

ASCLD/LAB-*International*

Program Overview

2010 Edition

An ISO/IEC 17025 Program of Accreditation

Applicable to both testing and breath alcohol calibration laboratories

ASCLD/LAB-*International* is a program of the
American Society of Crime Laboratory Directors / Laboratory Accreditation Board
ASCLD/LAB

Copyright © 2010 by ASCLD/LAB

Approval Date: May 13, 2012

Approved By: Executive Director

Effective Date: May 13, 2012

ASCLD/LAB Document Control Number: AL-PD-3041-Ver 2.1

Document History / AL-PD-3041

Date	Version	Description of Activity or Revision	Approved By	Effective Date
September 10, 2010	1.0	Initial review and adoption by the ASCLD/LAB Board of Directors	Board of Directors	October 1, 2010
N/A	1.1	Minor administrative changes.	Board of Directors	N/A
November 22, 2011	2.0	Conformance File – Modified to refer users to the current policies in effect Assessment Process Timeline changed Section 5.1 – Revised the Frequency of Surveillance Visits Changed the terminology of "International Program Manager" to "Accreditation Program Manager"	Executive Director	November 22, 2011
May 13, 2012	2.1	Clarify Extension of Scope of Accreditation process; update the internal process for reviewing Surveillance Reports	Executive Director	May 13, 2012

© Copyright ASCLD/LAB 2010

All intellectual property rights in this publication are the property of the

American Society of Crime Laboratory Directors / Laboratory Accreditation Board (ASCLD/LAB)

ASCLD/LAB
 139 J Technology Drive
 Garner, North Carolina 27529
 USA
 919-773-2600
www.asclld-lab.org

PART 1 - INTRODUCTION

The ASCLD/LAB-*International* accreditation programs of the American Society of Crime Laboratory Directors / Laboratory Accreditation Board (ASCLD/LAB) are programs of accreditation in which any crime laboratory or forensic science breath alcohol calibration program providing covered services may participate to demonstrate that its technical operations and overall management system meet ISO/IEC17025:2005 requirements and applicable ASCLD/LAB-*International* supplemental requirements.¹

Accreditation is part of a laboratory's quality management program which should also include proficiency testing, continuing education, customer liaison, and other programs to help the laboratory provide more effective overall service.

Operating policies of the accreditation programs are approved by the ASCLD/LAB Board of Directors (hereafter Board) or the ASCLD/LAB Executive Director. The Board is elected by and responsible to the ASCLD/LAB Delegate Assembly. The Delegate Assembly is composed of the directors² of all laboratories and laboratory systems accredited by ASCLD/LAB, Inc.

The ASCLD/LAB Bylaws govern the authority and responsibilities of the Board, the Delegate Assembly and ASCLD/LAB, Inc. The most current version of the ASCLD/LAB Bylaws is available at www.ascl-d-lab.org.

OBJECTIVES

ASCLD/LAB has adopted four objectives which define the purposes and nature of its accreditation programs:

- To improve the quality of laboratory services provided to the criminal justice system.
- To adopt, develop and maintain standards which may be used by a laboratory³ to assess its level of performance and to strengthen its operation.
- To provide an independent, impartial, and objective system by which laboratories may benefit from a total operational review.
- To offer to the general public and to users of laboratory services a means of identifying those laboratories which have demonstrated conformance with established standards.

¹ - In developing the ASCLD/LAB-*International* Supplemental Requirements for forensic science testing laboratories, ASCLD/LAB has considered and included appropriate language from *Guide 19 (2002)*, as published by the *International Laboratory Accreditation Cooperation (ILAC)*.

² - The laboratory director or laboratory system director may designate an alternate to serve as the delegate assembly member by submitting a written notification to the ASCLD/LAB Executive Director.

³ - The term "laboratory" throughout this document includes stand-alone forensic units (e.g. crime scene units, fingerprint units, etc.) and forensic science breath alcohol calibration operations.

ACCREDITATION REQUIREMENTS

Any laboratory seeking ASCLD/LAB-*International* accreditation must demonstrate conformance to the applicable requirements in ISO/IEC 17025:2005 - *General requirements for the competence of testing and calibration laboratories*, the applicable ASCLD/LAB-*International* supplemental requirements, and the laboratory's own documented management system.

There are two ASCLD/LAB-*International* accreditation programs, each with a separate set of supplemental requirements. Depending on the services provided to customers, a laboratory may apply for accreditation in either one or both of the ASCLD/LAB-*International* accreditation programs:

- ASCLD/LAB-*International* Accreditation for Forensic Science Testing Laboratories
- ASCLD/LAB-*International* Accreditation for Forensic Science Breath Alcohol Calibration Laboratories

Conforming to the numbered requirements in ISO/IEC 17025:2005 and the respective set(s) of supplemental requirements is mandatory to achieve and/or retain accreditation, unless a requirement does not apply to the work conducted in the laboratory. In such cases, the requirement will be regarded by ASCLD/LAB as "*not applicable*."

"Notes" in each requirements document are intended to provide clarification or examples and do not constitute additional accreditation requirements.

To achieve accreditation, conformance with each applicable requirement must be demonstrated to the satisfaction of the assigned Lead Assessor prior to a vote to accredit by the ASCLD/LAB Board.⁴

Additionally, where applicable⁵, laboratories performing DNA analysis will be assessed in accordance with the requirements of the most current version of the *Quality Assurance Standards for Forensic DNA Testing Laboratories* and the *Quality Assurance Standards for DNA Databasing Laboratories*.⁶ In most cases, a nonconformance in the DNA discipline against one of these standards will be correlated to an ASCLD/LAB-*International* accreditation requirement. As applicable, any required corrective action will be tracked against the corresponding ASCLD/LAB-*International* requirement.

ASCLD/LAB's responsibility for the separate DNA audit ends when the completed audit document is provided to the laboratory, except that in the case of private and international laboratories ASCLD/LAB may choose to monitor all corrective actions and may consider the status of all corrective actions prior to accreditation.

⁴ - See *Results of Assessment* section in this document for an explanation of grading non-conformities

⁵ - Laboratories performing non-human DNA testing, or laboratories not subject to the US federal DNA regulations and standards, will have the option of being assessed against the *Quality Assurance Standards for Forensic DNA Testing Laboratories* and the *Quality Assurance Standards for DNA Databasing Laboratories*, but such an assessment is not required to achieve accreditation.

⁶ - A separate audit document will be provided to the laboratory.

ASCLD/LAB-*International* SCOPE OF ACCREDITATION

ASCLD/LAB-*International* accredits in the broad field of forensic science. A laboratory may apply for accreditation in either "forensic science - testing" or "forensic science - calibration" or both.

Within each field, ASCLD/LAB-*International* offers accreditation in the following disciplines:

Forensic Science - Testing

Drug Chemistry
Toxicology
Trace Evidence
Biology
Firearms/Toolmarks
Questioned Documents
Latent Prints
Crime Scene
Digital & Multimedia Evidence

Forensic Science - Calibration

Toxicology – Breath Alcohol Measuring Instruments Breath Alcohol Reference Materials
--

Accreditation in additional disciplines may be offered by ASCLD/LAB in the future, but only after an extension of scope process is completed in accordance with ASCLD/LAB Bylaws and operating procedures.

The ASCLD/LAB-*International* accreditation program considers the conformance, competence and effectiveness of the overall management system in granting accreditation. For that reason, a testing laboratory must apply for accreditation in all testing disciplines in which ASCLD/LAB provides accreditation and the laboratory provides services, except crime scene. Crime Scene is the only testing discipline for which a laboratory has the option to not apply for accreditation.

Note: See the **ACCREDITATION MANDATED BY LEGISLATION** section found later in this document.

Accreditation as a breath alcohol calibration laboratory is also optional.

LABORATORY SCOPE OF ACCREDITATION

Within each discipline, the laboratory will identify a complete listing of the categories of testing or calibration in which work is conducted in the laboratory. During the assessment process, the assigned Lead Assessor will work with the laboratory to ensure that the lists of disciplines and categories are accurate and complete.

ASCLD/LAB-*International* Scope of Accreditation documents will specify the field(s), discipline(s), and any categories of testing or category of calibration for which accreditation is granted.

After accreditation is granted, a laboratory may elect, at any time, to begin performing work in a non-accredited discipline or category but may not, in any way (including testimony), state, infer or imply ASCLD/LAB-*International* accreditation in that discipline or category. Any discipline or category added after accreditation, for which ASCLD/LAB offers accreditation, must be included in the laboratory's next application to renew accreditation, except that the Crime Scene testing discipline and Forensic Science Calibration will remain optional. Alternatively, a laboratory may submit an application to seek an extension of scope of accreditation in a new discipline(s) or category at any time during the five year cycle of accreditation.

ACCREDITATION MANDATED BY LEGISLATION

Laboratories providing services in more than one discipline for which ASCLD/LAB offers accreditation may apply for and obtain ASCLD/LAB-*International* accreditation in a single discipline when accreditation in that discipline is mandated by legislation – and when the laboratory is seeking accreditation for the first time. Accreditation granted in a single discipline for this purpose will be granted for a two-year period, during which time the laboratory must apply for ASCLD/LAB-*International* accreditation in all disciplines in which it provides services.⁷ At the discretion of ASCLD/LAB, an annual on-site surveillance visit may or may not be a part of this two-year accreditation, although all other conformance monitoring requirements apply.

ACCREDITATION PRIOR TO PROVIDING SERVICES IN CRIMINAL CASES

For laboratories required to achieve accreditation prior to providing services in criminal cases, ASCLD/LAB offers a one-year ASCLD/LAB-*International* accreditation cycle. The one-year program will allow a laboratory wishing to provide services in criminal cases the opportunity to demonstrate its capability to satisfy ASCLD/LAB-*International* requirements for accreditation through the processing of mock criminal evidence in lieu of actual evidence collected in criminal investigations.

The only difference in the accreditation process and the on-site assessment under the one-year program is the use of mock or simulated evidence, instead of actual evidence. To achieve the one-year accreditation, a prospective one-year applicant laboratory shall comply with all requirements which apply to all ASCLD/LAB-*International* accredited laboratories.

Under the one-year accreditation program, the applicant laboratory must arrange for and obtain sufficient mock criminal casework from an external source. The mock criminal casework must realistically simulate actual evidence normally processed by the laboratory and must include casework examinations in all disciplines and categories for which accreditation is sought. Analysts (however named) that will be performing casework in the laboratory must complete a minimum of five (5) simulated cases in each of their respective disciplines. The completed mock cases will be reviewed during the initial assessment of the new laboratory.

⁷ Accreditation in the Crime Scene and Breath Alcohol Calibration disciplines remain optional.

Within nine months of the date that a one-year accreditation is granted the laboratory must submit an application for a full-term accreditation assessment. A one-year accreditation may be granted only once to a laboratory. No extensions to the one-year accreditation period may be granted until an on-site assessment has been conducted, during which the laboratory's processing of actual criminal evidence is assessed.

PART 2 – PREPARING FOR THE ASSESSMENT

SELF-EVALUATION PRIOR TO APPLICATION

A required part of the laboratory's preparation for an assessment is the determination and documentation by the laboratory that it meets all applicable accreditation requirements. To make this determination, ASCLD/LAB requires several actions prior to application for accreditation.

To begin preparing for ASCLD/LAB-*International* accreditation, the laboratory must first obtain a licensed copy of ISO/IEC 17025:2005. ASCLD/LAB does not distribute copyrighted ISO documents, so each laboratory must obtain ISO/IEC 17025:2005 from an authorized source. Within the United States, ISO standards may be easily purchased from the American National Standards Institute (ANSI – www.ansi.org). Laboratories operating in other economies should check with the national standards-setting body of their country or region. Other authorized distributors of ISO documents may also be found by searching the internet.

Once a laboratory is in possession of a licensed copy of ISO/IEC 17025:2005, the laboratory must submit to ASCLD/LAB a *User License Agreement* to obtain a copy of the applicable ASCLD/LAB-*International* supplemental requirements and corresponding program documents. The laboratory must also certify to ASCLD/LAB the acquisition of the licensed edition of ISO/IEC 17025:2005 by submitting an *ISO/IEC Certification* statement. The license agreement for the ASCLD/LAB-*International* documents and the *ISO/IEC 17025 Certification* statement may be downloaded at www.ascl-d-lab.org.

After a properly completed license agreement and certification statement are on file at ASCLD/LAB, the laboratory will be provided with an electronic copy of the current version of the applicable *ASCLD/LAB-International* supplemental requirements document(s), the corresponding *ASCLD-LAB-International Field Assessment Guide(s)*, and the corresponding *ASCLD/LAB-International Conformance File(s)*. The applicable *ASCLD/LAB-International Field Assessment Guide* must be completed through self-evaluation prior to application, **but is not submitted with the application**. Following self-evaluation, and prior to making application for accreditation, the laboratory should implement appropriate corrective actions to address any nonconformance identified during the self-evaluation.

A laboratory may also choose not to seek accreditation after obtaining the program documents. Directors may elect to evaluate their own laboratory for the purpose of self-improvement without seeking accreditation.

FORMAL APPLICATION

Formal application for accreditation is made by submitting the *ASCLD/LAB-International Application for Accreditation*,⁸ along with all attachments and supporting documents as specified on the application form. An appropriate application fee must be submitted with the application.

The application must be submitted in English in an organized electronic format using software approved by the ASCLD/LAB office or in a ring binder with tabs marking each of the required documents.

When a laboratory system consisting of two or more laboratories elects to apply for accreditation, a separate application must be submitted for each laboratory. Required application attachments which are common to all laboratories within a system need not be duplicated for each laboratory within the system.

CONFORMANCE FILE

In preparing for the on-site assessment, the laboratory must create and submit a *Conformance File*, using a formatted, electronic document provided by ASCLD/LAB. The conformance file includes all applicable documentation of conformance with each requirement and identifies the source or location of applicable laboratory policies, procedures or other objective evidence that reflect conformance.

Applicant laboratories should clearly understand that a hard copy conformance file requires much more time to review and will extend the assessment process and delay the on-site assessment. Any laboratory unable to submit a formatted, electronic, appropriately hyperlinked Conformance File should contact ASCLD/LAB before making application to discuss this issue.

While not required to be submitted with the application, an electronic version of a conformance file submitted with the application tends to accelerate the accreditation process. In any case, the conformance file must be completed and provided to the Lead Assessor before a document review can be conducted. A document review based on the Conformance File is a required part of the assessment process.

Any laboratory preparing for ASCLD/LAB-*International* accreditation, in either program, should be in possession of the applicable and most current version of the following program documents:

- ISO/IEC 17025:2005 (from an authorized distributor)
- ASCLD/LAB-*International* Program Overview
- ASCLD/LAB-*International* Supplemental Requirements (for applicable program)
- ASCLD/LAB-*International* Field Assessment Guide (for applicable program)
- ASCLD/LAB-*International* Conformance File (for applicable program)
- ASCLD/LAB-*International* Application for Accreditation (with 4 attachments)
- ASCLD/LAB Statement of Qualifications
- ASCLD/LAB Policy on Measurement Uncertainty
- ASCLD/LAB Policy Traceability of Measurement Results, Reference Standards and Reference Materials
- ASCLD/LAB Proficiency Testing and Review Program

⁸ - Application documents for ASCLD/LAB-*International* accreditation are available at www.asclcd-lab.org

In addition, the laboratory should visit and become familiar with all information available at the ASCLD/LAB website (www.asclcd-lab.org), including any current interpretations and applications of accreditation requirements. General questions about preparing for ASCLD/LAB-*International* accreditation may be directed to 919-773-2600, or to the email address of any staff member listed on the ASCLD/LAB website.

PART 3 - THE ASSESSMENT PROCESS

SELECTION AND APPOINTMENT OF LEAD ASSESSOR

Upon receipt of an application for ASCLD/LAB-*International* accreditation, ASCLD/LAB will select an appropriate Lead Assessor. The applicant laboratory will be notified of the selection and provided the opportunity to accept the selection or to raise any conflict of interest or other justifiable concern. Once the Lead Assessor has been accepted by the laboratory, ASCLD/LAB will provide a written communication to the laboratory formally appointing the Lead Assessor. ASCLD/LAB reserves the right to assign the Lead Assessor, but feedback from the laboratory will be given due consideration.

REVIEW OF THE APPLICATION

Upon receipt by ASCLD/LAB, an application for accreditation will be assigned to a Lead Assessor for review to verify that all required documents and records are included and properly completed. Proper completion and submission of records and documents will be required before the process proceeds further.

Once the application has been formally accepted by the Lead Assessor as complete, the initial document review phase will commence. **The scheduling of the full, on-site visit will not be confirmed until the document review phase of the assessment process is complete.**

DOCUMENT REVIEW and OPTIONAL PRE-ASSESSMENT VISIT

The assigned Lead Assessor will complete an initial document review of the laboratory's management system (using the Conformance File and related documents supplied by the laboratory) for the purpose of determining, to the extent possible, a laboratory's conformance with numerous accreditation requirements for policies, procedures, manuals, programs, etc. Once the initial document review is complete, the Lead Assessor will inform the laboratory of any "*gaps*" identified during the document review. A *gap* means that it is not clear how the laboratory conforms to an accreditation requirement, or it may indicate the absence of one or more required documents, which the laboratory must have in place to conform to specific accreditation requirements.

In every case, the laboratory will be informed of any *gaps* identified as a result of the initial document review. In some cases, an email, telephone call, or short written statement will be sufficient to clearly communicate any *gap* concerns. However, depending on the number or complexity of the *gaps* identified, the applicant laboratory may find it beneficial to have the Lead Assessor conduct a short (typically one-day or less) pre-assessment visit to the laboratory. **Such pre-assessment visits are optional and are not required to achieve accreditation.**

If there are no or very few *gaps* identified during document review, a pre-assessment visit would likely not be worthwhile. In many cases questions from the laboratory may be easily clarified via telephone or email communications. If any *gaps* are noted during the document review, the Lead Assessor will inquire about the laboratory's desire for a pre-assessment visit, but **the decision to schedule a pre-assessment visit rests solely with the applicant laboratory**. The decision to schedule a pre-assessment visit should not be made until the Lead Assessor has informed the laboratory of the results of the initial document review.

An applicant laboratory requesting a pre-assessment visit should clearly understand the limitations of the visit. The purpose of the pre-assessment visit is to review and discuss, in a face-to-face meeting, any *gaps* identified by the Lead Assessor as a result of the initial document review. ASCLD/LAB strictly prohibits assessors, or any representative of the accreditation program, from consulting with an applicant laboratory or an accredited laboratory. Advising a laboratory concerning corrective actions which may be taken is a form of consultation and is prohibited. Laboratory representatives should neither request nor expect a Lead Assessor to suggest corrective actions during a pre-assessment visit. The laboratory representative may propose a corrective action and the Lead Assessor may then discuss the appropriateness or sufficiency of the proposed action. General questions about the remaining assessment or accreditation process may also be addressed during a pre-assessment visit.

Another form of consultation is conducting an on-site pre-audit of a laboratory. A pre-audit is defined as conducting a general, on-site visit of the laboratory to determine conformance with accreditation requirements. Representatives of the ASCLD/LAB accreditation program are strictly prohibited from conducting an on-site pre-audit during a pre-assessment visit. Again, the only purpose of a pre-assessment visit is to review and clarify, in a face-to-face meeting, any *gaps* identified by the Lead Assessor as a result of the initial document review.

Excessive issues or concerns arising from an initial document review, or a failure to address the "gaps" identified within a reasonable period of time, could lead to a recommendation from the Lead Assessor to suspend the assessment process until the "gaps" are appropriately addressed.

SCHEDULING OF THE ON-SITE FULL ASSESSMENT

Once the document review phase is complete, the Lead Assessor will coordinate with the applicant laboratory director (or designated point of contact) to set an on-site assessment date that is satisfactory to the applicant laboratory and to ASCLD/LAB. **The on-site assessment date will not be confirmed until the document review process is complete and, in most cases, a confirmation has been received by the Lead Assessor from the laboratory that substantive gap analysis topics have been addressed.**

APPOINTMENT OF THE ASSESSMENT TEAM

The Lead Assessor, in conjunction with an ASCLD/LAB Accreditation Program Manager, will determine the number of technical assessors and the number of days required to conduct the on-site assessment. The assessment team will consist of two or more assessors, one of them being the Lead Assessor. Assessors will be selected from the pool of ASCLD/LAB-*International* qualified/certified assessors.⁹

⁹ - ASCLD/LAB also reserves the right to utilize Discipline or Technical Experts as required.

The assessment team will include technical assessors knowledgeable in the types of work performed by the laboratory. Prior to an assessor participating in any aspect of the assessment (including document review), the Lead Assessor will provide the applicant laboratory an opportunity to review the list of selected assessors for the purpose of identifying any potential conflict of interest or other justifiable concern. However, the final decision for the selection and appointment of all team members remains with ASCLD/LAB.

The primary function of the assessment team is to fairly and objectively evaluate the laboratory's conformance, competence, and effectiveness related to all accreditation requirements which apply to the applicant laboratory. The Lead Assessor will determine assessment conclusions based upon input from the technical assessors and the laboratory being assessed.

The applicant laboratory, upon notification by the Lead Assessor, must provide copies of appropriate management system documents to each member of the assessment team at least thirty (30) days prior to the on-site assessment. Documents may be provided to the assessment team in electronic format rather than as hard copies. The opportunity to review management system documents in advance of the on-site assessment is critical to the assessment process.

LOGISTICS OF ON-SITE ASSESSMENT

Once a date has been established for the on-site visit, a laboratory representative will make reservations for the assessment team members at a convenient hotel and arrange for all transportation to and from the airport and to and from the laboratory. A laboratory system must provide all in-state transportation for the assessment team so that maximum cost savings may be realized for both ASCLD/LAB and the system. Except for in-state transportation in a laboratory system, the applicant laboratory will not directly pay any of the assessment team's expenses for air travel, hotel, or meals. These expenses are included in the assessment fee.

A conference room or other suitable and adequate meeting space for use by the assessment team must be provided. The laboratory staff will be advised that the assessment team will need various documents and records, including analysts' notes and other information. Any other special needs of the assessment team will be made known prior to the visit.

OPENING MEETINGS

When appropriate or when requested by the laboratory director, an appointment may be made by the applicant laboratory director (or point of contact) for a private meeting between the assessment team and the administrator such as a sheriff or chief of police, who is in line of command over the laboratory. The purpose of this meeting is to elicit the administrator's opinion of the services of the laboratory. This meeting need not be lengthy.

In addition, the assessment team is required to also meet with the laboratory director (or point of contact) and others designated by the laboratory director to complete a final review of the on-site assessment plan and to provide an overview of the on-site assessment process. Any questions about what is to occur during the on-site assessment should be resolved at this meeting.

The applicant laboratory director (or point of contact) should take the assessment team on a brief tour of the laboratory in order to familiarize the assessors with the facility and to introduce them to the staff.

ON-SITE ASSESSMENT

Following the opening meeting and tour, the assessment team will conduct the rest of the assessment on its own and will arrange meetings with the laboratory director (or point of contact) at scheduled times during and at the conclusion of the assessment.

Employees of the laboratory will be interviewed by an assessor during the assessment process. While the goal of the assessment team will be to interview all employees who contribute to the quality of the laboratory's work, the Lead Assessor may conclude the assessment without the team having interviewed all employees. Interviews may take place in a variety of forms, including questions posed while witnessing a laboratory employee performing authorized job functions.

A number of records and documents must be reviewed by the assessment team. Any records and documents requested by the assessment team in advance should be available in the team's designated meeting space if possible. Additional records and documents may be requested by the team during the on-site assessment.

An important phase of the on-site assessment is the determination that laboratory reports¹⁰ are supported by adequate technical and examination records as well as by appropriate examinations. This is accomplished by reviewing a sample of case records, including all notes and data generated by the analyst (however named). For this reason, an important part of the assessment process will consist of reviewing a sample of case records for each analyst. While the goal of the assessment team will be to review a sample of each analyst's work, the Lead Assessor may conclude the assessment without the team having reviewed casework from all employees.

For each discipline in which the laboratory is seeking accreditation, the assessment team will completely review the records for at least one case from the time of receipt by the laboratory to completion by the laboratory. This process is referred to as following an "audit trail." The review will consider how the overall management system policies and procedures of the laboratory have been applied and adhered to. For example, in addition to the quality and documentation of testing and/or calibrations, the audit trail will consider, as applicable, evidence integrity, quality of reagents used, maintenance and calibration of the specific instruments used, etc.

Each analyst should have examination records at hand to support the findings in the case record. The assessors will interview trainees to evaluate the training program, and will also interview support personnel to evaluate the support capabilities of the laboratory. Some laboratory personnel will be asked to demonstrate specific testing or calibration activities which they are authorized to perform.

Testing operations within a laboratory that generate data input, store and/or compare information for individual characteristic databases (e.g. CODIS, NIBIN, AFIS) will be included in the assessment. With reference to individual

¹⁰ - "Laboratory reports" includes calibration reports, labels or certificates (however named by the laboratory).

characteristic database operations, the primary focus of the assessment team will be on those individuals whose work is dedicated to individual characteristic database functions.

RESULTS OF ASSESSMENT

For each accreditation requirement in ISO/IEC 17025:2005 and the applicable ASCLD/LAB-*International* supplemental requirement document(s), the assessment team will determine that the laboratory conforms to the requirement ("Yes"), the laboratory does not conform to the requirement ("No"), or that the requirement is not applicable to the work of the laboratory ("N/A"). In addition, the assessment team may record comments.

A "No" conclusion is further defined as a *nonconformance* with a published accreditation requirement. Each nonconformance must be supported by objective evidence identified and documented by the assessment team. Each nonconformance will be classified by ASCLD/LAB as Level 1 or Level 2.

Levels 1 and 2 are defined as follows:

- **Level 1** – The nature or cause of the nonconformance directly affects and has a fundamental impact on the work product of the laboratory or the integrity of evidence; **or** there is a concern that if the nonconformance continues for an extended period the work product of the laboratory or integrity of evidence could be negatively affected.
- **Level 2** – The nature or cause of the nonconformance does not, to any significant degree, affect the fundamental reliability of the work product of the laboratory or the integrity of evidence, and allowing the laboratory to complete corrective action over an extended period does not raise an immediate concern.

The Lead Assessor, in conjunction with the assessment team, will determine and assign the level of nonconformance and each must be linked to one or more specific accreditation requirement.

LEVEL 1 NONCONFORMANCE

Each Level 1 nonconformance must be corrected to the satisfaction of the Lead Assessor before a recommendation for accreditation may be made.

Laboratories are expected to complete corrective action for any Level 1 nonconformance to the satisfaction of the Lead Assessor within 180 calendar days of receiving the *Full Assessment Report*.

If a laboratory fails to complete corrective actions within the timeframe specified, the Lead Assessor will advise an ASCLD/LAB Accreditation Program Manager who will provide guidance as to the most appropriate course of action. ASCLD/LAB reserves the right to require a follow-up on-site revisit by the Lead Assessor and/or, if needed, one or more technical assessors to determine completion of corrective action and conformance with the accreditation requirement.

NONCONFORMANCE WITH ISO/IEC 17025:2005 – 4.1.2

When one or more Level 1 Corrective Action Requests are issued after an assessment, conformance with 4.1.2 of ISO/IEC 17025:2005 will be marked “No” in the *Full Assessment Report* and will remain “No” until all Level 1 Corrective Action Requests have been addressed to the satisfaction of the Lead Assessor. A Corrective Action Request will not be issued for 4.1.2.

LEVEL 2 NONCONFORMANCE

Corrective actions for Level 2 nonconformities may commence immediately and be addressed to the satisfaction of the Lead Assessor prior to the recommendation for accreditation, or the laboratory may, upon notification to the Lead Assessor, be granted the opportunity to complete corrective action prior to the next, annual on-site Surveillance Visit (for first time applicants and the first five year cycle) or prior to the due date of the next Annual Report (for second and subsequent accreditation cycles) at which time the documented, completed corrective actions will be evaluated.

Taking advantage of extending time to complete Level 2 corrective actions does not delay the accreditation decision. However, failing to adequately correct a Level 2 within the agreed upon time invokes the requirements of a Level 1 nonconformance and may, at the discretion of the Board of Directors, result in probation, suspension or revocation of accreditation.

COMMENTS

A comment in an ASCLD/LAB-*International* report does not constitute a nonconformance. A comment is a concern, suggestion for improvement, or a recommendation regarding the practice of a laboratory. The laboratory is not required to respond to comments in order to achieve accreditation.

ON-SITE CORRECTIVE ACTIONS

The Lead Assessor has the authority to review and accept *minor* corrective actions made during the on-site assessment process and to report to ASCLD/LAB conformance with an accreditation requirement based upon the completed corrective action observed during the on-site visit. The Lead Assessor may also choose to defer acceptance of on-site corrective actions, record the nonconformance on a *Corrective Action Request* and require a period of time (generally up to 90 days) to establish a pattern of conformance. Any corrective action accepted on-site will be noted in the Lead Assessor’s records of the assessment.

CLOSING MEETING

The on-site assessment concludes with a closing meeting held by the Lead Assessor and appropriate assessment team members with the laboratory director and any laboratory personnel the director wishes to be present. The purpose of the closing meeting is to formally present the assessment conclusions, including, as applicable, any documented nonconformities.

A *Preliminary Assessment Report* will be prepared and left with the laboratory. The preliminary report will, if applicable, list any nonconformance. Generally within about ten (10) business days following the closing meeting, the conclusions of the assessment cited in the preliminary report will undergo an ASCLD/LAB quality review prior to being issued as final assessment conclusions.

QUALITY REVIEW OF ASSESSMENT CONCLUSIONS

A quality review of any nonconformities or comments documented by the assessment team will be conducted prior to the issuance of a *Full Assessment Report*. Generally within about ten (10) business days following the closing meeting, a three member (minimum) ASCLD/LAB Quality Review Panel will be convened to review the conclusions of the assessment team. The panel may be chaired by the ASCLD/LAB Executive Director, an ASCLD/LAB Program Manager, the ASCLD/LAB Quality Manager or a senior Staff Inspector.¹¹ The remaining panel members will be selected and approved by the panel Chair based upon assessment experience with ASCLD/LAB and/or technical expertise. The Lead Assessor will coordinate the timing of the quality review with the assigned panel Chair.

A quality review of the assessment team's findings is an important element of ASCLD/LAB's internal quality control. The purposes of the quality review include considering consistency of interpretations, appropriate relationships between the nonconformance and the clause(s) to which the nonconformance is assigned, and to consider the recommended level assigned to each corrective action request by the assessment team.

A complete *Full Assessment Report* will be issued to the laboratory following the quality review of the assessment team's conclusions. The specified time periods for planning and completing any required corrective action begins on the date the *Full Assessment Report* is issued to the laboratory.

DEVELOPMENT AND ACCEPTANCE OF PROPOSED CORRECTIVE ACTION

When one or more Corrective Action Requests (CARs) are issued as the result of an assessment, the laboratory must communicate a proposed corrective action plan for each CAR (including Level 2) to the Lead Assessor within thirty (30) calendar days of receiving the *Full Assessment Report*. The Lead Assessor, with input from appropriate assessment team members, will evaluate the planned corrective action(s) and will advise the laboratory of his/her acceptance of the planned action or, when necessary, will advise if the planned action does not fully address the scope and intent of the CAR.

Prior to implementing any corrective actions related to assessment findings, laboratories should ensure that any corrective actions are carried out in accordance with the laboratory's own corrective action procedure (including root cause analysis where applicable) and that the planned corrective action has been reviewed and accepted by the Lead Assessor.

¹¹ - "Senior" Staff Inspector means a Staff Inspector designated by the ASCLD/LAB Executive Director or an Accreditation Program Manager as having sufficient experience to chair a Quality Assurance Panel.

FINAL ASSESSMENT REPORT

When all Level 1 corrective actions have been completed to the satisfaction of the Lead Assessor, ASCLD/LAB will prepare a *Final Assessment Report* for the Board. The *Final Assessment Report* will contain all Corrective Action Requests reflecting all corrective actions completed by the laboratory to address nonconformities documented in the Full Assessment Report.

The *Final Assessment Report* will go to the Board of Directors for their review and the Lead Assessor will be scheduled to make a recommendation for accreditation at the next available Board meeting. The ASCLD/LAB Board may accept the Lead Assessor's recommendation to accredit or may require further corrective action by the laboratory. The Board may require the laboratory to complete additional corrective action within a period of time up to twelve months from the date of the on-site closing meeting.

In the event the Board requires additional corrective action prior to accreditation, the *Final Assessment Report* will be held by ASCLD/LAB until any additional action required by the Board is completed by the laboratory and accepted by the Lead Assessor. Following acceptance of the additional completed corrective action, an updated *Final Assessment Report* will be prepared and presented to the Board for their review and the Lead Assessor will be rescheduled to make a recommendation for accreditation at the next available Board meeting.

The Board's accreditation decision is based on the *Final Assessment Report* and any other relevant information available to the Board. The laboratory will be provided with the *Final Assessment Report* following final Board action to consider accreditation.

STATUS OF REPORTS

All reports prepared or issued by ASCLD/LAB (Preliminary, Full and Final) will be labeled as "pre-decisional." The "pre-decisional" designation will be removed from the *Final Assessment Report* only after the Board has granted accreditation.

RIGHT TO APPEAL

The applicant laboratory director has the right to appeal at any time during the assessment process. An appeals process may be commenced by contacting the ASCLD/LAB Executive Director.

CONFIDENTIALITY OF THE ASSESSMENT PROCESS

ASCLD/LAB requires all participants in the assessment and accreditation process to recognize and respect the confidentiality of laboratories. To ensure confidentiality, Board members, assessors, committee members, and other participants in the assessment process are required to sign a Code of Conduct agreement prior to participating in the process.

At the conclusion of the assessment process for a laboratory, which results in either accreditation or withdrawal of an application, all assessors having associated documents will be instructed to return or forward documents to

ASCLD/LAB or they will be instructed to destroy certain documents. ASCLD/LAB will maintain the only records associated with the assessment of accredited laboratories, once the process has been completed.

CONFLICT OF INTEREST

To ensure public confidence in the impartiality and objectivity with which ASCLD/LAB carries out its mission, and to avoid any actual or perceived conflicts of interest, no ASCLD/LAB Board member, Delegate Assembly member, committee member, assessor, employee, or other individual acting on behalf of ASCLD/LAB may participate in a specific action concerning a laboratory in which he or she is employed, or a laboratory within the same laboratory system or agency as the laboratory in which he or she is employed. The same prohibition shall apply to these individuals with respect to laboratories, laboratory systems, or agencies from which the individual is negotiating for, or has an offer of, employment, or from which the individual has retired or otherwise left employment.

ASCLD/LAB Board members, Delegate Assembly members, committee members, assessors, employees, and others acting on behalf of ASCLD/LAB shall not participate in a particular matter in which he or she, or a member of his or her household, has a financial interest, or in which a financial interest of that individual, a member of his or her household, or an employee or owner of the laboratory which employs that individual, is directly and predictably affected by that matter.

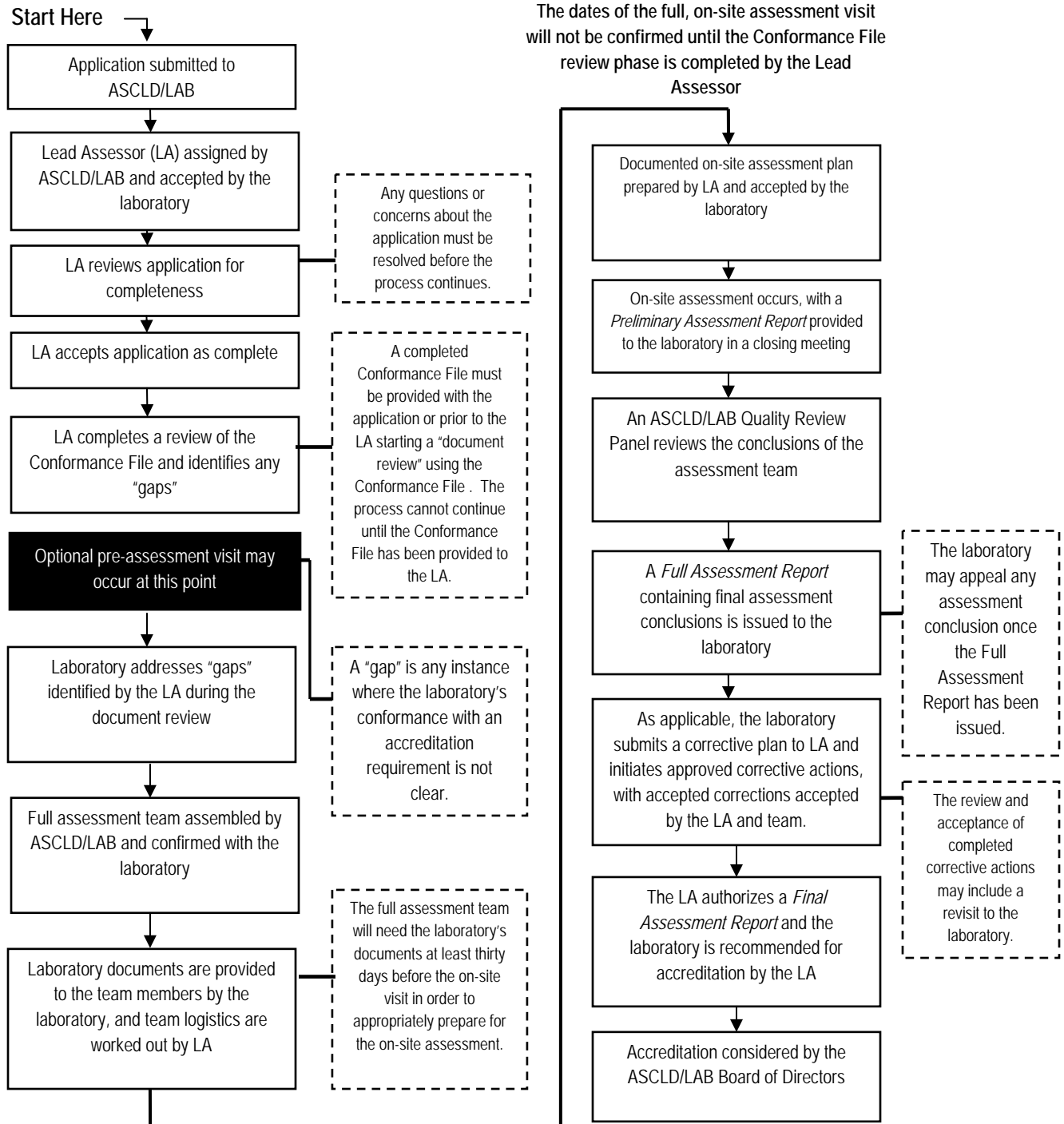
When a conflict or an appearance of a conflict becomes apparent to an individual described above, he or she shall immediately report that conflict to the ASCLD/LAB Board through the Executive Director.

ASSESSMENT PROCESS TIMELINE

The timeline of the assessment process varies from laboratory to laboratory, and is dependent upon many factors. For that reason, ASCLD/LAB does not commit to any specific date for granting accreditation and applicant laboratories should not enter the assessment process with any specific completion date in mind. ASCLD/LAB will make every reasonable effort to ensure that the assessment process progresses in a timely manner, but certain portions of the process are equally dependent on the laboratory making reasonable efforts to respond in a timely manner.

To avoid a lapse in accreditation, ASCLD/LAB accredited laboratories seeking to renew accreditation must submit completed applications, with all required attachments, at least six months prior to the expiration of accreditation. While six months is the minimum, it is preferred that the application be received nine months prior to the expiration of accreditation. Exceptions to this requirement will be considered upon written justification to the Board. To help applicant laboratories better understand the many elements of the assessment process, the flow-chart on the following page is provided as a general overview:

General Flow of the Assessment Process



PART 4 – ACCREDITATION

The decision to grant accreditation may be made only by the ASCLD/LAB Board and must be made within 12 months of the issuance of the *Full Assessment Report*. Failure to gain accreditation within twelve months of receiving the *Full Assessment Report* will result in an automatic suspension of the application process. Laboratories reaching that stage will generally be required to reinitiate the application process with the submission of updated application documentation and a follow-up site visit. The final decision as to the most appropriate course of action rests with the Board.

At any time prior to the final Board vote, a laboratory director may withdraw the application without prejudice. In such an event, the Board will make no accreditation decision. All documents and records concerning the withdrawn application will be destroyed or be returned to the laboratory director.

In the case of laboratory systems involving two or more laboratories, it is the policy of ASCLD/LAB to accredit each laboratory separately.

ASCLD/LAB does make a distinction between “regional” laboratories and “satellite” facilities. A regional laboratory is one in which a laboratory director is designated and the laboratory operates with some degree of autonomy. Each regional laboratory in a laboratory system will be assessed and accredited separately. A satellite facility is one or more premises from which a primary laboratory may conduct activities. Satellite facilities are assessed and accredited in conjunction with the primary laboratory.

POST ACCREDITATION EVALUATION

The effectiveness of the assessment and accreditation program depends largely on the preparation, presentation and performance of the assessment team, and the performance of ASCLD/LAB’s professional staff. A Post Accreditation Evaluation form will be provided for the laboratory director to evaluate the assessment process and accreditation program. Constructively critical comments are important for identifying problems in the program and topics for workshops on the assessment procedures. Laboratory directors are also encouraged to submit written suggestions for improvements at any time.

ACCREDITATION CYCLE

Except for the special one and two year provisions previously discussed, ASCLD/LAB-*International* accreditation is granted for a period of five years provided that the laboratory continues to meet all applicable accreditation standards, submits to scheduled on-site surveillance visits; completes and submits Annual Reports; and participates in prescribed proficiency testing programs.

To maintain accreditation, a laboratory must submit a new application for accreditation every fifth year, and undergo another full on-site assessment using the version of the accreditation program which is in effect at the time of the assessment.

DELEGATE ASSEMBLY MEMBERSHIP

Directors of laboratories which achieve accreditation become members of the ASCLD/LAB Delegate Assembly. When all laboratories within a laboratory system become accredited, the system director becomes a member of the Delegate Assembly. Delegate Assembly members are encouraged to attend and participate in the annual meeting of the Delegate Assembly. This meeting is held in conjunction with the annual ASCLD symposium.

Laboratory directors or laboratory system directors may designate someone other than themselves to be the delegate for their respective laboratory or laboratory system. To designate another individual as the delegate, the laboratory or system director must send a written notification to the Executive Director confirming the delegation.

To appoint an individual as a temporary designee for the purpose of voting at the annual meeting of the Delegate Assembly, the laboratory or system director must send a letter to the Executive Director making this proxy designation. No individual attending the Delegate Assembly meeting may have more than one vote. An individual may not be the delegate or proxy for more than one laboratory.

All Delegate Assembly members or their designees will receive all official correspondence from ASCLD/LAB and are encouraged to vote on all issues brought before the Delegate Assembly and sent out as mail ballots. Delegate Assembly members are also invited and encouraged to make themselves and other qualified members of their staff available for training and participation as assessors. The qualification requirements for assessors may be obtained at the ASCLD/LAB web site.

A laboratory that does not apply to renew its accreditation prior to the expiration date of its accreditation will no longer be accredited and will relinquish its membership in the Delegate Assembly.

ACCREDITATION CERTIFICATES

Once a laboratory is accredited, the laboratory will be presented a certificate of accreditation. The certificate will bear a unique certificate number and will designate the field in which the laboratory is accredited. The certificate will also indicate when the accreditation was granted and the date of expiration of accreditation. ASCLD/LAB will present a System Certificate of Accreditation to any laboratory system in which all of its laboratories have been accredited.

In addition to a certificate of accreditation, the laboratory will receive a corresponding Scope of Accreditation document. The scope document will specify the discipline(s) and each category in which the laboratory is accredited. During the assessment process, the assigned Lead Assessor will work with the laboratory to appropriately identify the scope of the accreditation. Accreditation will be limited in each discipline to the categories of testing or calibration in which the laboratory is working at the time of assessment. Each category will be identified by the laboratory, agreed to by the Lead Assessor, voted on by the Board, and listed on the scope of accreditation document.

Accredited laboratories may conduct analysis in other, non-accredited disciplines or categories added after the assessment, but the laboratory must take great care to avoid misrepresenting accredited status in those areas.

Although presented to a laboratory, each accreditation certificate and scope of accreditation document remains the property of ASCLD/LAB. Failure to remain compliant with accreditation standards could result in the revocation of accreditation and the return of the certificate to ASCLD/LAB.

A laboratory accredited as both a testing laboratory and a calibration laboratory will receive an accreditation certificate for each field and each certificate will have a corresponding scope of accreditation document.

OBLIGATIONS OF ACCREDITED LABORATORIES

As a condition of accreditation, each ASCLD/LAB accredited laboratory shall inform ASCLD/LAB, within thirty calendar days, of significant changes relevant to its accreditation, in any aspect of the laboratory's status or operation relating to:

- its legal, commercial, ownership or organizational status
- the organization, top management and key personnel
- main policies
- resources and premises
- scope of accreditation
- other such matters that may affect the ability of the laboratory to fulfill requirements for accreditation

Obligations of laboratories accredited by ASCLD/LAB also include:

- a commitment to fulfill continually the requirements for accreditation within the laboratory's scope of accreditation, including an agreement to adapt to changes in the requirements in accordance with schedules adopted by ASCLD/LAB
- afford such accommodation and cooperation as is necessary to enable ASCLD/LAB to verify fulfillment of requirements for accreditation
- provide access to information, documents and records as necessary for inspections or assessments and maintenance of accreditation
- where applicable, to provide access to documents or other information that provide insight into the level of independence and impartiality of the laboratory from any related body
- arrange the witnessing of the laboratory services when requested by the ASCLD/LAB
- claim accreditation only with respect to the scope for which the laboratory has been granted accreditation
- not use its accreditation in such a manner as to bring ASCLD/LAB in disrepute
- pay fees as shall be determined by ASCLD/LAB

ACCREDITATION CEREMONY

Once a laboratory has been granted accreditation, it is appropriate that this achievement be publicly recognized. Laboratories are encouraged to celebrate their achievement with a ceremony and, when requested, a representative of ASCLD/LAB will formally present the accreditation certificate.¹² The accreditation ceremony and attendant media coverage serve the dual purposes of demonstrating the capabilities of the laboratory to its users and of publicizing the accreditation program.

¹² - When this occurs, the laboratory will be invoiced an amount to cover the travel and per diem costs of the ASCLD/LAB representative.

RENEWAL OF ACCREDITATION

An accredited laboratory seeking to renew its accreditation must submit the required application documents at least six months prior to the expiration of the current accreditation to avoid a lapse in accreditation. Exceptions to this requirement will be considered upon written justification to ASCLD/LAB.

Upon renewal of accreditation, a laboratory's certificate shall show a month and day of accreditation that shall be five years from the month and day on the certificate of the previous accreditation, except when an accreditation expires prior to the submission of a new application for accreditation.

EXTENSION OF SCOPE OF ACCREDITATION

After accreditation is granted, a laboratory may elect, at any time, to begin performing work in a non-accredited discipline or category but may not, in any way (including testimony), state, infer or imply ASCLD/LAB-*International* accreditation in that discipline or category.

Any discipline or category added after accreditation, for which ASCLD/LAB offers accreditation, must be included in the laboratory's next application to renew accreditation, except that the Crime Scene testing discipline and the Breath/Alcohol Calibration category will remain optional. Alternatively, a laboratory may submit an application to seek accreditation in a new discipline(s) or category at any time during the five year cycle of accreditation.

A site-visit to consider a request to extend a laboratory's scope of accreditation to a new field, discipline, or category may be carried out in conjunction with a surveillance visit but will be considered a separate activity and will be reported on as a separate activity. The duration, team size and cost of the surveillance visit will be adjusted accordingly when an extension of scope is included with the surveillance visit.

An extension of scope request requires the submission of a completed application with all required supporting documentation – including a Conformance File. An extension of scope application need only contain information related to the new discipline or category.

The application review and assessment activities for scope of accreditation extensions are the same as those specified for a full assessment in the ASCLD/LAB-*International* accreditation programs. All of Part 3 of this document is applicable to scope of accreditation extension assessments. The decision-making process for granting an extension of scope of accreditation is the same as for granting accreditation following a full assessment – see Part 4 of this document. For added clarity, the decision to grant an extension of scope of accreditation may be made only by the ASCLD/LAB Board of Directors.

SUSPENDING OR DROPPING A DISCIPLINE OR CATEGORY

Any laboratory accredited by ASCLD/LAB is obligated to inform ASCLD/LAB within thirty calendar days of any change in testing and/or calibration services, including a decision to “suspend” or “drop” an accredited discipline or category. ASCLD/LAB uses these terms in the following ways:

Suspend – A decision by laboratory top management to temporarily discontinue a testing or calibration service, with the intent to resume the service after a certain condition(s) is met.

Drop – A decision by laboratory top management to permanently discontinue a testing or calibration service, with no intent to resume the service in the foreseeable future.

Notifications to ASCLD/LAB of a decision to “suspend” an accredited discipline or category must be in writing and directed to the Executive Director or an ASCLD/LAB Accreditation Program Manager. The notification must include the reason(s) for the suspension, and an anticipated timeline by which the service will be resumed. The laboratory may resume service and claim accreditation in the discipline or category any time within twenty-four (24) months of suspension. Any discipline or category remaining in suspended status greater than twenty-four (24) months will be considered dropped and the discipline or category will be removed from the laboratory’s scope of accreditation. Resuming work in a suspended category, within the time allowed, requires conformance with all applicable accreditation requirements before the work is resumed.

Notifications to ASCLD/LAB of a decision to “drop” a discipline or category must be in writing and directed to the Executive Director or an ASCLD/LAB Accreditation Program Manager. Upon notification, ASCLD/LAB will update the laboratory’s Scope of Accreditation document reflecting the change in services.

An accredited laboratory may elect, at any time, to resume service in a dropped discipline or category but may not, in any way (including testimony), state, infer or imply ASCLD/LAB-*International* accreditation in that discipline or category. Resumed service in a dropped discipline or category must be included in the laboratory’s next application to renew accreditation, except that the Crime Scene testing discipline and the Breath/Alcohol Calibration category will remain optional. Alternatively, a laboratory may submit an application to seek renewal of accreditation in a dropped discipline or category at any time during the five year cycle of accreditation.

PART 5 - CONFORMANCE MONITORING

To retain accredited status for a full five year term, a laboratory is expected to continue to meet the standards under which it was accredited. The principal means by which ASCLD/LAB monitors conformance are the *Annual Report*, results of annual surveillance visits, external proficiency testing reports submitted by approved test providers and, if needed, special interim assessments.

Any information suggesting nonconformance with the standards by an accredited laboratory will be addressed by the Board on a case-by-case basis. Upon receipt of such information, the Board will consider the information and determine if an investigation or a special interim assessment should be required. The laboratory director shall be notified of any sanctions under consideration and has the right to make representations in person at any subsequent meeting in which a conformance issue concerning that laboratory is considered. The Board will decide what, if any, sanction will be imposed.

CONFORMANCE RECORDS

Each accredited laboratory shall generate and maintain appropriate records of conformance with all applicable requirements of the accreditation program throughout each accreditation cycle. Once a laboratory becomes accredited, the laboratory must maintain records to demonstrate conformance with ASCLD/LAB requirements. Once the laboratory has been granted renewal of accreditation, the laboratory may, in accordance with the agency's regulations and the prevailing laws, dispose of records of conformance which were generated prior to the date of the last full assessment. An exception is that records must be available during every ASCLD/LAB assessment related to the training, competency testing, and authorizations to work for all current laboratory personnel authorized to perform testing and/or calibrations.

ANNUAL REPORT

Within thirty calendar days following the laboratory's accreditation anniversary date, the director of an accredited laboratory is required to submit an Annual Report based on a self-evaluation of the laboratory's status with respect to all accreditation requirements during the previous calendar year. Instructions for completing and submitting the annual report may be found in Appendix A - *ASCLD/LAB-International Surveillance Activities and Visits*.

DISCLOSURE OF NON-COMPLIANCE

Once accredited, a laboratory is required to remain compliant with the standards of the accreditation program through each accreditation cycle. In the ASCLD/LAB-*International* program, an accredited laboratory ***“shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer.”*** Annual Reports in the ASCLD/LAB-*International* program must include a summary of any nonconforming work events, and the actions taken, that have occurred since the last on-site visit, and a summary of any other substantive corrective actions (see Level 1 definition) completed (or in process) since the last on-site visit.

In keeping with the stated program objective of “identifying those laboratories which meet established standards”, ASCLD/LAB must be timely in reviewing instances of significant non-compliance. To further this objective, all accredited laboratories must disclose to ASCLD/LAB all substantive occurrences of noncompliance within thirty calendar days of determining that the non-compliance has occurred.

The requirement to disclose is applicable to any requirement when the non-conformity fits the Level 1 definition. Disclosure of such occurrences must be in writing to the Executive Director and must include a summary of the occurrence(s) and a statement of actions taken or being taken by the laboratory to:

- determine the root cause of the problem
- determine who may have been impacted by the occurrence(s)
- notify those who are potentially impacted by the occurrence(s), and
- appropriately correct and/or eliminate the cause of the occurrence(s).

ANNUAL SURVEILLANCE VISITS

During the first five-year accreditation period, an annual surveillance visit will be made to each accredited laboratory. Detailed information concerning annual surveillance visits may be found in Appendix A - *ASCLD/LAB-International Surveillance Activities and Visits*.

During second and subsequent accreditation cycles the frequency of surveillance visits will be determined by the Board of Directors on a case-by-case basis.

PROFICIENCY TESTING

The Board has adopted a comprehensive Proficiency Testing and Review Program and established a Proficiency Review Committee (PRC) for each of the accredited disciplines. These committees are responsible for reviewing the external proficiency test reports received from approved test providers for each of the accredited laboratories. The PRCs work under the direction of the ASCLD/LAB Proficiency Program Manager and serve as the initial contact with laboratories in evaluating apparent proficiency testing inconsistencies. *ASCLD/LAB-International* accredited laboratories must abide by the terms and conditions of the ASCLD/LAB Proficiency Testing and Review Program in order to retain accreditation. Failure to do so could adversely impact the laboratory's accredited status and result in a Board imposed sanction.

SPECIAL INTERIM ASSESSMENTS

When information comes to ASCLD/LAB which indicates that an accredited laboratory has failed to remain compliant with the requirements under which the laboratory was accredited, a special interim assessment may be initiated. The scope of the assessment will be determined by the Board, based on the nature of the concerns brought to the Board's attention. A laboratory may be required to provide relevant documentation to the assigned Lead Assessor prior to their visit to the laboratory. The findings of the assessment team will be reported to the Board and the laboratory director and/or parent organization.

In addition to the annual surveillance visits, a laboratory may elect to seek a special interim assessment for various reasons such as the addition of one or more disciplines since the laboratory was originally accredited, laboratory relocation, or for other management needs. The laboratory must submit a new application which includes all of the required application documents.

SANCTIONS

ASCLD/LAB-International accreditation is recognition that a laboratory has met a set of internationally recognized standards of operation for forensic laboratories. Once accreditation has been granted to a laboratory, it is expected that the laboratory will consistently remain in conformance with the requirements under which it was accredited. It is recognized that unforeseen circumstances may cause a laboratory to experience temporary nonconformance with some of the requirements. When it is recognized that the laboratory is experiencing or has experienced a period of nonconformance, actions must be taken by the laboratory to bring it back into conformance and to correct any potential miscarriages of justice.

Failure to take timely, appropriate and required corrective actions regarding nonconformance may result in any of the following sanctions:

- **Probation** for a specified time during which the laboratory must comply with specified requirements and/or conditions.
- **Suspension** for a specified time during which the laboratory must demonstrate that the problem has been remedied.
- **Revocation** for a specified time after which the laboratory may submit a new application for accreditation.

APPEAL OF SANCTION

If the accreditation status of a laboratory is classified by the Board as probationary, suspended, or revoked, the laboratory director may appeal.

Written reasons for appeal must be filed with the Executive Director within thirty days of the Board decision. The Executive Director will provide a copy of the appeal to the Board of Directors for action. The laboratory director has the right to appear in person before the Board to make representations.

REMOVAL OF SANCTIONS

Probation and suspension sanctions will be removed when the laboratory can demonstrate to the satisfaction of the Board that the deficiencies which resulted in probation or suspension have been corrected. This may require an interim assessment, a successful completion of the next regularly scheduled proficiency test, or other measures which the Board may deem appropriate.

A laboratory which has had accreditation revoked must submit a new application for accreditation and submit to the entire assessment and accreditation process.

PART 6 – USE OF ASCLD/LAB NAMES, ACRONYMS and LOGOs

The American Society of Crime Laboratory Directors/Laboratory Accreditation Board's name, acronym (ASCLD/LAB), and corporate logo, and the American Society of Crime Laboratory Directors/Laboratory Accreditation Board – *International* program name, acronym (ASCLD/LAB-*International*), and program logo (accreditation mark) are registered trademarks, reserved for the official use of ASCLD/LAB.

The names, acronyms, and logos may not be used, reproduced, or displayed for any purpose by any individual or organization, including accredited laboratories and members of the Delegate Assembly, without the express written permission of the ASCLD/LAB Executive Director or ASCLD/LAB-*International* Program Manager.

Designation of a laboratory or laboratory system as an ASCLD/LAB-*International* accredited laboratory on letterhead, stationary, laboratory reports, business cards, advertisements, signs, or other object or image, generally will be required to be in the following format:



® AN ASCLD/LAB-*International* ACCREDITED LABORATORY SINCE (DATE OF ACCREDITATION)

Laboratories must be careful not to use the ASCLD/LAB or ASCLD/LAB-*International* name, acronyms, or logos on any document reporting testing or calibration results in disciplines or categories for which the laboratory is not accredited, or in any other manner that will lead others to reasonably believe that the laboratory has been accredited in a discipline or category for which it has not been accredited. The ASCLD/LAB Board of Directors considers misrepresentations of accreditation to be a serious violation of ethics and the Board's policy.

Effective January 1, 2011, laboratories accredited in an ASCLD/LAB-*International* accreditation program may no longer use the ASCLD/LAB corporate logo. The corporate logo will be reserved for use by ASCLD/LAB and only the ASCLD/LAB-*International* program logo (as shown above) will be available for use by an ASCLD/LAB-*International* accredited laboratory.

PART 7 - CONSULTATION SERVICES

ASCLD/LAB-*International* does not provide consultation services to laboratories considering or seeking accreditation. A laboratory director wishing to conduct a pre-application assessment of his/her laboratory may wish to employ consultants with experience as ASCLD/LAB-*International* assessors. The selection of the consultant(s) will be at the sole discretion of the laboratory director. If the consultant(s) chosen for this task are ASCLD/LAB-*International* assessors they may not serve as a member of the next accreditation assessment team for the laboratory. ASCLD/LAB-*International* is not bound by recommendations made by consultant(s).

PART 8 - TECHNICAL ADVISORY COMMITTEE (TAC)

To assist the Board and ASCLD/LAB professional staff with addressing technical questions that may arise during any phase of the assessment or accreditation process, or while monitoring on-going conformance with accreditation, ASCLD/LAB maintains a Technical Advisory Committee (TAC) representing each discipline in which ASCLD/LAB offers accreditation. Special topics of interest, like uncertainty of measurement, may also be represented on the TAC.

Committee members serve a term of up to four years and members may be reappointed. TAC members will generally be employed in an ASCLD/LAB accredited laboratory, but ASCLD/LAB reserves the right to appoint any competent, qualified individual if doing so is in the best interest of the accreditation program.

Recommendations for appointments to the TAC may be made to ASCLD/LAB by the director of any accredited laboratory.

PART 9 – PROGRAM FEES

All fees are established and approved by the ASCLD/LAB Board of Directors. Some fees are based upon the number of proficiency tested positions in each discipline being assessed. A price estimate for any fee will be supplied by ASCLD/LAB upon request.

APPLICATION FEE

Laboratories submitting an application for accreditation must include a non-refundable application fee at the time the application is submitted. The application fee is based on the number of positions which the laboratory has for proficiency tested personnel at the time of the application. An application fee schedule is available at www.asclclab.org.

OPTIONAL PRE-ASSESSMENT VISIT FEE

The cost of the optional pre-assessment visit is separate and apart from the full assessment fee and will be invoiced to the laboratory once a date has been established and will be calculated using the same fee structure as is used for a full assessment.

FULL ASSESSMENT FEE

The fee for a full, on-site assessment is based on the size of the assessment team and the number of days required to conduct the full assessment.

Fees quoted or invoiced for a full assessment do not include the cost of any follow-up visits the Lead Assessor may make to confirm corrective action. When additional visits to a laboratory are necessary to determine conformance with accreditation requirements, the cost of the subsequent visit(s) will be the responsibility of the applicant laboratory.

OPTIONAL ACCREDITATION CEREMONY FEE

When, at the request of the laboratory, an ASCLD/LAB representative attends an accreditation ceremony, the laboratory will be invoiced a fee to cover the cost for travel and travel-related expenses.

ANNUAL ACCREDITATION FEE (including Surveillance Visit Fee)

An annual accreditation fee will be assessed to each laboratory accredited by ASCLD/LAB, including any periods of probation or suspension. The annual accreditation fee funds all administrative expenses of the program, including but not limited to costs for the annual surveillance visit, program management, other essential staff and an office to conduct the affairs of ASCLD/LAB. The annual accreditation fee will be based upon ASCLD/LAB's approved Annual Administrative Budget and projected costs of the annual surveillance visit.

The invoice for the annual accreditation fee is due and payable by the laboratory within three months of the date of invoice. A late fee of \$100.00 will be imposed upon every laboratory which fails to timely pay the current year's annual accreditation fee. Any payment toward accreditation fees will be applied first to delinquent accreditation fees, second to late fees, and finally to the current year's accreditation fees. No application for renewal of accreditation will be accepted by ASCLD/LAB until all accreditation fee arrearage, including late fees, has been paid in full.

SPECIAL INTERIM ASSESSMENT FEE

Based upon the circumstances and scope, a fee established by the Board will be charged for any special interim assessment.

See the attached Appendix A for additional information regarding annual reports and surveillance visits

ASCLD/LAB-*International*

Program Overview

2010 Edition

Appendix A - Surveillance Activities and Visits

ASCLD/LAB-*International* is a program of the
American Society of Crime Laboratory Directors / Laboratory Accreditation Board
ASCLD/LAB

Copyright © 2010 by ASCLD/LAB

1 Scope

To maintain confidence in ASCLD/LAB-*International* accreditation and to provide assurance to interested parties of the on-going competence and quality of ASCLD/LAB-*International* accredited laboratories, surveillance activities and visits shall be conducted between full assessments by ASCLD/LAB.

The policies, procedures and instructions provided in this document are applicable to all ASCLD/LAB-*International* accredited laboratories.

The ASCLD/LAB Accreditation Program Managers have the authority and responsibility to ensure that the provisions of this document are consistently carried out in an effective manner.

2 References

ISO 17011:2004 "*Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*"

ISO 17025:2005 "*General requirements for the competence of testing and calibration laboratories*"

ILAC G10:1996 "*Harmonized Procedures for the Surveillance and Reassessment of Accredited Laboratories*"

3 Definitions

Throughout the remainder of this document:

"Board" means the ASCLD/LAB Board of Directors

"Executive Director" means the ASCLD/LAB Executive Director

"Accreditation Program Manager" means an ASCLD/LAB Accreditation Program Manager

"Quality Manager" means the ASCLD/LAB Quality Manager

"AB" means the accrediting body ASCLD/LAB

"accreditation program" means the ASCLD/LAB-*International* accreditation programs

"accredited laboratory" means an ASCLD/LAB-*International* accredited laboratory

The following terms and definitions are incorporated from ILAC G10:

Surveillance activity: any activity undertaken by the AB at any time to monitor the performance of an accredited laboratory.

Surveillance visit: any on-site visit to an accredited laboratory or any satellite facility of that laboratory, undertaken by the AB at any time between full assessments, to ensure that the laboratory continues to operate in conformance with requirements of the accreditation program.

4 Surveillance Activities

4.1 General Inquiries

The AB may contact an accredited laboratory at any time during the accreditation cycle and inquire about any aspect of accreditation.

4.2 Annual Reports from Accredited Laboratories

Each accredited laboratory shall submit an Annual Report to the AB within thirty (30) calendar days following the laboratory's accreditation anniversary date. An extension may be approved by the Executive Director, a Program Manager or the Quality Manager.

The submission of an annual report is not required in the calendar year in which a full assessment to renew accreditation occurs.

A required element of the report shall be a cover letter containing a declaration from the director of the accredited laboratory of the laboratory's on-going conformance with all accreditation requirements and the requirements of the laboratory's own management system.

Attached to the cover letter, the report shall contain the following elements:

- A current organizational chart, indicating all administrative and technical management positions.
- A listing of all proficiency tested personnel by name and title with the following information of all proficiency tests completed by each person: (1) Test identifier; (2) Discipline; (3) Category; (4) Type (Internal or external); and (5) Outcome.

For all external tests used to satisfy the ASCLD/LAB requirements for external proficiency testing, the information provided in the Annual Report must clearly identify the approved test provider's assigned test number (such as IQAS 2902; CTS 10-572; etc.). If an exemption from using an approved test provider has been issued to the laboratory by ASCLD/LAB, the source of the external test(s) for the reporting period covered in the Annual Report must be identified as well as the specific category of testing that was tested.

- A listing of any changes to management, both administrative and technical, and proficiency tested personnel that have occurred since the date of the last on-site visit (employment status changes, training programs completed, authorizations to work issued, etc.).
- A *Statement of Qualifications* (using the approved AB form) for any management or proficiency tested personnel employed since the last on-site visit.

- Any changes in scope of testing services since the last on-site visit. This includes adding, suspending, or dropping a discipline or category.¹³
- A summary of any nonconforming testing or calibration work or other substantive corrective actions, and the actions taken, that has occurred since the last on-site visit.¹⁴
- Objective evidence of addressing any outstanding Level 2 Corrective Action Request issued by the AB during a previous visit.
- A summary of the results of the laboratory's most recent internal audit.
- A summary of the results of the laboratory's most recent management review.
- As applicable, a report of the laboratory's progress in transitioning to conformance with any new accreditation requirements.

4.3 Requests for Additional Laboratory Documentation and Records

In addition to the elements of the required Annual Report, the AB may request documentation and/or records related to any aspect of accreditation from an accredited laboratory at any time during the accreditation cycle.

4.4 Assessing Performance in External Proficiency Testing

In accordance with the *ASCLD/LAB Proficiency Testing and Review Program* and limited to the laboratory's scope of accreditation, the AB shall monitor the participation and performance of each accredited laboratory in external proficiency testing schemes or programs.

Participation and performance in external proficiency testing schemes or programs shall be a consideration in confirming the continuation of accreditation between full assessments as specified in Section 6.4 of this document.

4.5 Other Means of Monitoring Laboratory Performance

The AB retains the right to monitor the on-going performance of all accredited laboratories through all other reasonable means available to the AB, including but not limited to:

- Complaints received
- Other forms of feedback
- Public media (including the Internet)

4.6 Timing of Surveillance Activities

¹³ A laboratory may not use the Annual Report to request an extension of scope of accreditation. Any request to seek accreditation of a new discipline or category must be submitted as a separate application for accreditation to ASCLD/LAB.

¹⁴ - "Nonconforming testing or calibration work" occurs "when any aspect of [the laboratory's] testing and/or calibration work, or the results of the work, do not conform to [the laboratory's] own [testing or calibration] procedures or the agreed requirements of the customer." (See 4.9.1 of ISO/IEC 17025:2005).

Surveillance activities specified in this document may be carried out by the AB at any time.

5 Surveillance Visits

On-site surveillance visits shall be conducted by the AB at each accredited laboratory in accordance with the provisions of this document.

5.1 Frequency of Surveillance Visits

During the first five-year cycle of ASCLD/LAB-*International* accreditation, the headquarters or main laboratory facility, as identified by the laboratory system, shall be visited during each surveillance visit.

During the first five-year cycle of ASCLD/LAB-*International* accreditation, regional or satellite laboratory premises may be sampled during any given year, as long as every premise (other than the headquarters or main laboratory) is physically visited at least once during a five year accreditation cycle.

During the second cycle and beyond of ASCLD/LAB-*International* accreditation, sampling of premises during surveillance visits will be dependent upon the plan assigned by the ASCLD/LAB Board of Directors.

- **Plan A:** All sites (premises) shall be visited.
- **Plan B:** All sites (premises) shall be visited.
- **Plan C:** The headquarters or main laboratory facility, as identified by the laboratory system, shall be visited during each surveillance visit. Regional or satellite laboratory premises may be sampled during any given year, as long as every premise (other than the headquarters or main laboratory) is physically visited at least once during a five year accreditation cycle.

While the requirement of ASCLD/LAB is to physically visit all regional and satellite laboratory sites at least once during the five year cycle of accreditation, the non-binding goal of ASCLD/LAB will be to physically visit all laboratory sites once every twenty-four (24) months.

5.2 Performance-Based Surveillance Visit Schedule

After a laboratory successfully completes the first full reassessment, the AB may take into account the collective performance of the laboratory's previous visit(s) in determining the frequency of surveillance visits. Past positive performance may lead to fewer surveillance visits during the second and subsequent accreditation cycles. However, if the conformance with accreditation requirements or the quality related performance of a laboratory deteriorates during any period of the accreditation cycle, the frequency of surveillance activities or visits may be increased at the discretion of the AB.

5.3 Notices to Laboratories of Surveillance Visit

The AB shall provide a reasonable notice to the laboratory of any planned surveillance visit. Reasonable notice is defined as not less than 90 calendar days.

For an accredited laboratory operating under a Board imposed sanction of probation, a surveillance visit may be conducted with no or very short notice.

5.4 Scope of Surveillance Assessments

Surveillance visits are less comprehensive than full reassessments. The competence and effectiveness of the entire laboratory does not have to be assessed during each surveillance visit. However, an effort will be made to sample every aspect of the laboratory's management system over the five year cycle of accreditation.

Representative samples of the scope of accreditation shall be assessed during each on-site surveillance visit. However, at a minimum, the assigned assessor shall complete the following:

An off-site review of the laboratory's Annual Report and an on-site review of any issues arising from the review

An on-site review and confirmation of:

- Annual audit records
- Annual management records
- Proficiency test records (sampling is acceptable)
- Qualifications of any management or proficiency tested personnel employed since the last on-site visit
- Training records for any person who has completed training since the last assessment
- Competency test records for any newly authorized personnel
- Court testimony monitoring records and feedback to analysts (sampling is acceptable)

In addition, an on-site assessment to determine conformance with a sample of accreditation requirements as selected by the AB will be included. The laboratory shall be notified of the specific accreditation requirements to be assessed **no earlier than** thirty calendar days prior to the planned surveillance visit.

5.5 Extensions of Accreditation Scope

A site-visit to consider a request to extend a laboratory's scope of accreditation to a new field, discipline, or category may be carried out in conjunction with a surveillance visit but will be considered a separate activity and shall be reported on as a separate activity. The duration, team size and cost of the surveillance visit shall be adjusted accordingly when an extension of accreditation scope is requested by the laboratory.

6 Other Surveillance Visit Elements

Whenever possible and practical, the first surveillance visit after an initial full assessment shall be assigned to and conducted by the Lead Assessor who conducted the initial full assessment. If assigning the original Lead Assessor is determined by the AB to not be possible or practical, an alternate assessor may be assigned.

A surveillance visit may be conducted by a single qualified or certified assessor or by a team of assessors as determined by the AB.

In those cases where the AB is a signatory to a Memorandum of Understanding (MOU) or other cooperative agreement, surveillance visits in laboratories affected by the agreement may be conducted by an assessor from the partner accrediting body.

6.1 Surveillance Activity or Site Visit Conclusions

When, during surveillance activities or visits, nonconformities are identified, the AB shall issue corrective action requests (CAR) in accordance with the same process for issuing a CAR during a full assessment. The timeframe for the laboratory proposing and completing corrective action in response to a CAR issued during a surveillance visit is the same as the timeframe during a full assessment. Specifically:

- Level 1 CAR – 180 days
- Level 2 CAR – prior to the next schedule visit or due date of Annual Report (clarified by the AB in each instance)

6.2 Surveillance Visit Reports

The assessor assigned to conduct a surveillance visit shall create and submit surveillance visit notes within 15 calendar days of the completion of the on-site visit. An extension may be granted by an Accreditation Program Manager or the Executive Director.

The notes shall contain a recommendation to the Board regarding the continuation of accreditation of the laboratory.

6.3 Preparation and Audit of Surveillance Visit Reports

An audit of the surveillance visit notes shall be conducted by the AB using whatever resources are deemed appropriate by the Accreditation Program Managers. Using the audited notes a report will be prepared, reviewed and approved by the surveillance assessor, and then provided to the Executive Director.

6.4 Confirming the Continuation of Accreditation

The final, audited Surveillance Visit Report shall, upon completion, be provided to the Executive Director for review. The Executive Director shall review the report, consider the recommendation

of the assessor, and may either accept the report and grant the continuation of accreditation of the laboratory or take any other action deemed appropriate.

Whenever there are findings of non-conformance, during a surveillance visit, which raise serious concern about the quality or integrity of the laboratory's work, the Executive Director shall present the concerns to the Board for consideration at the next possible meeting of the Board.

Based upon the notification and/or recommendation of the Executive Director, the Board of Directors may vote to continue accreditation for an additional year, or take any other action deemed appropriate.

7.0 Interim Assessments

As a result of information gathered during any surveillance activity or visit, the Board of Directors may determine the need for and commence an interim assessment.

This provision does not preclude the Board from commencing an interim assessment for reasons other than information related to surveillance activities or visits.