ISO/IEC 17025

ISO Without Tears: What Every DNA Scientist Should Know

By Patricia C. Wojtowicz
Manager of Accreditations, Forensic Quality Services—International, Clearwater, Florida, USA

INTRODUCTION

Many forensic DNA laboratory managers and scientists are working to prepare for accreditation to the ISO/IEC 17025 standard (1). In many cases their agencies have been audited or accredited with respect to other performance standards and criteria, but ISO/IEC 17025 seems to have special significance—and the phrase "ISO accreditation" can strike terror into the hearts of even the most audit-hardened scientists and managers. The reasons for the anxiety are varied but often include a perception that conformance with the ISO/IEC 17025 requirements will be complicated and difficult, a feeling that ISO/IEC 17025 accreditation means more paperwork without any appreciable improvement in the quality of laboratory testing, or a belief that ISO/IEC 17025 will severely restrict the ability of scientists to make professional judgments in conducting their work. In many cases these feelings and perceptions are expressed by individuals who have little or no knowledge of ISO/IEC 17025.

One way to lessen anxiety and uncertainty is to gain knowledge and understanding about ISO/IEC 17025 and what it means to be accredited to that international standard.

If knowledge is power, then one way to lessen anxiety and uncertainty is to gain knowledge and understanding about ISO/IEC 17025 and what it means to be accredited to that international standard. The purpose of this article is to provide basic information about ISO accreditation through a discussion of the ISO/IEC 17025 hierarchy of standards and its place within forensic testing accreditation programs. The goal is not to make anyone an ISO expert but to put to rest misconceptions and dispel anxiety.

WHAT IS ISO?

ISO is the term used worldwide for the International Organization for Standardization, a network of national standards institutes from over 150 countries. ISO was formed in 1947 with the express purpose of developing standards that facilitate the international exchange of goods and services. Working with input from thousands of scientists and engineers from around the world, ISO committees have developed well over 17,000 standards in a variety of areas. Many of the standards apply to manufacturing and international trade, but some are "best practice" standards, such as the ISO 9001 requirements for quality management systems (2). An important point to remember is that ISO is a standards-creating body, not an accreditation body.

ISO/IEC 17025

ISO/IEC 17025 is an international standard for best professional practice in testing and calibration laboratories. Because it applies to many different types of laboratories, it is written in broad, general terms. The standard is a combination of management system elements that meet the principles of ISO 9001 and technical elements, many of which had their origin in a previous ISO guidance document, ISO/IEC Guide 25 (3). ISO/IEC 17025 emphasizes a proactive systems approach

ISO/IEC 17025

to quality built around the following activities:

- Planning—Designing the laboratory management system according to quality standards and customer needs
- Doing—Using good laboratory practices to conduct testing
- Checking—Verifying results through quality control measures, audits and customer feedback
- Acting—Using available information to improve the management system

A laboratory that creates and implements an ISO/IEC 17025-conformant system has the Right People (trained, competent) doing things in the Right Way (per policies and procedures that conform to best practice) to produce the Right Results (accurate, unbiased). The focus on the system helps to deflect attacks based upon bias and individual competence.

The required components of a laboratory management system are defined in Sections 4 and 5 of ISO/IEC 17025. Section 4 contains management elements that are nontechnical in nature and typically laboratory-wide in application such as document control, purchasing, corrective actions and internal audit programs. Section 5 contains technical requirements relating to issues that directly impact laboratory testing—personnel, methods and method validation, equipment and so on.

A positive characteristic of ISO/IEC 17025 is its flexibility. While ISO/IEC 17025 is quite specific about the elements that a laboratory must have in its management system, it does not specify how a laboratory must conduct its operations. It should be obvious that a small, single-site, one-discipline laboratory will operate differently from a multisite, multidisciplinary laboratory system with hundreds of employees. Both types of agencies must have document-control systems, and both must have internal audit programs, for example, but the operational details for each activity will reflect their differing organizational structures and customer requirements.

ISO/IEC 17025 provides the outline for how a laboratory management system must be structured, but it is up to the laboratory to fill in the details in an appropriate way.

This doesn't mean that "anything goes", however. When creating the policies and procedures that define their operations, laboratories of all types are required to " . . . establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel." (ISO/IEC 17025:2005, clause 4.2.1)

The bottom line: ISO/IEC 17025 provides the outline for how a laboratory management system must be structured, but it is up to the laboratory to fill in the details in an appropriate way.

AMPLIFICATION DOCUMENTS AND OTHER STANDARDS

Although ISO/IEC 17025 is a rather extensive requirements document, it is general in nature, and forensic science is a field of testing where additional, specific requirements or interpretive guidance are thought to be necessary to ensure an adequate level of laboratory performance. Documents that contain additional requirements or guidance for a specific field of testing are known variously as amplification documents, field-specific criteria or supplemental requirements.

There are several sources for amplification documents in forensic science. At the international level, the International Laboratory Accreditation Cooperation (ILAC) has published a general guidance document for forensic science that expands upon a number of the clauses (mostly technical) of ISO/IEC 17025. This document is ILAC G19:2002 (4), and ILAC allows accrediting bodies (ABs) to use it as a supplemental standards document. Supplemental standards also can be created at a national level and might or might not amplify clauses of ISO/IEC 17025. An example is the FBI Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories (5), which is used as an additional requirements document in accreditation of forensic DNA laboratories in the United States. Finally, an individual AB can create its own supplemental accreditation requirements and policies. In all cases, a laboratory will develop its policies and procedures to conform to the standards and policies used by its accrediting body.

ISO/IEC 17025

The hierarchy of accreditation requirements is thus: (1) ISO/IEC 17025, (2) supplemental standards and AB policies and (3) laboratory policies and procedures.

PREPARING FOR ISO/IEC 17025 ACCREDITATION

ISO/IEC 17025 accreditation is a process in which a laboratory is evaluated by an independent third party—an accreditation body—and deemed to be conformant with established performance criteria and competent to perform certain tests.

Preparing for ISO/IEC 17025 accreditation is no different than preparing for any other accreditation or audit. The ISO/IEC 17025 requirements are not difficult, but there are "gaps" with the FBI DNA QAS and other non-ISO/IEC 17025 standards, particularly with respect to the Section 4 management clauses of ISO/IEC 17025. Even where there are similarities, the correlations are not always exact. Therefore, a laboratory needs to:

- Become familiar with the accreditation standards. Attend workshops; train staff; read guidebooks; refer to guidance documents from ISO and ILAC; talk to colleagues in laboratories accredited to ISO/IEC 17025.
- Identify the gaps in laboratory conformance with the standards. Conduct internal and/or external audits; record specific, objective evidence of conformity or nonconformity to construct a conformance file; involve multiple staff members to increase "buy-in".
- Bridge the gaps. Create a project plan to correct the nonconformities, concentrating on "ISO hot spots" (e.g., document control) if time is short; write and revise the laboratory Quality Manual, policies, and procedures as needed; train staff on the new and revised policies and procedures; conduct follow-up audits to measure the progress of implementation.

ISO/IEC 17025 is an extension of quality management systems already in place in most DNA laboratories. Scientists simply need to put the quality knowledge and practices they use everyday into an "ISO world".

Because it will take time, effort and funding to accomplish these steps, it is critical that accreditation efforts have the support of the laboratory's senior management. It is also important that the quality manager, a staff position mandated by ISO/IEC 17025, be selected early in the preparation process because someone has to be responsible for moving the process along or it probably won't happen. The quality manager can be a DNA technical manager, but in many laboratories it will be a separate individual.

YOU CAN DO IT!

ISO/IEC 17025 is an extension of quality management systems already in place in most DNA laboratories. It is based on three precepts: a good management system, competent personnel and objective proof of the quality of testing. All that remains is for DNA scientists to put the quality knowledge and practices they use everyday into an "ISO world".

REFERENCES

1. ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories, International Organization for Standardization.
2. ISO 9001:2000, Quality management systems—requirements, International Organization for Standardization.
3. ISO/IEC Guide 25, General requirements for the competence of calibration and testing laboratories, International Organization for Standardization.
4. ILAC-G19:2002, Guidelines for forensic science laboratories, International Laboratory Accreditation Cooperation.
5. Federal Bureau of Investigation (2000) Quality assurance standards for forensic DNA testing laboratories. *Forensic Science Communications*, Volume 2, Number 3. This can be viewed online at: www.fbi.gov/hq/lab/fsc/backissu/july2000/codis2a.htm