

No. 210

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International Organization for Standardization Technical Committee (ISO/TC) 212

by Harold Richardson, BSc, MD, FRCPC

The International Organization for Standardization Technical Committee (ISO/TC) 212 continued with the work of creating international standards for clinical laboratory testing and *in vitro* diagnostic testing during the third annual meeting in June. On this occasion, Canada was the host country from June 8–10, at the National Conference Centre in Ottawa. The delegates of the Standards Council of Canada to ISO/TC 212 are: Dr. M.A. Noble from British Columbia, Dr. H. Richardson of Ontario and Dr. M. Dupras from Quebec.

Dr. Klaus Stinshoff of Geneva, Switzerland, was recommended for appointment as Chair of the Technical Committee for the next three years.

The Working Groups on Quality Management in the Medical Laboratory, Reference Systems, and *in vitro* Diagnostic Products had met twice during the preceding year and tabled their reports and working documents. It is anticipated that the draft documents on the international standards in each of these areas will be completed within the next year and adopted in 1999, or shortly thereafter, following a vote by the ISO member countries.

The working document on *Quality Management in the Clinical Laboratory* is in its final phase, prior to adoption. The standard deals in a comprehensive manner with all “management requirements” in the clinical laboratory, namely:

- The quality management system
- Organization and management
- Document and information control
- Referral of tests to other laboratories
- External services and supplies
- Control of non-conforming testing
- Corrective actions
- Preventive actions
- Records
- Internal audits
- Management review

and covers the “technical requirements” including:

- Personnel
- Accommodation and environmental conditions
- Equipment
- Pre-analytical procedures
- Analytical procedures
- Quality assurance
- Post-analytical procedures

Annexes to the *Quality Management* standard will address:

- Laboratory computer services
- Ethics in laboratory medicine.

As a separate work item there had been considerable discussion of the requirements for a safe workplace. After having reviewed and considered a number of national documents, policies and procedures; there was agreement to develop an internationalized version of NCCLS’s GP17 document on clinical laboratory safety for adoption as an ISO standard.

Working group 3 recommended a change in the title and scope for one of its work items. The new title *Determination of Analytical Performance Goals for Laboratory Procedures Based on Medical Needs* was adopted. The scope of this item addresses analytical goals in relation to medical practice. The group also recommended a change in the scope of a second work item — “to specify procedures for the determination of performance criteria for quantitative *in vitro* blood glucose monitoring systems for management of human diabetes mellitus.” The primary goal of this latter standard is to assure the performance of blood glucose monitoring systems for self-testing and similar applications and to specify tests by which compliance with the requirements can be verified.

The next meeting of ISO/TC 212 will be held in Geneva, Switzerland, from July 8–10, 1998. ■

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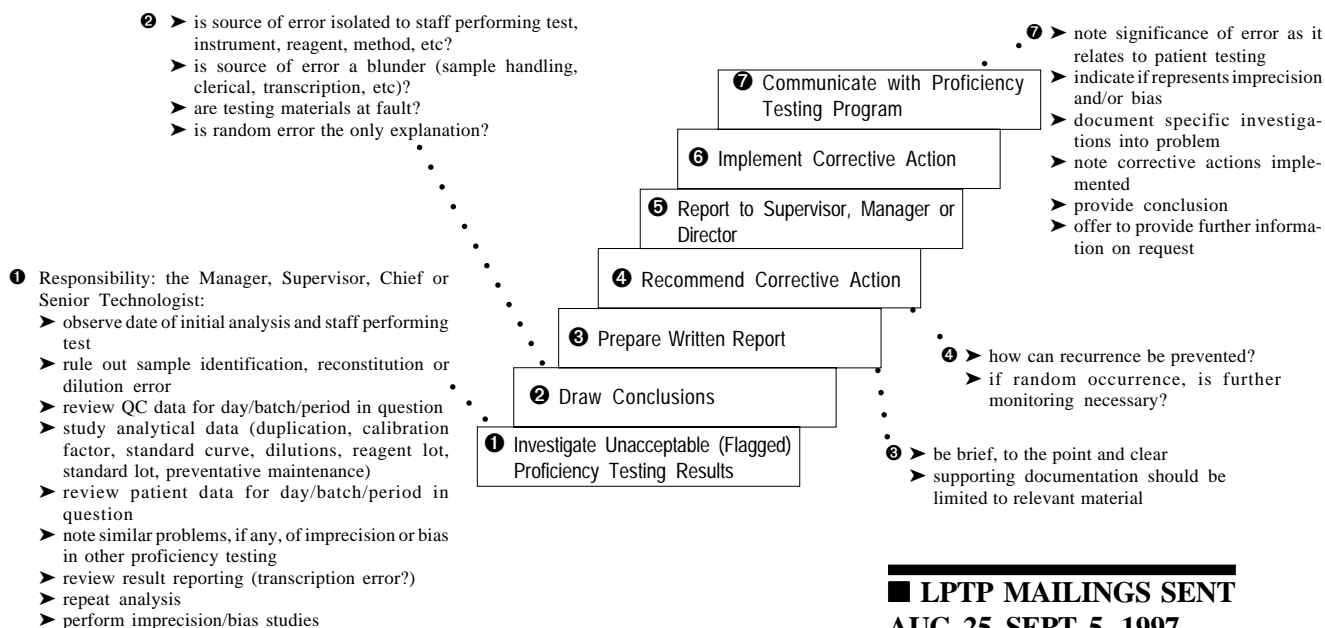
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Utilizing Proficiency Testing as a Quality Improvement Tool

Linda Crawford, MLT, (ASCP) and Debora McKay, MLT, (ASCP) SC, MSc

- ❑ Careful selection and utilization of proficiency schemes will aid the laboratory manager's development of a cost-effective quality improvement program.
- ❑ Use of performance data derived from peer-group proficiency testing can be utilized to develop decision criteria for quality improvement with regard to future testing and techniques.

STEPS TO IMPROVING PERFORMANCE



The above information is an excerpt from a poster presentation at the Clinical Laboratory Management Association (CLMA) 1997 Annual Conference held in Toronto August 16-20, 1997. This poster will also be on display at the OSMT convention in London September 25-26, 1997.

BACTERIOLOGY SURVEY B-9709

Survey B-9709 will be comprised solely of "STAT" Gram stain challenges and all laboratories, currently licensed for Gram stains, will be expected to participate in this survey. Laboratories that are licensed to perform blood cultures, in addition to Gram stains, will receive four "fresh" simulated blood cultures for Gram stain only. Those licensed only for Gram stains will receive prepared slides. The survey material will be sent on September 16th, 1997 and should arrive at laboratories on September 17th. The material is to be processed immediately upon receipt and results reported to LPTP as soon as possible. The turnaround time from receipt of material to reporting of results will be assessed. Complete instructions will be included on the Analysis Worksheets that accompany the material.

If you have any questions or concerns regarding this survey, please contact Christine Fleming at extension 238.

LPTP MAILINGS SENT AUG 25-SEPT 5, 1997

- M-9707 Hematology-Morphology Committee Comments
- S-9708 Maternal Serum Screening Analysis Worksheets & Testing Material
- S-9706 Maternal Serum Screening Survey Report and Committee Comments
- T-9705 Parasitology Committee Comments and Survey Reports
- I-9709-A Transfusion Medicine Analysis Worksheet and Testing Material

Shipped separately:

- I-9709-B Transfusion Medicine Analysis Worksheets and Testing Materials

✍ Mailings may be shipped separately during the period shown above. Each laboratory will receive only selected items. If you consider you should have received an item and have not done so, please contact LPTP.