

**R305 - General Requirements:**

**Accreditation of ISO 15189**

**Medical Testing Laboratories**

**May 2007**

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**R305 - GENERAL REQUIREMENTS: ACCREDITATION OF  
ISO 15189 MEDICAL TESTING LABORATORIES  
May 2007**

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## PART A

### INTRODUCTION

The AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA) is a non-profit, non-governmental, public service, membership organization dedicated to operating a nationwide, broad spectrum laboratory accreditation system. Accreditation is defined as a formal recognition of competence that a laboratory can perform specific tests or. Accreditation is available for many types of testing laboratories, both in the private sector (independent or in-house) and 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.

Under the Medical Testing Laboratory program A2LA provides a meaningful accreditation process by using the international standard ISO 15189:2007 *Medical laboratories-Particular requirements for quality and competence* and by using medical laboratory experts to perform the assessments.

The international standard provides a framework for a laboratory to plan and operate a medical testing laboratory with an effective Quality Management System (QMS) that has strong elements of Quality Assurance, Quality Control and Quality Improvement. When medical testing laboratories effectively implement this QMS they also have continuous assurance that they are meeting their customers' needs and expectations for consistent, accurate and timely test results.

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

- a) it is competent to perform specific medical laboratory tests on samples from humans in the specialties and subspecialties, listed on its Scope of Accreditation;
- b) its management system addresses and conforms to all elements of ISO 15189, and is documented per ISO 15189 and is fully operational; and
- c) it is operating the Preanalytic, Analytic and Postanalytic systems in accordance with its management system.



, President

## **PART B**

### **CONDITIONS FOR ACCREDITATION**

In order to attain and maintain accreditation, laboratories must comply with the *RI02 - Conditions for Accreditation* 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 determine that the Authorized Representative and a deputy are knowledgeable about the accreditation requirements and require that the Authorized Representative and a deputy sign a statement that the Conditions for Accreditation will be upheld.

## **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 Board of Directors, and provide detailed supporting information, including:

- Proposed scope of testing in terms of specialties/subspecialties, test methodologies and test systems;
- Quality manual;
- Organization structure;
- Key staff qualifications
- Proficiency testing results
- Facilities description
- List of major equipment
- List of tests
- Hours of operation

In order to use both the assessor's and the laboratory staff time effectively, A2LA will also ask you to have the following information accessible and retrievable at the time of the on site visit:

- Standard operating procedures with all test procedures (package inserts and supplemental information ,as necessary)
- Records of tests referred to other laboratories
- Records that support personnel qualifications, training, experience, competency assessment, responsibilities and authority
- Quality Control records: with remedial actions, calibration and calibration verification, statistical limits, instrument maintenance and function checks
- Proficiency testing (PT) reports including the test runs and results, printouts, report forms, reviews and attestation signatures
- Quality system assessment plans and records: policies and procedures directed towards monitoring, assessing and correcting identified problems,
- Documentation of ongoing assessment activities including corrective action effectiveness reviews, policy and procedure revisions made to prevent recurrence of a problem, discussion of assessment reviews with staff.
- Patient test records including requisitions, instrument printouts and test reports.

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 of non-standard tests and 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, without prejudice, if there is not sufficient accessibility to the method, records, equipment and/or facilities.

If a laboratory wishes to pursue 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 5.5 of ISO 15189).

## 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 for which accreditation is sought. However, when accreditation is required to demonstrate compliance with additional criteria which may be imposed by other authorities, 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.

### Pre-Site Visit

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 expertise in order to perform a thorough, effective and efficient evaluation. 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.

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 assessment 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 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 15189 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.

#### On-Site Assessment

The full assessment generally involves:

- An entry briefing with laboratory management;
- Interviews with technical staff; (including health care providers outside the laboratory in hospital based laboratories)
- Demonstration of selected tests including, as applicable, tests; including tests performed at other sites within the scope of the accreditation.
- Examination of equipment and calibration records; test records, supplies and reagents
- Audit of the management system to verify that it is fully operational and that it conforms to all sections of ISO 15189, including documentation;
- Review of training records and competency assessments
- A written report of assessor findings; and
- An exit briefing including the specific written identification of any deficiencies.

The laboratory is expected to meet every individual requirement; however, the assessor seeks to determine the laboratory's overall compliance. The assessor's use an outcome-oriented approach that emphasizes the provisions that have a direct impact on the laboratory's overall test performance. Is the laboratory producing quality results (accurately, reliably, and timely)?

The assessor is looking for effective processes (preanalytic, analytic and post analytic) that function well together. The assessor will also look at the systems that the laboratory uses to detect, prevent and control non-conformances and assure quality testing and services. The assessor focuses on the effectiveness of the management system in all aspects of the laboratory.

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, for which it seeks accreditation;
- a laboratory's management system does not conform to a clause or section of ISO 15189, 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 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., policies, lab procedures, instrument/test data, equipment maintenance documents, 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.

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 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

Any extensions to an accreditation beyond the anniversary date **must be requested and justified in writing** by the laboratory. **A2LA does not automatically grant extensions of accreditation.** Extensions beyond 60 days are not normally granted. 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. When a laboratory is granted an extension, a revised Scope of Accreditation is issued which reflects the extended anniversary date. Upon completion of the renewal process, both documents are reissued, reflecting the renewed anniversary date.

#### VII. Proficiency Testing

Proficiency testing is a process for checking actual laboratory testing performance, usually by means of interlaboratory test data comparisons. The laboratory must enroll in a proficiency program or programs, that are approved by The Department of Health and Human Services (HHS) for details on the requirements for proficiency testing, please refer to the *R306 – General Requirements: Proficiency Testing for ISO 15189 Medical Testing Laboratories*.

#### 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 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 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).

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 specialties, subspecialties, analytes and services 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 XIV).

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.

## 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 at the Standard level (i.e., the non-compliances do not pose reasonable risk of harm to a patient) 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 (Conditional Level the non-compliances), 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, another assessment at the laboratory's site is normally required. When the assessor can recommend a scope addition without an assessment, this recommendation will likely require an extensive review of the supporting

documentation and will likely require more than one hour's time; therefore, A2LA may invoice the laboratory for this review time at the prevailing assessor rate. If the additional tests involve a new specialty/subspecialty, another assessment is likely 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.

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

**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 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).

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;
- 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.

Failure to meet with the criteria for acceptable proficiency test results can result in automatic suspension of accreditation for the specialty under question (not the entire scope). These are identified in the specific requirements in 42CFR493 or in *R306 – General Requirements: Proficiency Testing for ISO 15189 Medical Testing Laboratories*.

## 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 and investigation reveals serious deficiencies in the management system and/or competence in conducting the specific tests
- 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, return receipt requested:

- 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.

## 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 vote of those voting 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 is communicated in writing to the appellant.

#### XVIII. Confidentiality Policy

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. Such information is examined by a small group of A2LA staff, assessors, and Accreditation Council and external bodies as needed for recognition of the program. All are made aware of its confidentiality. Such information shall not be released unless the applicant provides A2LA permission in writing to do so.

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

In response to a question about whether or not a particular laboratory has applied for accreditation, A2LA simply responds by saying that the laboratory is not accredited. Staff neither confirms nor denies 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 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.

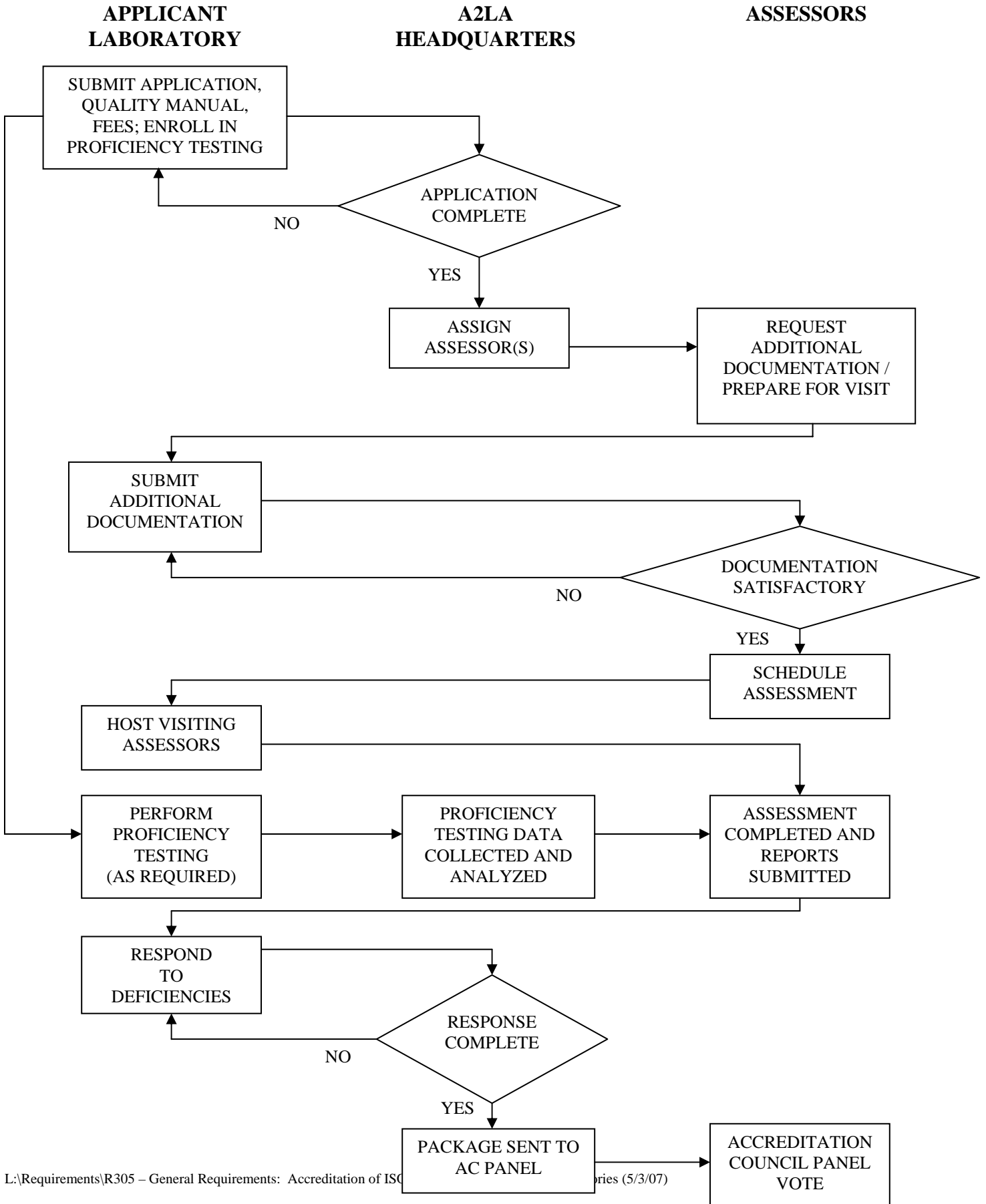
If an inquiry is made about a laboratory whose accreditation has lapsed but is in the renewal process, staff can indicate that the laboratory is not now accredited but is in the process of renewal, if that is the case. If the renewal laboratory's accreditation has lapsed with no indication (return of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

#### XIX. Conflict of Interest Policy

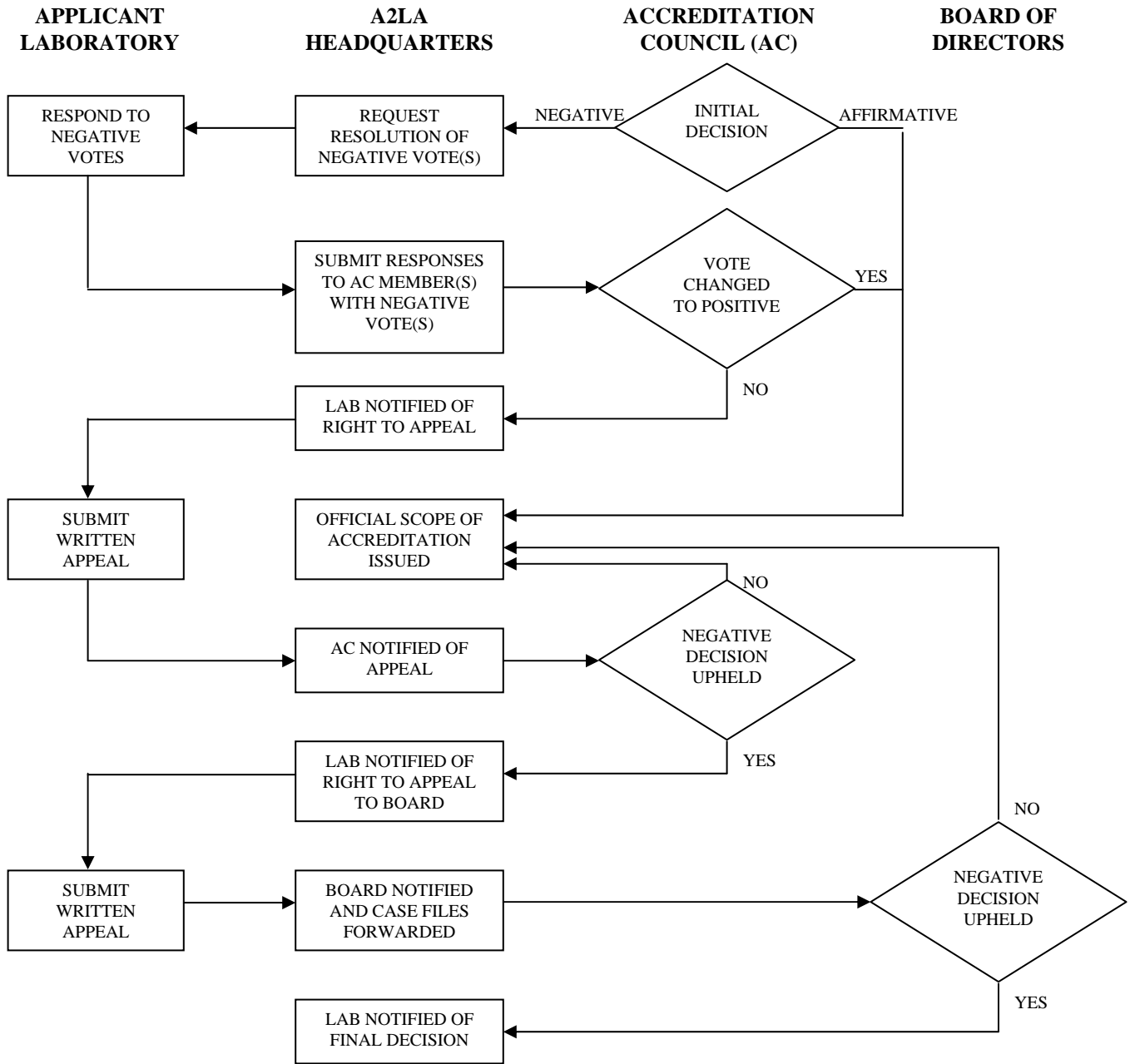
Since its inception, A2LA has had a policy that actual or apparent conflicts of interest must be avoided as mandated by normal business ethics. Consistent with the principles set forth in ISO/IEC 17011, *Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment 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 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



## Document Revision History

Date	Description
May 2007	Issued