

## Form 214 Surveillance Flow Chart

### 1) Quote Process and Required Documentation

Assessment due	Four months prior to the due date, L-a-b informs the accredited laboratory that a surveillance visit is due. The notice will include a quote for the surveillance process.
Required Documentation and Scope Review	A Form 214.4 Documentation checklist will be sent to the laboratory stating the required documentation necessary for the upcoming assessment. The accredited laboratory reviews their Scope of Accreditation to determine whether it remains appropriate. The laboratory makes required changes to Scope, and where necessary calculates the Best Measurement Capability (BMC) for the additions to the Scope and provides an estimation of uncertainty. All required documentation and the revised scope or acknowledgement that it will remain the same shall be sent to L-A-B within thirty days of receipt of the notification.

### 2) Notifying the Assessor of Pending Assessment

Assignment Of Lead Assessor And Assessment Team	Based on the Proposed Scope of Accreditation of the client, L-A-B Technical Staff reviews the required man-days and qualifications of available L-A-B qualified assessors, determines the most appropriate lead assessor and any team assessors. If the assessor(s) is different from the previous assessment the biographies are sent to client and client description to assessor, to confirm the absence of conflict of interest. The lead assessor is provided with the laboratories proposed Scope of accreditation and allocation that includes the estimated number of man-days.
Scheduling The Assessment	The lead assessor shall tentatively schedule a mutually agreeable time for the assessment. The visit shall be within thirty days on either side of the assessment anniversary date.

### 3) Documentation Review

Client Submits the appropriate Documentation	The client must submit Form 214.4 Documentation Checklist which states the required documentation including an organization chart, latest internal audit, management review, Form 28.12 PT/ILC Tracking, proficiency test results, and uncertainty budgets that support the BMC reported. The client shall highlight any changes in their system on Form 48B—Quality System Review & Assessment Checklist. This form is not used to document the surveillance, but only as a reference of items that have changed in the past year. This checklist and all changed documentation referenced on the checklist shall be sent to L-A-B Operations Office.
L-A-B Operations Documentation Review	L-A-B performs a review of the Proposed Scope of Accreditation and associated uncertainty budgets, and the Proficiency Testing/Interlaboratory Comparisons. The documentation is checked to assure that all documents necessary to perform the assessment are present, before sending the package to the assessor.
Lead Assessor Documentation Review	The assessor will review the documentation to assure that changes in the documentation have not affected the laboratory's compliance with 17025. Lower level documentation and specific test methods may be requested for review as well.

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### 5) On-Site Surveillance Assessment

Team Meeting Prior To Surveillance	Assessment team meets privately the night before or prior to the start of the assessment on the first day. At this time the team shall discuss the approach and assignment for the assessment.
Opening Meeting	A formal opening meeting is held with 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 occurs involving the examination of objective evidence of conformance to ISO/IEC 17025 and specific test method/calibration competencies. The assessment shall be performed in accordance with SOP 214.
Final Day Team Meeting	Assessment team meets privately to discuss the findings. A final Form 214.2 or 214.3 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 214.2 or 214.3 Checklist, and Form 33 noncompliances.

### 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 214.2 or 214.3 Checklist, 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 and implemented corrective action. The severity of the noncompliances may warrant a follow up assessment to verify the effectiveness of the corrective action. Unless the lead assessor specifies that on-site follow-up verification is required, effective implementation of the approved corrective actions will be confirmed at the next visit. If a follow-up corrective action assessment is needed, an approximate schedule is defined. The client provides corrective action and evidence of implementation to the L-A-B Operation Office for review and acceptance.
Follow-Up Assessment	If required a member 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 Continued Accreditation By L-A-B	After the recommendation is received from the Lead Assessor, L-A-B Technical Staff reviews the report. If the reviewer is satisfied that requirements are met they may grant accreditation, in some circumstances were further technical expertise is needed or a scope has been revised it may be necessary for one or more qualified reviewers to assess the documentation or portions thereof for approval. The reviewer(s) may confirm approval or identify noncompliances that must be resolved prior to approval. The Lead Assessor or client is responsible for providing more information and/or performing necessary follow-up. After confirmation of acceptance by the reviewer(s), L-A-B formalizes the decision to continue the accreditation and communicates the results to client.
Appeals	If the client disagrees with the reported noncompliances from the lead assessor or decisions of the reviewers, or with the decision to suspend or withdraw accreditation, the client has the option to register a complaint or enter a formal appeal IAW SOP 203.