

Quality Qorner

This Small World

The room was organized like a mini United Nations. The representatives from each country in attendance sat together with a sign specifying their country's name. Each country's spokesperson had carefully prepared notes for introducing their respective delegates by name, affiliation, and work group. The committee chairperson and members of the secretariat sat at the head table facing personal computer screens that projected to them what the delegates were viewing on the large screen behind. Microphones were present at each table. We were about to begin the plenary session of the International Organization for Standardization (ISO) Technical Committee (TC) 212, Work Groups (WG) 1, 2, and 3 in Berlin, Germany this past June.

I took a deep breath, and looking around the room, experienced a definite anxiety. What was I doing here in the middle of a world-wide delegation, not representing a professional organization as did the others, but rather, representing an individual laboratory staff person's perspective on an international medical laboratory standard?

Me—whose first job was as an afternoon-shift staff generalist in a 170-bed community hospital in Milwaukee so many years ago. Me—one of thousands of United States medical technologists, any number of whom may have qualified to be there, instead. Me—who, at the conclusion of this opening plenary session, would be asked to facilitate the intense discussion of revising the latest draft of the international laboratory standard. After another deep calming breath, I looked around the room again and this time, smiled. I imagined how my parents might have excitedly described to relatives and family friends where I was and their fractured version of what I was doing.

Market globalization has reduced this world to a very small place indeed. As part of our everyday jobs, we circulate e-mails to global committees that contain drafts of projects, books, and papers; we participate in international audio and video conference calls at all hours of the day and night to work on these and other projects; and we interact in real-time, online Web-based training and educational sessions in virtual international universities. However, no matter how much instant communication is available to us, nothing will ever replace the basic human need to meet and interact face-to-face—and all the more fun and interesting if it is in a different country and city than one's own! So here we were in Berlin, Germany, in the middle of what had once been a communist country not so long ago.

After serving several years as a Work Group 1 e-mail correspondent and observer, I had been invited to participate as a work group member in the writing of the next version of the international medical laboratory standard, *ISO 15189, Medical laboratories—Particular requirements for quality and competence*. This standard, originally published in 2003, is scheduled for renewal and update in 2008. However, due to the lengthy time periods allowed for ISO member countries to review and comment on the draft and final draft versions, the revision efforts need to begin shortly after the initial final version is published.

In the United States, the CLIA '88 regulation sets the national standard for medical laboratory practice; therefore, our laboratory accreditation organizations (eg, JCAHO, CAP, AABB,

COLA) need to specify accreditation standards and requirements at least as stringent as those in the CLIA '88 legislation and subsequent CLIA updates. However, in other countries such as Canada, Australia, New Zealand, and members of the European Union, ISO 15189 is the national standard for medical laboratories. Each country has a laboratory accreditation program based upon the requirements in that international standard.

Accordingly, almost all of the delegates and WG members represent their country's regulatory and accreditation organizations. After all, if we are going to have a standard that can be used for laboratory accreditation, then the accreditation organizations should have input into what the standard requires laboratories to do. But what about representation from those who are on the receiving end of the accreditation organizations' activities? Who will speak up to make sure that the standard is comprehensible to those who have to implement the standard's requirements? This is where I felt I needed to step up and be heard, and that is how I found myself in the thick of the action. What an exciting place to be!

The WG's writing effort is actually quite challenging. We need to specify what actions laboratories must take to ensure patient safety and laboratory service quality. We need to communicate the requirements (the *what* is to be done) without being too prescriptive (the *how* to do it). We need to write requirements that can actually be met within a country's available resources. We need to sequence the requirements in an order that represents how work flows through the laboratory so that readers can see when to do what is to be done. Also, we need to write these requirements in clear succinct English that every member country can translate into its native tongue.

It's an honor and a privilege to participate in such an encompassing endeavor. No wonder I was feeling anxious. It's a balancing act between the accreditors and the accredited, and I am often outnumbered as a representative of the latter—but at the end of the long days, we all agree that we are in this endeavor for the patients. Then, we enjoy the host country's social program, get to know about each other's lives outside the laboratory environment, and learn about the cultures these different countries represent.

For many accreditation professionals, global travel and international meetings are often part of their jobs. Not so for me. I will always be looking around the room, reflecting on my "bench" background, and being a little overwhelmed by the honor and responsibility of representing our chosen profession.

This Month's Quality Quote:

"There can be no improvements where there are no standards."

—Masaaki Imai

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