ASCLD/LAB-*International* ® Accreditation Program

Program Overview

INTRODUCTION

The ASCLD/LAB-*International* accreditation program of the American Society of Crime Laboratory Directors / Laboratory Accreditation Board (ASCLD/LAB) is a program of accreditation in which any crime laboratory may participate to demonstrate that its technical operations and overall management system meet ISO/IEC17025 requirements and ASCLD/LAB-*International* Supplemental Requirements.[1]

Accreditation is part of a laboratory's quality assurance 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 program are developed and/or approved by the ASCLD/LAB Board of Directors. The Board is elected by and responsible to the ASCLD/LAB Delegate Assembly. The Delegate Assembly is composed of the directors[2] of all laboratories and laboratory systems accredited by either accreditation program of ASCLD/LAB, Inc.

The ASCLD/LAB Bylaws govern the authority and responsibilities of the Board, the Delegate Assembly and ASCLD/LAB, Inc.

OBJECTIVES

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

They are:

- To improve the quality of laboratory services.
- To adopt, develop and maintain standards which may be used by a laboratory 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.

1 - In developing the ASCLD/LAB-*International* Supplemental Requirements document for testing laboratories, ASCLD/LAB has considered and included appropriate language from *Guide 19*, as published by the *International Laboratory Accreditation Cooperation* (ILAC). Supplemental requirements for breath/alcohol calibration laboratories are currently under further development.

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.

- To offer to the general public and to users of laboratory services a means of identifying those laboratories which have demonstrated compliance with established standards.

ACCREDITATION REQUIREMENTS

Any laboratory seeking ASCLD/LAB-*International* accreditation must demonstrate conformance to the requirements in ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories* as well as the *ASCLD/LAB-International Supplemental requirements for the accreditation of forensic science testing laboratories* (2006). [3]

Conforming to the numbered requirements in each document 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-*International* as "*not applicable*."

"**Notes**" in each 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 of Directors.[4]

Additionally, where applicable, laboratories performing DNA analysis will be assessed in accordance with the requirements of the *Quality Assurance Standards for Forensic DNA Testing Laboratories* and the *Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories.*[5] In most cases, a nonconformance in the DNA discipline against one of these standards will be correlated to an ASCLD/LAB-*International* accreditation requirement. Any required corrective action will be tracked against the corresponding ASCLD/LAB-*International* requirement.

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

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-*International* requires several actions prior to application for accreditation.

3 - Supplemental requirements for breath/alcohol calibration programs are currently under further development. This note is applicable to any reference to breath/alcohol accreditation throughout this document. ASCLD/LAB will publicly notify customers as soon as the breath/alcohol calibration accreditation requirements are approved for release by the ASCLD/LAB Board of Directors.

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

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

First, the laboratory must submit a *User License Agreement* to obtain a copy of the ASCLD/LAB-*International* supplemental requirements and corresponding field guide and conformance file. The laboratory must also certify acquisition of a licensed edition of ISO/IEC 17025:2005 by submitting an *ISO/IEC Certification* form. The license agreement for the ASCLD/LAB-*International* documents and the *ISO/IEC 17025 Certification* form may be downloaded at www.ascld-lab.org.

After a properly completed license agreement and certification form are on file at ASCLD/LAB, the laboratory will be provided with an electronic copy of the current version of the *ASCLD/LAB-International Supplemental Requirements* document, the *ASCLD-LAB-International Field Assessment Guide*, and the *ASCLD/LAB-International Electronic Conformance File*. The *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 non-conformity identified during the self-evaluation.

FORMAL APPLICATION

Formal application for accreditation is made by submitting the *ASCLD/LAB-International Application for Accreditation*,[6] along with all attachments and supporting documents as specified on the application form. An appropriate application fee must be submitted with the application from a laboratory seeking initial accreditation.[7] The most current application fee schedule may be found on the ASCLD/LAB web site.

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 a *Conformance File*. 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. A conformance file may be in hard copy form or an electronic file.

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 and gap analysis will be conducted.

6 - Applications for ASCLD/LAB accreditation are available at www.ascld-lab.org

7 - An application fee is not applicable to a laboratory currently accredited by ASCLD/LAB, Inc. (in either program).

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

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

Forensic Science - Calibration[8]

Toxicology – Breath Alcohol Measuring Instruments

NOTE: Accreditation in additional disciplines may be offered by ASCLD/LAB-*International* 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 importance and effectiveness of the overall management system in granting accreditation. For that reason, the laboratory must apply for accreditation in all testing disciplines in which ASCLD/LAB-*International* provides accreditation and the laboratory provides services, except crime scene (**See note immediately below**). Crime Scene is the only testing discipline for which a laboratory has an option to not apply for accreditation.

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

In order to be eligible for accreditation in the crime scene discipline a laboratory must be performing casework in and make application for accreditation in at least one additional ASCLD/LAB-*International* accredited testing discipline.

Accreditation in the breath/alcohol calibration discipline is also optional.

8 - ASCLD/LAB reserves the right and may elect to subcontract the assessment of calibration operations. In the event of subcontracting, the applicant laboratory will be kept fully informed and given the opportunity to accept or reject the subcontractor.

LABORATORY SCOPE OF ACCREDITATION

Within each discipline, the laboratory shall identify a complete listing of the sub-disciplines 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 list of sub-disciplines is accurate and complete.

ASCLD/LAB-*International* accreditation certificates will specify the field(s), discipline(s), and any sub-discipline(s) (types of tests) 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 sub-discipline but may not, in any way (including testimony), state, infer or imply ASCLD/LAB-*International* accreditation in that discipline or sub-discipline. Any discipline or sub-discipline 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 discipline will remain optional. Alternatively, a laboratory may submit an application to seek accreditation in a new discipline(s) or sub-discipline(s) at any time during the five year cycle of accreditation.

ACCREDITATION MANDATED BY LEGISLATION

Laboratories may apply for and obtain ASCLD/LAB-*International* accreditation in a single discipline when accreditation in that discipline is mandated by legislation. Accreditation granted in a single discipline for this purpose will be granted for a two-year period, during which the laboratory must apply for ASCLD/LAB-*International* accreditation in all disciplines in which it provides services. 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, it will be the responsibility of the applicant laboratory to arrange for and obtain sufficient mock criminal casework from an external source which will realistically simulate actual evidence normally processed by a laboratory performing casework examinations in all disciplines for which accreditation is sought. Analysts/examiners who will be performing casework in the new 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.

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 new 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.

REVIEW OF THE APPLICATION

Upon receipt by ASCLD/LAB, the application will be assigned to a Lead Assessor for review to verify that all required documents are included and properly completed. If all required documents are not included and/or properly completed, proper completion and submission will be required before the process proceeds further.

OPTIONAL PRE-ASSESSMENT VISIT (Gap Analysis)

While ASCLD/LAB-*International* does not provide consultation services to laboratories considering accreditation, once an application for accreditation has been submitted and accepted by ASCLD/LAB, arrangements may be made with the assigned Lead Assessor for a pre-assessment visit.

Pre-assessment visits are not required for accreditation. The purpose of the pre-assessment visit is to complete a *gap-analysis*. A gap analysis is the process of identifying and discussing any area(s) of concern and to determine the laboratory's readiness for full assessment. Pre-assessment visits may be conducted by the Lead Assessor or the Lead Assessor and one or more technical assessors.

Pre-assessment visits are not intended to and will not provide a general consultation service to an applicant laboratory. Applications for accreditation are accepted with the assumption that the laboratory has made a good faith effort to prepare for assessment. Excessive issues or concerns arising from a pre-assessment visit, or a failure to address gap-analysis concerns within a reasonable period of time, could lead to a recommendation from the Lead Assessor to suspend the application process.

SCHEDULING OF THE ON-SITE FULL ASSESSMENT

The Lead Assessor will coordinate with the applicant laboratory director to set an assessment date that is satisfactory to the applicant laboratory, the assessment team and to ASCLD/LAB. The on-site assessment date will not be set until the document review and gap analysis process is complete and 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 the ASCLD/LAB-*International* Program Manager, will determine the number of technical assessors and the number of days required to conduct the assessment. The assessment

team will consist of two or more assessors, one of them being the Lead Assessor. Assessors shall be selected from the pool of ASCLD/LAB-*International* qualified/certified assessors.[9]

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 conflicts of interest. However, the final decision for the selection and appointment of the Lead Assessor and all team members remains with ASCLD/LAB.

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

It is the responsibility of the applicant laboratory, upon notification by the Lead Assessor, to provide copies of appropriate management system documents to each member of the assessment team. The assessment team should receive all required documents at least thirty days prior to the on-site assessment. When agreeable to the Lead Assessor, 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 very important to the assessment process.

LOGISTICS OF ON-SITE ASSESSMENT

Once a date has been established, the applicant laboratory director 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 assessors so that maximum cost savings may be realized for both ASCLD/LAB-*International* and the system. The applicant laboratory will not pay directly 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 case records including analysts' notes and other information.

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 administrator such as a sheriff or chief of police, who is in line of command over the laboratory, and the assessment team. The purpose of this meeting is to elicit the administrator's opinion of the services of the laboratory. This meeting need not be lengthy.

9 - ASCLD/LAB may also utilize Technical Experts as required.

In addition, the assessment team must also meet with the laboratory director (or point of contact) and others designated by the laboratory director to review the on-site assessment plan and to provide an overview of the on-site assessment process.

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.

ASSESSMENT PROCESS

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 generally 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 a conference room if possible. Additional records and documents may be requested by the team during the on-site assessment.

An important phase of the assessment is the determination that the laboratory reports are supported by adequate case records and examination documentation 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. 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 documentation 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 too. For example, in addition to the quality and documentation of analysis, the audit trail will consider evidence integrity, quality of reagents used, maintenance and calibration of the specific instruments used, etc.

The assessment team will be careful not to embarrass the analysts, but will expect them to have written procedures and other documentation at hand to support the findings in the case files. The assessors will interview trainees to evaluate the training program. They will also interview support personnel to evaluate the support capabilities of the laboratory. Some laboratory personnel will be asked to demonstrate specific testing and/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 characteristic database operations, the primary focus of the assessment team will be on

those individuals whose work is dedicated to characteristic database functions. Those individuals will be expected to have completed appropriate training, competency testing, and internal proficiency testing to the extent that work is performed. Regardless of working titles, complying with accreditation requirements for Technical Support personnel is generally expected for these individuals.

RESULTS OF ASSESSMENT

For each accreditation requirement in ISO/IEC 17025 2005, *General requirements for the competence of testing and calibration laboratories* and in the *ASCLD/LAB-International Supplemental requirements for the accreditation of forensic science testing laboratories* 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" finding is further defined as a *non-conformity with published accreditation requirements*. Each non-conformity must be supported by objective evidence identified and documented by the Lead Assessor on a *Corrective Action Request.*

Non-conformities will be classified as Level 1 or Level 2.

Levels of non-conformities are defined as follows:

- **Level 1** – The nature or cause of the non-conformity directly affects and has a fundamental impact on the work product of the laboratory or the integrity of evidence.

- **Level 2** – The nature or cause of the non-conformity does not, to any significant degree, affect the fundamental reliability of the work product of the laboratory or the integrity of evidence.

The Lead Assessor will determine and assign the level of non-conformity and each must be linked to a specific accreditation requirement.

LEVEL 1 NON-CONFORMITY

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

New applicant laboratories will be expected to complete corrective action for a Level 1 non-conformity to the satisfaction of the Lead Assessor within 180 calendar days of the assessment Summation Conference.

Laboratories seeking to continue or renew ASCLD/LAB-*International* accreditation will be expected to complete corrective action for a Level 1 non-conformity to the satisfaction of the Lead Assessor within 120 calendar days of the Assessment Summation Meeting.

If a laboratory fails to complete corrective actions within the timeframes specified, the Lead Assessor will advise the ASCLD/LAB-*International* 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.

NON-CONFORMITY WITH ISO/IEC 17025:2005 – 4.1.2

When one or more Level 1 non-conformities are found during an assessment, the 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 non-conformities have been corrected to the satisfaction of the Lead Assessor. A corrective action request will not be issued for 4.1.2.

LEVEL 2 NON-CONFORMITY

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, at which time the documented, completed corrective actions will be evaluated. Taking advantage of extending the completion of Level 2 corrective actions until the next, annual on-site surveillance visit does not delay the accreditation decision.

Failure to adequately correct a Level 2 non-conformity by the next, annual on-site Surveillance Visit invokes the requirements of a Level 1 non-conformity and may result in suspension or revocation of accreditation.

COMMENTS

A comment in an ASCLD/LAB-*International* report does not constitute a non-conformity. A comment is any of a number of suggestions for improvement or recommendations regarding the practice of a laboratory. The laboratory is not required to respond to comments in order to achieve accreditation.

AUTHORITY OF LEAD ASSESSOR

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 corrective action observed during the assessment. The Lead Assessor may also defer acceptance of on-site corrective actions, record the non-conformity on a *Corrective Action Request* and require a period of time (up to 90 days) to establish a pattern of conformance.

QUALITY REVIEW OF CORRECTIVE ACTION REQUESTS

A quality review of any *Corrective Action Requests* or documented comments will be conducted prior to the summation conference. A three member Quality Review Panel will be designated by the Program Manager for each ASCLD/LAB-*International* assessment. The panel may be chaired by the ASCLD/LAB Executive Director, the ASCLD/LAB-*International* Program Manager, the ASCLD/LAB Quality Manager or a senior Staff Inspector.[10] 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 on-site Lead Assessor will coordinate the timing of the quality review with the assigned panel Chair, but the review will occur before the formal presentation of the corrective action requests or documented comments to the laboratory director.

A quality review of the assessment team's findings is an important element of the ASCLD/LAB-*International* internal quality assurance program. The purpose of the review is to ensure consistency in applying accreditation requirements and in grading non-conformities.

Because the quality review is conducted prior to the Summation Conference, the laboratory may begin an appropriate corrective action process immediately after the Summation Conference.

SUMMATION CONFERENCE / SUMMARY REPORT

At the end of the assessment, the assessment team will meet with the laboratory director, and any others the director chooses, to review the findings including all non-conformities and comments.

A *Summary Assessment Report* listing all non-conformities and documented comments reviewed during the Summation Conference will be provided to the laboratory director at the conclusion of the Summation Conference. The summary report will include a *Corrective Action Request* for each non-conformity, individually recording each Level 1 and Level 2 non-conformity. The Lead Assessor will use the *Corrective Action Request* forms to track and document the completion and acceptance of corrective actions.

DEVELOPMENT AND ACCEPTANCE OF PROPOSED CORRECTIVE ACTION

When one or more Corrective Action Request (CAR) is issued during a Summation Conference, the laboratory must communicate a proposed corrective action plan for each CAR (including Level 2) to the Lead Assessor within thirty calendar days of the Summation Conference.[11] The Lead Assessor, with input from appropriate team members, will evaluate the planned corrective action 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.

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

11 - While a laboratory may elect to address any Level 2 nonconformity prior to the next Surveillance Visit, it is still important for the laboratory and the Lead Assessor to concur on the appropriateness of the laboratory's planned corrective actions.

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 cause analysis) and that the planned corrective action has been reviewed by the Lead Assessor.

FULL ASSESSMENT REPORT

A Full Assessment Report will be completed by ASCLD/LAB and provided to the laboratory as soon as practical after the Summation Conference. The full assessment report will include all non-conformities documented and reported during the Summation Conference, as well as reflect all areas of conformance.

A quality review of the report will be conducted by ASCLD/LAB prior to providing the report to the laboratory.

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 non-conformities documented in the Summary Report.

The Program Manager will provide copies of the Final Assessment Report to the Executive Director and Board members 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 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 assessment Summation Conference.

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 a Final Assessment Report within 15 calendar days of Board action on the report.

STATUS OF REPORTS

All reports issued by ASCLD/LAB (Summary, 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 acted on the report.

RIGHT TO APPEAL

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

ACCREDITATION DECISION

The decision to grant accreditation may be made only by the ASCLD/LAB Board and must be made within 12 months of the Summation Conference date. Failure to gain accreditation within twelve months of the assessment Summation Conference 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.

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

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 concerning the withdrawn application will be destroyed or be returned to the laboratory director.

POST-ASSESSMENT EVALUATION

The effectiveness of the assessment and accreditation program depends largely on the preparation, presentation and performance of the assessment team. A Post Assessment Evaluation form is provided for the laboratory director to evaluate the assessors and to comment on the assessment program. Constructively critical comments are important for identifying problems in the program and topics for workshops on the assessment procedures. Directors are also encouraged to submit to ASCLD/LAB-*International* at any time written suggestions for improvements in the accreditation process.

ACCREDITATION CYCLE

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 an Annual Accreditation Audit Report; 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 application.

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 generally held in conjunction with the annual meeting of ASCLD.

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 letter 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 are placed on the mailing list for all official correspondence from ASCLD/LAB and ASCLD/LAB-*International* 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.

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 the 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 all sub-disciplines (types of tests) 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 sub-discipline(s) in which the laboratory is working or fully prepared to work at the time of assessment. All accredited sub-disciplines will be identified by the Lead Assessor, agreed to by the Laboratory director, voted on by the Board, and listed on the scope of accreditation document.

Accredited laboratories may conduct analysis in other, non-accredited disciplines or sub-disciplines 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 document remains the property of ASCLD/LAB-*International*. Failure to remain compliant with accreditation standards could result in the revocation of accreditation and the return of the certificate to ASCLD/LAB-*International*.

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

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.

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 Accreditation Audit Report*, results of annual surveillance visits, proficiency testing reports submitted by approved test providers, and special interim assessments if needed.

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 conformance issues concerning that laboratory are considered. The Board will decide what, if any, sanction will be imposed.

ANNUAL ACCREDITATION AUDIT REPORT

By the laboratory's accreditation anniversary, the director of an accredited laboratory is required to submit an Annual Accreditation Audit 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 audit report may be found in Appendix A - *ASCLD/LAB-International Surveillance Activities and Visits*

Laboratories which have been accredited to an earlier version of the program may not be required to be in conformance with new versions or new requirements documents by the laboratory's accreditation anniversary. However, laboratories are required to conduct their annual audit using the requirements from the version of the accreditation program which is in effect at the time of the audit and report in the Annual Accreditation Audit Report steps that are being taken to come into conformance with the current version of the program.

OTHER LABORATORY REPORTING

In addition to the *Annual Accreditation Audit Report*, an accredited laboratory shall notify and inform ASCLD/LAB in writing without delay of significant changes relevant to accreditation, in any aspect of the laboratory's status or operation, or instances of non-conforming work requiring customer notification

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

ANNUAL SURVEILLANCE VISITS

During the 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*.

PROFICIENCY TESTING

The Board has adopted a comprehensive Proficiency Review Program (PRP) 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 Board through the ASCLD/LAB Quality 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 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.

ASCLD/LAB and ASCLD/LAB-*International* Name, Acronym and LOGO

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

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, acronym, or logo on any document reporting findings in disciplines or sub-disciplines 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 sub-discipline 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.

SANCTIONS

ASCLD/LAB-*International* accreditation is a 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 to the Delegate Assembly.

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 each member of the delegate assembly at least thirty days prior to its next annual meeting. The laboratory director has the right to appear in person at this meeting to make representations. The Delegate Assembly, at its annual meeting, will make a decision by a majority vote of those in attendance and this decision will be final.

When timing is such that appeal to the Delegate Assembly at its annual meeting will cause an undue hardship due to the delay, the appealing laboratory director may prepare a written appeal and request that the appeal be presented to the Delegate Assembly. The Board shall then prepare a written response and distribute both documents to the Delegate Assembly through the mail for a determination by majority vote of the responding delegates.

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 accreditation process.

CONSULTATION SERVICES

ASCLD/LAB-*International* does not provide consultation services to laboratories considering 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).

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.

CONFIDENTIALITY OF THE ASSESSMENT PROCESS

It is the responsibility of all participants in the accreditation process to recognize and respect the confidentiality of applicant laboratories. To ensure confidentiality, Board members, assessors, committee members, and other participants in the accreditation process are required to sign a Code of Conduct agreement prior to participating in the process.

At the conclusion of the accreditation process for a laboratory, which results in either accreditation or withdrawal of an application, all assessors and Board members 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.

ASCLD/LAB-*International* TECHNICAL ADVISORY COMMITTEE (TAC)

To assist the Board and ASCLD/LAB staff with addressing technical questions that may arise during any phase of the accreditation process or while monitoring on-going conformance with accreditation, the Board will appoint Technical Advisory Committee members for each discipline in the ASCLD/LAB-*International* scope of accreditation.

Committee members serve at the pleasure of the Board for a term of up to four years. Members may be reappointed by the Board. Technical Committee members will generally be employed in an ASCLD/LAB or ASCLD/LAB-*International* accredited laboratory, but the Board 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.

ACCREDITATION FEES

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

APPLICATION FEE FOR NEW APPLICANT LABORATORIES

Laboratories submitting an application for accreditation for the first time[13] 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.

13 - Laboratories currently accredited under the ASCLD/LAB Legacy program will not be charged an application fee when making application for ASCLD/LAB-International accreditation.

OPTIONAL PRE-ASSESSMENT VISIT FEE

The cost of a 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
(Includes Annual Surveillance Visit)

An annual accreditation fee will be assessed to each laboratory accredited by ASCLD/LAB-*International*, 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.

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

APPENDIX A

ASCLD/LAB-*International* Surveillance Activities and Visits

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-*International* Program Manager has 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

"Program Manager" means the ASCLD/LAB-*International* 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 program

"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 by the laboratory's accreditation anniversary date. An extension may be approved by the Executive Director, Program Manager or Quality Manager.

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 an indication (by at least test number, type, and outcome) of any and all proficiency tests completed by each person
- 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
- A summary of any nonconforming work events, and the actions taken, that have occurred since the last on-site visit
- A summary of any other substantive corrective actions (see Level 1 definition) completed (or in process) since the last on-site visit
- 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 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

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 accreditation, surveillance visits to accredited laboratories shall be carried out annually at about twelve month intervals from the date of accreditation, but no greater than eighteen months between visits.

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 that 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. The laboratory shall be notified of the specific accreditation requirements to be assessed no earlier than 30 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 testing area (sub-discipline) 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 – 120 days
- Level 2 CAR – prior to the next surveillance visit

6.2 Surveillance Visit Reports

The assessor assigned to conduct a surveillance visit shall prepare and submit a Surveillance Visit Report to the AB within 15 calendar days of the completion of the on-site visit. An extension may be granted by the Program Manager or Executive Director.

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

6.3 Audit of Surveillance Visit Reports

An audit of the Surveillance Visit Report shall be conducted by the AB using whatever resources are deemed appropriate by the Program Manager. Any modifications made to the report shall be communicated to the laboratory as soon as practical.

6.4 Confirming the Continuation of Accreditation

The final, audited Surveillance Visit Report shall be provided to the Board for their review prior to the next scheduled board meeting. The Board shall review the report, consider the recommendation of the assessor, and may either accept the report and confirm the continuation of accreditation of the laboratory 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.