosed to any third party without written consent of the applicant laboratory unless required by law or judicial or administrative process or regulation (such as through a properly issued and served subpoena).

All information provided by applicants in connection with a request for an application package, an application for accreditation, an assessment or proficiency test is confidential. Documents necessary to convey information about accredited laboratories and their scopes of accreditation are not confidential. In response to a question about whether or not a particular laboratory has applied for accreditation, A2LA simply responds by saying that the laboratory is not accredited. Staff neither confirm nor deny whether a laboratory has ever applied for accreditation. If the laboratory itself is saying that it has applied for accreditation, it is the laboratory's

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010 Page 18 of 23

responsibility to release the information regarding its applicant status. If the caller says that the laboratory claims it applied, staff shall take the name, address and phone number of the laboratory to check to see if the laboratory is misleading the client but staff still will not verify the laboratory's application. Should an applicant laboratory require that staff verify for a potential client that it has applied to A2LA, staff shall indicate that it has applied only if the applicant makes such a request to A2LA in writing or designates on the application for accreditation that A2LA is authorized to release information regarding the applicant's status.

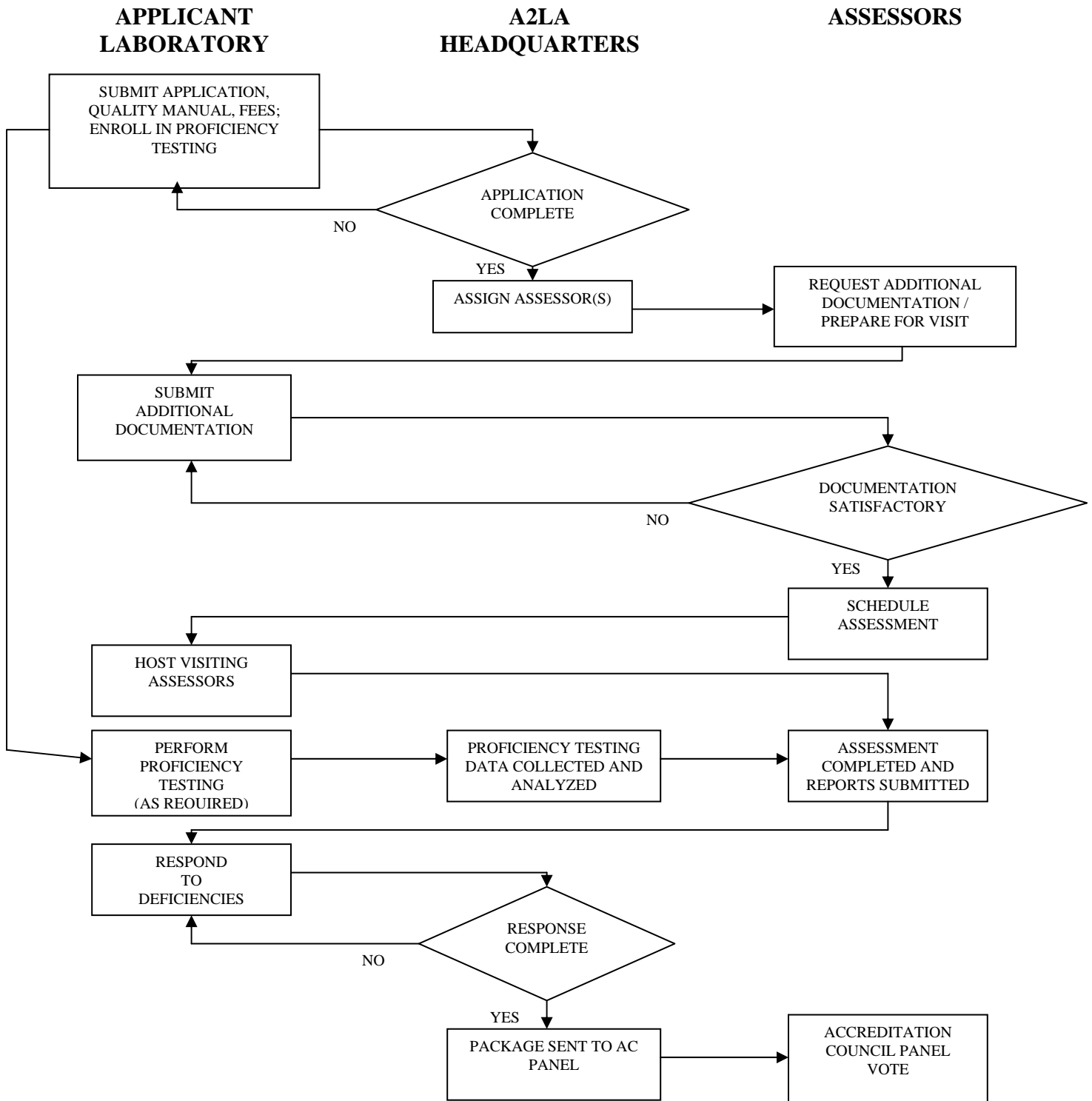
If an inquiry is made about a laboratory whose accreditation has lapsed but is in the renewal process, staff can indicate that the laboratory is not now accredited but is in the process of renewal, if that is the case. If the renewal laboratory's accreditation has lapsed with no indication (return of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

XIX. 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. Consistent with the principles set forth in ISO/IEC 17011, *Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*, A2LA believes that it is vital that its accreditation services be impartial and objective, uninfluenced by the private interests of individuals acting for A2LA. Accordingly, any person directly involved in actions relating to the A2LA accreditation process shall avoid direct participation in A2LA actions that may involve an actual or apparent conflict of interest. The Audit & Ethics Committee 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.

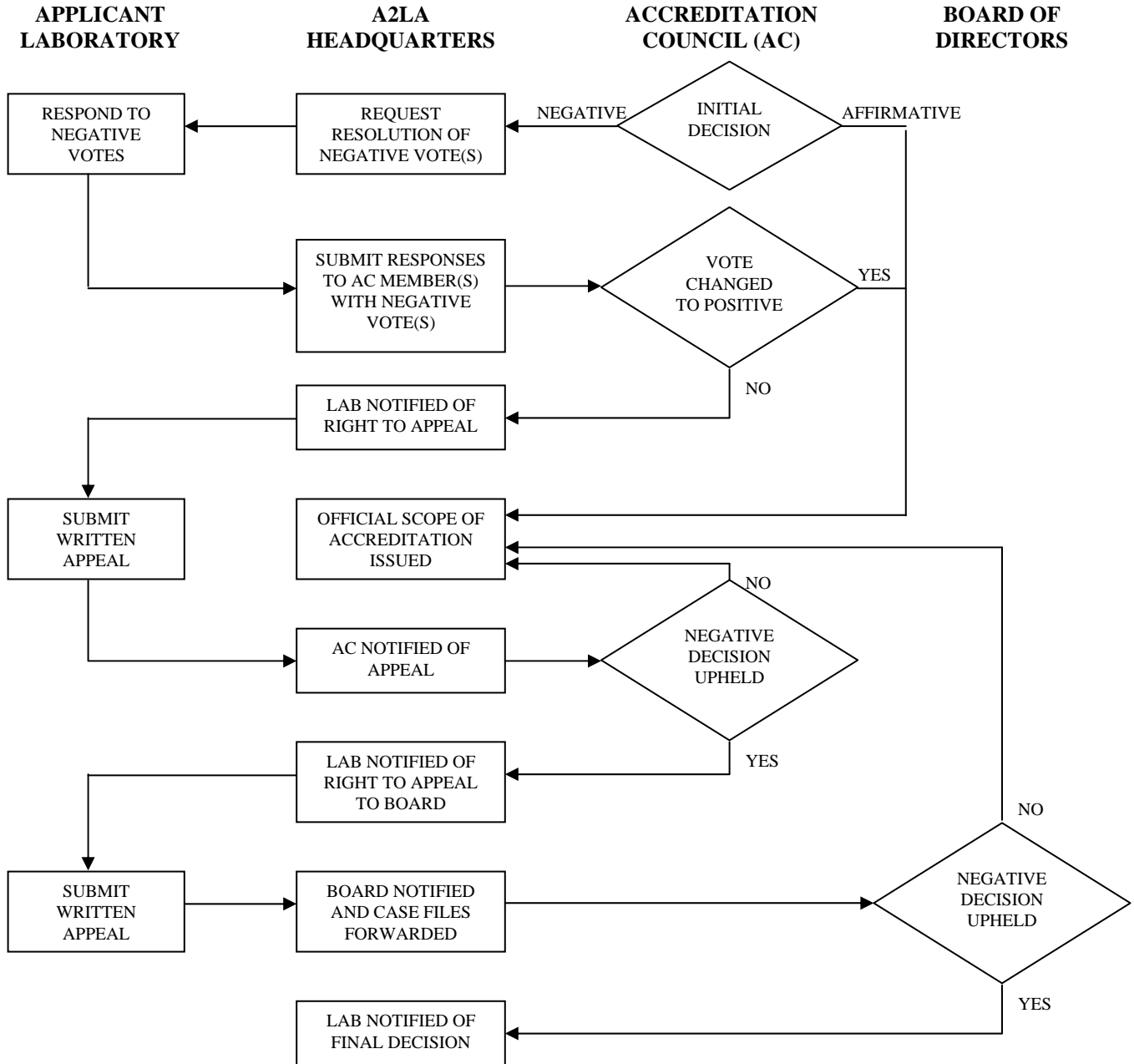



### A2LA ACCREDITATION PROCESS





### A2LA APPEALS PROCESS DIAGRAM




	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010
		Page 21 of 23

## Document Revision History

Date	Description
January 2003 (revision of August 2000 version)	<p>Explanatory notes removed from Part A (moved to FAQ section of A2LA website)</p> <p>Replaced text of <i>Conditions for Accreditation</i> with reference</p> <p>Referenced updated <i>Advertising Policy</i></p> <p>Updated description of application process to include submission of quality manual</p> <p>Clarified corrective action response deadlines for renewal laboratories</p> <p>Clarified Accreditation Council panel selection process and appeals process</p> <p>Removed cross reference from ISO/IEC 17025:1999 to ISO/IEC Guide 25:1990</p>
August 2005	<p>Updated reference to ISO/IEC 17025-2005 which replaced ISO/IEC 17025-1999</p> <p>Updated reference to ISO/IEC 17011 which replaced ISO/IEC Guide 58</p> <p>Added the requirement for laboratories to submit their root cause analysis along with their objective evidence of deficiency resolution</p> <p>Added a section on assessors writing ‘observations’</p> <p>Updated terminology of ‘A2LA Accredited’ symbol consistent with the <i>A2LA Advertising Policy</i></p> <p>Broke out Corrective Action Process and Extraordinary Assessments into their own sections</p> <p>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</p>
February 2007	<p>Addition of the Information Technology field of testing</p> <p>Statement that labs are expected to implement the A2LA applications of ISO/IEC 17025 requirements contained on the website was added</p> <p>Automatic extension to the accreditation anniversary date and new ‘Laboratories in the Renewal Process’ website listing added</p>



<p>October 2008</p>	<p>Updated the Conditions for Accreditation</p> <p>Addition of definitions of types of laboratories</p> <p>Addition of an evaluation of the laboratory’s compliance to A2LA P101, P102, P103, and R103 requirements during the on-site assessment</p> <p>Addition of allowance of a minimal number of second field of testing capabilities on main scope of accreditation.</p> <p>Further clarification on handling extensions of accreditation</p> <p>Further clarification on the appeals process and the applicable responsibilities</p>
<p>May 2009</p>	<p>Added a note in Part B</p> <p>In Part I the hyperlink was added for Branch Laboratories and the delayed assessment policy and refund policy was added from F101</p> <p>In Part II information on pre-assessments from F101 was added</p> <p>In Part VII the hyperlink for Proficiency Testing document was added</p> <p>In XII the paragraph was corrected from one hours time to two hours time</p> <p>In XVIII the confidentiality policy paragraph was revised</p>
<p>September 2009</p>	<p>Notification of document updates via email removed from Part B.</p> <p>Discussion of accreditation for sampling added to Part C, Section 1.</p> <p>Requirements for providing insurance coverage added to part C, Section IIa.</p> <p>Additional circumstances warranting an on-site surveillance visit added to Section IX - Annual Reviews.</p> <p>Removal of “Delinquent” status from Section XIV.</p> <p>Confidentiality policy expanded to address legal requests for confidential information.</p> <p>Discussion of parameter-based Scopes.</p>
<p>July 2010</p>	<p>Forensics field added.</p> <p>Clarity on withdrawn and/or cancelled test methods and allowance of modifications/exceptions to test methods added.</p> <p>Immediate suspension for evidence of indictment added.</p>

	<i>The American Association for Laboratory Accreditation</i>	
	R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories	Document Revised: August 27, 2010
		Page 23 of 23

August 2010	Editorial change for clarity on withdrawn and/or cancelled test methods appearing on a Scope.
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