Quality Qorner

Let's be Careful out There!

DOI: 10.1309/5P4NFVT3ECPJW861

Funny. I can't remember where I laid my glasses, yet I can remember the opening quote from the old TV show, Hill Street Blues, "Let's be careful out there!" That sentiment rings as true today as when the police sergeant cautioned his staff at the beginning of each weekly program.

All over the medical laboratory world, we are seeing more international effort toward "being careful out there." As a case in point, the month of May sees yet another plenary meeting of ISO TC 212 and working sessions of its 4 work groups in Beijing, China.

Work group 1 has been responsible for updating the important medical laboratory international standard ISO 15189: *Medical laboratories—Particular requirements for quality and competence*. This standard sets forth requirements beyond what appear in United States CLIA '88 regulations, JCAHO standards, and CAP inspection checklists. Major differences include requirements for a documented quality-management system, a quality manual, and an internal laboratory audit program.

Whereas CLIA '88 requirements serve as the national standard for United States laboratories, other countries use ISO 15189 as a basis for their medical laboratory accreditation programs. Canada and Australia are examples. However, in the United States, both the CMS and the CAP are slowly adding items from ISO 15189 to their programs. For example, one recent major transfer to United States requirements from the international standard includes control of the development, approval, distribution, review, modification, and archiving of laboratory documents.

Some United States laboratories are actually preparing their managerial and technical operations for obtaining laboratory accreditation to the ISO 15189 standard. To do so, these laboratories need to have a documented quality-management system meeting all the requirements specified in the ISO standard. United States standards do not require laboratories to have a quality-management system; therefore, interested laboratories need to seek information and guidance on how to develop and implement one.

So, why my admonition to be careful out there? Well, things have changed a lot since the non-Internet days of "Hill Street Blues." As a modern adage has it, "As you Google, you will find." However, it is what you may find that is problematic. For example, several Web sites are selling "ISO 15189 implementation packages," and some state their product "allows medical laboratories to be successfully accredited to ISO 15189." These packages provide "document templates that will save much time in typing alone," "quality records," "prewritten quality manuals that you customize," and "document titles and numbers that exactly match the standard."

But, be careful! Do not be fooled into buying what you think is a ready-made quality-management system. Do not make your laboratory experience the same painful lessons learned by transfusion services only a decade ago. In the 1990s, in a well-meant attempt to help transfusion services be prepared for quality system-based AABB assessments, the AABB published a prewritten "Model Quality System for the Transfusion Service" that facilities could customize simply by attaching their respective facility identification. Problems immediately arose when AABB assessors asked to see the records supporting the prewritten, "boiler plate" statements claiming the facility maintained a document control system, or an internal audit program, or an occurrence-management program. Laboratory professionals thought the prewritten quality manual was the documented quality-management system itself. They did not understand that the paper manual was not enough, that it was the actions taken by staff—performing the processes and procedures, and generating supporting records—that provided the evidence that the facility met the intent of the standard.

Also, do not be fooled by document titles and numbers that match those of any standard. Do not make your laboratory experience the painful lessons learned by businesses certified to the 1994 version of ISO 9001 when, in 2000, the revised standard had been entirely renumbered and every quality manual prenumbered in concert with the previous standard version was, thus, obsolete. Consultants easily cashed in by luring companies to buy yet another quality manual numbered in accordance with the new 2000 standard. However, what will soon happen to those same companies when the next version of ISO 9001 is released with its expected numbering and standards changes? What value is there in having a quality manual numbered to a single standard when our medical laboratories are subject to the regulatory requirements of so many different organizations, each with its own numbering system, which periodically changes?

The painful truth about quality-management systems is that each laboratory has to develop its own policies, processes, and procedures to meet all the varied requirements. Smart laboratories build and implement one set of policies, processes, and procedures that meet all the requirements for which they are responsible.

Thus, the secret to developing quality documents covering all the CMS, JCAHO, CAP, AABB, COLA, ISO 15189—or any other accreditation institution—requirements is really no secret at all. Simply organize your laboratory's policies, processes, and procedures around the Quality System Essentials. Whereas standards and checklist item numbers change constantly, the Quality System Essentials are basic unchanging building blocks of quality that form the foundation of a quality-management system and a quality manual that will meet any standard.

So, go out there and round up the bad guys—the problems that compromise quality and patient safety. Just remember, be careful out there!

This Month's Quality Quote:

"*Caveat emptor*. (Let the buyer beware.)"

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