

1105 – Typical Steps in Preparing for the Accreditation Process

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### 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) and Proficiency Testing Providers Accreditation Program (ISO/IEC 17043).

Accreditation at A2LA requires a yearly activity beginning with an initial assessment (or in some cases a pre-assessment). When an organization becomes accredited they are referred to as a Conformity Assessment Body (CAB). After the initial assessment a two (2) year anniversary (expiration) date is established.

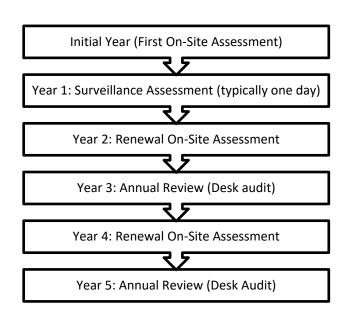
At the mid-point of the initial accreditation cycle the CAB is required to undergo a surveillance visit (typically one day) by an A2LA assessor. This surveillance assessment is performed to confirm that the CABs management system has been fully implemented, corrective actions taken since the last on-site assessment were effective and technical capabilities remain in compliance with the accreditation requirements.

The renewal process is similar to the initial assessment process except that the surveillance visit is typically not mandated at the mid-point of the next accreditation cycle, unless significant problems were noted during the last on-site assessment that warrant follow-up or if significant issues have arisen since the last on-site assessment that could call into question the organization's compliance with the accreditation requirements.

At the mid-point of subsequent assessment cycles the CAB is required to submit updated information on its organization, facilities, key personnel, etc. along with specific quality system records that will be requested through the A2LA customer portal. The organization's assigned Accreditation Officer (AcO) will perform a desk audit of this information.

#### Overall Accreditation Cycle:

Note: Accreditation is a yearly activity. Renewal assessments are to be completed every 2 years with Annual reviews to be completed on the off years.



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#### II. PREPARING FOR INITIAL ACCREDITATION

If at any point, while preparing for accreditation, you have questions or need further assistance please contact A2LA using the contact us form found at <a href="https://www.A2LA.org/form/contact-us">https://www.A2LA.org/form/contact-us</a> or email <a href="mailto:businessdev@A2LA.org">businessdev@A2LA.org</a> directly.

- 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 <a href="https://www.A2LA.org/accreditataion">www.A2LA.org/accreditataion</a> 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*.
- 3. For additional information on the estimated cost of accreditation (i.e. applicable accreditation fees and on-site assessment costs), complete the "Get a Quote" form that is linked from the A2LA home page (<a href="https://www.A2LA.org/form/estimate-request">https://www.A2LA.org/form/estimate-request</a>). In order for us to generate an accurate estimate, please provide a completed selection list or a draft scope of accreditation. Selection lists for various disciplines are located on our website at <a href="https://portal.A2LA.org/documents/">https://portal.A2LA.org/documents/</a>. Search for 'Selection Lists' and choose the form that is applicable to your program.
- 4. Appropriate conformity assessment checklists are required to be completed by applicant organizations during the application submission stage. These checklists are useful tools to use when preparing your system for accreditation as well. To obtain the applicable conformity assessment checklist, please complete and submit the corresponding 'Ownership Confirmation' form which can be found on our website:
  - a. F102 Ownership Confirmation ISO/IEC 17025:2017;
  - c. F306 Ownership Confirmation ISO 17034;
  - b. <u>F310 Ownership Confirmation ISO/IEC 17065;</u>
  - c. F326 Ownership Confirmation ISO/IEC 17020.

Please Note: The 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 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 2 business days of application submittal.



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- 5. Create and implement a Management System with 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.
- 6. Perform an internal audit to verify compliance with all A2LA requirements, applicable conformity assessment standard requirements (e.g. ISO/IEC 17025, ISO/IEC 17020, etc.), the CAB's 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, identify the organization's weak points and implement corrective actions where necessary. It is important to seek feedback from all applicable individuals to get the most comprehensive evaluation of the organization.
- 7. Perform a management review and document the results.

Where applicable, ensure that all supporting documents are translated into English prior to applying for accreditation. In most cases, 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. Please note any requested exceptions for assessments conducted in English on the submitted estimate <a href="https://www.A2LA.org/form/estimate-request">https://www.A2LA.org/form/estimate-request</a> or application <a href="https://www.A2LA.org/form/estimate-request">https://www.A2LA.org/form/estimate-request</a>, however, please note, that some documents (e.g. corrective action responses, etc.) must still be provided in English. A2LA staff will provide further details as appropriate, upon request.

- 8. Identify an individual as the "A2LA authorized representative" to assume responsibility for upholding the accreditation requirements and for making them available to relevant staff and applicable resources. This individual shall have binding authority from your organization to enter into the accreditation agreement with A2LA.
- 9. The application can be accessed from A2LA website, by clicking on the 'Apply' link at the top of the page or using this link: https://www.A2LA.org/form/estimate-request
- 10. A2LA will process your application within 2 business days and you will be notified via email of your assigned Accreditation Officer (AcO) with the necessary login information to access the Customer Portal. In the portal, you will need to upload supporting documentation that will be required to complete this portion of the application, and the invoice for the initial fees can be accessed. 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



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assessments and annual reviews are accessible from your Customer Portal. Please note that an application will not be deemed complete until all supporting information and payment for the initial fees are received.

- 11. A2LA will notify you through the Customer Portal of the name(s) of the selected assessor(s) and provide a brief biography. If you have justifiable objections (e.g. conflicts of interest) to the proposed assessor(s), changes in the assignment(s) may be made.
- 12. The lead assessor will contact you directly to schedule the initial assessment.

#### III. OPTIONAL PRE-ASSESSMENT

- 1. A2LA does offer the option of having a pre-assessment. 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.
- 2. 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.
- 3. When the CAB feels that they have addressed the items noted during the pre-assessment they should contact their AcO to proceed with the initial assessment as described above.

#### IV. PREPARING FOR SURVEILLANCE ASSESSMENT

- 1. Your organization will be required to undergo a surveillance assessment. This is typically a one-day assessment to confirm implementation of the management system. Reaffirmation of accreditation to the established anniversary date will be based upon having the surveillance assessment, A2LA's receipt of the appropriate final payment of fees, and resolution of all (where applicable) deficiencies cited during the surveillance.
- 2. The surveillance assessment will be initiated 6 months prior to the midpoint of your initial accreditation cycle. When you are alerted that the surveillance assessment has been generated you will log on to your designated Customer Portal, confirm your CAB information, agree to abide by the A2LA R102 Conditions for Accreditation, and submit/make payment.
- 3. Upload an up-to-date organization chart identifying by name, the key personnel involved for

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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.

- 4. Upload the applicable, requested documentation via your Customer Portal.
- 5. 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. The assessor will schedule and perform the surveillance assessment.

#### V. PREPARING FOR ANNUAL REVIEW OF ACCREDITATION

- 1. Annual reviews occur during the midpoint of each 2-year renewal accreditation cycle. This process is initiated 3 months prior to the midpoint of your renewal accreditation cycle. Once alerted that the annual review of accreditation has been initiated, log on to your designated Customer 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.
- 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 management review and any further documents that are requested via the Customer Portal.
  - **Please Note**: The annual review documentation must be submitted by the designated due date (assigned by A2LA and communicated to each CAB through the Customer Portal) or remedial action could occur. Please do not hold up submission of the required annual review documentation if certain functions (e.g. the internal audit, management review, etc.) are scheduled for a timeframe after the required annual review submission date. Please submit the most recent complete set of records.
- 4. Once all the appropriate information is provided and payment is received, A2LA will reaffirm the accreditation of your organization.

#### VI. PREPARING FOR RENEWAL OF ACCREDITATION

1. The renewal of accreditation process is initiated 6 months prior to the expiration date of your current accreditation. Once the assessment has been generated you will log on to your

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Customer Portal, confirm your CAB information, agree to abide by the A2LA *R102 – Conditions for Accreditation*, and submit/make payment.

- 2. Review the applicable requirements documents that are readily located on your Customer Portal, and also from the A2LA website at <a href="www.A2LA.org">www.A2LA.org</a>. 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 Customer Portal <a href="https://www.a2la.org/portals/cab">https://www.a2la.org/portals/cab</a>).
- 5. Upload an uncontrolled copy of your current management system documentation that is 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 the Customer Portal 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.
- 7. The assessor schedules and performs the renewal assessment.

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#### DOCUMENT REVISION HISTORY

DATE	DESCRIPTION
12/6/18	Update the requirements to address the A2LA Customer
	Portal and website changes