

Walking the Walk—CMPT’s Journey to Meet ISO Standards

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Over the last several years, I have been keeping you up to date with the proposed new International Organization for Standardization (ISO) standards for clinical laboratories. The message is consistent—the new standards will be a positive impact on the quality management of laboratories in Canada. While implementation of quality management programs creates a lot of work, the laboratories will be better off having gone through the experience. That’s fine for us to say, but I am sure some of you (or maybe *all*) are wondering that if international standards are so good for laboratories, how about for proficiency testing programs. If we are going to talk the talk about quality management for laboratories, should we not also be expected to walk the walk. Fair comment—we agree.

There are a number of international standards for proficiency testing programs. One is created by the ISO and is known as Guide 43, another was created by the International Laboratory Accreditation Cooperative (ILAC), and the third was created under US federal regulation Clinical Laboratory Improvement Act (CLIA). Fortunately, and not surprisingly, there are marked similarities between the three standards. CMPT has started the process of becoming recognized by these international bodies as meeting the standards.

There are several sections for which standards have been established. These can be categorized as: maintaining a quality management system, providing appropriate and sufficient information to program participants, ensuring thorough and valid evaluation of results, providing useful reports to program participants, enabling a process of dialogue, performance of internal and external audits to confirm compliance.

So far we have had discussions, have had visits by our consultant and had our preliminary audit, and set out the pathway to registration and recognition. The audit suggested that we were starting at about 75 percent of the way towards meeting international standards. For CMPT as with all laboratories and programs, the journey is at least as important as the destination. Going through the process of implementing a formal quality program is a valuable learning experience.

Will this process make us a better program? We would like to think that to date we provide a good external quality assurance service, which includes—consistent samples, a recognized educational component and many options for participants to communicate with us. We have received very good feedback regarding the newly formatted critiques, the web site and CMPT Connections. And many of you tell us that **Shirley Nikiforuk** and **Caleb Lee** provide excellent advice, assistance and expertise. *But* as with all programs there is always room for making things better (we call that continuous quality improvement!).

We will keep you abreast as we “journey” through the process.

[Ed. notes:

1. Michael Noble has been a member and Chair of the ISO Technical Committee 212 Delegate Group since the inaugural meeting in Philadelphia in 1995. He has concentrated his efforts towards establishing the Canadian Advisory Committee, ensuring a funding and resource base, and his participation in the Working Group 1 created the documents *Quality Management for the Medical Laboratory* (15189) and *Safety Management for the Medical Laboratory* (15190). Both documents have been completed and are being circulated as Draft International Standards (DIS) for international voting and acceptance.
2. Noble MA. 1997. Canada and International Standardization for Clinical Laboratories. *CMPT Connections* 1:2 p. 2-3.]

Ever wonder about ISO’s name?

“Many people will have noticed a seeming lack of correspondence between the official title when used in full, International Organization for Standardization, and the short form, ISO. Shouldn’t the acronym be “IOS”? Yes, if it were an acronym—which it is not.

In fact, “ISO” is a word, derived from the Greek *isos*, meaning “equal”, which is the root of the prefix “iso-” that occurs in a host of terms, such as “isometric” (of equal measure or dimensions) and “isonomy” (equality of laws, or of people before the law).

From “equal” to “standard”, the line of thinking that led to the choice of “ISO” as the name of the organization is easy to follow.”

[Ed note: This information was copied from the ISO web site. If you wish to learn even more about ISO try visiting www.iso.ch/info/intro.htm]

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