I.   INTRODUCTION

This document details the various accreditation processes at A2LA for all programs and fields except the A2LA Clinical Laboratory Accreditation Programs (i.e. ISO 15189 and CLIA).

Accreditation at A2LA is typically broken down into a yearly activity for Conformity Assessment Bodies (CABs) beginning with an initial assessment (or in some cases a pre-assessment). Once a CAB gains accreditation an anniversary (expiration) date of twenty-four (24) months is established.

At the mid-point of the initial accreditation cycle the CAB is required to undergo a one-day surveillance visit by an A2LA assessor. This surveillance assessment is performed to confirm that the CABs quality management system and technical capabilities remain in compliance with the accreditation requirements.

Six months prior to the accreditation expiration date the renewal of accreditation process is initiated. The renewal process is generally like the initial assessment process except that the one-day surveillance visit is not mandated at the mid-point of the next accreditation cycle unless actions or findings identified during the renewal assessment warrant one.

At the mid-point of subsequent assessment cycles the CAB is required to submit updated information on its organization, facilities, key personnel, etc. and your Accreditation Service Officer (AcO) will perform a desk audit of this information.

II. PREPARING FOR INITIAL ACCREDITATION

1. Obtain an official copy of the conformity assessment standard(s) to which you are seeking accreditation to (e.g. ISO/IEC 17025, ISO/IEC 17020, etc.).

2. Review the applicable requirements documents for the areas in which you are seeking accreditation from the applicable pages on the A2LA website at www.A2LA.org (under 'Accreditation Programs', select the applicable conformity assessment standard and then review the 'Additional Information' links). This will help to ensure a basic understanding of the accreditation process and the general criteria for accreditation. ***Please note that your organization will be evaluated against these requirements during your assessment***.

   Please Note: *If you need assistance in locating information on the A2LA website, please contact A2LA at info@A2LA.org or by calling 301 644 3248. An individual staff listing can also be located at http://www.a2la.org/genweb/stafflist2.cfm.*

3. To determine the applicable, estimated cost of accreditation (i.e. accreditation fees and on-site assessment costs), complete and submit an A2LA *F119 – Estimate Request Form*.

4. To obtain the applicable conformity assessment checklist, please complete and submit the corresponding 'Ownership Confirmation' form:

a. *F102 – Ownership Confirmation – ISO/IEC 17025*;
b. *F306 – Ownership Confirmation – ISO Guide 34*;
c. *F310 – Ownership Confirmation – ISO/IEC 17065*;
d. *F324 – Ownership Confirmation – ISO/IEC 17043*;
e. *F326 – Ownership Confirmation – ISO/IEC 17020*.

Please Note: *these checklists contain the full text of the applicable ISO standards and are not available on the A2LA public website. To obtain a checklist(s) from A2LA you may either complete and submit the aforementioned Ownership Confirmation form OR await receipt of log-in information for the A2LA **Conformity Assessment Body (CAB)** Portal, which will be provided to you upon A2LA's receipt of your application for accreditation. CAB log-in information is usually provided within 24 hours of application submittal.*

5. Complete the appropriate selection list or provide a draft scope of accreditation. Selection lists are located on our website at www.A2LA.org on each of the individual 'Download Application Documents' links (identified with an orange block on the upper right hand side of each individual 'Accreditation Program' page).

6. Create and implement Quality Management System policies and procedures that meet the applicable conformity assessment standard and A2LA requirements in the program for which you are seeking accreditation (e.g. ISO/IEC 17025, ISO/IEC 17020, etc.). Ensure that these documents fulfill the applicable requirements and that the personnel concerned are aware and accept the content.

7. Perform an internal audit to verify compliance with all A2LA requirements, applicable conformity assessment standard requirements, the Conformity Assessment Body's (CAB) own management system requirements and all applicable technical requirements and document the results of this audit. Discuss all relevant accreditation criteria thoroughly with those directly involved and identify the organization's weak points. It is important to seek feedback from all applicable individuals to get the most comprehensive evaluation of the organization.

8. Perform a management review and document the results.

9. Where applicable, ensure that all supporting documents are translated into English prior to applying for accreditation.

10. Identify an individual to assume responsibility for upholding the accreditation requirements and for making available to relevant staff and applicable resources.

11. Identify the person in charge of the management system (e.g., the Quality Manager). **Please Note**: An effective management system functions only with support and commitment from top management. In a large organization, the coordination of these

activities may be too considerable a task for the top manager and it is imperative that the individual(s) decide how to handle this important subsidiary function. Top management may need assistance from an individual(s) who would be responsible for the development and maintenance of the documented quality management system.

12. Obtain and complete the applicable A2LA application for accreditation. See #5 above for directions on how to locate these forms.

13. Return your completed application (including the applicable *conformity assessment checklist*), supporting documents (as indicated in the application), and appropriate payment to A2LA to initiate an assessment of your organization. Upon receipt of your application you will be provided with log-in information and guidance to access your A2LA CAB Portal. All applicable documentation (including full text checklist(s)) specific to your area(s) of accreditation, DRAFT scope(s) of accreditation, open invoices and the ability to make credit card or eCheck payments, as well as, a means to track open assessments and annual reviews are accessible from your CAB Portal. If your supporting documentation is substantial or you have email size limitations, you may delay providing your supporting documentation until your application has been received and processed by staff. At that point, you may simply upload the supporting documentation through your CAB portal.

14. A2LA will notify you through email of the name(s) of the selected assessor(s) and provide a brief biosketch. If you have justifiable objections to the proposed assessor(s), changes in the assignment(s) may be made.

15. **OPTIONAL PRE-ASSESSMENT**
A2LA assessors are permitted to conduct pre-assessments. A pre-assessment provides an opportunity for the organization to evaluate its preparedness for the initial assessment. In most cases the same (lead) assessor assigned to perform the initial assessment will perform the pre-assessment. The assessor will usually spend a day at the facility evaluating the management system. This is an opportunity to identify areas of possible non-compliance before a full assessment is performed.

During this pre-assessment visit, the management system will be assessed for implementation and compliance with the applicable conformity assessment standard as well as the applicable A2LA requirements. If requested, a sampling of technical activities may also be evaluated. Note that the A2LA assessor is not permitted to provide consulting services during this visit.

For more information on pre-assessments please review the applicable requirements documents for the areas in which you are seeking accreditation.

16. The assessor schedules and performs the pre-assessment (if requested or recommended) or the initial assessment.

III. PREPARING FOR SURVEILLANCE ASSESSMENT

1. Once alerted that the surveillance assessment has been initiated, log on to your designated CAB Portal, confirm your CAB information, agree to abide by the A2LA *R102 – Conditions for Accreditation*, upload the required *Surveillance Assessment Supporting Information*, and submit/make payment. This process is initiated 6 months prior to the midpoint of your initial accreditation cycle.

2. Upload an up-to-date organization chart identifying by name, the key personnel involved for each function. Highlight any changes since the initial A2LA assessment. If your organization is part of a larger organization, provide the organizational chart of that organization and identify reporting relationships within that organization.

3. Upload the applicable, requested documentation via your CAB Portal.

    Your organization will be required to undergo a surveillance assessment 1 year following your initial accreditation and then a renewal assessment at the 2-year mark. An assessor (usually the same person who performed your initial assessment, where practicable) will be proposed to your organization upon receipt of the aforementioned documents and payment in the correct amount. Reaffirmation of accreditation to the established anniversary date will be based upon having the surveillance assessment, A2LA receipt of the appropriate final payment of fees, and resolution of all (where applicable) deficiencies cited during the surveillance.

IV. PREPARING FOR ANNUAL REVIEW OF ACCREDITATION

1. Annual reviews occur during the midpoint of each 2-year renewal accreditation cycle. Once alerted that the annual review of accreditation has been initiated, log on to your designated CAB Portal, confirm your CAB information, agree to abide by the A2LA *R102 – Conditions for Accreditation*, upload the required *Annual Review Supporting Information*, and submit/make payment. This process is initiated 3 months prior to the midpoint of your renewal accreditation cycle.

2. Upload an up-to-date organization chart identifying by name, the key personnel involved for each function. Highlight any changes since the last A2LA assessment. If your organization is part of a larger organization, provide the organizational chart of that organization and identify reporting relationships within that organization.

3. Upload the results of your most recent internal audit and most recent management review.

    Please Note: The annual review must be confirmed and documentation must be submitted by the designated due date (assigned by A2LA and communicated to each CAB through a letter) or remedial action could occur. Please do not hold up confirmation and/or submission of the required annual review documentation for if certain functions (e.g. the internal audit, management review, etc.) are scheduled for a timeframe after the required annual review submission date.

4. Once all the appropriate information is provided and payment is received, A2LA will reaffirm the accreditation of your organization for an additional year - to the established expiration date - at which time you will be prompted to submit the appropriate renewal information and fees.

V. PREPARING FOR RENEWAL OF ACCREDITATION

1. Once alerted that the renewal of accreditation has been initiated, log on to your designated CAB Portal, confirm your CAB information, agree to abide by the A2LA *R102 – Conditions for Accreditation*, upload the required *Renewal of Accreditation Supporting Information*, and submit/make payment. The renewal process is initiated 6 months prior to the expiration date of your current accreditation.

2. Review the applicable requirements documents that are readily located on your CAB Portal, and also from the A2LA website at www.A2LA.org. This will help to ensure that your organization remains in compliance with any revisions that have been made to the requirement documents. ***Please note that your organization will be evaluated against these requirements during your assessment***.

3. Upload an up-to-date organization chart identifying by name, the key personnel involved for each function. Highlight any changes since the last A2LA assessment. If your organization is part of a larger organization, provide the organizational chart of that organization and identify reporting relationships within that organization.

4. Complete and upload the applicable conformity assessment checklist(s) (located on your CAB Portal).

5. Upload an uncontrolled copy of your current quality manual and any supporting documentation referenced in the completed assessor checklist(s) (e.g. operating procedures, work instructions, etc.).

6. Upon receipt of all the necessary documentation and payment of fees, A2LA will notify you through email of the name(s) of the selected assessor(s) and provide a brief biosketch. If you have justifiable objections to the proposed assessor(s), changes in the assignment(s) may be made.

DOCUMENT REVISION HISTORY

DATE	DESCRIPTION
07/31/2013	Document refresh; Document revised to cover accreditation of all conformity assessm programs.
5/12/2015	Document refresh; Added Introduction and information on pre-assessment option; Clarified that document covers all programs/fields with the except of the A2LA Clinical Accreditation Programs