

## Form 11A

### Initial Assessment and Re-assessment Procedures Flow Chart

#### 1) Application & Quote Process

Request For Quote	Applicant sends completed ISO/IEC 17025 “Survey for Application for Accreditation Quote” Form 28, to L-A-B office in order to obtain a cost proposal.
Establish Accreditation Scope And Cost	L-A-B receives the Form 28 application; the responsible technical staff reviews all aspects of application, and prepares a quote worksheet that is sent to the Accounting Manager who prepares an Estimate and sends a copy to Operations.
Acceptance Of Proposal	To confirm acceptance of the estimate, the applicant submits to the L-A-B Accounting Office: <ul style="list-style-type: none"> <li>a. A signed Estimate, the application fee (initial only) and prep/reporting fee.</li> <li>b. A purchase order for total anticipated on-site assessment time, including pre-assessment, if applicable. Assessor expenses and travel time not included on proposed estimate are reimbursable at cost.</li> <li>c. A Copy of the signed Estimate will be forwarded to Operations to start Accreditation process.</li> </ul>

#### 2) Notifying the Assessor and Client of Pending Assessment

Notifying Lead Assessor And Assessment Team	Based on the proposed Scope of Accreditation, L-A-B will select a technically qualified lead assessor and any team assessors. The assessors' biographies are sent to the client and the client description is sent to the assessor(s) to confirm the absence of conflict of interest. The assessors are provided with an allocation report illustrating the man-days required and contact information for the client.
Notifying Client	The client is sent notification of pending assessment via a letter with the assessor biography. L-A-B will inform the client what documents are required prior to the onsite assessment.
Tentative Scheduling of The Assessment	The lead assessor shall tentatively schedule a mutually agreeable time for the assessment with the laboratory (and team members if applicable).

#### 3) Documentation Review

Client Submits required documentation.	The client shall complete the form 48B—Client-Assessor Checklist. The checklist and all supporting documentation referenced on the checklist shall be sent to the L-A-B Operations Office. The client shall send an organization chart, latest internal audit, management review, uncertainty budgets that support the best measurement capability reported on the proposed Scope of Accreditation, Form 28.12 PT/ILC Tracking, the proficiency test procedure, latest proficiency test or interlaboratory comparison (PT/ILC) results to the Operations Office.
L-A-B Operations Documentation Review	Operations shall review the scope, uncertainty budgets or appropriate testing uncertainty documentation, PT/ILC documentation, and the completeness of all other documentation. If Operations identifies any non-compliance, the client must be notified in writing and the non-conformance resolved prior to on site assessment.
Lead Assessor Documentation Review	The Lead Assessor performs the documentation review prior to the assessment visit. Lower level documentation and specific test methods may be requested for review as well. The lead assessor shall review all documentation submitted to them by L-A-B Operations prior to the assessment.
Pending Non-Compliance	If the Lead Assessor identifies any non-compliance, the client shall notified in writing and the non-conformance resolved prior to on site assessment. Submission of Corrective Actions in writing is necessary 30 days prior to scheduled assessment. Delays in response to noncompliances may result in a delay of the assessment visit.

#### 4) Optional Pre-Assessment

Optional Pre-Assessment	The goal for the Pre-Assessment is to ascertain the readiness of the laboratory for the initial accreditation process. A documentation review will be completed and corrective actions taken. A minimum of a one-day visit to the lab is required. Review and critique of uncertainty budgets and scope may also be undertaken if necessary. If needed, revisions in documentation are requested.
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#### 5) On-Site Accreditation Assessment

Team Meeting Prior To Assessment	Assessment team meets privately the night before or prior to the start of the assessment on the first day. The team shall discuss the approach and assignment for the assessment.
Assessment Opening Meeting	A formal opening meeting is held with the client. The meeting attendees should be the top management of the laboratory, and those persons who are directly responsible for the quality management system and technicians. The meeting minutes shall be kept on Form 205.2
Assessment	The assessment involves the examination of objective evidence of conformance to ISO/IEC 17025 and specific test method/calibration competencies. The assessment shall verify that the laboratory is competent to perform all the test/calibration technologies/parameters listed on the proposed Scope of Accreditation. The assessor shall complete a Form 48A and Gap analysis or Form 48B during the assessment.
Form 205.1 Competency Assessment	The assessor shall use Form 205.1 to verify the technical competence of the laboratory to perform all the technologies or parameters defined on their proposed Scope of Accreditation. Failure to perform the tests/calibrations competently or implement appropriate corrective action for failure to perform it correctly will result in the removal of the technology/parameter from the final Scope.
Final Day Team Meeting	Assessment team meets privately to discuss the findings. A final Form 48A and Gap analysis or Form 48B will be prepared and must include a statement of the laboratory's compliance with all elements of ISO/IEC 17025, including any observations or opportunities for improvement. Form 33 must be completed for any nonconformances.
Closing Meeting	A closing meeting will be completed IAW Form 14 which must include a summary of the assessment activities and assessor expenses. Assessment team presents the client with a copy of the Form 14, Form 48A and Gap analysis or Form 48B Checklist, and Form 33 noncompliance.

#### 6) Reporting and Corrective Action Procedures

Reporting	The Lead Assessor, with input from the other assessment team members, shall prepare an assessment report on Form 14. This report must include a summary of any nonconformances and any observations noted during the assessment. A copy of Form 14, Form 48A and Gap analysis or Form 48B, and Form 33 noncompliances shall be left with the client.
Corrective Action Plans And Evidence	The client has 30 or 60 days to respond with evidence of completed corrective action and submit them to the Operations Office of the L-A-B. The number or severity of the noncompliances may warrant a follow up assessment to verify the effectiveness of the corrective action. Unless the lead assessor specifies an on-site follow-up, the effective implementations of the approved corrective actions are confirmed at the first Surveillance Assessment. If a follow-up corrective action assessment is needed, an approximate schedule is defined.
Follow-Up Assessment	If required, one or more members of the assessment team shall conduct a Follow-up Assessment. This assessment will focus on evaluating the client's implementation of the corrective actions defined in their report.
Decision On Accreditation By L-A-B	After receipt of the Technical Package the appropriate qualified staff member performs a technical review. If the package is complete it will continue through the approval process. If the package is incomplete, L-A-B staff will contact the appropriate people and gather the necessary information to complete the process.
Appeals	If the client disagrees with the reported noncompliances from the lead assessor or decisions of the reviewers, or with the decision to withhold or withdraw accreditation, the client has the option to register a complaint or enter a formal appeal IAW SOP 203.
Certificate Issuance	After meeting all accreditation requirements, and paying all outstanding fees, the laboratory is issued an accreditation certificate and scope of accreditation and added to the Directory of Accredited Laboratories published at <a href="http://www.l-a-b.com">www.l-a-b.com</a>

#### 7) Maintaining Accreditation

Annual Surveillance/ Conformance Monitoring	An on-site surveillance assessment is conducted each year during the three-year accreditation period. The Surveillance Assessor(s) verifies continued conformance to requirements through review IAW SOP 214
Fees	The accredited laboratory must maintain all fees, and other obligations of the accreditation process as defined in the requirements and contract.
Renewal Assessment	A full system renewal assessment is required at the end of three years. L-A-B reviews the renewal assessment reports and must approve each renewal.