E20 How Good is That Laboratory? Accreditation Standards: Comparing ASCLD/LAB, ISO Standards, and CLIA

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Upon completion of this presentation, attendees will learn about the various regulatory and procedural mechanisms forensic and clinical laboratories use to gain accreditation, document their procedures, and provide Quality Assurance/Quality Control. Accreditation has become commonplace in laboratories over the last decade, especially with the advent of forensic DNA analysis. Nonetheless, there are competing standards, and indeed ASCLAD/LAB is weighing adoption of ISO Standards in the near future. Attendees will learn about these standards, the current debate about adopting ISO standards, how standards differ, and the implications of various standards for the users of laboratory services, including the courts. The definition of accreditation standards could be a pivotal issue, as forensic testing and the use of DNA databases potentially expand beyond national borders in the investigation of criminal matters, mass disasters, and terrorist incidents.

The trend towards using some method of accreditation to assess the level of a performance in clinical and forensic laboratories has continued over the last two decades. In the U.S., ASCLAD/LAB has been used widely to accredit forensic laboratories. Federal regulations bind clinical laboratories in the U.S. through the Clinical Laboratory Improvement Amendments of 1988 (CLIA). However, the accreditation process put forth by the International Organization for Standardization (ISO) has gained momentum beyond the borders of the U.S. and outside the pool of forensic laboratories. In part, this comes as a result of the need to standardize laboratory accreditation and the acceptance of test data throughout the world. The definition of accreditation standards could be a pivotal issue, as forensic testing and the use of DNA databases potentially expand beyond national borders in the investigation of criminal matters, mass disasters, and terrorist incidents.

While more than 232 laboratories are accredited by ASCLAD/LAB, the accreditation process and the standards employed are in a state of evolution. As recently noted in an ASCLAD/LAB communication, the: "ASCLD/LAB accreditation program must move forward, or in the future be viewed by the uninformed world as an inferior program which is recognized only by forensic scientists. *The outside world will point to the fact that U.S. citizens are only monitored by their own standards*." (Emphasis added) Whether critiques come from "the uninformed world," from courts, consumers or other end-users concerned about quality and transparency in laboratory work, the issue will still stand – forensic laboratories set their own standards by which they are judged.

This self-regulatory scheme is in contrast to the highly specific external regulatory structure the federal government has put in place for clinical laboratories, certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). (57 FR 7139, § 493.1, Feb. 28, 1992.) In the past, the most controversial aspect of this distinction has been the CLIA requirement for blind proficiency testing, a requirement successfully avoided by forensic laboratories to this date.

However, over the last few years another potential yardstick has come to the fore, the standards promulgated by the International Organization for Standardization (ISO), specifically standard 17025, the "General Requirements for the Competence of Calibration and Testing Laboratories." ISO 17025 is specific to laboratory functions, and covers the technical competence of personnel, the ethics of staff, the use of well-defined test and calibration procedures, and participation in proficiency testing, including inter-laboratory comparisons. Independence of laboratory personnel, a topic of recent controversy, might be addressed through ISO 17025, as the standard requires arrangements to ensure that personnel are free from any commercial, financial, and *other pressures which might adversely affect the quality of their work*. ISO 17025 standard also demonstrates the laboratory's abilities to carry out specific tests. The accreditation certificate indicates the tests and equipment used, and significantly, *the degree of accuracies obtained.* The potential to estimate measurement uncertainties would be useful in assessing forensic work. This could be of crucial importance in, for example, in assessing the ability of a laboratory to resolve complex DNA mixtures, an area of expertise shown by recent studies to contain significant variation in proficiency. An additional reason for the growth of ISO standards has been the need to standardize laboratory accreditation and the acceptance of test data throughout the world. The definition of accreditation standards could be a pivotal issue, as forensic testing and the use of DNA databases potentially expand beyond national borders in the investigation of criminal matters, mass disasters, and terrorist incidents.

These issues have not gone unnoticed. Indeed, as far back as 1996, the Board of Directors of ASCLD/LAB voted to commit ASCLD/LAB to moving toward becoming an ISO accrediting organization. In December 2001, the members of the ASCLAD/LAB Delegate Assembly voted on a first phase toward revising the ASCLAD/LAB accreditation manual to move toward ISO standards. Ballots were mailed to the 236 Delegates. Although a year had passed since the Bush-Gore election debacle, 181 ballots were returned to ASCLD/LAB, but only 173 ballots were received or postmarked by the published deadline of February 4. (No indication is apparent if these were from Florida.) Of the 173 counted ballots, 112

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Delegates (64.7%) favored ISO changes. Had the late ballots had been counted, the result would have been 66.3 % in favor of the ISO proposal, just two votes short of the two-thirds vote required to pass the proposed revisions.

In the wake of the close vote, ASCLAD/LAB's Board surveyed by phone the Delegate Assembly membership, which, the Board contends, expressed an interest in more information about ISO 17025 and the desire to review a draft of the final amplification document prior to any further review. According to the ASCLD/LAB NEWSLETTER, the Board intends to:

> "(1) identify and propose, to the Delegate Assembly, the incorporation into the ASCLD/LAB accreditation program certain elements consistent with other internationally recognized standards; (2) institute a process of providing on-going education to all Delegate Assembly members regarding the incorporation of ISO standards into the ASCLD/LAB accreditation program; (3) complete efforts to bring the ASCLD/LAB office and all of its operations into compliance with ISO 58 by January 2003; (4) make the official ISO 17025 standards document available to every Delegate Assembly member by January 2003; and (5) complete a final draft of an ISO 17025 forensic science amplification document by July 2003 for Delegate Assembly review."

While the ASCLA/LAB debate over ISO standards continues, the focus should not shift from fundamental legal principles when accreditation is involved in the judicial process. Regardless of the particular standards adopted, the frequent end-user of accreditation is the court system. If the accreditation process is used to gain the confidence of courts, it must be transparent, and conform to the requirements of the legal discovery process. This is critical in criminal practice, especially in cases involving scientific or other expert testimony and evidence, such as DNA. Full discovery of the accreditation process and laboratory evaluations is essential to evaluate evidence and to properly prepare for both the introduction of such evidence and for cross examination of an expert witness. Indeed, courts must have access to such material to fulfill their role of assuring that evidence introduced at trial is reliable. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589, 125
L. Ed. 2d 469, 113 S. Ct. 2786.

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