

Significant Changes from the ASCLD/LAB 2005 Legacy Accreditation Manual to the 2008 Legacy Accreditation Manual

In early 2007, the Delegate Assembly approved, by mail ballot, a few significant changes to the 2005 Accreditation Manual. In the process of making the approved changes, clarifying language was added to the discussion in several areas which were found to be unclear during previous inspections. The changes which resulted in the creation of the 2008 version of the ASCLD/LAB Legacy Accreditation Manual are summarized below.

Language which has been added to the manual is shown in **red text**. Language which has been deleted from the manual is shown by ~~strikeout~~.

Changes in the Introduction

Change # 1: Language was modified on page 3 of the manual, as follows, to allow accreditation of a stand-alone crime scene laboratory.

“FORMAL APPLICATION

Should the director elect to proceed with accreditation, formal application is made by returning to ASCLD/LAB the Application for Accreditation (Appendix 1), along with all supporting documents listed on the application form. It is preferred that the application be submitted in an organized electronic format using software which is approved by the ASCLD/LAB office. Interactive forms are available on the ASCLD/LAB website at www.asclcd-lab.org. The application may be submitted in a ring binder with tabs marking each of the required documents. When a laboratory system consisting of two (2) or more laboratories elects to apply for accreditation, independent applications must be submitted for each laboratory. Required documents which are common to all laboratories within a system need not be duplicated for each laboratory within the system, when applications are submitted for multiple laboratories.

Unless a laboratory meets the requirement for an exception, a laboratory must apply for accreditation in all disciplines in which ASCLD/LAB provides accreditation and the laboratory provides services, except crime scene. Crime scene is the only discipline for which a laboratory has an option to not apply for accreditation. An exception to ~~this~~ **requirement to apply for accreditation in all disciplines in which services are provided** may be made only when legislation requires a laboratory to obtain accreditation in a specific discipline. Laboratories may apply for and obtain accreditation in a specific discipline when mandated by legislation. Accreditation granted in single disciplines for this purpose will be granted for a two-year period, during which the laboratory must apply for accreditation in all disciplines in which it provides services.

~~Crime scene is the only discipline for which a laboratory has an option to not apply for accreditation.~~

ASCLD/LAB will accredit any laboratory which provides services in one or more of the disciplines for which accreditation is offered, including Crime Scene. To be accredited in a discipline for which the laboratory only conducts screening or processing within the laboratory, the laboratory must be accredited in at least one additional discipline **in which it provides full services.** **As an example, a laboratory may be accredited in Latent Prints (processing only) if the laboratory becomes accredited in one of the other disciplines.**

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 inspection.”

Change # 2: Language was added on pages 3 and 4, as follows, to clarify that while laboratories seeking accreditation for the first time have a full year to come into compliance with the requirements of the program, laboratories seeking renewal of accreditation are expected to remain in compliance and may be granted up to 180 days to correct any areas of non-compliance.

“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 the Board. **While laboratories seeking accreditation for the first time may be given up to twelve months following the initial inspection to become compliant with the applicable requirements for accreditation, laboratories seeking renewal of accreditation are expected to remain in compliance with the requirements of the accreditation program at all times. When a laboratory, which is seeking renewal of accreditation, is found to not be in compliance with one or more of the Essential requirements of the program, the Board may allow up to 180 days to achieve full compliance if the laboratory has submitted an application for renewal in a timely manner and has demonstrated appropriate actions to remain compliant with the requirements of the accreditation program. Any extension beyond 180 days may be considered on a case by case basis by the Board.**”

Change # 3: Language was added on pages 11 and 12, as follows, to reiterate ASCLD/LAB’s previously published requirement that accredited laboratories are obligated to notify ASCLD/LAB when there are occurrences of significant non-compliance which could potentially impact the quality of the laboratory’s work.

“INTERIM INSPECTIONS

When information comes to the Board which indicates that an accredited laboratory has failed to remain compliant with the standards under which the laboratory was accredited, an interim inspection may be initiated by Board action. The scope of the inspection 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 inspection team prior to their visit to the laboratory. The findings of the inspection team will be reported to the Board and the laboratory director and/or parent organization.

DISCLOSURE OF NON-COMPLIANCE

Once accredited, a laboratory is required to remain compliant with the standards of the accreditation program through each accreditation cycle. Accredited laboratories are required to report substantive occurrences of non-compliance with Essential criteria on the Annual Accreditation Audit Report. “Substantive” is defined as potentially having a significant bearing on the quality of the work of the laboratory, even if for a short period of time. As an accrediting body, ASCLD/LAB is obligated to be timely in reviewing instances of significant non-compliance by an accredited laboratory. To further this objective, all accredited laboratories must disclose to ASCLD/LAB all substantive occurrences of non-compliance with any Essential criteria within thirty (30) calendar days of determining that the non-compliance has occurred. 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: (1) determine the root cause of the problem, (2) determine who may have been impacted by the occurrence(s), (3) notify those who are potentially impacted by the occurrence(s), and (4) appropriately correct and/or eliminate the cause of the occurrence(s).”

Changes in Laboratory Management and Operations Section

Change # 4: Language was added on page 19, as follows, to require laboratories to include training in “the application of ethical practices in forensic science” in the laboratory’s training program.

“DISCUSSION

A laboratory or laboratory system’s training program must emphasize and teach the skills and knowledge required to achieve the minimum standards of competence and good laboratory practice within a specific area of work. A laboratory’s training program may be an outline with references to more detailed training modules which may be in other laboratory documents. The training program must be sufficiently comprehensive to cover all aspects of the work performed by a laboratory for each discipline in which the laboratory performs casework. Training programs for the various disciplines may be maintained separately. Training must also include a substantial knowledge of forensic science across its wide spectrum, **the application of ethical practices in forensic sciences** and of criminal and civil law and procedures. A demonstration of competence to perform what is expected must be included in the program. It is recommended that the laboratory establish a formal means of recognition of successful completion of the training such as a certificate, letter, or memorandum (1.3.3.1).”

Change # 5: Language was added on page 29, as follows, to clarify that although methods and procedures may be externally validated, the laboratory must verify that the validated methods and procedures perform as expected in the laboratory’s environment and on the laboratory’s equipment. It is clarified that such verifications must be documented and that the laboratory must maintain the documentation.

“DISCUSSION

The proper validation of a new technical procedure (1.4.2.6) requires a complete understanding of the theoretical basis for the method. Such knowledge provides a means of assessing the specificity and limitations of the method and predicting possible sources of error. The method must be tested using known samples. Should the new method parallel or supersede an existing one, the two should be compared on split samples. The known samples should be designed to resemble actual evidence materials as closely as possible so that the effects of such factors as matrix, sample age, degradative environment, and sample homogeneity are taken into account. This is particularly important when attempting to apply to forensic materials some methodology originally developed for routine chemical or clinical samples. If the analysis provides quantitative data, the validation study should include an estimation of its accuracy and precision at concentrations which are representative of casework samples (1.4.2.6).

The method must be subjected to a validation study. This may be done internally, externally, and/or collaboratively. **Whenever methods and procedures are externally validated, the laboratory must verify and document that the new method or procedure performs as expected in the laboratory’s environment and on the laboratory’s equipment.** Exchange of blind and reference samples with another competent laboratory is particularly useful for detecting any internal systematic error. Written documentation for each validation study and **each performance verification needs to must** be maintained for future reference.”

Change # 6: Language was added on page 30, as follows, to clarify that the routine documented use of controls is an acceptable way of ensuring the reliability of reagents.

“DISCUSSION

The written technical procedures (1.4.2.7) should include descriptions of sample preparation methods,

controls, standards, and calibration procedures. They should also include a discussion of precautions, possible sources of error, and literature references. Reagents must be labeled with the identity of the reagent and the date of preparation or "lot" number. Records must be maintained identifying who made the reagent and that it was tested ~~before use and worked as expected~~ to check the reliability of the reagent. **The routine documented use of appropriate controls is a suitable method to ensure the continued reliability of reagents. Stored reagents which are not used routinely, i.e. monthly, must be retested before subsequent use. Validated shelf life data may be used to determine how often infrequently used reagents must be tested.** This will give the examiner the necessary resource material to support written conclusions and expert testimony (1.4.2.9 to 1.4.2.10)."

Change # 7: Language was added on page 35, as follows, to clarify that an author or co-author of a report may not be the technical reviewer of the report.

"Technical reviews must be conducted by individuals having expertise gained through training and experience in the discipline being reviewed. **An author or co-author of a report may not serve as the technical reviewer of the report.** An individual conducting the technical review need not be an active examiner or currently being proficiency tested. The reviewer must have sufficient knowledge of the discipline to verify compliance with the laboratory's technical procedures and that the conclusions reached are supported with the examination documentation."

Change # 8: Language was added on pages 38 and 39, as follows, to make it the responsibility of the laboratory to identify those areas of work, performed by the laboratory, which are not specified as subdisciplines by ASCLD/LAB but are subdisciplines for the laboratory.

"Each Examiner should be proficiency tested annually in each subdiscipline in which casework is performed.

1.4.3.3 (I) WAS EACH EXAMINER PROFICIENCY TESTED ANNUALLY IN EACH SUBDISCIPLINE IN WHICH CASEWORK WAS PERFORMED?

Laboratories should proficiency test annually in clearly defined subdisciplines in which the laboratory conducts examinations. Although it is not ~~ASCLD/LAB's intention~~ to identify all subdisciplines in which proficiency testing should be conducted, generally recognized subdisciplines include: DNA and serology in the biology discipline; fire debris, explosives, fibers, GSR, glass, hairs and paint in the trace evidence discipline; firearms and toolmarks in the firearms/toolmarks discipline; alcohol and drugs in the toxicology discipline; computer forensics, forensic audio, video analysis and image analysis in the digital and multimedia evidence discipline. Although footwear/tiretrack and other similar impression evidence may be assigned to different ~~sections~~ **disciplines** in different laboratories, it is recognized as a subdiscipline. **It is the responsibility of each laboratory to determine when another type of examination, which is not specified above as a subdiscipline, is performed by the laboratory to the extent that type of testing becomes a subdiscipline for that laboratory. When additional subdisciplines have been identified by a laboratory, the laboratory must treat those additional subdisciplines in the same manner as subdisciplines specified by ASCLD/LAB for the purpose of proficiency testing."**

Change # 9: A new Essential requirement (criterion 1.4.3.5) was added on page 38, as follows, which requires each examiner to be proficiency tested at least once, during each five-year accreditation cycle, in each subdiscipline in which the examiner performs casework. The proficiency testing may be either internal or external proficiency testing.

“Each examiner must be proficiency tested at least once, during each five-year accreditation cycle, in each subdiscipline in which the examiner performs casework examinations and issues reports.

1.4.3.5 (E) WAS EACH EXAMINER PROFICIENCY TESTED AT LEAST ONCE, DURING THE PREVIOUS FIVE-YEAR ACCREDITATION CYCLE, IN EVERY SUBDISCIPLINE IN WHICH THE EXAMINER PERFORMED CASEWORK EXAMINATIONS AND ISSUED REPORTS?

DISCUSSION

To meet the requirements of criterion 1.4.3.5, each examiner must be proficiency tested at least once during each five-year accreditation cycle, in each subdiscipline identified by ASCLD/LAB and/or by the laboratory (see discussion following criterion 1.4.3.3), if the analyst performs casework in the subdiscipline during the five-year accreditation cycle. To satisfy this requirement, laboratories must have a documented plan for proficiency testing which is being followed by each examiner.”