



**LABORATORY
ACCREDITATION
BUREAU**

**CLIENT INSTRUCTION
MANUAL
(Laboratory Accreditation Criteria)**

This instruction Manual defines the procedures that the client must follow to obtain accreditation from Laboratory Accreditation Bureau, LLC (L-A-B). It also defines the relationship between L-A-B and their accredited laboratories. It describes the accreditation process that will be carried out for each client.



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OBJECTIVE

This instruction manual defines the procedures that the client must follow to obtain accreditation from Laboratory Accreditation Bureau, LLC (L-A-B). It also defines the relationship between L-A-B and their accredited laboratories. It describes the accreditation process that will be carried out for each client.

SCOPE

This manual applies to all applicant and accredited laboratories. It also defines the methods used by L-A-B, and its assessors when accrediting laboratories.

REFERENCE DOCUMENTS

ISO/IEC 17025 - *General Requirements for the Competence of Testing and Calibration Laboratories.*
ISO/IEC 17011 - *Conformity Assessment - General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*

The following L-A-B procedures, forms and policies in their current revision form an integral part of this manual. These are available on the L-A-B website at www.l-a-b.com or available upon request.

APPLICATION PROCESS

[Web site Application for Accreditation Quote](#)

The applicant laboratory should start by completing the [Application for Accreditation Quote located on the L-A-B website](#). The laboratory should complete as much information as possible. L-A-B will contact you to confirm receipt and discuss. L-A-B will produce an estimate of the cost for the accreditation based on the submitted information.

Costs are based on the number of technicians, type of service in-house or on-site, the number of tests or calibrations defined on the Scope Preparation Matrix(s) and the number of laboratory sites. The following costs may apply:

FEE STRUCTURE

Form R20.4 - L-A-B Laboratory Accreditation Agreement

Explanation:

The initial application fee covers the cost of reviewing documents submitted by the client and assigning/coordinating the assessor assigned to the client.

The annual fees are based on the number of fields and sites, which pays the cost of maintaining the credentials, staff, relative committee participation and maintenance of the L-A-B website. The accreditation is valid for three years; renewable based on the successful completion of a re-assessment.

Preparation/Report is the cost of L-A-B staff and assessor's review of the relevant documents. This takes place prior to the initial or pre-assessment visit to assure that your documentation indicates that you are ready for your visit from the assessor. The fee also covers the time needed to complete the concluding report.

An assessment manday rate is the charge per day for the assessor. Reasonable assessor(s) expenses are charged to the client over and above the L-A-B fees.

The quote and a copy of Form R 20.4—L-A-B Laboratory Accreditation Agreement shall be sent to the client for approval and signature.



TO START THE ACCREDITATION PROCESS

Form 308 - Confidential Application and Cost Estimate
Form R20.4 - L-A-B Laboratory Accreditation Agreement

The laboratory shall send a check for the initial charges, a signed copy of Form 308, Confidential Application and Cost Estimate, complete with Terms and Conditions and a Purchase Order for the remaining costs indicated on the estimate. Upon receipt of the previous information L-A-B shall allocate an assessor for the laboratory.

Once Accreditation has been granted, the laboratory will be required to enter into Agreement with L-A-B by signing and returning two originals of the L-A-B Laboratory Accreditation Agreement (Form R20.4). One original will be signed by L-A-B and returned to the client with the laboratory Accreditation Certificate; the second original will be retained by L-A-B as a contractual Agreement between L-A-B and the laboratory.

ASSESSOR ALLOCATION

Assessor(s) are allocated based on their qualifications and technical competence in the fields to be assessed. With an adequate reason, the laboratory has the right to ask for another assessor if they object to the original allocation.

ACTIVITIES PRIOR TO ASSESSMENT

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories.

In addition to the requirements set forth in this document, the laboratory must maintain a management system that complies with all applicable requirements of ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*. The laboratory is required to own the most recent copy of ISO/IEC 17025.

PROFICIENCY TESTING POLICY

L-A-B Policy 002 - Proficiency Testing
ISO Guide 43-1(or latest version) - Proficiency Testing by Interlaboratory Comparisons - Part 1: development and operation of proficiency testing schemes

Laboratories that wish to become accredited and maintain their accreditation are responsible for participating in a proficiency testing, interlaboratory comparison or a round robin testing program that will meet the requirements of the international accreditation community and L-A-B Policy 002. At a minimum, the ILC/PT must meet the requirements of ISO Guide 43 or latest version. Any proficiency test, interlaboratory comparison or round robin (ILC/PT) that is not conducted by a L-A-B approved provider (see website for approved providers www.l-a-b.com), must be approved by L-A-B before conducting the test to have the results accepted as proof of compliance with the requirement. See Policy 002 for details of the requirements. ***It is critical that you understand this requirement prior to the accreditation process.***

INTERNAL AUDITS & MANAGEMENT REVIEW

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories.

Prior to the initial assessment, the laboratory shall have completed at least one Internal Audit of its activities that covers its compliance with ISO/IEC 17025 and technical competence. The Laboratory must also complete a Management Review, by the highest level of laboratory management, which is compliant with the requirements of ISO/IEC 17025.



TRACEABILITY AND MEASUREMENT UNCERTAINTY POLICY

L-A-B Policy 001 - Traceability

L-A-B Policy 001.1 - Uncertainty of Measurement

L-A-B Form 001 - Traceability Tracking

The laboratory shall follow Policy 001 to prove their traceability. The Laboratory shall follow all applicable sections when demonstrating traceability of measurements through all steps of the calibration chain from NIST (or other national equivalents) down to their laboratory. Calibration and Measurement Capability shall be calculated in accordance with Policy 001.1. The laboratory is required to submit these to L-A-B for evaluation prior to the onsite assessment visit. Laboratory must complete L-A-B Form 001 Traceability Tracking to detail the traceability of calibrated items within the laboratory. ***It is critical that you understand this requirement prior to the accreditation process.***

PREPARING THE SCOPE OF ACCREDITATION

SOP 216 – Handling Scopes of Accreditation

*Forms 28.10 and Form 28.8 **Calibration Labs***

*Forms 28.9 and Form 28.6 **Testing Labs***

*Forms 28.11 and Form 28.5 **Dimensional Inspection Labs***

The laboratory shall follow L-A-B procedure SOP 216 when preparing their Proposed Scope(s) of Accreditation according to the type of laboratory. **Calibration Labs** use Forms 28.10, 28.8. **Testing Labs** use Forms 28.9, 28.6. **Dimensional Inspection Labs** use Forms 28.11, 28.5.

Calibration and Dimensional Inspection laboratories shall calculate and report their Calibration and Measurement Capability, as defined above.

REPORTING UNCERTAINTY

Policy 001.1 - Uncertainty of Measurement

Calibration Certificates, Dimensional Inspection Report

Calibration laboratories shall report their uncertainty of measurement on all calibration certificates, unless it can be proven that the client does not want it reported. Evidence that the client does not want the calibration uncertainty reported shall be available for an assessor to review at the time of an assessment. Regardless of whether the client wants the measurement uncertainty reported, the laboratory shall retain sufficient information to report the uncertainty.

Testing Laboratories

Laboratories shall perform and have available for the assessor a Needs Assessment, Procedure(s), and calculated uncertainties for those tests that require to have it reported. They shall also create uncertainty budgets and have these for the assessor to review during your assessment or surveillance visit. Please see details in Policy 001.1 —Uncertainty of Measurement.

ASSESSMENT PROCEDURE FLOWCHART

Form 11A - Initial Assessment & Reassessment Flow Chart

Form 11B - Accreditation through an Affiliate Flow Chart

Form 214 - Surveillance Assessment Flow Chart

The assessment flow is defined in Forms 11A, 11B, or 214 whichever applies to your laboratory. These flowcharts are available on the website www.l-a-b.com. Please make sure that you understand the policies and procedures prior to scheduling an onsite visit for assessment.



OPTIONAL PRE-ASSESSMENT

ISO/IEC 17025 - *General Requirements for the Competence of Testing and Calibration Laboratories.*
Form 48B - Quality System Review & Assessment Checklist
SOP 209.2 - Instruction Guidelines for the use of Form 48B

L-A-B recommends that a laboratory have a pre-assessment to evaluate its preparedness for the accreditation process. The assessor(s) spends one to two days at the laboratory facility evaluating the management system, and will point out areas that need improvement prior to the full assessment process. This is an opportunity to identify areas of weakness, and correct them before a full assessment is performed.

At the time of the pre-assessment visit, the quality management system will be assessed for implementation and compliance with ISO/IEC 17025 and L-A-B policies. In addition, with time permitting, a sampling of tests/calibrations may be monitored for competence and documented. The laboratory, prior to the full assessment visit, shall resolve any noted noncompliances. It should be understood that any areas of noncompliance found during the pre-assessment will receive a more thorough investigation in the full, on-site assessment. If clients desire, they may request and contract for a more lengthy pre-assessment.

ASSESSMENT

ISO/IEC 17025 - *General Requirements for the Competence of Testing and Calibration Laboratories.*
SOP 205 - Assessment Process Procedure
Form 48B - Quality System Review & Assessment Checklist
Policy 004 - Delays caused by the Application or Laboratory

During an assessment visit the L-A-B assessor(s) will evaluate the laboratory's quality system documentation and implementation. All items listed on the proposed scope of accreditation will be technically witnessed to determine the laboratory's compliance with ISO / IEC 17025 and L-A-B policies and procedures. L-A-B Form 48B must be completed by the laboratory, and submitted to L-A-B along with the required laboratory documentation stated on the documentation checklist. L-A-B must have all required documentation prior to scheduling an assessment visit (Policy 004). L-A-B shall review the documentation for compliance with ISO/IEC 17025, and resolve any issues prior to sending the Form 48B and supporting documents to the assessor for use during the assessment. All noted areas of weakness shall be addressed by the laboratory prior to the assessment visit.

REASSESSMENT AND SURVEILLANCE OF LABORATORIES

SOP 205 - Assessment Process Procedure
SOP 214 - Surveillance Procedure

The initial full assessment will be conducted IAW SOP 205. Surveillance visits are conducted annually, and shall be performed in accordance with SOP 214 following the Form 214 Surveillance Flow Chart. Every three years a complete full reassessment will be performed. Special surveillance visits may be scheduled more frequently should circumstances indicate that a laboratory might not be compliant with the requirements of the L-A-B program. Please make sure that you have reviewed and understand the procedures and policies prior to scheduling an onsite visit for assessment.

RELATIONSHIP BETWEEN L-A-B AND LABORATORY

The laboratory shall accommodate L-A-B during the accreditation process to assure that they are provided with the necessary materials, and appropriately arrange access to all areas of the laboratory necessary to assess the compliance of the laboratory. These accommodations extend to surveillance, reassessments and for purposes of resolving complaints against the laboratory.



An accredited laboratory shall:

- 1) At all times comply with the provisions of the accreditation program, as defined in the Accreditation Program Documentation.
- 2) Claim that it is accredited only for those services for which it has been granted accreditation and which are carried out in accordance with these conditions.
- 3) Pays fees assessed by L-A-B.
- 4) Not use its accreditation in a way that brings the accreditation body into disrepute, and not make any statement relevant to its accreditation that the accreditation body may consider misleading or unauthorized.
- 5) If the accreditation is suspended or withdrawn, the laboratory shall discontinue the use of all advertising materials that contain any reference to L-A-B.
- 6) Not use its laboratory accreditation to imply product approval by L-A-B.
- 7) Endeavor to ensure that no certificate or report, nor any part thereof is used in a misleading manner.
- 8) Make sure that its references to its accredited status comply with the requirements of L-A-B in all communication media such as advertising, brochures or other documents.

GRANTING OF DENYING ACCREDITATION

SOP 203 - Appeals, Complaints and Disputes

Upon the completion of the assessment, one or more members of the L-A-B Technical Staff or where necessary a technically competent individual determined appropriate by L-A-B Technical Staff, will review the accreditation documentation. The decision to accredit the laboratory will be made by L-A-B Technical Staff based on the laboratory's compliances with the specific and L-A-B requirements.

L-A-B will then send a Certification of Accreditation along with an approved Scope of Accreditation to laboratories that are granted accreditation and will be added to the directory of accredited laboratories on the L-A-B website.

If a laboratory is denied accreditation, L-A-B shall notify the laboratory of the decision and provide them with the reasons for denying accreditation. If the laboratory disagrees with the reasons given for denial, it may appeal to the Operations Office of L-A-B, who will initiate the Appeals Procedure as defined within SOP 203. Appeal actions must be initiated within 30 days of the notification to deny accreditation.

MAINTAINING ACCREDITATION

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories. Policy 004 - Delays Caused by Applicant and Client

Accreditation is maintained by surveillance assessments annually for two years. The third year a full ISO/IEC 17025 assessment is performed. Satisfactory participation in the appropriate proficiency testing and interlaboratory comparison programs, Per Policy 002, is required. L-A-B does not maintain laboratory quality documentation on file. Laboratories are required to submit specific quality documentation prior to each year's assessment.

Based on surveillance findings, it is possible that the results of a surveillance visit may warrant a full ISO/IEC 17025 assessment. If noncompliances are such that the assessor believes that a systemic problem exists, they may recommend that a full ISO/IEC 17025 assessment be performed. The L-A-B Technical Staff shall review the assessment findings, and determine if a full assessment may be necessary, and the timeframe in which the assessment shall be performed.

Laboratories must submit evidence to any noncompliances within 30 or 60 days of the closing of the assessment as determined by the assessor. Evidence must detail the action taken and its effectiveness. Failure to respond may result in suspension, per L-A-B Policy 004. The L-A-B Technical Staff also have



the option to require a follow-up assessment of any laboratory (new or renewal) before an affirmative accreditation decision can be rendered.

EXTENDING OR EXPANDING THE SCOPE OF ACCREDITATION

Form 19 - Client Change Notice

There are several circumstances that might require the extension of an accreditation. In each instance L-A-B Technical Staff shall review all available documentation, which includes but is not limited to proficiency testing results, complaint files, and previous assessments, to determine whether the laboratory's accreditation may be extended for a defined period of time.

If a laboratory wishes to expand its scope of accreditation to include additional tests or fields of testing, the laboratory shall submit, in writing by Form 19, a request for the proposed expansion. This shall include a copy of the Proposed Scope, test/calibration methods, and necessary uncertainty documentation that supports the expansion requested. L-A-B Technical Staff shall review the proposed expansion request and supporting documentation to determine what actions may be necessary to grant the expansion. The actions may include, but are not limited to, the following:

1. If the tests/calibrations are similar to the ones that the laboratory is currently accredited to perform, the submitted information shall be reviewed by the L-A-B Technical Staff. L-A-B Technical Staff may seek the assessor's recommendation. L-A-B shall decide whether the laboratory can be granted the expansion, or whether an additional visit is necessary.
2. If the laboratory has asked for an expansion into a completely new field of testing or calibration, or the test/calibration method is not similar to that for which the laboratory is currently accredited, an assessment visit shall be scheduled. The assessment visit shall be limited to the technical assessor(s) capable of assessing the testing/calibration under consideration. The assessment visit will normally include only those elements that are necessary to determine the laboratory's technical competence with regard to the proposed expansion. However, if the assessor(s), during the investigation for the expansion, uncover evidence that indicates a systemic problem may exist, they may choose to follow the thread until they are assured that a larger problem does or does not exist.

DECREASING THE SCOPE OF ACCREDITATION

When a laboratory loses key personnel without replacing them, loses the use of equipment necessary to perform an accredited test without replacing it, or any other change that may affect the capability of the laboratory, the laboratory shall notify L-A-B immediately by the Form 19. L-A-B will determine a course of action based on the circumstances. In all instances the test(s) in question shall be removed from the laboratory's scope of accreditation, until such time as the laboratory has proved its competence. The laboratory may wish to voluntarily decrease its scope and is free to do so at anytime by notifying L-A-B of the desired changes.

Other actions may be necessary if the laboratory wishes to have the removed test method added to their scope of accreditation at a later date. These actions may include reassessment, review of test methods and documentation, and/or review of personnel qualifications.

TRANSFER OF ACCREDITATION

Policy 016 - Transfer of Accreditation

L-A-B shall consider each transfer of an accreditation from one accreditation body to L-A-B. The decision to accept a transfer is based on the review of the previous accreditation body's report, and/or assessment visit, and the accreditation body's recognition status. This is based on the time until expiration of the current accreditation.



TERMINATION OR SUSPENSION OF ACCREDITATION

Policy 012 - Control and Use of Symbol

SOP 306 - Suspension and Termination Procedures

SOP 203 - Appeals, Complaints and Disputes

In the event that L-A-B proposes to withdraw or suspend accreditation, the laboratory shall be notified of the reasons for such actions. The laboratory shall be given the opportunity to provide evidence that the reasons for withdrawal or suspension are not warranted. The laboratory may appeal the decision to withdraw or suspend accreditation, following the Appeals Procedure SOP 203 and as defined in this manual. Appeal actions must be initiated within 30 days of the notification to withdraw or suspend accreditation.

When an accreditation is suspended, the laboratory must cease using the L-A-B Symbol on its test and calibration reports and certificates, and notify their clients of the loss of the accredited status. The laboratory shall cease using the L-A-B Symbol in any way. See Policy 012 - Control and Use of Symbol for details.

ACCREDITATION OF LABS THAT HAVE BEEN DENIED, SUSPENDED OR WITHDRAWN

A laboratory who has been denied accreditation or had its accreditation suspended or withdrawn may apply for and be granted accreditation if the following requirements are met:

1. The laboratory management system must be in full compliance with ISO/IEC 17025, and L-A-B requirements.
2. The laboratory can prove its technical competence in the tests or types of tests for which accreditation is sought.

DISPUTES AND APPEALS

SOP 203 - Appeals, Complaints and Disputes

A laboratory may appeal L-A-B's decision to not grant, suspend, or terminate accreditation. This appeal shall be sent to L-A-B, in writing, within 30 days of notification of the decision. The appeal shall state the reasons why the laboratory believes it should receive or retain its accreditation.

COMPLAINTS RECEIVED ABOUT ACCREDITED LABORATORIES

When a complaint is filed against an accredited laboratory, L-A-B Technical Staff shall determine if the complainant has contacted the laboratory to seek resolution. If resolution is not possible with the laboratory, L-A-B Technical Staff will initiate an investigation into the matter. If the investigation or any other matter indicates that a laboratory no longer complies with the requirements of this program, L-A-B shall initiate an immediate surveillance assessment.

NOTIFICATION OF CHANGES

Form 19 - Client Change Request

L-A-B shall be notified of any matters that may affect the laboratory's capability, scope of accredited activities, or compliance with the requirements for accreditation. The laboratory must document any changes on Form 19 - Client Change Request and submit to L-A-B.

The laboratory shall inform L-A-B Operations Office immediately of any changes in:

1. Legal, commercial or organizational status
 - a. If the legal status (e.g. ownership) of an accredited laboratory changes, the information on the changes that have taken place shall be forwarded to L-A-B for review. L-A-B Technical Staff shall determine what actions may be necessary to continue the accreditation. These actions may include, but are not limited to the following:



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- b. Review and approval of changes, with no surveillance.
 - i. The review indicates that the changes could have an effect on the testing or calibrations; therefore, a surveillance visit is necessary immediately.
 - ii. The review indicates that the changes can be covered at the next scheduled surveillance visit.
- 2. Organization and management (e.g. key managerial staff)
- 3. Policies or procedures that directly affect the validity of data
- 4. Physical location or premises
- 5. Key personnel, equipment, facilities, working environment or other resources that would impact the validity of data, or the laboratory's ability to perform accredited tests/calibrations
 - a. Key personnel are defined by L-A-B as the Quality Manager, Technical Manager, and anybody who is the only trained and authorized person to perform a particular scope item, method or uncertainty of measurement.

Upon receipt of the Form 19, notice of changes relating to the requirement of accreditation, L-A-B shall ensure that the laboratory carries out the necessary adjustment to its procedures within a reasonable amount of time. The laboratory shall inform L-A-B when adjustments have been made.

L-A-B may choose to assess the changes as follows:

- 1. Perform a surveillance visit
- 2. Make a brief visit to the laboratory to assess the impact of the change
- 3. Perform a full surveillance
- 4. Request further proof of compliance with requirements
- 5. Revise the Scope of Accreditation to reflect the lost of capability

The laboratory shall inform L-A-B of the actions that it has taken or will be taking to adjust its procedures, to ensure that the laboratory remains compliant with the requirements of accreditation.

L-A-B shall inform its accredited laboratories of changes to the requirements for accreditation such as:

- 1. Changes to the standards
- 2. Changes to L-A-B policies and procedures

L-A-B will inform the laboratory of the allotted time in which it must become compliant with the new requirements.

USE OF L-A-B Symbol

Policy 012 - Control and Use of Symbol

Accredited laboratories are granted the right to use the L-A-B Symbol on the test reports and certificates, and calibration certificates, for those tests and calibrations for which they have been accredited. Tests/Calibrations that are not accredited shall be identified as such when they appear in a report that has the L-A-B Symbol on it. See Policy 012 - Control and Use of Symbol for further guidance.

GUIDANCE

Guidance Document 002 - ISO/IEC 17025:2005 Laboratory Guidance Document

L-A-B offers a guidance document that may help explain the requirements of ISO/IEC 17025 item by item. Please make sure that you have reviewed and understand ALL procedures and policies prior to scheduling an onsite visit for assessment.

REVISION HISTORY

	Revision Date	Revised By	Brief Description of Revision
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CLIENT INSTRUCTION MANUAL

(Laboratory Accreditation Criteria)

Written by:
Doug Leonard

Revision - 11
Date: 05/07/10

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Original	3/10/00	Lynne Neumann	Original Issue
1	4/22/01	Lynne Neumann	Updated the transition from G25 to 17025 to reflect new ILAC policy. Added a Table of contents. Changed the phone number for NAPT. Updated PT policy to reflect current practice.
2	2/07/02	Lynne Neumann	Clarified difference between commercial proficiency testing and interlaboratory comparisons conducted by the laboratory. Added the policy on measurement uncertainty for testing. Clarified decision-making process, voluntary withdraw of portions of scope by the lab, and notifying lab clients when it loses its accredited status. Added application instructions and Fee Schedule. Update the proficiency testing to include current requirements.
3	5/31/02	Robert Levine	PT information.
4	3/27/03	Lynne Neumann	Updated notification of change process. Removed repetitive information, and strengthened the references to the appropriate documents. Removed references to Guide 25.
5	11/11/03	Lynne Neumann	Revised to indicate current practices and organization structure
6	02/15/06	Jason Stine	Updated references to current policies. Modified format.
7	08/08/06	Doug Leonard	Added specific details to the "ASSESSMENT" section on page 6. In the section "MAINTAINING ACCREDITATION" added reference to recently updated Policy 004 and that L-A-B does not maintain laboratory quality documentation on file. Added reference to L-A-B Form 001 and the responsibility in the traceability and measurement uncertainty section.
8	7/25/07	Jason Stine	Added reference to new Policy 012. Removed reference to 17025:1999. Removed reference to SOP 204.
9	05/29/08	Linda Mumma	Revised verbiage to conform with process of R20.4 Agreement being signed and returned when Accreditation is granted
10	7/1/08	Ryan Fischer	Revised the Client Instruction Manual to account for current practices and L-A-B's definition of Laboratory Key Personnel (pg.10).
11	05/07/2010	Randy Long	Revised the Client Instruction Manual to account for changes to Policy 001, the addition of Policy 001.1, and the change from BMC to CMC. Added subtitle Laboratory Accreditation Criteria

APPROVED: _____



DATE: 05/07/10