

	<i>The American Association for Laboratory Accreditation</i>	
	F304 - APPLICATION FOR ACCREDITATION: ISO Guide 34 Reference Material Producer Accreditation Program	Document Revised: February 24, 2010
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For A2LA Office use Only: MASTER CODE:	ASSESSMENT NO:	CERT NO:
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Preface A - Preparation

Please take the following steps before you begin this application to ensure an effective application process. Note: All documents referenced in this application can be accessed by using the “document finder” link located on the home page at www.A2LA.org or by contacting A2LA Headquarters at 301 644 3248.

1. Please obtain and read a copy of the A2LA [R304 - General Requirements: Accreditation of ISO Guide 34 Reference Material Producers](#), [P102 A2LA Policy on Measurement Traceability](#), [R103 - General Requirements: Proficiency Testing for ISO-IEC 17025 Laboratories](#) and the A2LA [P101 – Reference to A2LA Accredited Status-A2LA Advertising Policy](#). These documents 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, and other requirements/policies referenced in the A2LA R304 General Requirements: Accreditation of ISO Guide 34 Reference Material Producer document.
2. Please obtain official copies of ISO Guide 34:2009 (or if you are applying to the old version ISO Guide 34:2000) and ISO/IEC 17025:2005 from <http://www.ISO.org/> or <http://webstore.ansi.org/>
3. Create and implement a Quality Manual and Management System (policies and procedures) that meet ISO Guide 34 and applicable A2LA requirements.
4. Perform a self-assessment/internal audit in accordance with ISO Guide 34 to verify compliance with all applicable A2LA requirements, ISO Guide 34, relevant sections of ISO/IEC 17025 the reference material producer’s own management system and applicable accredited methods and document the results.
5. Perform a management review in accordance with ISO Guide 34 and document the results.
6. Provide a list of reference materials for which accreditation is being sought. Use the listing provided in [ILAC G12 Appendix B](#) as a reference.
7. Please read the policies found in the “Policies” section (Preface B) of this application.
8. Download and complete the [F306 ISO Guide 34 Confirmation Form](#) and submit to A2LA.
9. Obtain and complete A2LA Assessor Checklist C307 General Checklist: ISO Guide 34 Reference Materials Producer Accreditation Program or C307 General Checklist: ISO Guide 34:2009 Reference Materials Producer Accreditation Program. Obtain and complete A2LA Assessor Checklist C101 General Checklist: ISO/IEC 17025 Laboratory Accreditation Program.

Preface B - Policies

A. A2LA Confidentiality Policy: See [R304 General Requirements: Accreditation of ISO Guide 34 Reference Material Producers, Part C, Section XVII](#). Please place a checkmark in the appropriate block.

1. I authorize A2LA to release information regarding our application status.
2. I do not authorize A2LA to release information regarding our application status.

B. Language Policy: 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



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facilitate the on-site assessment. Please refer to [R304 General Requirements: Accreditation of ISO Guide 34 Reference Material Producers, Part C, Section I.](#)

Part I. Application Information

A. Reference Material Producer's Name (as it will appear on your Scope of Accreditation and the A2LA website).

B. Reference Material Producer's Address (please enter the physical address of the organization, as it will appear on your Scope of Accreditation and the A2LA website).

Address (Street number, Street, City, State, Zip Code and Country)

C. Reference Material Producer's Website Address (please place a checkmark in the box and enter the web site address of your organization, if you wish to include a link to your website on the A2LA website).

Website address

D. Reference Material Producer's Mailing Address (if different from the Reference Material Producer's physical address).

Address (Street number, Street, City, State, Zip Code and Country)

E. Reference Material Producer's Billing Address (if different from the Reference Material Producer's physical address).

Address (Street number, Street, City, State, Zip Code and Country)



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Part I. Application Information (continued)

F. Reference Material Producer's Accounts Payable

1. Contact Name

2. Telephone

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3. Fax Number

4. Email

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G. If the reference material producer works in shifts, please note the times for each shift:

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Part II. Scope of Accreditation

A. Please complete this table for all reference materials/certified reference materials for which accreditation is being sought. Identify the reference materials and certified reference materials by referring to [ILAC G12 Appendix B](#) and using the numbering scheme and categories provided where possible.

Category and Sub-category of RMs Produced	ISO Guide 34 Task/Activities RMP Performs	Test, Analysis, Measurement (including ranges and uncertainties if appropriate)	Technical Standards / Methods	Measurement Technique (where appropriate)

Part III. Collaborators / Subcontractors Information

A. Please complete this table for all collaborator/subcontractors with which the reference material producer has formal arrangements that undertakes the aspects of processing, handling, homogeneity and stability assessment, characterization, storage or distribution of the reference materials.



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1. Collaborator / Subcontractor Name and address:	2. Accreditations held (if applicable):	3. Description of tasks/activities performed:	4. Type of testing, calibration and measurement activities:

Part IV. Conditions for Accreditation

A. To attain and maintain accreditation, an applicant must agree to:

- 1) Afford accommodation and cooperation as is necessary to enable A2LA to verify compliance with the requirements for accreditation including provision for examination of documentation (including documents that provide insight into the level of independence of the applicant from any other related activities undertaken by their organization, where applicable) and access to all calibration and testing areas, equipment, records and personnel (including arrangements for witnessing accredited activities when requested and practicable) for the purposes of assessment, surveillance, reassessment, resolution of complaints, and fulfillment of Mutual Recognition Arrangement (MRA) and/or specifier requirements;
- 2) Comply at all times with the criteria relevant requirements documents (e.g., [R304 General Requirements: Accreditation of ISO Guide 34 Reference Material Producer](#), [P101 – Reference to A2LA Accredited Status-A2LA Advertising Policy](#), [P102 A2LA Policy on Measurement Traceability](#)) and the conditions for accreditation;
- 3) Maintain impartiality and integrity;
- 4) Retain all quality records and technical records supporting reported results as defined in the relevant management system standard(s) (such as ISO Guide 34) throughout the period between A2LA full assessments. Please bear in mind that adequate records must be available to demonstrate full compliance with the requirements for accreditation;
- 5) Claim that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;
- 6) Pay such fees as shall be determined by A2LA;
- 7) Not use its accreditation in such a manner as to bring A2LA into disrepute and not make any statement relevant to its accreditation which A2LA may consider misleading or unauthorized;
- 8) Upon suspension, withdrawal or expiration of its accreditation (however determined) discontinue its use of all advertising matter that contains reference thereto and return any certificates and scopes of accreditation to A2LA;
- 9) Not use its accreditation to imply product approval by A2LA;
- 10) Endeavor to ensure that no certificate or report, nor any part thereof, is used in a misleading manner;
- 11) In making reference to its accreditation status in communication media such as advertising, brochures, comply with the requirements of A2LA;
- 12) Inform A2LA headquarters within 30 days and in writing of changes or pending changes in any aspect of the organization's status or operation that affects the organization's legal, commercial or organizational status; organization or management (e.g., managerial staff); policies or procedures, where appropriate; premises; personnel, equipment, facilities, working environment or other resources, where significant; authorized signatories; or such other



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Part IV. Conditions for Accreditation (continued)

matters that may affect the organization's capability, or scope of accredited activities, or compliance with the criteria, requirements and conditions for accreditation;

- 13) Carry out any adjustments to its procedures in response to due notice (by A2LA newsletter, email and/or hardcopy) of any intended changes by A2LA to the criteria, requirements, or conditions for accreditation, in such time as in the opinion of A2LA is reasonable;

Note: Updates to A2LA policies will be provided to enrolled and accredited organizations via email, whenever possible.

In order to apply, the applicant's AUTHORIZED REPRESENTATIVE and DEPUTY AUTHORIZED REPRESENTATIVE, must agree to the above 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 date this document is signed. In the absence of the AUTHORIZED REPRESENTATIVE the DEPUTY AUTHORIZED REPRESENTATIVE is responsible for ensuring that all of the relevant conditions for accreditation are met as of the date this document is signed. During the on-site assessment, the assessor(s) will examine records and documentation to verify compliance with these Conditions for Accreditation as of the date it was signed.

As the applicant Organization's Authorized Representative and Deputy Authorized Representative, I agree to the above conditions for accreditation. I attest that all statements made on this application are correct to the best of my knowledge and belief.

1. AUTHORIZED REPRESENTATIVE

A. Authorized Representative Printed Name

B. Authorized Representative Title

Mr. [], Mrs. [], Ms. []

C. Telephone Number

D. Fax Number

E. Email Address

F. Signature of Authorized Representative

G. Today's Date

2. DEPUTY AUTHORIZED REPRESENTATIVE

H. Deputy Authorized Representative Printed Name

I. Deputy Authorized Representative Title

Mr. [], Mrs. [], Ms. []



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J. Telephone Number

K. Fax Number

L. Email Address

Form fields for J, K, and L.

M. Deputy Authorized Representative Signature

N. Today's Date

Form fields for M and N.

Part V. Fee Schedule

A. Payment Options: Please remit a check payable to A2LA. If your organization utilizes Purchase Orders/Contracts please place a checkmark in the box on page 7 of the application. Please be sure to include the purchase order/contract with the application. An invoice will be provided by A2LA for payment. If you elect to make payment with a Credit Card, please contact the Financial Services Department at 301-644-3248 or visit our website at www.A2LA.org.

- 1. Initial Application Fee for Reference Material Producers: This is a one time non-recurring application fee for the reference material producer. This fee is non-refundable.
2. Annual Fee for Reference Material Producers: Although accreditation is granted for two years, payment of a yearly Annual Fee is required to continue accreditation into the following years.
3. A2LA Accredited Organizational Membership Discount: A reference material producer can become a member and purchase an organizational membership from A2LA. Please refer to the A2LA membership website link found on the A2LA web site for additional information and descriptions of benefits and discounts. If you do not have an A2LA membership, please skip to item number 7.
4. Assessor Deposit: The Assessor Deposit is \$2,000. Upon request the assigned Assessor can provide the organization with an estimate of the costs of travel and lodging and number of billable hours that are reasonably anticipated before the visit and will leave a written estimate of actual assessment costs upon departure. The reference material producer will be billed (or refunded) the difference between the actual cost of the assessment and the amount of this deposit. Accreditation will not be granted until all fees are paid. Actual costs are computed based on:
- Total Assessment Time at \$1080 per 8-hour day per assessor;
- Travel (airfare, rental car, or private auto @ IRS allowable rate); and
- Accommodations & Miscellaneous (hotel, meals, parking, calls, etc.).

Note: the assessor deposits are only partial payments of the assessment costs and it is likely that the actual assessor charges will exceed the deposit amount. Variable factors such as the reference material producer's size, desired scope of accreditation, documentation structure and adequacy of its preparation for the assessment as well as the costs of assessor travel and lodging will impact on the actual accrued assessment costs.

- 8. Total Amount Due: Please Remit Check Payable to A2LA. For Credit Card payments, please contact Financial Services to arrange processing or visit our website at www.A2A.org.

Note 1: If travel takes more than two hours, an additional cost at one half the assessment rate will be added for each additional hour. It is to the reference material producer's advantage to be prepared and to help prepare the assessor(s) beforehand. If any part of the management system documentation is not sent to the assessor(s) beforehand, the assessor(s) will need additional on-site time. If the scope of accreditation changes significantly as the assessment progresses, the assessor(s) will also need more time. If there are significant deficiencies, the assessor(s) follow-up time may also be charged. A2LA audits the expenses and pays assessors. Do not pay assessors directly. Do check the assessor's written estimate of assessment costs.



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Part VI. Fee Schedule (continued)

Note 2: If a reference material producer withdraws the application before completion of the assessment, it may apply for a refund of up to 50 % of the A2LA annual fee and the balance of the unexpended assessor deposit. There will be no refund of annual fee 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.

Payment Options

If your Organization utilizes Purchase Orders/Contracts please check here.

1. Initial Application Fee:

Note: This fee is waived if the applicant is already accredited with A2LA under another program, such as laboratory accreditation (at the same location).

2. Annual Fee

Note: This fee is reduced to \$1000 if the applicant is already accredited with A2LA under another program, such as laboratory accreditation (at the same location).

3. A2LA accredited organizational membership discount. If you do not have an A2LA membership, skip to item 7.

4. Assessor Deposit.

5. TOTAL AMOUNT DUE – Please Remit Check Payable to A2LA.

Calculation

Fee	Total
\$800	
\$1300	
\$(200)	
\$2000	\$2000
\$USD	

Part VII. Supporting Information

Please use this checklist to review your application package prior to submission to A2LA. Completion of the required items is necessary for the efficient processing of your application. Delays may occur if clarification or additional information is needed. Before mailing your application to A2LA, please be sure you have read and done the following:

- Read [R304 General Requirements: Accreditation of ISO Guide 34 Reference Material Producers](#) and other referenced requirement and policy documents to ensure a basic understanding of the accreditation process.
- Enclosed an organization chart.
- If the Reference Material Producer is part of a larger organization, enclosed a chart of its position and reporting relationships within that organization.
- Enclosed a completed A2LA ISO Guide 34 Assessor Checklist and ISO/IEC 17025 Assessor Checklist.



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- Enclosed a copy of the Reference Material Producer's current uncontrolled quality manual, operating procedures and work instructions.
- Completed all sections of the application.
- Read, understood, signed and returned the Conditions for Accreditation (pages 4 and 5).
- Reviewed the Fee Schedule and paid the appropriate fees. An application cannot be considered complete until payment, or an arrangement for payment is made.

Part VIII. Survey

A. Please indicate your reason(s) for pursuing accreditation with A2LA and list any sector specific requirements, including specific international technical directives and recognition requirements for approval.

B. Please indicate how you heard about A2LA (e.g. tradeshow, trade magazine, colleague, website, presentations, etc.). Please also identify any A2LA Staff Members that assisted you with this application.

C. Please list all accreditations currently maintained with any other accreditation body, accreditation/recognition with a government agency, or additional supplier audits. Note: A2LA may accept some or all portions of valid accreditations granted by other accreditation bodies on a case by case basis.

Part IX. Mailing Instructions

**Please return the entire application, along with the requested supporting documentation and payment of fees to:
The American Association for Laboratory Accreditation
5301 Buckeystown Pike, Suite 350
Frederick, MD 21704**