



Evolving International Standards for Laboratory Medicine
Harold Richardson, MD, FRCPC,
Managing Director, Quality Management Program-Laboratory Services
Toronto, Ontario

The International Organization of Standardization (ISO) in 1995 established a Technical Committee (TC212) to develop standards for the medical laboratory and in vitro diagnostic devices. Working in association with the European technical committee, CEN TC 140, the ISO technical committee has developed standards for the management of quality within the medical laboratory, standards for reference materials and those for medical devices. Most recently Working Group I of TC212 met in Mexico City to continue the development of standards concerning the management of quality in medical/clinical laboratories with **Mike Noble** and **Harry Richardson** as the Canadian delegates.

The Mexico City meeting was the first for the group under its new convener, Dr. Desmond Kenny of Ireland. Consideration of a draft technical report (ISO/DTR 22367) Medical laboratories – Reduction of error through risk management and continual improvement resulted in a decision, following discussion of the international comments, to strike a project group to re-write the draft. The technical report proposes a methodology for finding and characterizing medical laboratory error that would lead to its avoidance and improve patient safety. Laboratory error is defined as failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim; a defect occurring at any part of the laboratory cycle. The re-draft is intended to improve the clarity of the report particularly regarding corrective and preventive actions.

The draft International Standard ISO/DIS 22870, Point-of-care testing (POCT) – Requirements for quality and competence, was approved without dissent during its recent international vote. The working group considered the comments received and made minor changes to the draft standard largely of an editorial nature. The revised document will be submitted to the ISO Central Secretariat shortly for distribution as a final draft International Standard (FDIS) for vote. Publication can be expected early in 2006.

Readers will be familiar with the standard EN ISO 15189:2003 Medical laboratories – Particular requirements for quality and competence as the basis for the OLA requirements. Although it is only a short time since this standard was adopted, the time has come to look to the next revision. In the short term it is proposed to make minor changes in the form of an addendum to align this standard with the new version of ISO 17025, the standard for testing and calibration laboratories. The changes are largely editorial. Client will be replaced by customer, non-conformance by non-conformity, and quality system by management system as necessary. There will be some changes in the Introduction, Scope and Normative references. A definition of "accreditation" will be added. In the longer term ISO 15189 is scheduled for review no later than 2008 and the process is to begin now. A project group has been established for this task. One proposal is to draft the second edition as a process and outcome-based model designed as a system to manage quality in medical laboratories.

Following initial discussion of a new work item proposal on Genetic Testing, it was agreed that more work is required on the structure and content of the proposal prior to its formal consideration at the next meeting of the group in Washington, D.C. in May. Reflecting the work of this group it was suggested that its name be changed to the Quality and Competence in Medical Laboratories Working Group. The technical committee at its May meeting will consider this change.

[Ed. note: Dr. Richardson's article first appeared in QMP-LS News No. 88, March 2005. We thank QMP-LS for granting permission to publish this article in CMPT Connections 'on-line'.]

CMPT Connections 'on-line'
 The next submission deadline is **June 15, 2005**.
 Submissions criteria are available on the web site.

"Connect" with us via
 Telephone: 604-875-4685, 1-866-579-CMPT
 Facsimile: 604-875-4100, 1-866-580-CMPT
 Email: cmpt@interchange.ubc.ca