


Standard Operating Procedure

 LABORATORY ACCREDITATION BUREAU	Subject: Scope Modification	SOP 215
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POLICY/POLICY REFERENCE

ISO/IEC Guide 17011
L-A-B Quality Manual System

PURPOSE AND SCOPE

This procedure defines the method for modification of accredited scopes.

RESPONSIBILITY

The Managing Director, having overall responsibility for the program and operations of L-A-B, with the appropriate Manager, is jointly responsible for the conduct of assessment activities resulting in granting L-A-B accreditation.

ACTION/METHOD TO ACHIEVE THIS SYSTEM REQUIREMENT

Introduction:

From time to time, accredited laboratories will wish to have their scope of accreditation modified. Such modification may be a simple administrative process or may require additional assessment visitation.


It is also imperative that at the time of assignment of assessors for surveillance or re-assessment visits, that the scope be known to L-A-B. This will help to assure that only a qualified assessor is assigned to conduct the assessment.

Pre-Surveillance date:

The client and assessor are notified of the need to schedule a surveillance visit by receipt of a letter from L-A-B. This letter is sent approximately three months prior to the anniversary date of the last visit to the facility.

To be sure that the potential assessor assigned to the surveillance visit has all of the necessary technical qualifications for the scope under which the accreditation is to be maintained, a request will be made of the client to send a copy of their previously issued L-A-B scope. The client will have to indicate if there are any changes to the scope being requested or in the case of no change, a statement to that effect. This request will be made approximately four months prior to the next scheduled surveillance or re-assessment visit.

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Request by laboratory for interim change in scope

Accredited laboratories do not have to wait until the next scheduled visit to request changes in their scope of accreditation.

The laboratory should mark up a copy of their present scope showing the changes they wish to have made and send that to the L-A-B Operations office. L-A-B will make the determination if this may be handled administratively or if additional visitation will be required.

When the changes may be administratively handled, the scope will be modified and issued to the client.

If additional oversight is needed, L-A-B will issue an estimate to the client for the visit and scope change. At this point, the client will be able to determine if they wish to wait until the next surveillance visit or arrange for the additional oversight in the interim, based on the estimate provided.

Summary:

It is imperative that L-A-B know the scope of accreditation being requested by the accredited laboratory at all times. When changes are to be requested between scheduled visits, L-A-B will determine what is necessary to accomplish this change.

Clients must make it known before hand that they will be requesting a scope modification during the next surveillance visit. With this information, L-A-B then assigns an appropriate assessor with the required technical expertise considering the anticipated scope of accreditation.

REVISION HISTORY

Revision Level	Revision Date	Revised By	Brief Description of Revision
Original Issue	01-24-02	Robert Levine	Original Issue
Rev. 1	01/08/04	Lynne Neumann	Revised to reflect current business structure.
Rev. 2	10/22/05	Linda Mumma	Revised to ISO/IEC 17011 References
Rev 3	06/11/08	Linda Mumma	Updated to reflect current Operations staff titles and positions

APPROVED



DATE: 06/11/08