R307 - General Requirements: Accreditation of ISO/IEC 17065 Product Certification Bodies

(February 2015)

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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 accreditation system. A2LA was formed in 1978, as a practical and efficient organization to develop and manage a system to verify and recognize competent organizations. Accreditation in this area is defined as a formal recognition of competence that an organization can perform specific product/process/service certifications.

A2LA recognizes the very close relationship between certification, testing and inspection, yet understands that certification includes a variety of activities not covered in testing laboratory or inspection body accreditation alone. Certification includes products (e.g. services, software, hardware, and processed materials), as well as processes and services, including the examination of test reports for compliance with specified criteria – both domestic and international. A product certification body (PCB) which is engaged in testing, inspection, measurement or sampling work may apply for accreditation for this work concurrently with its application for accreditation of its certification activities.

Accreditation is based on the assessment of performance of a product certification body including (as appropriate) procedures, staff competence, inspection, review of product/process/service acceptability, and reporting. It is available to all Conformity Assessment Bodies (CABs) providing certification. A2LA welcomes applications for the accreditation of all types of product certifications, provided they fall within A2LA’s scope of activities. The following are examples of work for which accreditation may be sought:

<table>
<thead>
<tr>
<th>Appliances</th>
<th>Marine products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automotive lifting devices</td>
<td>Personal protective and safety equipment</td>
</tr>
<tr>
<td>Bottled water and packaged ice</td>
<td>Plastic piping systems and components</td>
</tr>
<tr>
<td>Building products</td>
<td>Plumbing products</td>
</tr>
<tr>
<td>Building and institutional furniture</td>
<td>Recreational clothing</td>
</tr>
<tr>
<td>Class II biohazard cabinetry</td>
<td>Occupational health and safety/personal protective clothing</td>
</tr>
<tr>
<td>Drinking water additives</td>
<td>Sanitation products</td>
</tr>
<tr>
<td>Drinking water treatment units</td>
<td>Sealed insulating glass</td>
</tr>
<tr>
<td>Electric appliances and accessories</td>
<td>Software</td>
</tr>
<tr>
<td>Electrical products</td>
<td>Solar energy</td>
</tr>
<tr>
<td>Fenestration products</td>
<td>Swimming pools, spas and components</td>
</tr>
<tr>
<td>Food service equipment</td>
<td>Telecommunications</td>
</tr>
<tr>
<td>Gas appliances and accessories</td>
<td>Treated wood</td>
</tr>
<tr>
<td>Gas and oil products</td>
<td>Wastewater treatment units</td>
</tr>
<tr>
<td>Waste water treatment</td>
<td>Windows and doors</td>
</tr>
<tr>
<td>Manufactured products and recreational vehicle plumbing products</td>
<td>Wood Products</td>
</tr>
</tbody>
</table>

Users of accredited product certification bodies should review the Scope(s) of Accreditation from any accredited product certification body when making decisions about which product certification body to use. The Scope(s) of Accreditation identifies the specific certifications for which the body is accredited.

L:\Requirements\R307 – General Requirements: Accreditation of ISO/IEC 17065 Product Certification Bodies
The general requirement (general criteria) for A2LA accreditation of product certification bodies is ISO/IEC 17065 - Conformity Assessment - Requirements for Bodies Certifying Products, Processes and Services. Additional requirements (specific criteria) which are necessary to meet particular user needs (i.e. C310 - Specific Checklist - 17065 - FCC Telecommunications Certification Body Evaluation and R308 - Specific Requirements - 17065 - Telecommunication Certification Body Accreditation Program) will compliment these general requirements, where relevant.

In effect, A2LA accreditation attests that a product certification body has demonstrated that:

a) it is competent to perform specific product/process/service certifications or specific types of product certifications;

b) its management system is documented, fully operational and addresses and conforms to all elements of ISO/IEC 17065 and the relevant certification scheme;

c) it is operating in accordance with its management system; and

d) it conforms to any additional requirements of A2LA or specific programs necessary to meet particular user needs (e.g. FCC, IC, IDA, OFCA, EPA (WaterSense, ENERGY STAR), RVIA, etc.).

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

[Signature]

President & CEO
PART B - CONDITIONS FOR ACCREDITATION

In order to attain and maintain accreditation, product certification bodies must comply with A2LA R102 - Conditions for Accreditation published by A2LA. This document is available on the A2LA website, www.A2LA.org, or from A2LA Headquarters.

In order to apply, the applicant organization’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 organization’s Authorized Representative is responsible for ensuring that all of the relevant conditions for accreditation are met as of the day it was signed. During the on-site assessment, the assessor will examine records and documentation to verify compliance with the Conditions for Accreditation as of the date it was signed.

PART C – A2LA ACCREDITATION PROCESS

I. Application

A product certification body applies for accreditation by obtaining the application package A2LA F309 – Application for Accreditation - ISO/IEC 17065 Product Certification Bodies (available from A2LA headquarters or the A2LA website www.A2LA.org) and submitting a completed application (with supporting information) to the website or physical address listed on the application. All applicants must agree to the Conditions for Accreditation (see Part B of this document), pay the appropriate fees set by the President & CEO, and provide detailed supporting information including (but not limited to):

- Proposed scope of accreditation (including certification schemes);
- Management system documentation;
- Organization structure; and,
- Compliance with the program requirements for the proposed certification scheme.

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.

Product certification attests that a product meets specified standards, especially for quality or safety and health issues. For product certification bodies accredited by A2LA, the scope of accreditation is normally identified in terms of a certification scheme(s) and specification(s) used to certify a product/process/service.
MULTIPLE CERTIFICATION SCHEMES

Organizations may apply for accreditation to multiple certification schemes. However, when the certification schemes are unrelated (e.g. Telecommunication and WaterSense) or are developed for different, specific regulators/specifiers in a given industry, the product certification body will be required to maintain separate scopes of accreditation for each certification program/scheme.

If you are applying for more than one certification program/scheme, a separate application must be completed for each certification program/scheme. Product certification bodies that have applied or hold multiple accreditations will be eligible to receive a fee discount. See the Product Certification Body Accreditation Fees in Part 4 of A2LA F309 – Application for Accreditation - ISO/IEC 17065 Product Certification Bodies for information regarding these fees.

The conditions for receiving the fee discount when applying for multiple certification programs are as follows:

- All applications, 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 certification programs/schemes must operate under the same management system; and,
- Product certification bodies accredited to multiple certification programs/schemes will be assigned related certificate numbers (e.g., 301.01, 301.02, 301.03, etc.).

II. Scope of Accreditation Formatting Requirements

In order to facilitate the assessment process, and to ensure consistency among Scopes of Accreditation of product certification bodies accredited by A2LA, all Scopes of Accreditation for accredited product certification bodies must meet the following requirements:

- All scopes must be in a three (3) column format, with those columns being:
  - Certification Scheme – this is the formal name of the certification scheme or system being operated by the accredited product certification body.
  - Product Type / Category – this is the description of the category or type of product (or products) the accredited product certification body is competent to certify.
  - Standards / Requirements – this is the documented set of requirements that the product (or products) is verified as complying with by the accredited product certification body.

Examples from a small number of certification areas follow:
<table>
<thead>
<tr>
<th>Certification Scheme</th>
<th>Product Type / Category</th>
<th>Standards / Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal Communication Commission (FCC) - TCB Roles and Responsibilities</td>
<td>Unlicensed Radio Frequency Devices (Scope A)</td>
<td>Scope A1, A2, A3, A4 of the FCC TCB Roles and Responsibilities</td>
</tr>
<tr>
<td></td>
<td>Licensed Radio Frequency Devices (Scope B)</td>
<td>Scope B1, B2, B3, B4 of the FCC TCB Roles and Responsibilities</td>
</tr>
<tr>
<td></td>
<td>Telephone Terminal Equipment (Scope C)</td>
<td>Scope C1 of the FCC TCB Roles and Responsibilities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Certification Scheme</th>
<th>Product Type / Category</th>
<th>Standards / Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPA ENERGY STAR</td>
<td>Residential Ventilating Fans (excluding certification of Luminaires)</td>
<td>ENERGY STAR Program Requirements for Residential Ventilating Fans (ver. A)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Certification Scheme</th>
<th>Product Type / Category</th>
<th>Standards / Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPA ENERGY STAR</td>
<td>Telephony</td>
<td>ENERGY STAR Program Requirements Product Specification for Telephony (ver. X)</td>
</tr>
<tr>
<td></td>
<td>Audio/Video Equipment</td>
<td>ENERGY STAR Program Requirements Product Specification for Audio/Video (ver. Y)</td>
</tr>
</tbody>
</table>
III. Assessment Process

The objective of an assessment is to establish whether or not a product certification body complies with ISO/IEC 17065, the A2LA requirements for accreditation, and can competently perform the certifications for which accreditation is sought. However, when accreditation is required to demonstrate compliance with additional criteria which may be imposed by other authorities (e.g. FCC, IC, IDA, OFCA, EPA (WaterSense, ENERGY STAR), RVIA, etc.) the A2LA assessment will include such additional criteria.

Assessors may also provide information, based on observations or in response to questions, in order to help the product certification body improve its performance. Assessors are restricted from providing consultation as this is not permitted under ISO/IEC 17011 Conformity Assessment - General requirements for accreditation bodies accrediting conformity assessment bodies, the standard A2LA operates and adheres to.

Delayed Assessment Policy: If a PCB fails to undergo its full assessment within one year of receipt of the application at A2LA headquarters, the PCB is prompted by A2LA to take action. If no action is taken within thirty (30) days of that reminder, the PCB is required to begin the application process again and pay the applicable accreditation fees in effect at that time. Any fees paid with the initial application are refunded according to the A2LA Refund Policy.

Refund Policy: While the A2LA Application Fee is non-refundable, if a product certification body withdraws the application before completion of the assessment, it may apply for a refund of up to 50% of the A2LA annual fee, the entire product certification surcharge, and the balance of the unexpended assessor deposit. There will be no refund of the annual fee(s) or product certification surcharge after the assessment has been completed. Refunds of any balance remaining on the assessor deposit will be made at the time of the accreditation decision. Any withdrawal or refund request must be in writing.

A. Initial Steps

Once the application information is completed and the appropriate fees are paid, A2LA headquarters staff identifies and tentatively assigns one or more assessors to conduct an assessment at the product certification body’s site (also including witness assessments as necessary). Assessors are selected on the basis of their technical expertise, knowledge of the specific certification scheme(s), and the requirements of ISO/IEC 17065 so as to be better able to provide guidance to the product certification body. They do not represent their employers (if so affiliated) while conducting assessments for A2LA. The product certification body has the right to ask for another assessor if it objects to the proposed assessor because of conflicts of interest (potential or existing). A2LA assessors are drawn from industry, academia, government agencies, consultants, and from the laboratory, inspection, certification and professional communities. 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 the product certification body. More than one assessor may be required.
Assessors are given an instruction manual and checklists to follow when performing an assessment. These documents are intended to ensure that assessments are conducted as uniformly and completely as possible among the assessors and from product certification body to product certification body.

Before the assessment is conducted, the assessment team requests copies of the management system documentation (including certification schemes) and representative technical, inspection, record control and other SOPs in order to prepare for the assessment. The management system and its 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 product certification body in writing, and may ask the product certification body to implement corrective action to fill any documentation gaps required by relevant requirements before scheduling the assessment.

Prior to scheduling the full assessment, the assessor(s) reviews the draft scope(s) to determine the certifications to review and checks on the availability of the personnel who perform the certifications. The assessor(s) of the product certification body will also provide an assessment agenda prior to the on-site assessment.

B. Pre-Assessment (when requested)

A2LA assessors are permitted to conduct pre-assessments. There are two situations when a pre-assessment may be conducted:

1. When the lead assessor finds major gaps in the management system documentation, or actually begins the assessment and finds a large number of problems. In this case, the assessor identifies them and suggests to the product certification body that a full assessment should wait until the problems have been addressed. This first identification of the problems would be considered a pre-assessment; or

2. When a product certification body requests a pre-assessment to better prepare for the full assessment. In this case, the product certification body has applied, but is unsure of its documentation or system and wants someone to perform a pre-assessment to identify problems. The full assessment follows later.

To implement the pre-assessment program, the product certification body must first apply for accreditation, paying the appropriate fees and assessor deposit. A lead assessor is assigned, with the product certification body’s concurrence. If, during the discussions between the product certification body and assessor in preparation for the assessment, the product certification body concludes that it is in its interest to have a pre-assessment, it informs the assessor. The assessor notifies A2LA that the product certification body wants a pre-assessment. The daily rate of the pre-assessment is the same as the regular assessment rate, and can be deducted from any assessor deposits held on account at A2LA. No additional accreditation fees apply.
Please note, however, that careful attention to the requirements should preclude the need for a pre-assessment.

C. On-Site Assessment

The full assessment involves, but is not limited to:

- An entry briefing with product certification body management;
- Interviews with technical staff, including any staff operating remotely;
- Observing witness assessments or other off-site activities as required by the certification scheme(s) being operated;
- Demonstration of selected certifications including, as applicable, certifications and related activities performed at representative field locations;
- Assessment of the management system to verify that it is fully operational, conforms to all sections of ISO/IEC 17065, and contains all the required documentation;
- A written report of assessor findings; and,
- An exit briefing including the specific written identification of any deficiencies.

During the full assessment, the assessor(s) has the authority to stop the process at any time and consult with A2LA staff and the product certification body'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 (new applicants only), or a suspension may be recommended if technical capability is questioned or lost (see Section XV). The full assessment is then rescheduled when the product certification body and assessor feel it is appropriate to proceed.

IV. Deficiencies

During the assessment, the assessor(s) may observe deficiencies. A deficiency is any nonconformity to accreditation requirements including:

- a product certification body's inability to perform a certification for which it seeks accreditation;
- a product certification body's management system does not conform to a clause or section of ISO/IEC 17065, is not adequately documented, or is not completely implemented in accordance with that documentation; or,
- a product certification body does not conform to any additional requirements of A2LA or regulatory agencies necessary to meet particular needs or certification schemes.

At the conclusion of an assessment, the assessor(s) prepares a report of findings, identifying deficiencies which, in the assessor's judgment, the product certification body must resolve in order to be accredited. The assessor(s) holds an exit briefing with top management of the product certification body to review the findings and present the list of deficiencies (if applicable).

The authorized representative of the product certification body (or designee) is asked to sign the assessment report to attest that the deficiency report has been delivered and reviewed with the
assessor(s). The signature does not imply that the product certification body representative concurs that the individual item(s) constitute a deficiency.

With authorization from the organization, the assessor(s) may also write an ‘observation(s)’ when they question the practice or competence of the product certification body, but there is not enough supporting evidence to justify a deficiency or the issue cannot be tied to the accreditation requirements. If this occurs, the product certification body 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(s) to visit the product certification body who will check to see if that observation was addressed by the organization, resulting in an improvement, or possibly may have progressed into a deficiency.

If the number and/or nature of the deficiencies are deemed by A2LA staff as extreme, A2LA may require a follow-up assessment be conducted to ensure that appropriate corrective actions have been implemented.

V. Corrective Action Process

The product certification body 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. The corrective action response must include the product certification body’s root cause analysis and a copy of any objective evidence (e.g., procedures, paid invoices, training records, etc.) to indicate that the corrective actions have been implemented and 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 two hours’ time, A2LA may invoice the product certification body for this time at the prevailing assessor rate. The assessor will discuss the possibility of this review with the product certification body during the exit briefing and obtain the product certifier’s concurrence.

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

A new applicant product certification body (i.e. initial assessment) must respond in writing within 30 days of the exit briefing, and resolve all deficiencies within four (4) months of the exit briefing. A new applicant certification body that fails to resolve all its deficiencies within four (4) months of being assessed shall be subject to being reassessed at its expense. A2LA staff has the option to ask for reassessment of an organization before an initial accreditation vote is taken based on the number, extent and nature of the deficiencies.

VI. Accreditation Anniversary Date

The anniversary date of a product certification body’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 product certification body’s enrollment.
VII. Extensions to the Accreditation Anniversary Date

If a product certification body is in their renewal process and is in good standing with A2LA when approaching their accreditation anniversary date, A2LA may extend their accreditation 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 product certification body submits objective evidence demonstrating that the non-conformances have been addressed. Likewise, extensions are not granted when delays are due to the product certification body’s failure to respond to requests within established deadlines, such as:

- receipt of complete renewal application (including payment for relevant fees) after imposed due date;
- assessment not performed within assessor availability;
- receipt of response to assessor deficiency report beyond 30 days of assessment exit briefing; and,
- closure of all deficiencies beyond 60 days of assessment exit briefing.

When a product certification body is granted an extension, a revised Scope and Certificate of Accreditation will be posted to the A2LA website, which reflects the extended anniversary date. Upon completion of the renewal process, both documents are reissued, reflecting the renewed anniversary date.

VIII. Accreditation Decisions

Before an accreditation decision ballot is sent to Accreditation Council members, staff shall review the deficiency response, including the product certification body’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 product certification body 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 product certification body’s capabilities is adequately covered by the Accreditation Council review. Especially in the case of those product certification bodies seeking (re)accreditation for multiple certification activities, it may be necessary to select more than three AC members in order to accomplish this. The product certification body 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 product certification body’s certification 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 the assessor(s) 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(s) 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 final decision.

Staff shall notify the product certification body 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 product certification body is asked to accept a reassessment. If the product certification body refuses the proposed reassessment, a nine-member Accreditation Council appeals panel is balloted (see Sections XIV, Adverse Accreditation Decisions and XV. Appeals Procedures below).

If accreditation is granted, the A2LA staff prepares and forwards a certificate and scope of accreditation to the product certification body. The product certification body should keep its scope of accreditation available to show clients or potential clients the certification capabilities 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 product certification body must pay annual fees (including applicable surcharges) and assessor fees and undergo a surveillance visit by an assessor. This surveillance visit is performed to confirm that the product certification body’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 IX) each product certification body must pay annual fees (including surcharges) and submit updating information on its organization, facilities and key personnel. Objective evidence of completion of the internal audit, management review and surveillance activities are also required. If the renewal product certification body does not promptly provide complete annual review documentation, or significant changes to the facility or organization have occurred, a surveillance visit and payment of the associated assessor fees is required. Telecommunication Certification Bodies will be required to undergo a surveillance assessment on each of the odd years between renewal assessments. Depending on the outcome of the previous year’s full assessment and the number and nature of FCC TCB audit issues, the surveillance assessment may be waived or performed remotely. This decision will be made by A2LA staff in consultation with a technical assessor on a case by case basis.
X. Reassessment and Renewal of Accreditation

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

Each accredited product certification body is sent an electronic renewal application notice (accessible from the A2LA website “CAB Access Portal” - https://www.a2la.org/labs/login.cfm) well in advance of the expiration date of its accreditation to allow sufficient time to complete the renewal process. A successful reassessment at the product certification body’s site (including witness assessments and other means of reviewing competence of remote operating personnel as necessary) must be completed before accreditation is renewed for another two years.

If deficiencies are noted during the renewal assessment, the product certification body is asked to write to A2LA within 30 days after the date of the exit meeting stating the corrective action(s) taken. All deficiencies must be resolved (within 60 days of the exit meeting) 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 or only a few deficiencies of a minor nature (i.e., the non-compliances do not directly affect the integrity of certifications) 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.

2) If there are major deficiencies (i.e., the non-compliances directly affect the integrity of the certifications), the staff advises the product certification body 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 product certification body may be required to undergo a surveillance assessment in conjunction with the next annual review to verify continued implementation of corrective actions (see Section VIII above).

XI. Extraordinary Assessments

Although rare, A2LA may require product certification bodies to undergo an extraordinary assessment as a result of complaints or significant changes to the product certification body’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 product certification body may request an expansion to its scope of accreditation at any time. Such a request must be submitted in writing to A2LA headquarters using the F330 – Request for Expansion of Scope of Accreditation – Product Certification form. Unless the previous assessor can verify the competence and capability of the organization to perform the additional certifications, another assessment at the organization’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’ time, A2LA will invoice the organization for this review time at the prevailing assessor rate. If an organization requests multiple scope expansion requests over the period following its previous assessment and until the assignment of the next assessor, assessor review time beyond the two hours’ cumulative gratis time will be invoiced to the organization at the prevailing assessor rate. If the scope expansion request is unrelated to a currently accredited certification scheme, another assessment will likely be required. Similarly, if a product certification body relocates, a follow-up assessment is normally warranted. Each request is handled on a case-by-case basis. Please also refer to Part C, Multiple Certification Schemes.

XIII. Product Certification Body 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 A2LA R105 – Requirements When Making Reference to A2LA Accredited Status. This requirements document is available from A2LA Headquarters or on the A2LA website, www.A2LA.org. Failure to comply with these requirements may result in suspension or revocation of a product certification body’s accreditation.

XIV. Adverse Accreditation Decisions

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

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

Inactive – A product certification body 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 product certification body must notify A2LA in writing of this desire, agree to undergo a full reassessment (when applicable), and pay all renewal fees and reassessment costs.

A product certification body that has relocated, changed ownership or has dramatically altered its management system may also be designated as inactive until compliance to all relevant requirements can be confirmed (i.e. by a visit to the product certification body’s site).
The Inactive status can be given to a product certification body for no longer than one year, after which time the product certification body is removed from A2LA records and designated as withdrawn.

XV. Suspension of Accreditation

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

- non-compliance with the requirements of a nature not requiring immediate withdrawal (i.e. identification of significant deficiencies during an assessment);
- improper use of the “A2LA Accredited” symbol (i.e., misleading prints or advertisements are not solved by suitable retractions and appropriate remedial measures by the product certification body); 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 product certification body is suspended, A2LA shall confirm an official suspension in a certified letter, return receipt requested (or equivalent means), to the product certification body'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 product certification body 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; and,
- that a further review will be conducted to consider such information and a further written notification will be sent to the product certification body by certified mail, return receipt requested, indicating whether the suspension has been terminated, modified, left in force or converted to a withdrawal of accreditation.

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 product certification body's reports/certifications and investigation reveals serious deficiencies in the management system and/or competence in conducting the specific certifications;
• if the certification scheme or accreditation rules have changed and the product certification body 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 product certification body;
• when such action is necessary to protect the reputation of A2LA; and,
• at the formal request of the product certification body.

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 product certification body on notice of the cause;
• that within thirty (30) days of receipt of the notice, the product certification body 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 product certification body name from the A2LA on-line directory and publicizing the action on the A2LA website.

A product certification body 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 VII). 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 product certification body's complete accreditation, must be agreed upon by a two-thirds of the (sum of the affirmative and negative – abstentions are not included) votes received from the nine-member appeals panel of the Accreditation Council. Votes must be received from all members with specific technical background necessary to review the product certification body's scope(s) of accreditation. The decision of the Accreditation Council’s appeals group is communicated in writing to the appellant.
If the decision is not favorable to the appellant, the appellant may lodge a further appeal within thirty (30) days of notification by forwarding a certified letter to A2LA for timely consideration by the Board of Directors. This letter shall include appropriate substantiation for the appeal.

This letter and appropriate background documentation will be promptly transmitted to the members of the Board of Directors appeals group, the composition of which to be determined by the Board Chairman taking into account any conflict-of-interest considerations and the nature of the appeal.

The decision of the Board of Directors shall be final and binding, except that any court having jurisdiction may set aside such decision when bias, fraud or misconduct of the Board has been determined, and is communicated in writing to the appellant.

XVIII. Confidentiality Policy

All information provided by applicants in connection with a request for an application package, an application for accreditation, or an assessment 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. The Association agrees to hold all disclosed confidential or proprietary information or trade secrets in trust and confidence. The information shall be used only for accreditation purposes, and shall not be used for any other purpose, nor shall it be disclosed to any third party without written consent of the applicant laboratory unless required by law or judicial or administrative process or regulation (such as through a properly issued and served subpoena).

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

In response to a question about whether or not a particular product certification body has applied for accreditation, A2LA simply responds by saying that the product certification body is not accredited. Staff neither confirms nor denies whether a product certification body has ever applied for accreditation. If the product certification body itself is saying that it has applied for accreditation, it is the product certification body’s responsibility to release the information regarding its applicant status.

If the caller says that the product certification body claims it applied, staff shall take the name, address and phone number of the caller to check to see if the product certification body is misleading the client but staff still will not verify the organization’s application.

Should an applicant product certification body 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 product certification body whose accreditation has lapsed but is in the renewal process, staff can indicate that the product certification body is not now accredited but is in the process of renewal, if that is the case. If the renewal product certification body’s accreditation
has lapsed with no indication (return of renewal forms or payment) of pursuit of renewal, staff indicates simply that the product certification body is not accredited.

**XIX. Conflict of Interest Policy**

Since its inception, A2LA has had a policy that actual or apparent conflicts of interest must be avoided as mandated by normal business ethics.

Consistent with the principles set forth in ISO/IEC 17011, *Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*, A2LA believes that it is vital that its accreditation services be impartial and objective, uninfluenced by the private interests of individuals acting for A2LA.

Accordingly, any person directly involved in actions relating to the A2LA accreditation process shall avoid direct participation in A2LA actions that may involve an actual or apparent conflict of interest.

The Audit & Ethics Committee of the Board and the President shall, as promptly as possible, take all possible means to prevent or overcome any such actions that may conceivably be in violation of this policy.
APPENDIX A - Document Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/27/2013</td>
<td>Issued new requirements document to cover ISO/IEC 17065</td>
</tr>
<tr>
<td>09/05/2014</td>
<td>Minor grammatical edits; updated references of “Quality Manual” to quality system documentation or management system documentation, as no “manual” is required by the standard. Added condition for follow up assessment in part III and changed referenced from P101 to R105.</td>
</tr>
<tr>
<td>02/06/2015</td>
<td>Added section C.II regarding scope formatting requirements, and renumbered all subsequent part C sections accordingly. Updated section C.V regarding corrective action submittal deadlines to be in line with changes to other A2LA general requirements documents. Added information about requiring observation of off-site activities for initial and renewal assessments (if called for by scheme) and review of remote personnel involved in certification activities to sections C.III and C.X. Other minor various grammatical updates and removal of repetitive content.</td>
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</tbody>
</table>
A2LA APPEALS PROCESS DIAGRAM

APPLICANT PRODUCT CERTIFICATION BODY

- RESPOND TO NEGATIVE VOTES

A2LA HEADQUARTERS

- REQUEST RESOLUTION OF NEGATIVE VOTE(S)
  - SUBMIT RESPONSES TO AC MEMBER(S) WITH NEGATIVE VOTE(S)

ACCREDITATION COUNCIL (AC)

- INITIAL DECISION
  - VOTE CHANGED TO POSITIVE
  - VOTE
    - CHANGED TO POSITIVE
    - AFFIRMATIVE
    - NEGATIVE

BOARD OF DIRECTORS

- OFFICIAL SCOPE OF ACCREDITATION ISSUED
  - NO
  - YES
  - VOTE
    - CHANGED TO POSITIVE
    - AFFIRMATIVE
    - NEGATIVE

- SUBMIT WRITTEN APPEAL
  - PRODUCT CERTIFICATION BODY NOTIFIED OF RIGHT TO APPEAL
  - PRODUCT CERTIFICATION BODY NOTIFIED OF RIGHT TO APPEAL TO BOARD
  - SUBMIT WRITTEN APPEAL

- BOARD NOTIFIED AND CASE FILES forwarded
  - NEGATIVE DECISION UPHELD
  - NO
  - YES

PRODUCT CERTIFICATION BODY NOTIFIED OF FINAL DECISION

AC NOTIFIED OF APPEAL

NEGATIVE DECISION UPHELD

L:\Requirements\R307 – General Requirements: Accreditation of ISO/IEC 17065 Product Certification Bodies