

Quality Qorner

Sweet Spring Means New Growth

Once past the winter solstice's shortest day of the year, we await the coming of spring, which begins at the vernal equinox. This event occurs on or about March 21—when the sun crosses the equator, making night and day equal in length over all the world. The Greek word for *equal* is “*isos*.”

In the laboratory community, we are hearing and reading increasingly more about an organization known as “ISO.” The actual name of the organization is the International Organization for Standardization. The acronym, “ISO,” was chosen to represent the equality of the member national standards organizations, each of which—despite the size of the originating country—gets 1 vote on proposed and final international standards.

For many years, ISO standards have been used in the manufacturing industry to attain equality in the quality of products being sold and traded across national borders. The premise is that when each country meets agreed-upon standardized international requirements, the comparative quality of their products is more likely to be predictably consistent and mutually acceptable. For example, when we buy electrical equipment, we look for the “UL” symbol for Underwriters Laboratories® because we know that the equipment has been manufactured and tested to meet rigorous quality standards.

One particular ISO industrial standard has been used in several countries to serve as the basis for accrediting medical laboratories. It is, however, strictly a generic industrial standard, void of any technical requirements specifically related to medical and clinical laboratories. Therefore, after several years of drafting and editing, Work Group 1 of the ISO Technical Committee #212, *Clinical laboratory testing and in vitro diagnostic test systems* (abbreviated as ISO/TC 212 WG1) developed an ISO standard specific for medical laboratories.

What is ISO 15189? ISO 15189, entitled *Medical laboratories—Particular requirements for quality and competence*, was released in 2003 but has received little attention in the United States. In the United States, the Centers for Medicare Services' (CMS) Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) and the recent CLIA update in 2003, had already set minimum requirements for laboratories that perform diagnostic testing. However, our neighbors in Canada quickly adopted ISO 15189 as their national laboratory standard because they did not already have any national regulation such as CLIA. This ISO standard is also being used in Europe and Australia as a basis for accrediting their medical laboratories.

What does ISO 15189 offer that the requirements of most U.S. medical laboratory regulatory and accrediting programs do not have? Most importantly, the ISO standard requires that each laboratory has a quality management system; that is, a *systematized* means of ensuring quality throughout all activities both in and supporting the laboratory's entire path of workflow—defined as the span of time from placing an order for a laboratory test or examination extending through all the activities necessary to finally providing the result report, which includes information about the meaning of the test or examination results. A quality

management system contains a quality policy; quality objectives; documented policies, processes, and procedures for management and technical activities; and a visibly active role for the laboratory's management in monitoring and ensuring the effectiveness of the system—which is much bigger than performing just quality control and quality assurance alone!

“What to do”—Not “How to do it.” The ISO 15189 standard is a set of statements that describe *what* a laboratory needs to do to fulfill requirements for quality, but does not provide details for *how* to implement them. Therefore, laboratories need other resources to understand the requirements and guide implementation. Thankfully, you have access to some excellent information for learning how you can implement the standard's requirements in your laboratory.

For example, the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) has published several guidelines to help you understand quality management systems. You can also obtain a copy of the ISO 15189 standard itself. Just visit their Web site at www.clsi.org.

Also note that a live presentation on ISO 15189 will be given at the CLMA/ASCP *ThinkLab '05* conference in Chicago on Tuesday, March 8. You'll have an opportunity to learn more and ask questions of the speaker, who serves on ISO TC 212/WG1.

Stay Tuned. Should the United States laboratory community pay attention to ISO 15189? You bet! It contains standards above and beyond CLIA requirements that help ensure quality. This standard provides the means to universally define medical laboratory quality around the world. Most importantly here at home, it is a sure-fire means to move your laboratory to better patient safety. That's what's really important!

In future Quality Qorner columns, we'll be exploring quality management system thinking in bite-sized pieces, concept by concept. In the meantime, remember that spring is a time of new growth...and there's new growth in the meaning of equality in quality in our medical laboratories.

This Month's Quality Quote. “In our springtime every day has its hidden growth in the mind...” *Felix Holt, The Radical, 1866.*

Contact Us. Question? Comment? e-mail me at: Imberte@worldnet.att.net.

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