



*The American Association for Laboratory Accreditation*

**R651- GENERAL REQUIREMENTS:  
ACCREDITATION OF MEDICAL TESTING  
LABORATORIES MEETING ISO 15189  
REQUIREMENTS**

Document Issued:  
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**R651: General Requirements:  
Accreditation of  
Medical Testing Laboratories  
Meeting the  
ISO 15189 Requirements  
  
(March 2010)**

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MEDICAL TESTING LABORATORIES  
MEETING THE ISO 15189 REQUIREMENTS  
March 2010**

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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 types of tests. 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 that uses the Quality Management strengths of the ISO 15189 Standard. A2LA provides accreditation to any medical laboratory performing moderate or high complexity testing (as defined in the Clinical Laboratory Improvement Amendment (CLIA), 42 CFR 493). Laboratories that provide *only* waived or Provider Performed Microscopy (PPM) are not eligible for accreditation through A2LA. If the laboratory does perform moderate or high complexity testing along with waived testing and/or PPM, A2LA will accredit for all of this testing and microscopy.

The ISO 15189 standard forms a complete 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 have continuous assurance that they are meeting their customers' needs and expectations for consistent, accurate and timely test results.

The A2LA program offers accreditation in the following Specialties and Subspecialties:

Histocompatibility	Hematology
Microbiology	-General Hematology
- Bacteriology	- Coagulation
- Mycobacteriology	- Flowcytometry
- Mycology	- Immunoematology
- Parasitology	ABO Group & Rh type
- Virology	- Antibody Detection (transfusion)
Diagnostic Immunology –	- Antibody Detection (non-transfusion)
- Syphilis Serology	- Antibody Identification
- General Immunology	- Compatibility Testing
Chemistry	Pathology
- Routine Chemistry	- Histopathology
- Urinalysis	- Oral Pathology
- Endocrinology	- Cytopathology
- Toxicology	- Molecular Pathology
Clinical Cytogenetics	Radiobioassay



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All medical testing laboratories are not alike and do not offer the same combinations of non-waived testing in the same facility configuration and staff organization. A2LA can customize the assessment process to match a laboratory's combination of specialties and subspecialties, whether a single application for multiple sites within a hospital campus and under a common director or multiple applications for laboratory sites within the same physical location A2LA can design a special program in response to the user needs.

The General Requirements (general criteria) for A2LA accreditation are the international standard, ISO 15189 (2007), *Medical laboratories – Particular requirements for quality and competence*. A2LA accreditation requirements apply to all moderate and high complexity testing that a laboratory seeks to include on their scope of accreditation.


A2LA will follow 42CFR493.17 test categorization requirements and use the U.S. Federal Register to identify complexity for all examinations. If a laboratory test system, assay or examination does not appear in the Federal Register notices, A2LA will consider it to be a high complexity examination until the laboratory can show documentation of a Public Health Service decision on other than high complexity.

A2LA also requires proficiency testing participation in accordance with CLIA regulation 42CFR493; Subparts H and I. Please refer to *R653: General Requirements: Proficiency Testing for Medical Laboratories Meeting the ISO 15189 Requirements* for further information.

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 in accordance with those requirements and is fully operational;
- c) it is operating the Preanalytic, Analytic and Postanalytic systems in accordance with its management system; and
- d) it conforms to any additional requirements of A2LA or specific fields or programs necessary to meet particular user needs.

A2LA will not accredit or renew accreditation of a laboratory that fails to meet *R652: Conditions for Accreditation for Medical Laboratories Meeting ISO 15189 Requirements* and the requirements of this document.

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## PART B

### A2LA ACCREDITATION PROCESS

#### I. Application

A medical 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 medical laboratory applicants must agree to a set of conditions for accreditation (see *R652: Conditions for Accreditation for Medical Laboratories Meeting ISO 15189 Requirements*), pay the appropriate fees, 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 (including copies of verifiable credentialing documents)
- Proficiency testing results
- Facilities description
- List of major equipment
- List of tests
- Hours of operation

A2LA has defined the following medical laboratory types as follows:

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

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

**Branch Laboratory** [multi-location system]: A medical laboratory system that consists of two or more permanent laboratories owned and operated by the same organization, utilizing the same management system and managed by a Corporate Representative. If you are applying as a multi-laboratory system, a separate application must be completed for each medical laboratory. The conditions for applying as a branch of another laboratory are as follows:

- All application, renewal of accreditation and annual review processes must be coordinated through one central person, the Corporate Representative;
- All fee payments and invoices must be coordinated through the Corporate Representative;
- All laboratories within a single branch system are given related certificate numbers (e.g., 301.01, 301.02, 301.03, etc.);



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- All laboratories within a single branch system must be visited, assessed and accredited regardless if they are performing the exact same testing as the main laboratory.

This central coordination and arrangement within our database allows for greater efficiency in handling various processes, therefore a discount on fees is offered to all branch laboratories. Branch laboratories can choose to have the same anniversary date or to have different anniversary dates based on the date of their assessment. Please understand, however, that for large branch systems, this central coordination with the same anniversary date can become cumbersome and all branch laboratories within the system are often unable to complete the various processes (renewals and annual reviews) by the same anniversary date or deadline.

Please consider these issues carefully as you decide whether or not to apply as a branch laboratory system. If you have any questions concerning this arrangement, please contact A2LA.

**Satellite Laboratory:** A branch laboratory that is allowed to place their medical testing 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), operates under the same management system as the main laboratory, can have prompt supervisory oversight from the main laboratory, when necessary, and has appropriate oversight from the same Laboratory director 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.

**Point of Care Testing:** A2LA will accredit for mid or high complexity Point of Care Testing (POCT) as part of the assessment of the applicant medical laboratory, if request by the laboratory. The POCT requirements are based on ISO 22870, – *Point of Care Testing (POCT) – Requirements for quality and competence* and ISO 15189: 2007 standard. Point of care testing is defined as tests done at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside of the physical facilities of the medical laboratory. The applicant laboratory's POCT services are assessed, if the medical laboratory requests accreditation for POCT.

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



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**Specimen Collection Sites:** Any specimen collection sites that support the activities of the applicant laboratory are assessed as part of the accreditation process for the laboratory. A sampling plan is used to ensure that all collection sites are eventually assessed over a span of accreditation periods. A specimen collection assessor checklist (available on the A2LA website and as part of the application process) is used to assess specimen collection sites.


In order to use both the assessor's and the laboratory staff's time effectively, A2LA requires that the following information be 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)
- Management system assessment plans and records: policies and procedures directed towards monitoring, assessing and correcting identified problems.\*
- Records of tests referred to other laboratories\*
- 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.
- Records that support personnel qualifications, training, experience, competency assessment, responsibilities and authority\*
- Patient test records including requisitions, instrument printouts and test reports.\*
- Quality Control records: with remedial actions, calibration and calibration verification, statistical limits, instrument maintenance and function checks\*
- Access to any specimen collection sites that A2LA may wish to assess as part of the accreditation process using the A2LA Collection Site Assessor Checklist
- Records that support validation of test methods\*
- Accommodation records: facility (environmental monitoring, water system, etc.) and Laboratory Information Management System (LIMS)\*
- Proficiency testing (PT) reports including the test runs and results, printouts, report forms, reviews, attestation signatures, and performance summary data.

\* Please see Part C for additional requirements for record and material retention.

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

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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 medical 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 5.5 of ISO 15189).

Where an A2LA accreditation requirement states “laboratory management” this means the same thing as “the Laboratory Director.” The Laboratory Director is the person who signs the Conditions for Accreditation attestation in the application for A2LA Accreditation for Medical Laboratories. The laboratory’s Director is responsible for all accreditation requirements.


The Laboratory Director’s responsibilities include the design, implementation, maintenance and improvement of the Quality System (ISO 15189, 4.1.5) as well as ensuring that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-examination, examination and post examination processes.

## II. Assessment Process

The objective of an assessment is to establish whether or not a medical 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.

### Pre-Assessment Visit

Once the application information is completed and the appropriate fees are paid, A2LA headquarters staff identifies and tentatively assigns one or more medical assessors to conduct an assessment at the laboratory’s site. Assessors are selected on the basis of their testing 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 medical laboratory has the right to ask for another assessor if it objects to the original assignment. A2LA medical 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.

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Medical assessors are given a *Medical Assessor Instruction Manual* 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 provide the document review results to the medical laboratory in writing, and may ask the medical 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 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 on site assessment of a medical testing laboratory consist of:

- An entry briefing with laboratory management;
- Interviews with technical staff; (including health care providers outside the laboratory in hospital based laboratories)
- Observation of staff performing assigned tasks in all three areas of the workflow process (pre-analytical, analytical and post-analytical);
- Observation of selected tests including, as applicable, tests performed at other sites within the scope of accreditation;
- Examination of equipment and calibration records; test records, supplies and reagents, and PT records;
- 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 medical laboratory is expected to meet every individual requirement; however the assessor seeks to determine the laboratory's overall compliance. The assessors use an outcome-oriented approach that emphasizes the provisions that have a direct impact on the laboratory's overall test performance and ask the question, "Is the laboratory producing quality results (accurately, reliably and timely)?"

The assessor is looking for effective processes (pre-analytic, analytic and post analytic) that function well together. The assessor will also look at the processes that the laboratory uses to detect, prevent



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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 medical 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 non-conformances 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.

During the assessment, if any deficiency is identified in an A2LA accredited laboratory that poses an immediate jeopardy (IJ) to the laboratory's patients or a hazard to the general public, or is identified as an illegal activity, A2LA may impose suspension or withdrawal of all or a portion of the medical laboratory's accreditation.

### III. Deficiencies

During the assessment, assessors may observe condition level or non-condition level deficiencies.

Condition Level Deficiencies: These are deficiencies against any of the requirements identified as "conditions" in subparts G through Q of the 42 CFR 493. These may also be serious, system wide non compliances with the requirements of ISO 15189 and may include non compliances related to IJ or illegal activities.

Non Condition Level Deficiencies: These are any other deficiencies that do not qualify as IJ, illegal activities or condition level deficiencies.

A deficiency to accreditation requirements may include:

- a medical laboratory's inability to perform a test, or type of test, for which it seeks accreditation;
- a medical 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 medical laboratory does not conform to any additional requirements of A2LA or the medical field of testing requirements 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 medical laboratory must resolve in order to be accredited. The deficiencies are categorized as condition level or non condition level deficiencies.

The assessor holds an exit briefing with top management of the organization and the medical laboratory, going over the findings and presenting the list of deficiencies (deficiency report). The Authorized Representative of the medical laboratory (or designee) is asked to sign the deficiency



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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 medical 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 medical 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 medical laboratory who will check to see if that observation was addressed by the medical laboratory, resulting in an improvement, or possibly may have progressed into a deficiency.

#### IV. Corrective Action Process

Every medical laboratory is requested to respond, in writing, within 30 days after the date of the exit briefing detailing either its corrective action or why it does not believe that a deficiency exists.

Each medical laboratory is required to provide corrective action for every deficiency (condition and non-condition level) cited, along with root cause analysis and objective evidence (e.g., policies, lab procedures, instrument/test data, equipment maintenance documents, and/or training records) to effectively close the deficiency. A2LA does not close any deficiencies based only on a plan of correction.

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

Immediately following the assessment or reassessment of a medical laboratory, A2LA staff will review the resulting deficiencies; if there is one or more condition level deficiencies that cannot be adequately responded to via a documentary exchange, this would automatically result in a follow up assessment. Upon receipt of the assessor's deficiency report, A2LA may also decide that due to the nature, incidence, severity or duration of the deficiencies cited and A2LA's history with the particular laboratory, it may be necessary to re-classify one or more of the deficiencies as conditional level deficiencies. A2LA would then take appropriate action (pursuit of corrective action response from the laboratory, follow up assessment at the laboratory's expense, suspension of all or part of the scope of accreditation) as is warranted by the finding.

If the new applicant medical laboratory fails to respond in writing with, at minimum, a plan of corrective action, 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 another full assessment at its expense, should it wish to pursue accreditation after that time. A new applicant laboratory that fails to resolve all its deficiencies with objective evidence of implementation within six months of being assessed shall be subject to a follow up assessment at its expense. Even if the laboratory responds within six months, A2LA staff still has the option to ask for a follow up assessment of a laboratory before an initial accreditation vote is taken based on the number, extent and nature of the deficiencies.



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Renewal laboratories must respond in writing within 30 days of the exit briefing, and resolve all deficiencies with objective evidence of implementation within 60 days of the exit briefing. Medical laboratories not completing the re-assessment process within the cited time frames, or a reassessment resulting in one or more condition level deficiencies that cannot be adequately responded to via a documentary exchange may result in an adverse accreditation action (e.g. a follow up assessment at the laboratory's expense, or suspension or withdrawal of accreditation).

The Accreditation Council (AC) panel also has the option to require a follow-up assessment of any medical laboratory (new or renewal) at the laboratory's expense, before an affirmative accreditation decision can be rendered.

It is possible that the assessor's review of the corrective action response may be needed to determine if the response is satisfactory. If this review is expected to take more than two hours, A2LA may invoice the medical 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.

#### V. Accreditation Anniversary Date


The anniversary date of a medical 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 medical laboratory's accreditation.

#### 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 non-conformances are identified during an assessment, extensions of accreditation are not considered until the laboratory submits objective evidence demonstrating that the non-conformances 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 reflect 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.

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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 the renewal process.

### 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 approved by The Centers for Medicare and Medicaid Services (CMS), for each of the specialties and subspecialties for which it seeks accreditation. For details on the requirements for proficiency testing, please refer to the *R653- General Requirements: Proficiency Testing for Medical Testing Laboratories Meeting the ISO 15189 Requirements*.

Medical laboratories are responsible for ensuring that their PT results and the summary data are provided to A2LA.

While every unsuccessful PT event is not reason to cite immediate jeopardy, each occurrence of intentional PT referral is cited as immediate jeopardy and there exists no acceptable path to corrective action. Laboratories that are cited for PT referral are subject to suspension of their A2LA Accreditation for those referred PT analytes for no less than one year.

### VIII. Accreditation Decisions

Before an accreditation decision ballot is sent to Accreditation Council (AC) members, staff shall review the deficiency response, including the medical 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 medical 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 AC members for voting. The panel is chosen so that the full range of the medical laboratory’s testing capabilities is adequately covered by the AC review. The laboratory is consulted about any potential conflicts of interest with the AC membership prior to sending their package to the AC. 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 medical 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



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decision are required to make a judgment whether or not cited 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 medical 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, the laboratory is asked to accept a reassessment. If the laboratory refuses the proposed reassessment, a nine-member AC appeals panel is balloted (see Sections XIV. Accreditation Status and 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 the medical field of testing. 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 scope 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 medical laboratory must pay annual fees and assessor fees and undergo a two-day surveillance visit by an assessor(s). 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 medical laboratory must pay annual fees and submit updating information on its laboratory, 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, or significant changes to the facility or organization have occurred, or proficiency testing results have been consistently poor, a 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 medical laboratories 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 medical 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

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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 required to write to A2LA within 30 days after the assessment stating the corrective action taken. All deficiencies must be resolved, with objective evidence provided, 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 through an internal review but without an AC panel vote.
- 2) If there are only a few deficiencies of a minor nature at the non condition 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 AC panel vote.
- 3) If there are major deficiencies (Condition Level non-compliances), the staff advises the laboratory of the required time-frame (normally 60 days) in which to resolve all deficiencies or be subject to further actions leading to suspension or withdrawal of accreditation (see Sections XIV. Accreditation Status and Adverse Accreditation Decisions, XV. Suspension of Accreditation, and XVI. Withdrawal of Accreditation). The number of deficiencies does not necessarily relate to whether or not a condition is found out of compliance, but rather its impact or potential impact on the quality of laboratory services and the results reported. A2LA considers a condition out of compliance for one or more deficiencies if, in its judgment, the deficiency(s) constitutes a significant or a serious problem that adversely affects patient test results/patient care, or has the potential for adversely affecting patient test results/patient care. Several related minor deficiencies or repeat deficiencies from previous assessments may also be considered a condition level deficiency. In these cases, a ballot of the AC panel is conducted using the same voting procedure as for initial accreditation decisions.

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

#### XI. For Cause Assessments

A2LA will require medical laboratories to undergo unannounced "for cause" assessments as a result of serious complaints or significant changes to the laboratory's management system. If a serious complaint is received or A2LA is notified that a significant question exists regarding the competency of a laboratory or the laboratory's continued compliance with the applicable accreditation requirements, an unannounced assessment is conducted. The laboratory is responsible for any assessment fees or expenses resulting from the "for cause" assessment.



## XII. Adding to the Scope of Accreditation

A medical 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, 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 hours, 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 medical 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 medical laboratories that cannot uphold the requirements for initial or continued accreditation:

Voluntary Withdrawal – A new applicant medical 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 nor will it advertise that a renewal laboratory has elected to voluntarily discontinue its accreditation.

Inactive – A medical 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.

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## XV. Suspension of Accreditation


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

- if surveillance or reassessment indicates that deficiencies are at the immediate jeopardy or condition level as judged by the President or AC panel;
- when complaints are received relating to one or more of the medical laboratory's test reports and investigation reveals condition level deficiencies in the management system and/or competence in conducting the specific tests;
- non-compliance with the requirements of a nature not requiring immediate withdrawal;
- 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 medical 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 medical laboratory is suspended, A2LA shall confirm an official suspension in a certified letter (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 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 or subspecialty under question (not the entire scope). These specialties/subspecialties are identified in the specific requirements in 42CFR493, Subpart H or in R653 – General Requirements: *Proficiency Testing for Medical Testing Laboratories Meeting the ISO 15189 Requirements*.

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## XVI. Withdrawal of Accreditation

A2LA shall withdraw accreditation for any of the following causes:

- under the relevant provisions for suspension of accreditation;
- if the accreditation requirements are changed and the medical laboratory either will not or cannot ensure conformance to the new requirements;
- on any other grounds specifically provided for under the Medical 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 stating:

- that an enforced withdrawal is being considered;
- of the reasons for the proposed withdrawal sufficient to put the medical laboratory on notice of the cause;
- that within thirty (30) days of receipt of the notice, the medical 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
- the effect of proposed withdrawal, including removing the medical 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) AC (nine-member appeals panel);
- 2) Board of Directors.

The A2LA staff shall advise the medical laboratory in writing of its right to challenge an adverse accreditation decision by the President or initial AC panel (see Section VIII). The appeals policy, including a medical laboratory's right to a hearing, are contained in the A2LA Bylaws.

An appeal shall be lodged by the medical laboratory 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 AC.

Any decision from an appeals vote which would deny or withdraw a medical laboratory's complete accreditation, must be agreed upon by a two-thirds vote of those voting from the nine-member appeals panel of the AC. Votes must be received from all members with specific technical

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background necessary to review the medical laboratory's scope of accreditation. The decision of the AC 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 is communicated in writing to the appellant and 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.

#### XVIII. Reinstatement Policy

Once a medical laboratory subjected to full withdrawal of accreditation fulfills all of the requirements for accreditation, including financial obligations, the Authorized Representative of that laboratory may request reinstatement of accredited status in writing. A2LA staff will review the corrective action responses provided by the laboratory and request that a reinstatement ballot be provided by the AC. As with all other AC ballots, the laboratory will be afforded the opportunity to reject any AC member who might present a potential conflict of interest. A three-member panel of subject matter experts from within the AC will review the revocation documentation and the laboratory's response to those citations. The panel will then vote for or against reinstatement.

#### XIX. Confidentiality Policy

All information provided by medical laboratories 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 AC and external bodies as needed for recognition of the program. All are made aware of its confidentiality. A2LA 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. It shall not be disclosed to any third party without written consent of the applicant laboratory, or as required by law or judicial or administrative process or regulation (such as through a properly issued and served subpoena).

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 medical laboratory has applied for accreditation, A2LA simply responds by saying that the medical laboratory is not accredited. Staff neither confirms nor denies whether a laboratory has ever applied for accreditation. If the medical laboratory itself is saying that it has applied for accreditation, it is the medical laboratory's



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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 medical 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 medical 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 medical laboratory is not accredited.

**XXI. 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 any 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.



**PART C**

**P604 – POLICY FOR MEDICAL RECORD AND MATERIAL RETENTION**

A2LA has established the minimum requirements for the retention of medical laboratory records and materials. These requirements are equal to or more stringent than the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).

Some states and or countries promulgate regulations requiring retention of records and/or materials for longer periods than are specified in this policy. It is recommended that each laboratory carefully review state or national laws when developing their individual record retention policies.

A2LA accredited medical laboratories must also have a written plan describing the process for sample retention should the laboratory go out of business. This plan will require that retained items be maintained secure until the posted retention period is reached.

Please note: It may be appropriate for laboratories to retain records and/or materials for longer periods of time when required for patient or operational purposes.

**PERIOD OF RETENTION**

<b><i>General Laboratory</i></b>	
Accession log	2 years or between full assessments whichever is longer
Instrument records including maintenance records, printouts, calibration and verification records	2 years or between full assessments whichever is longer
Quality control records including performance data, instrument printouts, and corrective action.	2 years or between full assessments whichever is longer
Proficiency Testing results including corrective actions	2 years or between full assessments whichever is longer
Management Review documentation	2 years or between full assessments whichever is longer
Reports of internal audits	2 years or between full assessments whichever is longer
Corrective Action Reports	2 years or between full assessments whichever is longer
Preventative Action Reports	2 years or between full



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	assessments whichever is longer
Quality Assurance Records and QA meeting minutes(Except as notated elsewhere in this guideline)	2 years or between full assessments whichever is longer
Records of employee signatures, initials, and identification codes	10 years
<b><i>Surgical Pathology (including bone marrows)</i></b>	
Wet tissue	2 weeks after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
<b><i>Cytology(GYN)</i></b>	
Slides (negative-unsatisfactory)	5 years
Slides (suspicious-positive)	5 years
Quality Assurance studies	5 years
Reports	10 years
<b><i>Cytology(non-GYN)</i></b>	
Fine needle aspiration slides	10 years
Body Fluid slides	10 years
Reports	10 years
Quality Assurance studies	10 years
Note: Cytology slides may be loaned to proficiency testing (PT) programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgment of the receipt of the slides by the PT program and maintains the acknowledgment to document the loan of these slides. Documentation of slides loaned or referred for purposes other than PT testing must be maintained and all slides must be retrievable upon request.	
<b><i>Non-Forensic Autopsy</i></b>	
Wet tissue	3 months after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
<b><i>Forensic Autopsy</i></b>	
Wet stock tissue	1 year
Paraffin blocks	Indefinitely
Reports	Indefinitely
Slides	Indefinitely
Gross photographs/negatives	Indefinitely



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Accession log	Indefinitely
Body fluids and tissues for toxicology	1 year
Representative tissue suitable for DNA Analysis	Indefinitely
<b><i>Clinical Pathology</i></b>	
Patient test records	2 years
Urine	24 hours
Serum/CSF/Body fluids (except urine)	48 hours
Peripheral blood smears/body fluid smears	7 days
Permanently stained slides – microbiology (i.e. gram stains).	7 days
Reports	10 years
<b><i>Cytogenetics</i></b>	
Permanently stained slides	3 years
Fluorochrome stained slides	3 years or longer at the discretion of the laboratory director
Wet specimen/tissue	Until adequate metaphase cells are obtained
Fixed cell pellet	2 weeks after final report
Final reports	20 years
Diagnostic images (digitized, prints or negatives)	20 years
<b><i>Flow Cytometry</i></b>	
Gated dot plots and histograms	10 years
<b><i>Blood Bank</i></b>	
Donor and recipient records	10 years
Patient records	10 years
Quality control records	5 years
Records of indefinitely deferred donors, permanently deferred donors, or donors placed under surveillance for the recipient's protection (e.g., those donors that are hepatitis B core positive once, donors implicated in a hepatitis positive recipient)	Indefinitely
Specimens from and potential and confirmed recipients	7 days post-transfusion
blood donors units	7 days post-transfusion



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**DOCUMENT REVISION HISTORY**

November 2009	Document issued; superseding the previous R305 document.
March 2010	Report retention times established for cytology and clinical pathology.