

Creating a New International Standard: a Slow But Important Process

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Readers of CMPT Connections are aware that the International Organization for Standardization has decided to create a new quality management standard for clinical laboratories. The standard is in a sense a specific extension of the primary quality management standard known as ISO 9000, which is used for all industries. When the new standard, which is referred to as ISO 15189 is completed it will form the basis for quality management processes for all laboratories in all countries and regions that recognize the value in meeting international standards. In Canada, this document when completed will be adopted by the Standards Council of Canada and the Canadian Standards Association as an official document of Canada. Many provincial accrediting bodies that have been a part of the process have acknowledged strong interest in adopting the standard either in part or in whole as a component of their accreditation process. Through recognition and participation in the international process, Canadian laboratories will achieve a level of national harmonization in this aspect of medical laboratory management. It is a critical part of the first steps to achieving assurance that medical laboratory care in Canada will be consistent throughout.

By now, many of us thought that the task had been completed and that the Standard would be available for laboratories to evaluate. Unfortunately, we are not there yet. The ISO is by its very nature an organization of rules, including that all ISO Standards should be consistent in format and structure with primary documents. This of course makes infinite sense; if the ISO cannot demand internal standardization of its own documents, why would any country give their position statements, guidelines and standards their fair due. Unfortunately ISO 15189 has been caught in a momentary trap because the ISO primary documents have recently gone through revision and publication under a new guise known as ISO 9000:2000, and it has become necessary to revise our document to the new format.

In many ways, changing formats is a fairly simple process, that requires changes to document structure and few text changes, however in this instance there are other considerations as well. In previous format ISO 15189 was seen to be very strong in the documentation of quality. This to laboratorians made infinite sense. We are very comfortable with the notion of developing and creating manuals including quality manuals. We understand creating job descriptions and accept the process of competency assessment and the process of recognizing errors or opportunities for improvement, and documenting the changes that result. While many may not routinely perform internal management review of processes, we certainly are used to regular external quality assessment (proficiency testing) and inspection and report. Again we monitor results, record deficiencies, and document investigation and implementation of change.

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ness, the requirements of the customer are specified and are met. Where they are not, the business investigates and determines where the challenges lay. For clinical laboratories, we too have a sense of customer satisfaction, although for us, often the first question is “who is our customer?”. In some respects our customer is the clinician that has ordered the test or procedure; in other respects, our customer is the patient. In the new format of ISO 15189, it is made clear that the primary customer of the medical laboratory is the patient. This creates certain interesting challenges and expectations for the laboratory. Routinely we address letters of concern and complaint with all the respect and courtesy due; this will not change. However some fundamental questions will rise. Will there be an expectation that laboratorians interact more directly with patients? Will customer feedback be directed to the patient or clinician? Will laboratories develop more patient and community oriented surveys,

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tours and visits. Will laboratories develop more layperson positions in their advisory committees? Clearly some of these are questions that will be easier to address in the abstract, rather than in reality.

Perhaps the more fundamental questions on laboratorian minds are “when are we going to see this process finished, and when are we going to see a direct impact on our daily lives?”.

The answer to the first part hopefully is within the year 2001. With the revision of document, there will be another international vote by all member countries of ISO. This final draft international standard (FDIS) vote will be held this summer. Assuming that the vote is positive we would anticipate a published version shortly after.

With respect to the other, larger question, time will tell. If the (Canadian) National Committee for Medical Laboratory Quality Systems endorses the newly formatted version, and the provincial accreditation programs see value in the document, changes will come quickly. Some provinces are already prepared to accept the document *in toto*. For some laboratories, ISO registration will become a new registration, replacing other international accreditations currently in place. In either event, while the process is slower than initially anticipated, when the document is completed, Canadian laboratories will benefit from the increased awareness. Good laboratory management is good business practice. Regardless of the setting — in-hospital, outpatient, or reference laboratory — increased awareness of quality management and the progressive process of continuous improvement make sense.

Readers interested in hearing more about ISO 15189 are recommended to contact either the author, or their provincial College of Physicians and Surgeons laboratory accrediting body.