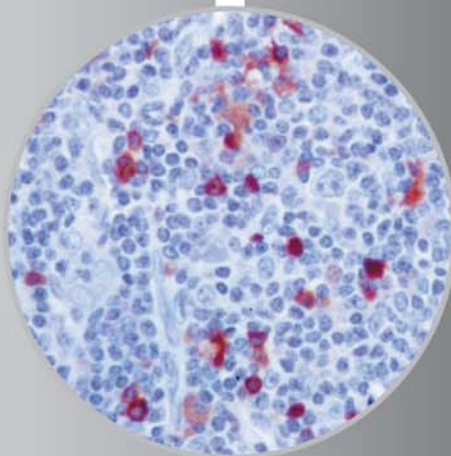
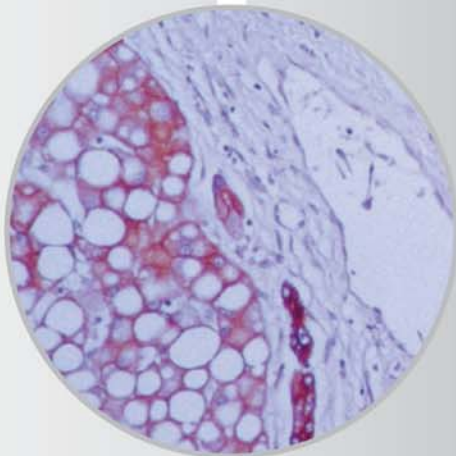
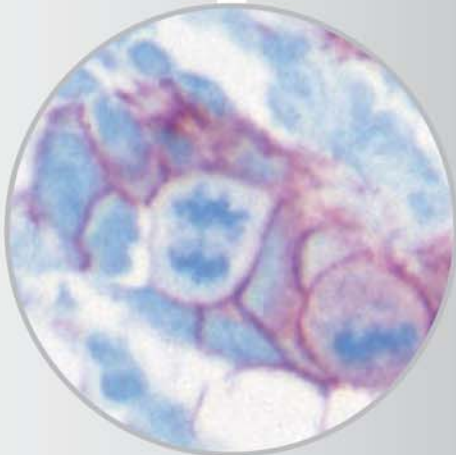
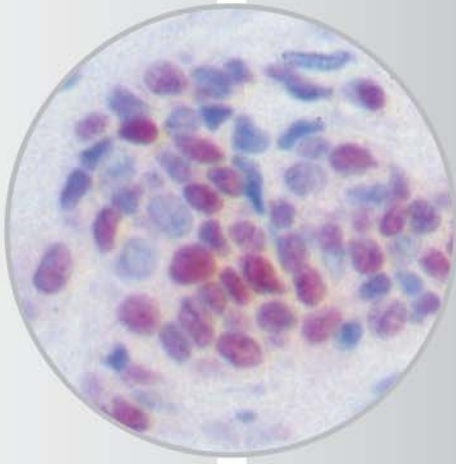




QUALITY MANAGEMENT PROGRAM LABORATORY SERVICES

2007 REVIEW



Cover images generously provided by **Bryan Hewlett**
QMP-LS EQA Consultant Technologist, Anatomic Pathology

Image Legend: QMP-LS Immunohistochemistry Surveys

From top to bottom, left panel:
breast tumour ER, breast tumour HER2, liver cytokeratins

From top to bottom, right panel:
breast tumour PR, small bowel vimentin, tonsil S-100

2007 Review cover design by **Vanessa Yee-Young**
Visual Merchandising Arts Graduate
Seneca College



VISION, MISSION, VALUES AND QUALITY POLICY

The QMP-LS 2007-8 Review of activities presents fiscal year data. Information reported in the 2007-8 Review is based on activities from April 1, 2007 to March 31, 2008.

VISION

To be a world-class provider of accreditation, quality assessment and supports to laboratories and related services for diagnosis and treatment of disease, and the promotion of health.

PURPOSE/MISSION

To promote quality improvement of laboratories and other related services for the public good and the benefit of health professionals.

VALUES

- Quality
- Collaboration
- Integrity

QUALITY POLICY

QMP-LS commits to maintain a quality management system to support high quality laboratory accreditation, external quality assessment and education services that:

- is customer focused;
- meets applicable regulatory, statutory and contractual requirements; and relevant national/international standards referenced below;
- evaluates and continually improves the effectiveness of the services provided;
- ensures this policy and all associated processes and procedures are communicated to and understood by all employees;
- provides a process for establishment, review and modification of quality objectives;
- ensures annual review of this policy for continued suitability.

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The reader is cautioned not to take any single item, or part thereof, of the 2007-8 Review out of context.

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MESSAGE FROM THE MANAGING DIRECTOR

This past year laboratory quality has become a national, if not an international, concern. The importance of accreditation, external quality assurance and laboratory oversight is widely accepted, and Ontario's Quality Management Program—Laboratory Services (QMP-LS) is increasingly viewed as a paragon in the realm of laboratory quality management. The program that was envisioned by the late Harold Richardson, built by QMP-LS staff and funded by the Ministry of Health and Long-Term Care in Ontario has provided a supportive and progressive, continually improving foundation for quality in laboratory medicine.

On this foundation, QMP-LS is working to improve our core offerings in the province of Ontario while at the same time positioning the organization to expand its knowledge transfer and intellectual products to serve our Ontario clients better and to provide advice and services outside our core client base.

To achieve these strategic goals QMP-LS made three key operational changes in 2007–8. Firstly, as a quality organization it is important for us to be appropriately accredited and have the necessary elements in place. We have achieved a demonstrable level of quality that meets international standards for External Quality Assessment (EQA) and Ontario Laboratory Accreditation (OLA). Our own quality system meets these standards.

Secondly, to deliver our programs we consolidated Information Services, Communications and Documents, and materials management into a single Corporate and Support Services division.

Finally, to manage relationships, knowledge transfer projects and develop markets, QMP-LS established a separate division, the Institute for Quality Management Healthcare (IQMH).

QMP-LS has had a small client base internationally and inter-provincially. We are expanding these offerings with Web-based modular programs to prepare laboratories for accreditation to ISO 15189:2007 and offering our EQA IHC hormone receptor testing nationally. We continue to be a credible source of advice on laboratory quality management.

This has been a repositioning year for QMP-LS. We have demonstrated progress in continual improvement of our client services in Ontario, and all our divisions are aligned with our strategic plan. We are ahead of the curve and the future is bright.

QMP-LS is the sum of its parts and we depend on the generous work of hundreds of committed laboratory professionals who serve as committee members (Appendix A) and volunteers (Appendix B). Without them we could not have the success we all share and enjoy.

We thank the following committee members who retired during 2007/2008 year:

Mr. Glen Dietz	Dr. Daniel Klass	Dr. Ken Newell	Mr. Jeffrey Sumner
Dr. Ola Kassim	Mr. Marvin K. MacLean	Dr. Ruth Padmore	Dr. Frank E. Thompson
Mr. Don Kerr	Ms. Rose McQueen	Dr. James Scott	

We also thank Mr. Jim Moran, our OLA assessor trainer, and Mr. Dan Tholen, our statistical consultant, for their invaluable expertise, advice and guidance.

Staff at QMP-LS (Appendix C) are commended for their continual support.



**Dr. Gregory J. Flynn,
QMP-LS Managing
Director**

CORPORATE PROFILE, FRAMEWORK AND GOVERNANCE

PROFILE

The Quality Management Program—Laboratory Services (QMP-LS) is a department of the Ontario Medical Association (OMA) that supports efficient and effective high-quality laboratory services.

FRAMEWORK

QMP-LS acts as the agent of the Ministry of Health and Long-Term Care (MOHLTC) for the external quality assessment and accreditation of licensed medical laboratories in Ontario.

QMP-LS provides:

- a mandatory accreditation process to licensed medical laboratories in Ontario that is:
 - based on explicit criteria that reflect identified federal and provincial laws, as well as international, federal and provincial standards and guidelines that represent generally accepted principles of good practice;
 - conducted periodically and for cause;
 - a peer-driven multidisciplinary team process;
 - encouraging of self-assessment;
 - involved in the promulgation of standards and practice guidelines.
- mandatory external quality assessment of the pre-analytical, analytical and post-analytical performance of laboratory services to licensed medical laboratories in Ontario;
- education services that focus on problem areas identified through external quality assessment or accreditation.

QMP-LS provides laboratories with accreditation, external quality assessment and education services through three divisions, the External Quality Assessment (EQA) division, the Ontario Laboratory Accreditation (OLA) division, and Support Services comprising Communications and Documents, Education, and Information Services.

The main function of EQA is performance improvement through assessment and education to optimize laboratory services for the benefit of the patient. This assessment is carried out through the interlaboratory comparison of laboratory performance.

OLA assists laboratories in delivering high-quality, efficient laboratory services according to recognized international standards through the achievement of full accreditation.

OLA ensures quality management processes are in place and EQA monitors the output of those processes.

Both EQA and OLA services are available to other laboratories voluntarily.

EXTERNAL QUALITY ASSESSMENT (EQA)

EQA is run according to principles based on internationally recognized standards for external quality assessment organizations. These principles emphasize:

- use of real patient material, where possible, to assess routine practice;
- involvement of peers to oversee assessment models;
- use of an assessment process that is transparent, objective and capable of distinguishing between good and poor performance.

Challenge Surveys

EQA assesses the quality of Ontario's laboratories through "challenge surveys" that are planned and assessed by 12 volunteer scientific committees covering the major disciplines of laboratory medicine. Committee members are laboratory physicians, scientists and technologists from Ontario laboratories.

EQA sends out more than 100 challenge surveys for approximately 400 tests annually. Every laboratory is tested at least twice a year and optimally three or four times so that the committees can see how it is performing over a period of time.

Challenge surveys test the proficiency of the laboratory's analytical processes. EQA provides undisclosed actual or simulated patient material for the laboratory to process and then receives the results for comparison and analysis.

If a laboratory's results are not within the norm, the peer volunteer committee asks it to review the processes that led to the result, determine the problem and implement a solution. The laboratory then has three weeks in which to respond.

If the laboratory has resolved the problem, there is no further action. If, however, its response indicates that it has not understood the problem, the committee continues to follow up through correspondence and, in some instances, offering an on-site consultation visit. During this visit, a team of committee members will consult on all facets of testing and develop a list of recommendations. These recommendations must be implemented.

If the laboratory still cannot improve its performance, it may be considered "non-proficient" and referred to the MOHLTC for further remedial action that may ultimately include suspension or loss of licence for the tests in question.

Education is an important component of the EQA program. The EQA peer committees not only assess the results of the surveys, they also provide advice and expert commentary to participating laboratories.

Patterns-of-Practice Surveys

QMP-LS also provides paper surveys that facilitate the assessment of pre-analytical and post-analytical phases of laboratory practice. Patterns-of-practice surveys assess focused areas of laboratory practice against referenced criteria through use of questionnaires and/or review of laboratory records or documents. By reviewing and analyzing performance, EQA can identify "state of the art" practice in Ontario. When appropriate, the scientific committee may develop best practice guidelines from information derived from these surveys.

ONTARIO LABORATORY ACCREDITATION (OLA)

OLA's program for accreditation of Ontario laboratories was developed from several sources:

- International Organization for Standardization (ISO) standards for medical laboratory competence, laboratory safety, and point-of-care testing competence;
- the Canadian national ISO standard CAN/CSA Z15189-03 *Medical laboratories—particular requirements for quality and competence*;
- ISO 17011:2004 *Conformity Assessment—General requirements for accreditation bodies accrediting conforming assessment bodies*;
- International Laboratory Accreditation Cooperation guidelines for assessor qualifications, training and competence;
- government legislation and regulation;
- consensus guidelines reflecting accepted principles of good practice;
- input from laboratory stakeholders.

Accreditation requirements (i.e. the standard for accreditation) contain:

- 513 general requirements that a laboratory must meet in order to gain accreditation;
- 3 good practice recommendations.

Ontario's 229 laboratories are assessed by pre-trained and certified volunteer peer assessors who work or have worked in a laboratory. Teams are screened for conflicts of interest and sent to laboratories where they have specific expertise in the work being carried out. OLA conducts about 50 assessments annually.

The Ontario Assessment Process

A laboratory undergoes an accreditation assessment visit at minimum every five years. Midway through the cycle, it carries out a formal self-assessment and submits the results to OLA. OLA reviews some 50 self-assessments every year including updated corrective action plans from non-conformances identified at assessment visits.

Laboratories are given four months' notice of the assessment visit and receive in advance the requirements for accreditation. Visits range from one day to a week (for multi-site laboratories) in length and at the conclusion, the laboratory receives a verbal summation of the findings.

Within 30 days of the assessment visit, the laboratory receives a formal report identifying all non-conformances. It then has two weeks to submit its own report on errors of fact. If areas of non-conformance are cited, the laboratory is expected to take corrective action within 90 days of the visit. A volunteer OLA Advisory Panel reviews the corrective action and recommends the issuance of an accreditation certificate.

If the laboratory has a plan of action but is unable to take corrective measures within 90 days, QMP-LS can issue a two-year certificate of accreditation. Once the action is completed successfully, the certificate may be upgraded to a five-year certificate.

If the laboratory is unable to correct any major non-conformance, it is referred to the MOHLTC, where it undergoes a further review process.

OVERSIGHT OF EQA AND OLA

The work of the EQA and OLA programs is overseen by an Advisory Council with representation from:

- the College of Medical Laboratory Technologists of Ontario
- the College of Physicians and Surgeons of Ontario
- the Ontario Medical Association
- provincial associations of the various disciplines within laboratory medicine.

SUPPORT SERVICES

Three QMP-LS teams provide support services to EQA, OLA and its committees.

Communications and Documents

Staff of this team produce QMP-LS publications, such as, but not limited to: Committee Comments, brochures, PowerPoint slide presentations, a monthly electronic newsletter, and the annual Review. Staff edit, design and format these publications, as well as maintain and manage the QMP-LS Web site including the job posting service, and Intranet.

Education Services

This department helps laboratories address issues or problem areas through publications, workshops and symposia. Many of these activities are conducted in collaboration with other organizations and associations.

Information Services

Information services provides QMP-LS and its clients with timely, reliable and accurate information processing and communication services. Staff develop and enhance decision support systems for the EQA and OLA divisions and provide desktop application support, including technical support for telephone, network, printing and Internet services.

SENIOR MANAGEMENT GROUP

The Senior Management Group comprising the Director, EQA; Director, OLA; Director, Corporate and Support Services; Quality Manager; Manager, Business Development and Education; Supervisor, Communications and Documents; and Coordinator, Financial and Support Services is supported by the Senior Administrative Assistant, Corporate and chaired by the Managing Director. It provides leadership in a creative environment, oversees the quality management system, and manages daily operations within allocated resources.

EXTERNAL LIAISON

QMP-LS has provided external liaison to national and international bodies including:

- Canadian Coalition for Quality in Laboratory Medicine
- Standards Council of Canada Partner Advisory Group, and Technical Group on Laboratories
- Canadian Association of Environmental Analytical Laboratories
- International Laboratory Accreditation Cooperation
- International Organization for Standardization Technical Committee and Working Group on ISO 15189.

COLLABORATION WITH OTHER JURISDICTIONS

QMP-LS is recognized nationally and internationally as a leader in the quality management approach to laboratory services. Other jurisdictions, both in Canada and overseas, recognize this leadership and seek to work collaboratively with QMP-LS and its personnel.

British Columbia

QMP-LS sub-contracts to the British Columbia Clinical Microbiology Proficiency Testing program for the provision of testing material for the EQA survey for *Clostridium difficile* toxin detection.

Alberta

Since 1997, QMP-LS has been providing the Alberta laboratories with cytology EQA surveys. Originally sent annually, the challenge surveys are now sent to Alberta twice a year. The results are analyzed by QMP-LS and returned to the College of Physicians and Surgeons of Alberta, which writes its own report.

Overseas

International jurisdictions have also benefited from Ontario's quality management of laboratory service.

QMP-LS works extensively with 22 countries of CARICOM, the Caribbean Community, providing EQA challenge surveys in Microbiology.

GOVERNANCE

RELATIONSHIP WITH THE ONTARIO MINISTRY OF HEALTH AND LONG-TERM CARE (MOHLTC)

QMP-LS is governed in accordance with the terms and conditions of an agreement between the MOHLTC and the OMA. QMP-LS carries out its obligations and activities in accordance with generally accepted standards and is subject to periodic operational reviews or evaluations as determined by the Minister of Health and Long-Term Care.

It is a condition of licensure that Ontario's medical laboratories meet QMP-LS requirements. QMP-LS develops policies, processes and procedures with the advice of a stakeholder Advisory Council, a Professional Advisory Committee and an Ontario Laboratory Accreditation Advisory Panel.

QMP-LS COMMITTEES

Advisory Council

Membership comprises representatives of various stakeholder organizations, such as the Ontario Hospital Association and the Ontario Association of Medical Laboratories. It advises QMP-LS on development and implementation of QMP-LS policies, processes and procedures from a stakeholder perspective.

Professional Advisory Committee

Comprising chairs of the QMP-LS Scientific Committees, the Professional Advisory Committee advises QMP-LS on issues concerning EQA programs and operations.

The committee:

- reviews and approves development of EQA survey models;
- reviews and recommends on progress of laboratories with performance issues;
- reviews and recommends on appeals and disputes regarding performance evaluation through EQA.

Ontario Laboratory Accreditation Advisory Panel

This body provides advice, guidance and direction in the operation of the accreditation program in accordance with OLA operating principles, international guidelines and Ontario regulations. Panel members reflect a rural-urban mix, have broad management skills, and are prominent accreditation surveyors or possess in-depth knowledge of laboratory programs and quality assurance practices.

The panel:

- receives documentation from the OLA secretariat for review prior to any conference calls or meetings;
- reviews, recommends and approves accreditation policies and processes;
- reviews and approves accreditation requirements;
- reviews and approves follow-up to assessment visits and laboratory corrective action;

- recommends and approves the issuance of individual accreditation certificates;
- recommends the withdrawal of accreditation certificates.

Conjoint Committee

The Ministry of Health and Long-Term Care agreement establishes a Conjoint Committee, with equal representation from the OMA and the Ministry, whose focus is on risk management, quality and accountability for the quality management program.

This committee makes recommendations to the Minister of Health and Long-Term Care on matters relating to the QMP-LS program and approves all QMP-LS policies. It is the forum in which the OMA reports to the Director of Laboratory and Specimen Collection Centre Licensing that the operation of a laboratory does not meet the requirements of the quality management program.

The committee:

- approves all policies relating to the review and referral of concerns regarding laboratory performance in EQA and difficulties in meeting accreditation requirements;
- receives from the Advisory Council, Professional Advisory Committee and Ontario Laboratory Accreditation Advisory Panel reports and recommendations for action, as required by legislation, the current Ministry of Health and Long-Term Care/OMA Memorandum of Agreement, and the accountability framework;
- receives reports from laboratories experiencing difficulties with EQA survey performance and in meeting accreditation requirements, and receives recommendations of non-proficiency and withdrawal of accreditation;
- determines committee action on reports and recommendations.

Scientific Committees

EQA has established scientific committees in the following disciplines of laboratory medicine:

- anatomic pathology
- chemistry (including point-of-care testing)
- cytology
- endocrinology and immunology
- genetics
- hematology
- maternal serum screening
- microbiology
- mycology
- transfusion medicine
- virology

The scientific committees guide the design, implementation and operation of external quality assessment programs in the relevant disciplines, in accordance with QMP-LS and EQA operating principles, international standards and regulatory and contractual requirements.

The number of members varies between committees and is determined by the scope and volume of activities. The membership reflects the geography of the province and the laboratory community and includes hospital- and community-based representation.

Accountable to the Conjoint Committee, the Scientific Committees, through the Professional Advisory Council, are responsible for:

- facilitating QMP-LS support to laboratories by advising on:
 - design of the external quality assessment model;
 - content of instructions, reports and educational material for participants;
 - preparation and evaluation of participant correspondence;
 - educational material for events such as workshops, seminars and Internet courses.
- recommending to the Director, EQA appropriate:
 - analytes to be tested;
 - nature of testing material;
 - range of values to be expected for test items;
 - frequency of testing schedules;
 - methods of performance evaluation.
- receiving and addressing reports from QMP-LS Consultant Technologists with regard to:
 - difficulties associated with homogeneity, stability or delivery of test materials;
 - summaries of the comparative performance of laboratories;
 - notice of problems regarding methodology or instruments;
 - notice of proposed changes in the program regarding tests and testing in any class;
 - testing schedules;
 - complaints, appeals or non-compliance with participation or performance in the testing program.
- reviewing individual laboratory performance, investigating discordant findings and errors, determining acceptable and unacceptable performance; recommending remedial measures; recommending:
 - an on-site consultation;
 - a report of non-proficiency;
 - a report of non-compliance by a laboratory;
 - a report of collusion or improper reporting practices.
- providing reports for the Professional Advisory Committee, Conjoint Committee and the Advisory Council;
- receiving reports from the Ministry of Health and Long-Term Care (MOHLTC) via the Professional Advisory Committee with regard to action taken on laboratories to remedy performance difficulties or non-compliance;
- reviewing standards of practice in laboratory medicine and recommending guidelines to the Director, OLA.

Test Review Committee

The Test Review Committee undertakes a review of quality requirements for tests that are not on the Schedule of Benefits, then advises the Laboratories Branch of the MOHLTC of these requirements. Members of the six-person committee include prominent provincial laboratory physicians, laboratory scientists and medical laboratory technologists.

The Laboratories Branch identifies a candidate test for licensing where the test is not covered under the Schedule of Benefits and where the quality requirements for the test have not been considered. It asks QMP-LS to undertake a quality review of the candidate test and to recommend the quality requirements to be fulfilled. The Test Review Committee conducts the review and considers a number of quality criteria:

- the clinical utility of the examination or test specified in the referral; the sensitivity and specificity of the test; and the predictive value of the determination;
- the health care cost implications in terms of further investigations, procedures or additional health facility costs versus the health benefit;
- analytical policy and technical procedures, including:
 - analytical principle;
 - analytical methods, available instruments and reagents;
 - special considerations;
 - process to establish reference intervals.
- the quality management system required by the testing laboratory:
 - preparation of the patient;
 - collection and handling of the specimen;
 - quality assurance process, quality control procedures and quality indicators.
- external quality assessment through interlaboratory comparisons;
- available and required practice guidelines.

QMP-LS seeks expert opinion and arranges for appropriate critical appraisal of the medical and scientific literature. It immediately refers the expert opinion to the appropriate scientific committee for its review and input. The Test Review Committee then considers the expert opinion. It reports findings of the quality review to the Laboratories Branch and recommends the quality requirements for the test.

PERFORMANCE HIGHLIGHTS

2007-8

EXTERNAL QUALITY ASSESSMENT

INTRODUCTION

Efficiency and effectiveness; more for less; “Lean” — all words and phrases familiar to health care workers in terms of meeting objectives and the bottom line — all words and phrases that also drive the need for the changes that are occurring within the External Quality Assessment program. The main driver is the development and sustainability of a world-class program with limited human and financial resources. In addition to providing core EQA services to Ontario participants, the projects addressed during 2007-8 were aimed at achieving this objective:

- alignment of QMP-LS EQA surveys with international standards,
- use of information systems applications to create LEAN EQA operations,
- development of improved EQA information for participants.

PROJECT HIGHLIGHTS

Alignment of QMP-LS EQA Surveys with International Standards

There are two current international guidelines that address activities associated with EQA:

- ISO/IEC 43.1 (1997). *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*
- ILAC G13:2007. *ILAC Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes*

ISO standard ISO/IEC CD 17043 2008. *Conformity Assessment — General Requirements for proficiency testing* is under development and is based on the above guidelines.

This document is currently a committee draft. Once it is an approved standard, it will replace the former two documents. During the past few years, QMP-LS has been striving to align all processes with all three of these documents. The changes associated with use of robust statistics and introduction of scoring schemes provide assessors with tangible evidence of conformance to standards. During 2007-8, the following were accomplished in achieving alignment with these standards:

- completion of validation of performance scores for quantitative EQA surveys,
- continued development of performance scores for qualitative EQA surveys,
- standardization and revision of processes and procedures for all discipline surveys,
- revision and publication of program information for all EQA surveys,
- internal audit of the program against ILAC G13 and ISO/IEC CD 17043.

Use of Information Systems Applications to Create Lean EQA Operations

Lean manufacturing may be defined as a systematic approach to identifying and eliminating waste through continuous improvement. Basic tenets of “Lean” are to handle a product only once wherever possible, ensuring that all processes add value and flow from customer demand. “Lean” identifies seven sources of waste: over-production (extra features), inventory (requirements), processing (additional steps), motion (finding information),

defects, waiting (by staff and participants) and transportation (hand-off time). In previous years, the “Lean” principles had been applied to the packaging and distribution of testing material from QMP–LS. QMP–LS also identified four major processes that were prime candidates for the application of “Lean” principles as seen in Table 1. During 2007–8 the development of new information systems processes to address the inefficiencies was completed, ready for implementation in 2008–9.

Table 1. Applying Lean Principles to Four Major EQA Processes

EQA Process	Source of Waste	I.S. Solution
Use of hard copy worksheets	Processing; motion; waiting; transportation	Develop Web-based data entry system with worksheets posted in QView™
Manual performance evaluation	Processing; motion; waiting; transportation	Develop computer-assisted scoring systems
Use of hard copy correspondence	Processing; motion; waiting; transportation	Improve survey reports posted in QView™ to include scores and required corrective action and to minimize the need for correspondence
Use of hard copy discordant finding investigation	Processing; motion; waiting; transportation	Develop Web-based data entry system with completed forms posted in QView™

These new processes should be fully implemented by the end of 2008. The benefits to participants will be ready access of and availability to information regarding EQA reporting, performance and improvement activities.

Development of Improved EQA Information for Participants

Not only is QMP–LS working to improve the delivery of information but also to improve the content of information provided regarding the EQA program. In 2007–8, improvements were made to the content of EQA program information and survey reports. In addition, use of Webinars was adopted as the QMP–LS method of choice for delivery of education and information to participants, particularly when interaction is required.

Improved EQA Program Information

During 2007–8, the hard copy EQA program information contained in the Laboratory Proficiency Testing Program (LPTP) discipline binders was revised and posted on QView™, QMP–LS’ password-protected extranet document server. An overview of this information was also posted on the EQA section of the QMP–LS Web site. This information will be automatically updated by QMP–LS as required.

EQA Survey Reports

EQA survey reports have been developed to include detail of performance scores and required action to be taken by the participant. Cumulative survey reports graphically display performance over time and provide a summary of performance for management and supervisory personnel. These reports will be available with the 2008–9 EQA surveys.

Webinars to Introduce Changes to EQA Surveys

QMP–LS has acquired the capability to provide Webinars and Webcasts to its participants to provide active exchanges of information with participants as changes in the EQA program occur. The first Webinar/Webcast was entitled: *Performance Scores for Quantitative Chemistry and Hematology EQA Surveys*, which introduced participants to the use of Percent Allowed Difference (PAD) scores and the associated survey reports. It is

anticipated that the use of Webinars and Webcasts will continue throughout 2008 to introduce to participants the use of Web-based data entry of EQA data as well as qualitative performance scores for the various disciplines.

EQA CORE ACTIVITIES

Provision of EQA Services to Ontario Medical Laboratories

Provision of EQA services to Ontario medical laboratories is the primary objective of the EQA division. In 2007-8, QMP-LS provided 107 challenge surveys (including 6 Web-based surveys), 4 patterns-of-practice surveys and 1 questionnaire. The parameters monitored by the surveys are listed by discipline in Table 2. The scope of EQA surveys provided is shown in Table 3. The number and type of laboratory participant are shown in Table 4. The testing material sub-contractors for each discipline and the reference laboratories are shown in Table 5.

Table 2. Parameters Monitored by QMP-LS, by Discipline

CHEMISTRY

Chemistry-General

Albumin
Albumin Excretion Rate (AER)
Bicarbonate
Bilirubin, Total
Blood Gases (pH, pCO₂, pO₂, Na⁺, K⁺, Glucose, Ionized Calcium)
Hb A_{1c}
Calcium, Total
Chloride
Creatinine
Glucose
Magnesium
Phosphate
Potassium
Protein, Total
Sodium
Total Iron, TIBC, UIBC, Transferrin Saturation
Urate
Urea
Urine Chemistry (Quantitative Protein, Sodium, Potassium, Creatinine, Osmolality)

Drug Monitoring

Acetaminophen
Carbamazepine
Digoxin
Drugs of Abuse
Ethanol
Gentamicin
Lithium
Phenobarbital

Drug Monitoring (continued)

Phenytoin
Salicylate
Theophylline
Tobramycin
Valproic Acid
Vancomycin
Endocrinology
Thyrotropin (TSH)
Free Thyroxine (FT₄)
Free Triiodothyronine (FT₃)
Vitamin B₁₂
Ferritin
Cortisol
Total Testosterone
Follicle Stimulating Hormone (FSH)
Luteinizing Hormone (LH)
Parathyroid Hormone
Progesterone
Prolactin
Chorionic Gonadotropin (CG)
Alpha Fetoprotein (AFP)
Estradiol
Prostate Specific Antigen (PSA)
Free PSA
Dehydroepiandrosterone sulphate (DHEA-S)
Vitamin D3

Enzymes, Cardiac Markers & Lipids

Alkaline Phosphatase (ALP)
Alanine Aminotransferase (ALT)
Amylase
Aspartate Aminotransferase (AST)

Table 2. Parameters Monitored by QMP-LS, by Discipline (continued)**Enzymes, Cardiac Markers & Lipids (continued)**

Gamma Glutamyl Transferase (GGT)
 Lactate Dehydrogenase, Total (LD)
 Lipase
 Total Creatine Kinase (Total CK)
 CK-2
 Serum Myoglobin
 Serum Troponin I
 Serum Troponin T
 Cholesterol
 Triglycerides
 HDL-cholesterol (HDL-C)
 LDL-cholesterol (LDL-C)

Immunology

Antinuclear Antibody (ANA)
 Rheumatoid Factor (RF)
 Antimicrosomal Antibody (MAH)
 Anti-TPO
 High Sensitivity CRP (hsCRP)
 Anti ds-DNA

Specific Proteins:

IgG
 IgA
 IgM
 IgE
 C3
 C4

Protein Electrophoresis

Maternal Serum Screening**Serum Analytes:**

Alpha Fetoprotein (AFP)
 Total Human Chorionic Gonadotropin (Total hCG)
 Unconjugated Estriol (μE_3)
 Dimeric Inhibin-A (DIA)
 Free beta Human Chorionic Gonadotropin
 (free β -hCG)
 Pregnancy-Associated Plasma Protein A (PAPP-A)

Multiple of Median (MoM):

AFP, hCG, μE_3 , DIA, free β -hCG and PAPP-A

Initial Positive Rate (IPR):

Trisomy 18
 Trisomy 21
 Open Neural Tube Defect (ONTD)
 All screening modalities (i.e. MSS3, MSS4 and IPS5)

Hematology**Bone Marrow**

Aspirate and/or Biopsy preparation
 Descriptive Morphology
 Diagnosis

Coagulation

International Normalized Ratio (INR)
 Activated Partial Thromboplastin Time (APTT)
 Heparin Assay
 Factor VIII
 Factor IX
 D-dimer
 Thrombophilia Investigation:
 Activated Protein C (APC) Resistance
 Antithrombin
 Protein C
 Protein S
 Anticardiolipin Antibody (ACA)
 Factor V Leiden
 Prothrombin Gene Mutation
 Russell Viper Venom (dilute and confirm)

Flow Cytometry

Lymphocyte Immunophenotyping (HIV)
 Leukocyte Immunophenotyping
 (Hematological Investigation)
 CD34+ Stem Cell Enumeration

Red Cell Disorders

Hemoglobin S Screen
 Hemoglobin Fraction Quantitation

Morphology

Peripheral Blood Film:
 Differential Leukocyte Count
 Descriptive Morphology
 Diagnosis

Routine Hematology

Leukocyte Count
 Erythrocyte Count
 Hemoglobin
 Hematocrit
 Mean Corpuscular Volume
 Thrombocyte Count
 Automated Leukocyte Differential
 Reticulocyte Count
 Body Fluid Cell Count

Table 2. Parameters Monitored by QMP-LS, by Discipline (continued)**Transfusion Medicine**

ABO and Rh Grouping and Interpretation
 Antibody Detection
 Antibody Identification
 Direct Antiglobulin Testing (DAT)
 Crossmatching
 Phenotyping
 Antibody Titration

MICROBIOLOGY**Bacteriology**

Aerobic and anaerobic isolation and identification of organisms from:
 Blood
 Genital specimens
 Throat swabs
 Urine
 Body fluids
 Other swabs/pus
 Sputum
 Stool samples
 Quantitative urine cultures
 Interpretation and reporting of cultures
 Antimicrobial susceptibility testing
 Interpretation and reporting of susceptibility findings
 Serological grouping and identification
 Gram stain interpretation
 Detection of *Clostridium difficile* toxin
 Mycobacteriology
 Detection of acid-fast bacilli from direct smears
 Quantification of acid-fast bacilli

Mycology

Isolation and identification of:
 Dermatophytes
 Moulds
 Yeasts
 Wet preparations for fungal elements

Parasitology

Wet preparation examination of stool samples
 Preparation of faecal concentrates
 Staining of samples for gastrointestinal parasites
 Identification and quantification of parasites
 Use of special stains

Virology

Antibody detection:

Virology (continued)

Cytomegalovirus (CMV)
 Hepatitis A , B, and C
 HIV
 Rubella IgG
 Varicella-zoster virus (VZV)
 Antigen Detection:
 Chlamydia trachomatis
 Respiratory Syncytial Virus (RSV)
 Influenza A virus
 Influenza B virus
 Parainfluenza virus

GENETICS**Cytogenetics**

Blood
 Bone Marrow
 Tumour
 Tissue
 Amnion Cells
 Fixed cell culture

Molecular Diagnostics of Inherited Diseases

– Suspended for 2007

ANATOMIC PATHOLOGY**Histopathology****Histotechnology**

Routine stains
 Special stains
 Immuno-histochemistry stains

Cytopathology

Gynecological
 Non-Gynecological

Respiratory:

Sputum
 Bronchial washings
 Bronchial brushings

Urinary

Body fluids
 Fine needle aspiration of breast
 Fine needle aspiration of head and neck:
 Thyroid
 Lymph node
 Salivary glands

OTHER**Point-of-Care Testing**

Glucose Meters

Table 3. 2007–8 EQA Surveys for Ontario

Survey	Challenge	Dry	Pattern of Practice	Questionnaire
Bacteriology	6	...	1	1
Acid Fast Stain	2	...	...	...
Routine Chemistry	11	...	...	...
Drugs	6	...	...	...
Enzymes	4	...	...	...
Lipids	3	...	...	...
Blood Gases	2	...	...	...
Cytogenetics	2	...	...	...
Inherited Diseases	0	...	...	...
Cytology	3	...	1	...
Routine Hematology	7	1	...	...
Coagulation	10	...	...	...
Red Cell Disorders	4	1	...	...
Morphology	3	1	...	...
Bone Marrow	2	1	...	...
Flow Cytometry	6	1	...	...
Endocrinology	3	...	...	...
Immunology	3	...	...	...
Maternal Serum Screen	NA*	NA*	NA*	NA*
Transfusion Medicine	6	1	1	...
Virology	10	...	...	...
Mycology	2	...	...	...
Intestinal Parasites	2	...	...	...
Histotechnology	2	...	...	...
Glucometers	2	...	1	...
Total Surveys	101	6	4	1

* No surveys conducted in 2007–8

Table 4. Comparison of Types of Ontario Laboratories Participating in QMP–LS

Laboratory Facility Type	Number of Laboratories						
	2001	2002	2003	2004	2005	2006	2007
Community	53	54	47	44	40	34	34
Hospital	181	182	180	182	182	179	178
Public Health	11	12	12	12	12	12	12
Psychiatric	0	0	0	1	1	1	0
Canadian Blood Services	6	6	6	6	5	2	2
Federal Government	2	1	1	1	1	1	1
Other	1	2	2	1	1	2	1
Total	254	257	248	247	242	231	228

Table 5. Testing Material Suppliers and Reference Laboratories, 2007-8

Testing Material Suppliers	Reference Laboratories
CHEMISTRY DISCIPLINES	
Chemistry-General	
Bio-Rad Laboratories (Canada) Ltd.	Reference Laboratory, Ortho Clinical Diagnostics Inc., Rochester, New York
Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario	Diabetes Diagnostic Laboratory, University of Missouri-Columbia, Columbia, Missouri
The Credit Valley Hospital, Mississauga, Ontario	
Drug Monitoring	
Centre for Addiction and Mental Health, Toronto, Ontario	Centre for Addiction and Mental Health, Toronto, Ontario
The Credit Valley Hospital, Mississauga, Ontario	
Endocrinology	
ThermoFisher Scientific, Austin, Texas	
Toronto General Hospital, University Health Network, Toronto, Ontario	
Enzymes, Cardiac Markers and Lipids	
Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario	Reference Laboratory, Ortho Clinical Diagnostics Inc., Rochester, New York
The Credit Valley Hospital, Mississauga, Ontario	Northwest Lipid Research Core Laboratory, University of Washington, Seattle
Immunology	
Keystone Biologicals, Hatboro, Pennsylvania	
Maternal Serum Screening	
United Kingdom National External Quality Assessment Service (UK NEQAS)	
Point-of-Care Testing (Glucose Meters)	
Bio-Rad Laboratories, Benicia, California	
HEMATOLOGY DISCIPLINES	
Hematology-Routine	
Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario	Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario
R&D Systems, Inc., Minneapolis, Minnesota	
Hematology-Red Cell Disorders	
Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario	Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario
Hematology-Flow Cytometry	
London Health Sciences Centre, London, Ontario	
R&D Systems, Inc., Minneapolis, Minnesota	
Coagulation	
Affinity Biologicals Inc., Ancaster, Ontario	Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario
Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario	
Somagen Diagnostics Inc., Edmonton, Alberta	
South Manchester University Hospitals, Manchester, U.K.	
Morphology and Hematology-Bone Marrow	
Various laboratories throughout the province of Ontario	London Health Sciences Centre, London, Ontario Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario

Table 5. Testing Material Suppliers and Reference Laboratories, 2007–8 (continued)

Testing Material Suppliers	Reference Laboratories
HEMATOLOGY DISCIPLINES (continued)	
Transfusion Medicine	
Immucor/Gamma, Houston, Texas	The Credit Valley Hospital, Mississauga, Ontario
London Health Sciences Centre/Canadian Blood Services, London, Ontario	Royal Victoria Hospital, Barrie, Ontario
MICROBIOLOGY DISCIPLINES	
Bacteriology	
London Health Sciences Centre, London, Ontario	Central Public Health Laboratory, Toronto, Ontario London Health Sciences Centre, London, Ontario
AFB Smears	
Central Public Health Laboratory, Toronto, Ontario	Mount Sinai Hospital, Toronto, Ontario The Credit Valley Hospital, Mississauga, Ontario The Ottawa Hospital, Ottawa, Ontario Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario Sunnybrook Health Sciences Center
<i>Clostridium difficile</i> Toxin	
Clinical Microbiology Proficiency Testing (CMPT), Vancouver, BC	
Mycology	
Sporometrics Inc., Toronto, Ontario – purchased from culture collections:	Central Public Health Laboratory, Toronto, Ontario Wadsworth Centre for Laboratories and Research, Albany New York
University of Alberta Microfungus Collection and Herbarium, Edmonton, Alberta (UAMH);	Laboratoire de Santé Publique du Québec, Ste-Anne-de-Bellevue, Quebec
The Centraalbureau voor Schimmelcultures (CBS), The Netherlands, and;	
Agricultural Research Service (ARS) Culture Collection, National Center for Agricultural Utilization Research, Peoria, Illinois, U.S.A.	
Parasitology	
Various participating laboratories (distributed by London Health Sciences Centre)	
Virology	
London Health Sciences Centre, London, Ontario	Central Public Health Laboratory, Toronto, Ontario
ZeptoMetrix Corporation, Franklin, Massachusetts	National HIV Reference Laboratory, Health Canada, Ottawa, Ontario
Interstate Blood Bank, Memphis, Tennessee	
ANATOMIC PATHOLOGY	
Various participating laboratories	
CYTOLOGY	
Various participating laboratories	
GENETICS	
Various participating laboratories	

QMP-LS Scientific Committees and Volunteers

Eleven scientific committees provide advice and support to the EQA program. In 2007-8, QMP-LS hosted a total of 39 scientific committee meetings involving 66 laboratory physicians, scientists and medical laboratory technologists. The names of these volunteers are listed in Appendix A. As representatives of the Ontario laboratory community, scientific committee members provide advice to QMP-LS regarding the fundamental design of EQA surveys and ensure clinically relevant selection of challenges and appropriate performance evaluation.

In January 2008, the process for selection and appointment of scientific committee members was modified to include the nomination of candidates from the laboratory community at large. At the beginning of each calendar year, a list of available committee positions is now published in the *QMP-LS News* and on the QMP-LS Web site. Interested candidates may be nominated through completion of the nomination form, which provides a description of the required qualifications of candidates. This process was highly successful in attracting many well-qualified individuals to join the committees. As always, QMP-LS is extremely grateful for the commitment and support of Ontario laboratory professionals and wishes to thank all of those individuals who donate so much of their valuable time and expertise to the program.

EQA Survey Highlights

Information regarding 2007-8 EQA survey activity is well described in the survey reports and committee comments, available through QMP-LS' password-protected document server, QView™.

Clinical Chemistry Highlights

As recommended by the Canadian Society of Nephrology, in order to report an estimated glomerular filtration rate (eGFR) laboratories must use serum/plasma methods traceable to the isotope dilution mass spectrometry (IDMS) reference method. This requires instrument manufacturers to re-calibrate their methods for creatinine, which will lead to a probable change in creatinine concentrations by approximately 5%-10%. During this conversion period, QMP-LS is requiring participants to report when their method has been calibrated to the IDMS method so that results may be analyzed separately. By the end of 2007-8, 87% of Ontario laboratories had reported creatinine method traceability to the IDMS standard.

Statistical Analysis of Small Peer Groups

Participants performing quantitative surveys in chemistry and hematology surveys were advised that laboratories reporting results in peer groups of less than five participants could not be analyzed statistically and as a result, such laboratories will not be able to use their participation in QMP-LS as evidence of satisfactory performance in external quality assessment (EQA) activities for accreditation purposes. They were advised to seek an alternative assessment program (AAP), which may be a non-QMP-LS proficiency testing/EQA scheme or a program of split sample testing. Due to the rapid changes in methodology, which impact peer group sizes, laboratories are expected to continue to notify QMP-LS of changes in methodology and participate in QMP-LS surveys even when participating in an AAP.

Patterns-of-Practice Surveys

- Process Validation in Transfusion Medicine
- Status of Practice in Cytology
- Use of Quality Indicators in Microbiology
- Update on Use of Point-of-Care Tests in Hospitals

Questionnaires

- Antimicrobial Resistance in Common Hospital Pathogens in Ontario

Laboratory Performance

The scientific committee evaluation of survey responses during 2007–8 included assessment of error based on the clinical significance of discordant findings. Lesser errors are assessed for results that exceed the established acceptable limits and significant errors for results that have the potential to cause mistreatment or misdiagnosis. Scientific committees correspond with participating laboratories regarding the discordant findings, requesting feedback on the cause and corrective action. Unacceptable or incomplete participant responses prompt further communication, continuing to monitor performance and/or an offer of an on-site consultation.

One on-site consultation in Hematology (Coagulation) was conducted during 2007–8. No laboratory was declared non-proficient.

Reports to Participants

Reports provided to participants include preliminary reports of the assigned values (consensus or reference values), summary information of all participant responses as well as reports of individual laboratory performance. In addition, the scientific committees provide educational feedback in the form of committee comments, broadsheets and practice guidelines. During 2007–8, the following were provided to participants:

- 102 provisional reports
- 109 general survey reports
- 104 committee comments
- 3 broadsheets

The titles of the broadsheets published this year are:

- *Body Fluid Cell Counts and Differential Analysis*
- *Precision Goals in Clinical Chemistry*
- *Estimated Glomerular Filtration Rate*

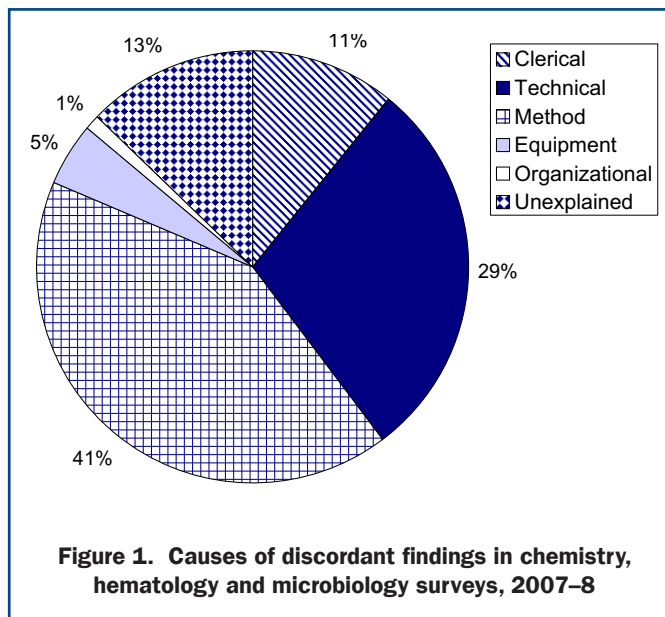
- 1 guideline

The title of the guideline published this year is:

- *Guidelines for Split Sample Testing – Quantitative EQA Surveys*

Investigation of Discordant Findings

Participants that report discordant results in EQA surveys are requested to investigate and report a summary of the investigation and corrective actions to QMP–LS. The overall discordance rate for the 12-month period between April 2007 and March 2008 was 0.97%. Summary information for causes of discordance in Chemistry, Hematology and Microbiology surveys is included in Figure 1.



The most common categories of discordance were associated with method-related issues (41%) and technological causes (29%). The method-related issues involved problems with accuracy and precision of automated systems and kit methods, erroneous calibrator value assignment by the manufacturer, use of inadequate or inappropriate quality control programs and use of inadequate or out-dated procedures or reporting protocols. Technological issues included inadequate response to quality control results, failure to follow written procedures and sample handling issues.

The nature and contributing causes of discordant results have not changed significantly over the past five years. Laboratories would be able to eliminate a significant proportion of problems with EQA (and also patient) results if the following was adequately implemented:

- initial and on-going validation of methods and their associated quality control programs;
- initial and on-going training and competency assessment of staff;
- maintenance of procedures.

For more detailed discussions regarding causes of discordant findings, see the discipline-specific supplementary committee comments posted on QView™.

Services to Other Jurisdictions

In addition to services provided to Ontario laboratories, QMP-LS provides EQA services to other jurisdictions on a cost-recovery basis. The surveys most commonly provided are listed in Table 6. In addition, we provide separate microbiology surveys to 22 member countries of CARICOM and separate cytology surveys to Alberta laboratories.

**Table 6. Number of Participating Ontario Laboratories in 2007-8 vs. Out-of-Province
(April 2007 to March 2008)**

Discipline	Ontario	Out-of-Province
Anatomic Pathology	73	1
Chemistry-General	196	2
Drug Monitoring	163	0
Endocrinology	133	1
Enzymes, Cardiac Markers	193	2
Lipids	131	0
Immunology	61	3
Maternal Serum Screening	NA*	NA*
Hematology-General	205	4
Flow Cytometry	24	14
Red Cell Disorders	73	1
Coagulation	187	3
Hematology-Morphology	194	0
Transfusion Medicine	178	0
Bacteriology	105	0
Mycology	21	2
Parasitology	18	0
Virology	87	3
Genetics	11	9
Cytology	78	1
Point-of-Care Testing	186	1

* No surveys conducted in 2007-8

LOOKING AHEAD

During 2008–9, the changes to EQA survey models should be completed. By the end of 2008, participants should be able to:

- enter EQA survey responses on-line using Web-based data entry system;
- view the majority of survey reports within 2–3 weeks of completion of the survey and perform any necessary investigation and implementation of corrective actions;
- submit discordant findings investigations on-line using Web-based data entry system;
- access all current EQA survey related descriptions, reports and educational information through QView™ at any time.

It is anticipated that on-line submission of information will facilitate prompt analysis and evaluation of information, and rapid correction of any problems.

In 2009, when changes to the programs are complete, QMP–LS will offer basic survey information to manufacturers to enable them to track performance of their kits, instruments and reagents and enable them to implement prompt corrective actions for their products as required.

PERFORMANCE HIGHLIGHTS

2007-8

ONTARIO LABORATORY ACCREDITATION

INTRODUCTION

Ontario Laboratory Accreditation (OLA) was conceived in 2000 to set a recognizable standard for Ontario's licensed medical laboratories. On the international scene, *15189 Medical laboratories — Particular requirements for quality and competence* was under development by the International Organization for Standardization (ISO). ISO 15189 was the logical choice on which to base accreditation requirements for medical laboratories, to recognize Ontario's 25-year history as a leader in medical laboratory quality assurance. Thus ISO 15189 — augmented with identified national and regional standards — became the basis for Ontario's accreditation requirements. This set the stage for the implementation of a quality management system in every Ontario laboratory.

When OLA was implemented in 2003, Ontario laboratories were among the world's first medical laboratories to demonstrate international competence using ISO 15189. In 2005, the Standards Council of Canada (SCC) recognized these efforts and work began to establish a partnership to provide international recognition to Ontario's medical laboratories.

In 2007, two important events occurred: 1. A second version ISO 15189:2007 was released and, 2. OLA's requirements for accreditation were revised. The convergence of these two events allowed for formalization of the partnership between QMP-LS and the SCC. OLA's accreditation requirements now include all clauses of ISO 15189:2007 and generally recognized principles of good practice outlined in national and regional guidelines, standards and legislation. Beginning in 2008, Ontario laboratories will be eligible to apply for an ISO 15189 certificate from SCC.

Gaining international recognition for Ontario's medical laboratories has only been possible because OLA, too, meets an international standard — ISO 17011:2004 *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*. In 2007, QMP-LS was audited by SCC and demonstrated that the QMP-LS quality management system and OLA's operations conform to this rigorous standard. An internal audit later in the year identified opportunities for improvement to demonstrate continued competence. QMP-LS also belongs to the International Laboratory Accreditation Cooperation, and contributes to its development of guidelines and other documents that aid in the utilization and application of ISO standards. QMP-LS is now an internationally recognized provider of accreditation services. By assessing laboratories against ISO 15189:2007, QMP-LS and SCC are poised to offer accreditation services on a broader scale within and outside Canada.

The strategic direction in 2007-8 was to strengthen the accreditation program and prepare for long-term growth. Specific goals were:

- to provide accreditation services to the Ontario medical laboratory community,
- to enhance the design of OLA, and
- to integrate OLA and EQA assessment and surveillance activities.

PERFORMANCE HIGHLIGHTS 2007-8

Providing Accreditation Services to the Ontario Medical Laboratory Community

Status Report

The accreditation assessment process is outlined in Appendix D. Initial assessment visits to Ontario's licensed laboratories were scheduled over a five-year period, with self-assessments required at the mid-point (two and one-half years after the assessment visit). Four staff technologists coordinate assessments and review self-

assessment reports. In 2007–8, OLA neared completion of this implementation phase to Ontario's 229 licensed medical laboratories (Table 7).

- Initial accreditation assessment visits were conducted in 43 laboratories and one additional (surveillance) assessment was conducted in a laboratory due to a change in its ownership (Table 8).
- Ninety-eight assessors were contracted for these assessments and they spent a combined 388 days completing these assessments (Appendix B).
- Forty-three self-assessment notifications were sent, 49 reports reviewed and 48 summary reports issued (Table 9).
- Forty 5-year and three 2-year accreditation certificates were issued (Table 8).

Table 7. Ontario Laboratories Subject to OLA

Community	34
Hospital	178
Hospital-owned Clinic	1
Public Health	12
Psychiatric	0
Canadian Blood Services	2
Federal Government	1
Other	1
Total	229

As of March 31, 2008, 210 (92%) of 229 licensed Ontario laboratories had been assessed and 195 (85%) were holding OLA accreditation certificates. All licensed Ontario laboratories will be assessed by September 2008, and it is anticipated that all will hold OLA accreditation certificates in early 2009.

Table 8. OLA Assessment Visit Activity (April 1, 2007 to March 31, 2008)

Laboratories Notified of Assessment	56 full, 2 focused
Assessment Visits Conducted	43 full, 1 focused
5-year Certificates Issued	40
2-year Certificates Issued	3

Table 9. OLA Self-assessment Activity (April 1, 2007 to March 31, 2008)

Laboratories Notified	43
Laboratories Submitting Self-assessment Data	49
Summary Reports Issued by OLA	48

Ontario laboratories continue to show remarkable conformance to the OLA requirements. Since the inception of the program, an average conformance of 94.90% has been observed in accreditation assessment visits. The majority of laboratories must correct fewer than five major non-conformances to receive an accreditation certificate, and address less than 20 minor non-conformances prior to the next assessment visit (see Table 10 and Figure 2). The top 10 non-conformances observed in 2007–8 are shown in Table 11. They relate to quality systems, physical facilities, equipment, pre-analytical processes, analytical processes, quality assurance, post-analytical processes, and point-of-care testing:

- analytical methods and procedures at the discipline level that fail to meet requirements;
- mechanisms lacking for comparability of results;
- floors, chairs and work surfaces not impermeable or readily cleanable;
- incomplete point-of-care testing patient records (e.g. reference ranges missing)
- incomplete equipment maintenance or records;

- transport systems not evaluated to ensure specimen integrity;
- inadequate monitoring of environmental conditions or incomplete records;
- clinically appropriate turnaround times not established; and
- responsibility for authorizing resumption of testing not established.

Table 10. Laboratory Conformance at Assessment Visits

Year	Average Conformance	Average Number of Applicable Requirements
2003-4	92.98%	471
2004-5	93.71%	480
2005-6	95.20%	440
2006-7	94.09%	422
2007-8	94.45%	445
All Assessments to March 31, 2008	94.90%	433

Table 11. Assessment Visit Top Ten Non-conformances (April 1, 2007 to March 31, 2008)

Rank	No.	Requirement	Total Non-conformances/ Times Assessed	No. Majors	No. Minors
1	VI.3	All laboratory technical procedures, including manufacturer's instructions used as procedures and electronic instructions, shall be documented and available at the workstation for relevant staff.	17/44	0	17
2	VI.1	All laboratory examinations shall be based on methods cited in published peer-reviewed texts or journals, or be recommended by international, national, or regional guidelines. If in-house developed procedures are used, they shall be validated for their intended use and fully documented.	16/44	0	16
2	VII.12	For examinations performed using different methods and/or equipment or at different testing sites, there shall be a defined mechanism to verify comparability of results.	16/39	0	16
4	V.B.3	There shall be instructions describing the necessary specimen preservatives to ensure integrity, and the acceptable temperature range for transit. Systems used to transport specimens to the laboratory shall be evaluated to ensure that designated temperature range requirements can be met during transit and that the preservatives used are an effective means to ensure stability during transit.	14/44	2	12
4	III.6	Work surfaces shall be chemical resistant, impermeable, durable and readily cleanable.	14/44	1	13

Table 11. Assessment Visit Top Ten Non-conformances (April 1, 2007 to March 31, 2008) (continued)

Rank	No.	Requirement	Total Non-conformances/ Times Assessed	No. Majors	No. Minors
4	IV.14	Maintenance of laboratory equipment shall ensure proper performance and assure accurate and reliable test performance.	14/44	0	14
4	XI.J.3	The patient record shall include the point-of-care test result in clearly defined units, the date and time the test was performed, and the reference interval for the test.	14/32	0	14
8	III.8	The laboratory shall monitor and record environmental conditions (as appropriate) to ensure they do not adversely affect the quality of examination results (e.g. dust, humidity, temperature, sound levels, vibration levels, ventilation).	13/44	3	10
9	VIII.7	Laboratory management, in consultation with the requesters, shall establish clinically appropriate turnaround times for each of its examinations.	12/43	2	10
10	II.D.5.9	Laboratory management shall define the responsibility for authorizing the resumption of examinations.	11/44	5	6

Figure 2. Definitions: major and minor non-conformances

Major non-conformance: must be resolved to receive longest possible accreditation — if not resolved but satisfactory action plan received, two-year accreditation may be granted

- Requirement not addressed by laboratory's quality manual or operating procedures or
- Procedures are consistently NOT followed or
- Existing protocols fail to address requirement or
- Non-conformance directly impacts patient safety or
- Consistent/persistent incidence of non-conformance or
- Repeated incidence of non-conformance in the majority of sections of the laboratory.

Minor non-conformance: acceptable action plan to address must be submitted to receive accreditation

- Isolated incident of non-conformance or
- Adherence to procedures is inconsistent (usually followed but sometimes not) or
- Existing protocols address requirement but are not necessarily followed.

Biennial Review of Accreditation Requirements

The cornerstone of any accreditation program is the standard (requirements) on which it bases its assessment of competence. For mandatory accreditation, the recognizable standard must be reasonable and achievable

and at the same time set a quality benchmark. When an accreditation body issues an accreditation certificate, it is recognizing that the laboratory is competent to carry out the applicable scope of testing. So then, any accreditation body has the responsibility to ensure that its requirements for accreditation are up-to-date. QMP-LS reviews the complete set of OLA requirements biennially. This review includes all “what to look for” guidance information and reference sources, with stakeholder input. Revisions are released by providing reports to explain the nature and impact of changes.

This process to review version 3 commenced in March 2007 and was completed in December 2007. It started with requests for feedback from personnel within Ontario's laboratories, OLA assessors and stakeholder organizations. While awaiting feedback, staff began the detailed task of checking each and every reference source to identify any newly released documents and what impact they may have on wording of requirements. Once feedback was received, it was collated with that received during the last two years, and vetted by QMP-LS scientific advisors. Draft changes underwent a thorough review by the OLA Advisory Panel and staff. The OLA Advisory Panel approved all changes prior to release. Three contract employees assisted in this monumental task: Lynn Allen, Elizabeth King, and Betty Anne Clark, and their contributions were invaluable.

Version 4 (December 2007) was released in January 2008 and changes to legislation required the subsequent release of sub-version 4.1 in July 2008. OLA requirements now include all clauses of ISO 15189:2007. Notable additions are requirements for internal audits, management reviews and contract reviews. With 513 requirements and three good practice recommendations, there are more requirements but significantly fewer good practice recommendations than in version 3 (Tables 12 and 13). A total of 36 duplicate requirements were removed, eight new requirements were added and 36 good practice recommendations were reclassified as requirements. An additional 96 pieces of discipline-specific guidance were revised. Many additions to the guidance information applying to transfusion medicine were added in keeping with CAN/CSA-Z902-04 *Blood and Blood Components*. To ensure that all requirements are supported by respectable reference sources, 685 references were updated. The following international and national standards are referenced, in addition to generally accepted principles of good practice sources from consensus guidelines (e.g. Clinical Laboratory Standards Institute) and law:

- International Organization for Standardization. ISO 15189:2007(E) *Medical laboratories — Particular requirements for quality and competence*
- International Organization for Standardization. ISO 22870:2006(E) *Point-of-care testing (POCT) — Requirements for quality and competence*
- Canadian Standards Association. CAN/CSA-Z15190-05 *Medical laboratories — Requirements for safety*
- Canadian Standards Association. CAN/CSA-Z902-04. *Blood and blood components March 2004*

The new version 4.1 of accreditation requirements will be utilized in all assessments occurring after September 1, 2008. It is available through the password-protected QView™ section of the QMP-LS Web site.

Table 12. Number of OLA Requirements for Accreditation and Good Practice Recommendations

	Current Version		Previous Versions		
	Version 4.1 Jul 2008	Version 4 Dec 2007	Version 3 Sep 2005	Version 2 May 2003	Version 1 Jan 2002
Requirements	513	514	506	551	618
Good Practice Recommendations	3	3	40	61	68

Table 13. Number of Version 4.1 OLA Requirements and Good Practice Recommendations, by Section

Section	Number
I. Organizational Structure, Personnel Policies and Laboratory Management	38
II. Quality Management System	65
III. Physical Facilities	13
IV. Equipment, Reagents and Supplies	38
V. Pre-Analytical Process	58
VI. Analytical Process	13
VII. Quality Assurance of Laboratory Examinations	31
VIII. Post-Analytical Process (Reporting)	38
IX. Laboratory Information System	50
X. Safety	119
XI. Point-of-Care Testing	53

Internal Audit of OLA Operations

Much has been written about quality management systems and descriptive models include circles of excellence and quality pyramids. Essentially, a quality management system is the framework or infrastructure of an organization that promotes consistency, reproducibility, traceability and reliability of the services provided. OLA conducted its second internal audit in November 2007 to monitor compliance with the QMP-LS quality system and ISO 17011:2004 *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*. The internal audit was led by Advisory Panel member Cathie McCallum whose team consisted of QMP-LS staff employed outside of OLA: Shelly Rowe, Maritess Koerner and Anne Raby. Their audit was thorough and 18 non-conformances were identified — half of these have been addressed and corrected and the remaining nine non-conformances will be corrected in 2008, in anticipation of the next external assessment by SCC.

Assessors

Assessment visits are conducted by pre-trained and certified volunteers whose competence is evaluated at each assessment, using identified competencies. In addition to ISO 17011:2004, the training curriculum conforms to ILAC-G11:07/2006 *Guidelines on Qualification and Competence of Assessors and Technical Experts* and ILAC-G3:1994 *ILAC Guidelines for Training Courses for Assessors Used by Laboratory Accreditation Schemes*. Training consists of 18 hours of self-study, 2½ days of classroom training, formal examination and annual refreshers. To maintain certification, assessors must participate in a minimum of one assessment annually, or complete an on-line refresher exercise. Even so, some certified assessors questioned their own competency in the acquired skills and in March 2007 QMP-LS distributed a survey using SurveyMonkey.com, to determine satisfaction with the current training curriculum and to identify additional means of building competencies. The response rate was 74% and the majority of respondents said they would benefit from additional training to hone their assessment skills. The following three topics were the top priority:

1. wording of non-conformances;
2. interpretation/application of requirements, and;
3. drafting open-ended assessment questions.

As a result, no initial training was conducted in 2007-8, and instead OLA staff developed a new one-day, face-to-face refresher exercise that was offered twice in November 2007. Titled “Reach for Success,” it is

designed to enable assessors to develop a new perspective on assessment. Designed to be interactive and fun, it introduces the FISH! Philosophy® of “Be There, Play, Make Their Day and Choose Your Attitude™.” The feedback was overwhelmingly positive. In the future, all assessors will be expected to participate in a face-to-face refresher exercise once every 3–5 years.

As of April 1, 2008, there were 258 active assessors. Their contribution is greatly appreciated, and the time they have spent in support of OLA is shown in Table 14.

Table 14. Volunteer Assessment Activity, by Fiscal Year (January 1, 2003 to March 31, 2008)

Year	No. of Assessment Visits	No. of Volunteers Serving as Team Leaders	No. of Volunteers Serving as Assessors (Total)	No. of Assessment Days (Total)
2002-3	6	4	20	58
2003-4	14	8	34	99
2004-5	55	30	113	415
2005-6	50	28	93	314.5
2006-7	47	25	78	258
2007-8	44	26	98	388

Development of Quality Requirements for Tests Not Listed on the Schedule of Benefits

As a service to the Laboratories Branch, the Test Review Committee (TRC) undertakes a review of quality requirements for tests that are not on the Schedule of Benefits. The TRC process begins with a MOHLTC request to QMP-LS of tests under consideration. The committee considers each request and determines whether the test is established with defined and accepted quality requirements or whether quality requirements are needed de novo. If quality requirements are needed, experts (selected on the basis of their knowledge and expertise) are asked to provide an opinion using a template within the established timeline. Depending on the test under consideration — and the advice of the appropriate QMP-LS scientific committee — more than one expert opinion may be requested. The finalized expert opinion is vetted by the appropriate scientific committee. The TRC submits its report and recommendations to the MOHLTC based on the submitted expert opinion and the scientific committee's input. During 2007-8, 49 reports were submitted. These included 19 new requests and a few revisions to previous quality criteria. In an effort to improve the applicability of quality criteria, the template was revised to include a suggested review date of the quality criteria for each test. Since the inception of the TRC, 165 quality criteria have been endorsed by the MOHLTC.

Enhancing the Design of OLA

Surveillance

By issuing accreditation certificates, QMP-LS publicly states that laboratories are competent. QMP-LS must have surveillance measures in place to monitor competence between assessments. Ongoing surveillance of participation and performance in proficiency testing/external quality assessment in accredited laboratories is one mechanism to ensure ongoing competence. While QMP-LS/EQA offers an extensive external quality assessment menu, its services do not cover the complete scope of testing in accredited laboratories. OLA now requires enrolment in formal interlaboratory comparison programs such as proficiency testing (PT) or external quality assessment (EQA) for all tests, unless formal programs are not available or feasible. During 2007-8, QMP-LS established policies and procedures for ongoing participation and performance monitoring, as part of its surveillance program.

- Formal interlaboratory comparison programs shall offer at least two surveys per year, each survey shall contain at least two samples, and the program must provide tangible evidence of performance evaluation.
- Satisfactory performance is defined as acceptable results on the majority of samples in a single survey. Over time, satisfactory performance is defined as satisfactory performance in at least two out of three surveys.

QMP-LS staff developed a Web-based system through which laboratories could report both their enrolment in formal external programs, and if results were satisfactory. This Web-based system was piloted in the spring and summer of 2008, with further refinement and introduction to all laboratories anticipated in the fall of 2008. OLA will review PT/EQA participation and performance data during assessment visits and the self-assessment review.

Education

Educating laboratory personnel in accredited laboratories remains a high priority. The primary vehicles for communication are *QMP-LS News* and the QMP-LS Web site. OLA's expectations for traceability and uncertainty of measurement were published in *QMP-LS News*, and further collaboration on these topics with QMP-LS/EQA is anticipated to benefit laboratories. Additional articles in *QMP-LS News* introduced new requirements and explained what was expected for internal auditing. The "Eye on OLA" monthly column introduced in 2006 remains popular and it will continue to share conformance data, highlight particular requirements and respond to participant feedback. OLA staff members continue to attend conferences and symposia to share information with their colleagues. Three one-hour sessions titled *Steering a Course to Excellence* were provided at the 2007 Ontario Society of Medical Technologists (OSMT) conference, *OLA Guidelines for Flow Cytometry Laboratories* was presented at a user group meeting, and *OLA News and Reviews* were shared at a blood bank seminar. Staff members attend the meetings of the Ontario quality managers group. As part of the project to implement ongoing surveillance of participation and performance in PT/EQA by accredited laboratories, OLA staff members are compiling a list of known external programs that meet the acceptance criteria and this list will be published later in 2008, for the information of laboratories.

OLA Advisory Panel Approves Shortened Accreditation Cycle

The OLA Advisory Panel comprising nine individuals with senior management experience in Ontario laboratories (physicians, scientists and technologists – see Appendix A). It continues to advise on program operations, approves corrective actions following assessment visits, and recommends certificate issue. During 2007–8, it met nine times (quarterly with five additional teleconferences). An important decision reached in 2007–8 was to endorse a plan to shorten the 5-year accreditation cycle. Various models were studied and the final decision was to shorten the cycle to four years. As the existing 5-year certificates expire and laboratories are re-assessed starting in September 2008, 4-year certificates will be issued and assessment visits will occur every four years. Self-assessments will be conducted every two years. This shortened accreditation cycle provides increased surveillance and meets the requirements of ISO 17011:2004 for the operation of a recognized accreditation program. Considerable deliberations occurred regarding incorporating a patient care scorecard into the assessment visit summary report, but the final decision was that a legally defensible and statistically valid scoring scheme was not feasible.

Identifying Efficiencies

Some work has continued to introduce improved technology in the processes for assessment visits, assessor training, and self-assessments. OLA staff members continue to work with staff within Information Services to identify electronic solutions that will streamline processes for staff and laboratories alike. Projects underway are the Web-based submission of assessment evaluation data and self-assessment conformance data. Another

proposed enhancement was the translation of the accreditation requirements into French. Due to limited funding, QMP-LS made the decision to offer its accreditation program in English only for the short-term future.

Continued use of QView™ to post correspondence and other accreditation documents and records provides laboratories with a secure repository of OLA records, and streamlined communication. The “General OLA” folder available in QView™ contains PDF files of reports from the accreditation database — change records, customized checklists and lists of references to support requirements.

Monitoring Turnaround Times

During the development of OLA, other accreditation bodies cautioned against overburdening the program with bureaucracy that might slow the process. OLA monitors its turnaround times on a monthly basis to determine if staff members are meeting targets, if targets are realistic/appropriate, and to identify opportunities for improvement. Data for this monitoring is captured and extracted from the OLA database, summarized and reviewed by the Director, OLA, OLA staff and the QMP-LS Quality Manager. Results in 2007-8 were satisfactory, with two opportunities for improvement implemented. Staff are diligent in entering correct dates into the database, and the target for assessment visit summary reports has been shortened from 30 to 14 days (Table 15).

Table 15. OLA Assessment Visit Turnaround Times (April 1, 2007 to March 31, 2008)

	Time From Assessment Visit to Certificate Issue	Time From Corrective Action to Certificate Issue	Time From Assessment Visit to Receipt of Corrective Action	Time From Visit to Issue of Summary Report
Year	2007-8	2007-8	2007-8	2007-8
Target	150 days	60 days	90 days	30 days
Actual Mean	122 days	40 days	82 days	12 days
Range	6-166 days	0-76 days	0-92 days	5-27 days
N	43	43	43	43

Integrating OLA and EQA Assessment and Surveillance Activities

Within QMP-LS, the activities of EQA and OLA are complementary, and efforts continue to integrate those activities into a seamless quality management program for Ontario's licensed medical laboratories. A formal agreement is pending to formally acknowledge that QMP-LS/EQA will monitor participation and performance in its surveys and will report to QMP-LS/OLA when laboratories fail to meet the criteria for acceptable EQA participation and/or performance described earlier in this report (see “Surveillance”). Avoiding duplication of efforts between the two divisions is paramount. QMP-LS/EQA and QMP-LS/OLA jointly developed the Web-based system through which laboratories will report participation and performance in other PT/EQA programs because QMP-LS/EQA will also utilize this system. QMP-LS/OLA staff members apprise QMP-LS/EQA staff of important changes to the accreditation program, and QMP-LS/EQA staff and scientific committee members apprise QMP-LS/OLA staff of consensus guidelines and standards to substantiate guidance information supporting OLA requirements for accreditation. In 2007, consultant technologists and scientific committee members provided valuable feedback during the biennial review of requirements.

Planning the Future Direction of the Organization

Partnerships

Partnering with SCC, QMP-LS offers its accreditation program on a voluntary basis to English-speaking laboratories within and outside of Canada. Following the assessment and decision-making processes, SCC

will issue an ISO 15189 accreditation certificate to successful laboratories. French-speaking laboratories are encouraged to apply for voluntary accreditation with the Bureau de Normalisation du Québec. A marketing brochure was developed for this program, and OLA assessed the first applicant laboratory in February 2008, which will receive an ISO 15189 certificate from SCC.

Additional partnerships are valuable to OLA, and staff maintain links to Accreditation Canada, the Canadian Coalition for Quality in Laboratory Medicine, the Canadian Institute for Health Information, Health Canada Provincial Blood Coordination Office, International Laboratory Accreditation Cooperation, International Organization for Standardization, and Canadian Standards Association's (CSA) Technical Committee Z252 Medical Laboratory Quality Systems/Canadian Advisory Committee to ISO/TC 212.

LOOKING AHEAD

QMP-LS/OLA joins every laboratory in Ontario in celebrating world-class competence demonstrated by their remarkable conformance (94.90%) to a rigorous international standard. In August 2008, OLA will complete initial assessment visits in Ontario's licensed medical laboratories, and begin to re-assess Ontario laboratories in September 2008. Significant changes will occur:

- A shortened accreditation cycle will be introduced in the fall of 2008. The maximum length of an accreditation certificate will be four years. To transition this change, 4-year certificates will be issued as the current 5-year certificates expire.
- Enhanced surveillance of participation and performance in PT/EQA will be introduced.
- New electronic tools will aid in accreditation processes and procedures.
- Face-to-face refresher one-day seminars will be offered to assessors.

OLA will share its experience and expertise locally and internationally, at meetings and in publications. Education will be provided on what OLA expects of laboratories to demonstrate conformance to new requirements regarding internal audits, management review, traceability and uncertainty of measurement. QMP-LS/OLA will continue to use proven quality management system tools to maintain and improve its core services. Liaison with other organizations will continue. The partnership with SCC promises increased international recognition of accredited laboratories. Accreditation services will be offered on a broader scale within and outside of Canada.

PERFORMANCE HIGHLIGHTS

2007-8

CORPORATE

EDUCATION

Introduction

QMP-LS' philosophy is to deliver education within areas identified through our EQA or OLA activities. Collaborations and shared experiences continue with partners in health care nationally and internationally. In addition, specific educational activities are detailed in the EQA and OLA reports.

In 2007, we published two articles on significant developments in the medical and scientific literature. Seven invited presentations were made at national meetings and 1 at an international meeting; 3 posters were presented at international meetings and 1 at a national meeting; and 1 Webinar was conducted (Appendix E).

QMP-LS News is the principle communication vehicle that is posted once a month on our Web site where additional information on products and services is also available. It highlights developments in laboratory medicine, details of QMP-LS operational changes and provides information on upcoming activities and events. Information is also shared with participants through the Web site via secure password-protected access to QMP-LS' QView™. New tools have been developed to enable Web-based communication.

QMP-LS collaborated with other organizations in the development and promulgation of knowledge:

- Report to Health Canada: Recommendations for the Implementation of the *Organization for Economic Co-operation and Development (OECD) Guidelines for Quality Assurance in Molecular Genetic Testing* in Canada
- Cancer Care Ontario Molecular Oncology Task Force
- Canadian Network for Public Health Intelligence, Breast Cancer Project

Providing Planned Services to the Ontario Medical Laboratory Community

Key Objectives

- Provide education within areas identified through EQA or OLA activities.
 - Developing virtual microscopy capabilities for EQA surveys has been incorporated within the Professional Interpretation and Its Quality Management (PiQM) Task Force.
 - Development of the Ontario breast cancer molecular genetics database.
 - Developing an EQA survey for immunohistochemistry for breast tumour markers.
 - Developing a series on "Decoding ISO 15189," a comprehensive and interactive Web-based program to assist laboratories in any jurisdiction to prepare for ISO 15189 accreditation.
- Develop Web-based training, education and interaction capabilities with participants.
 - Collaborated with Information Services to investigate/evaluate options to educate, train and interact with participants regarding EQA and OLA.
- Provide education to physicians and health care providers as direct consumers of laboratory services regarding guidelines for laboratory services in the prevention and management of chronic diseases.
 - Development of Chronic Disease Management Guidelines.
 - In accordance with MOHLTC direction, develop and publish the following guidelines for the use of laboratory services in the management of chronic disease and prevention of complications:

Diabetes:

- Primary glycemic control
- Monitoring for hyperlipidemia and chronic renal disease secondary complications

Cardiac:

- Cardiac Markers in Acute Coronary Syndrome
- BNP in Congestive Heart Failure diagnosis and management

- Collaborating with the Guidelines Advisory Committee at the Centre for Effective Practice for resource support.
- Corporate oversight of educational resources, staff training, enrichment and travel are coordinated through this department.

Looking Ahead

In 2008-9, Education Services will be renamed the Institute for Quality Management Healthcare division. The key objective is to support EQA and OLA knowledge transfer by providing marketing and project management services. Provision of products and services are on a full cost recovery basis.

Special projects are managed through this department. In 2008-9, Chronic Disease Management guideline development and the Professional Interpretation and Its Quality Management (PiQM) Task Force are key divisional objectives.

Relationship management with other organizations and support for the development of non-core business are new functions for this department.

INFORMATION SERVICES

Introduction

In 2007-8 Information Services (I.S.) continued to develop and deliver improved data collection facilities and enhanced client reports. Additionally, we expanded our knowledge transfer capabilities by bringing Webinar and Webcast production services to QMP-LS.

Developing Comprehensive On-line Capabilities for QMP-LS Services

Key objectives

- Provide Web-based data collection means for laboratories to directly enter self-assessment conformance feedback into the OLA database.
 - Development of the Web-based data entry application was completed utilizing QView™, QMP-LS' Web-based document and data collections server. The site-specific electronic self-assessment templates will be implemented in 2008-9.
- Develop Web-based training modules for OLA assessors as well as for EQA and OLA participants.
 - We acquired and implemented tools for Web-based training of OLA assessors, as well as for EQA and OLA participants. Webinars introducing the new EQA scoring algorithms and reports were conducted

for Ontario participants in March 2008. Another Webinar to demonstrate the external proficiency testing performance and reporting application was also presented in March. Additional Webinars for OLA and EOA participants will be delivered in 2008–9.

- Provide Web-based data collection means for laboratories to directly enter EQA method codes, survey results and discordant findings into EOA databases.

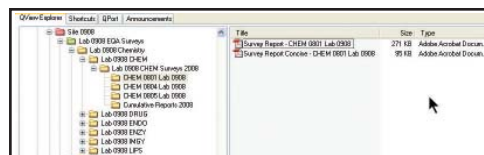
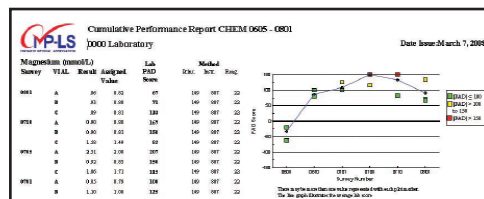
- I.S. completed the development of the Web-based data entry application along with the initial form templates. The QView™ EQA Method Maintenance application was also implemented. Survey-specific electronic analysis worksheets and discordant findings forms will be implemented in 2008–9.

- Develop cumulative EQA performance reports for internal and participant use based on objective scoring criteria.

- I.S. completed the development of scoring algorithms and cumulative performance reports for quantitative EQA surveys. These were implemented effective with the April 2008 surveys. Development and implementation of cumulative performance reports for qualitative surveys will continue in 2008–9.

- Implement Web-based filing of EQA correspondence into OView™.

- I.S. developed the functionality to automate electronic filing of QMP–LS participant correspondence. The implementation of this capability will occur concurrent with the introduction of electronic data collection for discordant findings and survey responses in 2008–9.



Planning the Future Direction of the Organization

Key Objective

- Initiate strategic planning with key stakeholders.
 - Several strategic planning sessions were conducted in 2007–8 and a course for future direction was identified.

Providing Planned Services to the Ontario Medical Laboratory Community

Key Objectives

- Conduct assessment visits to approximately 44 laboratories.
 - I.S. provided OLA application support for 44 laboratory assessment visits.
- Implement the process for biennial review of requirements, and release Version 4
 - I.S. provided application support for the release of Version 4 of OLA Requirements in January 2008.

- Provide EQA surveys in accordance with survey plans
 - In 2007–8, I.S. performed data entry and analysis, and generated participant survey reports for 107 EQA challenge surveys, 4 pattern-of-practice surveys and 1 questionnaires.

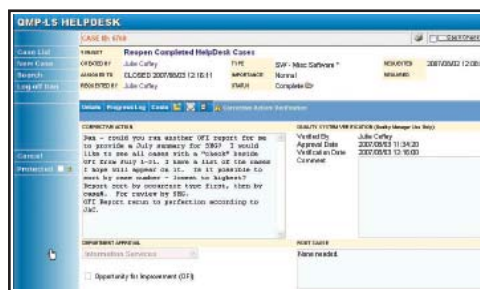
Monitoring the Effectiveness of the Program

Key Objective

- Work with the Quality Manager to implement the necessary software and processes to effectively monitor corrective actions and facilitate management review.
 - In 2007, I.S. modified the internal Help Desk application to identify and record opportunities for improvement as well as report corrective actions to allow QMP–LS management to effectively make decisions on quality improvement opportunities.

Looking Ahead

In 2008–9, I.S. will continue to implement Web-based data collection for EQA and OLA programs along with the implementation of cumulative EQA performance reports for all disciplines. The Webinar and Webcast production capabilities will be expanded. Development and implementation of improved registration and receivables processes will begin this year to ensure timely and convenient client access to QMP–LS products and services.



QUALITY SYSTEM

Like each laboratory in Ontario, QMP–LS has been building its quality system steadily over the past six years. The construction began with document control, and gradually the various system bricks and wedges were added, with the final addition of internal audits and management reviews in 2006–7. With a mature system in place, the organization is in a position to use these quality management tools to progressively improve and ensure conformance to the International Organization for Standardization's documents for accreditation and proficiency testing (EQA) providers. These standards are based on the same quality management system requirements that are mandatory for the laboratories in Ontario.

Two internal audits were conducted this year; one focused on OLA the other on EQA. The audits were completed by a combination of trained QMP–LS staff and external consultants. Both audits included a detailed assessment of compliance to the ISO standards and compliance to internal processes and procedures. In addition, the audits took the team members outside the walls of QMP–LS with a witness audit of one laboratory accreditation assessment, and a second party audit of one external sub-contractor that supplies survey material to the EQA program. These audits provided senior management with a reliable measurement of our quality system processes and 54 opportunities for improvement were identified.

A management review of 2007–8 was conducted by the senior management group. This was the second such review conducted by senior management and once again proved to be a valuable day in which the divisions presented reports on objectives met, identified pressure points and resource requirements, and reviewed all opportunities for improvement identified in the past year. The completion of a management review underscores importance of defining very specific, measurable and achievable objectives.

Performance monitoring continued, with a primary focus on turnaround times of OLA report and certificates, and in the EQA division the turnaround times of survey reports and committee comments. Assessment visit summary reports are consistently issued sooner than the target of 30 days, as such, the target will be shortened to 14 days. Within EQA, turnaround times have improved by 6% for survey reports, and 28% for committee comments. Further measures will be implemented to improve the turnaround time for committee comments.

All opportunities for improvement identified through internal and external audits, client contacts, occurrences, and staff suggestions are logged into an application that enables division directors and supervisors to log corrective actions. These are reviewed by senior management on a monthly basis. An analysis of a full year's events has revealed the following areas for further monitoring and improvement:

- Shipping/mailing
- QView™ posting
- Errors on instructions and worksheets
- External suppliers of EQA materials

Looking Ahead

In the next fiscal year, the organization will remain focused on continual improvement and adherence to international standards. The EQA program will prepare for external assessment against ILAC Guide 13:2007 by Standards Council of Canada.

In addition, a survey will be administered to allow assessed laboratories to comment on how well QMP-LS/OLA has met its program values.

APPENDIX A

2007–8 QMP–LS COMMITTEES AS AT MARCH 31, 2008

Conjoint

MOHLTC Representatives:

Ms. Marnie Cooper, Co-Chair

Mrs. Patricia Anderson

OMA/QMP–LS Representatives:

Dr. Gregory J. Flynn, Co-Chair

Dr. Michael Thoburn

Dr. Virginia Walley

Advisory Council

Ministry of Health and Long-Term Care

Ms. Marnie Cooper

Ministry of Health and Long-Term Care

Ms. Patricia Anderson (Observer)

Ontario Medical Association Board

Dr. Virginia Walley

Ontario Medical Association

Dr. Michael Thoburn

Ontario Society of Clinical Chemists

Dr. Lynn Allen

Ontario Hospital Association

Mr. Glen Dietz (Retired Sep 2007)

Ms. Sudha Kutty (Commenced Oct 2007)

OMA Section on Laboratory Medicine

Dr. John Doucet

College of Physicians & Surgeons of Ontario

Dr. Daniel Klass

Ontario Society of Medical Technologists

Ms. Blanca McArthur

Ontario Association of Medical Laboratories

Mr. Jeffrey Sumner

Ontario Association of Pathologists

Dr. Frank E. Thompson

College of Medical Laboratory Technologists of Ontario

Mrs. Kathy Wilkie

Association of Medical Microbiologists of Ontario

Dr. Deborah Yamamura

Chair, Professional Advisory Committee

Dr. Sheila Boss

Chair, Ontario Laboratory Accreditation Advisory Panel

Ms. Kathryn Snell

Managing Director, Quality Management Program—
Laboratory Services

Dr. Gregory J. Flynn (Ex-officio)

Director, Ontario Laboratory Accreditation, Quality
Management Program—Laboratory Services

Mrs. Linda Crawford (Observer)

Director, External Quality Assessment, Quality
Management Program—Laboratory Services

Ms. Jane Gun-Munro (Observer)

Professional Advisory Committee

Dr. Sheila Boss, Chair

Mr. Michael Keeney, Vice-Chair

Dr. Margaret Fearon

Dr. Karen Harrison

Mrs. Laura J. Harrison

Dr. Nathalie Lepage

Ms. Laurie Mason

Dr. Golnar Rasty

Dr. Baldwin W. Toye

Dr. Pui-Yuen Wong

Mrs. Patricia Anderson (Ex-officio)

Ontario Laboratory Accreditation Advisory Panel

Ms. Kathryn Snell, Chair

Mr. Barry Vermeersch, Vice-Chair

Ms. Ruth C. Jaeger

Dr. James Kerry MacDonald

Ms. Cathie McCallum

Dr. Anna G. Morris

Dr. Godfrey Moses

Ms. Janice Nolan

Dr. William Brien

Mrs. Patricia Anderson (Ex-officio)

Ms. Marnie Cooper (Ex-officio)

Mrs. Linda Crawford (Ex-officio)

Dr. Gregory J. Flynn (Ex-officio)

Test Review Committee

Dr. Robert Moore, Chair

Dr. Kenneth Arnold

Dr. Frank E. Thompson

Mr. Sam Thomson

Ms. Marnie Cooper (Ex-officio)

Ms. Patricia Anderson (Observer)

Chronic Disease Prevention & Management Guidelines

Diabetes Expert Panel

Dr. Valerie Palda, Chair

Dr. Lynn Allen

Dr. Ronnie Aronson

Dr. Sheila Boss

Dr. Peter Bunting

Dr. Maureen Clement

Dr. Denise Feig

Dr. Jon Johnsen

Ms. Jan Kasperski

Dr. David Mendelssohn

APPENDIX A

2007-8 QMP-LS COMMITTEES AS AT MARCH 31, 2008

Chronic Disease Prevention & Management Guidelines (continued)

Diabetes Expert Panel

Ms. Rhoda Reardon
Mr. Jeff Sumner
Ms. Joan Canavan (Ex-officio, non-voting)
Dr. Gregory Flynn (Ex-officio, non-voting)
Ms. Joanne Miyazaki (Ex-officio, non-voting)
Mrs. Sharon Webb (Ex-officio, non-voting)
Ms. Susan A. Wolnik (Ex-officio, non-voting)
Dr. Roy Wyman, (Ex-officio, non-voting)

Anatomic Pathology

Ms. Laurie Mason, *Chair*
Dr. Frank E. Thompson
Dr. Ola A. Kassim
Ms. Sue Seguin
Mr. William R. Parks
Ms. Cathie Crukley
Dr. Kathy Chorneyko
Dr. Kelly Laurence

Chemistry-General and Enzymes

Dr. Sheila Boss, *Chair*
Dr. Stephen A. Hill, *Vice-Chair*
Dr. Ken Newell
Dr. Alex Romaschin
Dr. Douglas Gornall
Dr. Lynn Allen
Ms. Jackie Barten
Dr. Edward Dunn, *Advisor, Drug Monitoring*

Cytology

Dr. Golnar Rasty, *Chair*
Mr. Marvin MacLean
Ms. Sharon Crafter
Dr. Michelle Sapp
Dr. Caroline Rowlands

Endocrinology and Immunology

Dr. Pui-Yuen Wong, *Chair*
Mr. Mark Donahoe, *Vice-Chair*
Dr. David E. Cole
Dr. Lois E. Shepherd
Dr. Sonya Tokmakejian

Genetics

Dr. Karen Harrison, *Chair*
Dr. Diane Allingham-Hawkins, *Vice-Chair*

Genetics (continued)

Dr. Kathy Chun
Dr. Ron Carter
Ms. Michelle Wood
Dr. Jean McGowan-Jordan

Hematology

Mr. Michael Keeney, *Chair*
Dr. Mark Crowther
Mr. Jeffrey Sumner
Dr. Ruth Padmore
Dr. Ian H. Chin-Yee
Dr. Adam Ninos
Mr. John Lafferty, *Advisor, Red Cell Disorders*

Microbiology

Dr. Baldwin W. Toye, *Chair*
Dr. Alicia Sarabia, *Vice-Chair*
Dr. Susan Poutanen
Ms. Candy Rutherford
Ms. Chee-Yuen Meaney
Dr. Frances B. Jamieson, *Advisor*

Parasitology Advisory Group

Ms. Rose McQueen

Mycology Advisory Committee

Dr. James Scott
Ms. Ursula Bunn
Dr. Debbie Yamamura

Maternal Serum Screening

Dr. Nathalie Lepage, *Chair*
Dr. Barry Hoffman
Dr. Alan Dennis
Ms. Shamim Rashid
Ms. Ellis Chow, *Consultant, OMSSD*

Transfusion Medicine

Mrs. Laura Harrison, *Chair*
Mrs. Debbie Lauzon, *Vice-Chair*
Dr. Alan Tinmouth
Mr. Jeff Kinney
Dr. Kathryn Webert

Virology

Dr. Margaret Fearon, *Chair*
Mr. John Nishikawa, *Vice-Chair*
Dr. Astrid Petrich

APPENDIX B

VOLUNTEERS WHO ASSISTED QMP-LS IN 2007-8

External Quality Assessment

Ms. Laura Baillie
Mrs. Linda Borycheski
Ms. Wendy Brown
Ms. Debra Browning
Ms. Laura Burton
Ms. Alison Carey
Ms. Jessica Carson
Ms. Ping Chao
Mrs. Patti Cheatley
Ms. Pam Chedore
Mr. Leio Coloquio
Mr. Diaram Deokharan
Ms. Karen DeRuiter
Ms. Jacky Fok
Dr. John Freedman
Ms. Esther Geisbrecht
Ms. Anne Hamid-Allie
Mr. Michael Ho
Ms. Jennine Kafka
Dr. John Kim
Ms. Leona Kotowich
Ms. Tina Kozlowski
Mr. Ivan Lam
Mr. Scott MacDonald
Ms. Theresa Mahony
Ms. Laurie Malloch
Dr. David Murray
Mr. Sam Nagra
Mrs. Connie Pletch
Dr. Russell Price
Ms. Georgina Ralevski
Mr. Prasad Rawte
Dr. Michael J. Raymond
Ms. Gwen Rosenfield
Dr. Corwyn Rowsell
Ms. Debra Saunders
Ms. Nancy Senk
Ms. Elisa Shore
Ms. Heather Siebert
Mr. Glen Small
Ms. Deirdre Soares
Ms. Carol Swantee
Ms. Lynn Towns
Ms. Liese Walchuk
Ms. Lai Ling Wat
Mr. Billy Yu

Ontario Laboratory Accreditation

Ms. Mona Ackerman
Ms. Marjorie Allen
Ms. Beate (BJ) Anding
Ms. Janice Archer
Ms. Jeanine Baker
Ms. Alison Bear
Ms. Pamela Bennett
Ms. Johanne Bietola
Mr. Chris Blagg
Ms. Diana Booth
Ms. Karen Bortolon
Ms. Linda Borycheski
Ms. Patti Boyd
Ms. Mary Breadner
Ms. Len Burger
Ms. Pamela Calverley
Ms. Johanna Campbell
Dr. Nancy Carson
Mr. Robert Cheslo-Trengrove
Dr. Pak Cheung Chan
Mr. Tom Clancy
Ms. Betty Anne Clark
Ms. Nancy Cober
Ms. Sandra Comand
Mr. Daryl Corriveau
Ms. Brenda Cutting
Ms. Susie Davies
Ms. Deborah Elliott
Ms. Susan Evans
Ms. Mary Falls
Ms. Lisa Farinacci
Ms. Louise Farrar
Ms. Marikay Files
Ms. Robert Fitz-James
Ms. Mary Fountas
Ms. Suzanne Froment
Dr. Douglas Gornall
Ms. Margaret Grabowski
Ms. Susan Hodgins
Mr. Gary Holly
Ms. Tammy Ison
Ms. Tanya Jorden
Mr. Kevin Katz
Mr. Robert Kendrick
Mr. Robert Kerekes
Ms. Peggy Kerk
Ms. Tanya Knopf
Ms. Susan Leask
Mr. Albert Lee
Ms. Aline Letourneau

Ms. Pauline Lo
Ms. Patricia Ludlow
Mr. Al Lupish
Ms. Christine Mackay
Ms. Joanie Mackay
Ms. Lorraine MacLean
Ms. Marg Maddock
Ms. Carol Major
Ms. Debbie Maki
Mr. Rick Mancini
Ms. Viki Massey
Ms. Tina Mattice
Ms. Judy Maxwell
Dr. Tony Mazzulli
Ms. Cathie McCallum
Ms. Marion McChesney
Mr. Michael McConnell
Ms. Patricia McGillis
Ms. Laurie McIntosh
Ms. Heather McMullen
Ms. Shawne Milne
Mr. Jim Moran
Mr. David More
Ms. Doris Neurath
Mr. Wayne Ozanne
Ms. Bonnie Page
Mr. Patrick Paulusse
Ms. Anne Marie Phillips
Dr. Karam Ramotar
Ms. Susan Randell
Ms. Stephanie Rossanese
Ms. Lydia Salvino
Ms. Susan Schaub
Ms. Dawn Scott
Ms. Judy Sherman-Jones
Ms. Donna Shields
Ms. Marilyn Spagnoli
Ms. Carolin Smart
Ms. Sandra Smith
Ms. Deidre Soares
Ms. Joanna Tam
Ms. Linda Turner-Smith
Ms. Cheryl Watt
Ms. Heather Watts
Ms. Marsha Ward
Mr. Kevin Webb
Ms. Laura White
Ms. Katherine Wong
Ms. Michelle Wood
Mr. Greg Young

APPENDIX C

QMP-LS STAFF AS AT MARCH 31, 2008

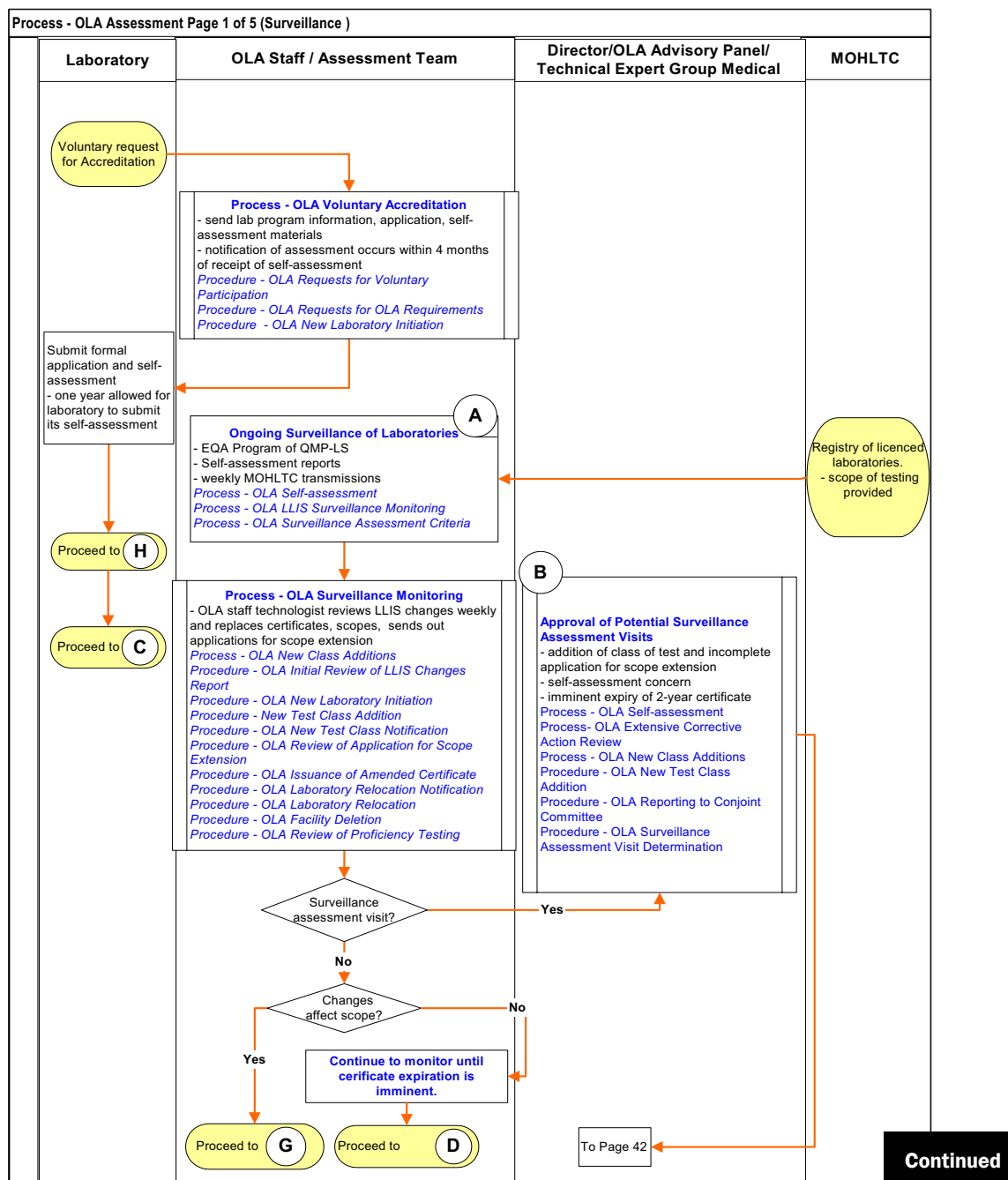
40>

QMP-LS Review 2007-8

Gregory Flynn	Managing Director
Joanne Bishop	Staff Technologist, OLA
Darlene Cameron	Data Officer
Jason Chard	Systems Analyst
Julie Coffey	Staff Technologist, OLA and Quality Manager
Linda Crawford	Director, Ontario Laboratory Accreditation
Christine Fleming	Senior Consultant Technologist, EQA— Bacteriology, Mycobacteriology and Parasitology
Christine Fry	Staff Technologist, OLA
Jane Gun-Munro	Director, External Quality Assessment
Bryan Hewlett	Consultant Technologist, EQA—Anatomic Pathology
Carol Julian	Consultant Technologist, EQA—Cytology
Neela Khatri	Senior Systems Analyst
Maritess Koerner	Supervisor, Communications & Documents
Emily Lee	Receptionist
Alex Lesniara	Senior Systems Analyst
Dan MacFayden	Director, Corporate & Support Services
Janine Marmulak	Senior Administrative Assistant, EQA (on maternity leave)
Joanne Miyazaki	Consultant Technologist, EQA— Genetics and Maternal Serum Screening, and Manager, Business Development & Education
Matt O'Connor	Coordinator, Financial & Support Services
Astrid Petersons	Consultant Technologist, EQA— Flow Cytometry, Transfusion Medicine, Point-of-Care Testing
Anne Raby	Consultant Technologist, EQA— Hematology, Coagulation, Morphology, Bone Marrow and Red Cell Disorders
Julio Rodriguez	Data Officer
Shelly Rowe	Senior Systems Analyst
Maureen Singh	Senior Administrative Assistant, EQA
Sukanya Shankar	Senior Administrative Assistant, EQA (contract)
Miralla Suares	Senior Administrative Assistant, OLA
Donna Thompson	Consultant Technologist, EQA—Mycology and Virology
Brenda Todd	Senior Administrative Assistant, Corporate
Carol Turner	Staff Technologist, OLA
Sharon Webb	Consultant Technologist, EQA— Chemistry-General, Drug Monitoring, Endocrinology, Immunology and Enzymes, Cardiac Markers and Lipids
Margaret Hall Yousefi	Web site Officer
Manny Zamora	Expeditor

APPENDIX D

PROCESS – OLA ASSESSMENT

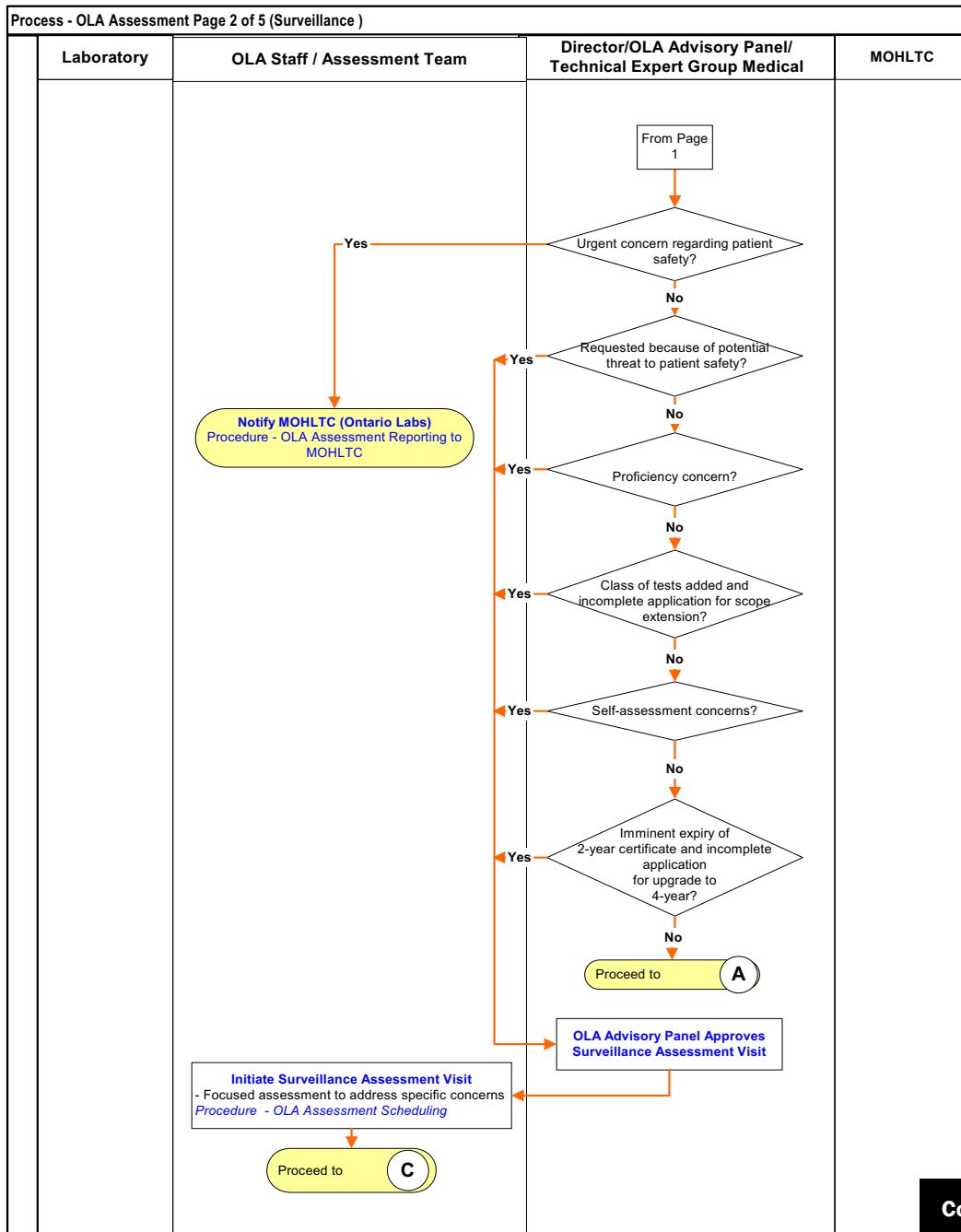


APPENDIX D

PROCESS – OLA ASSESSMENT

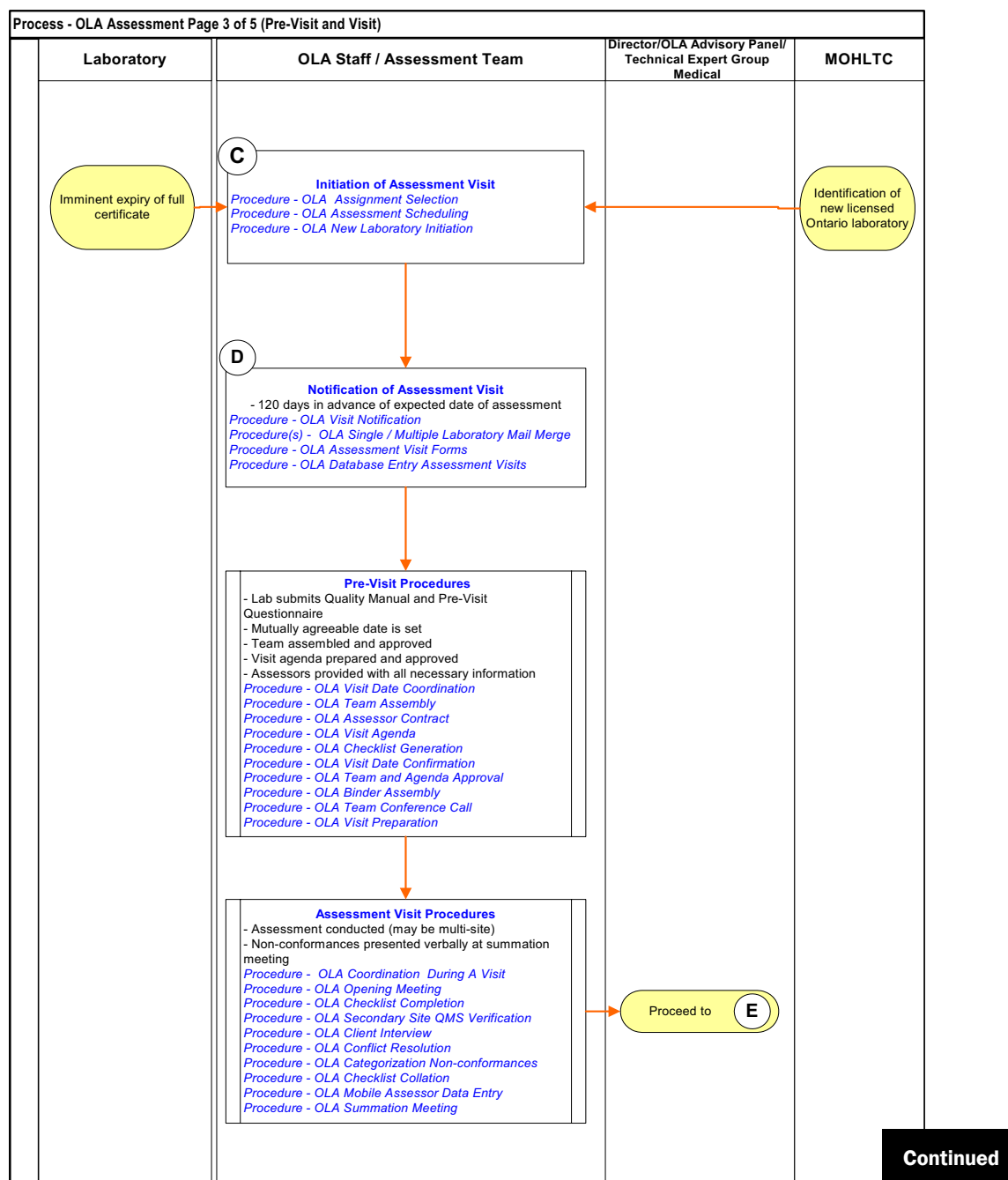
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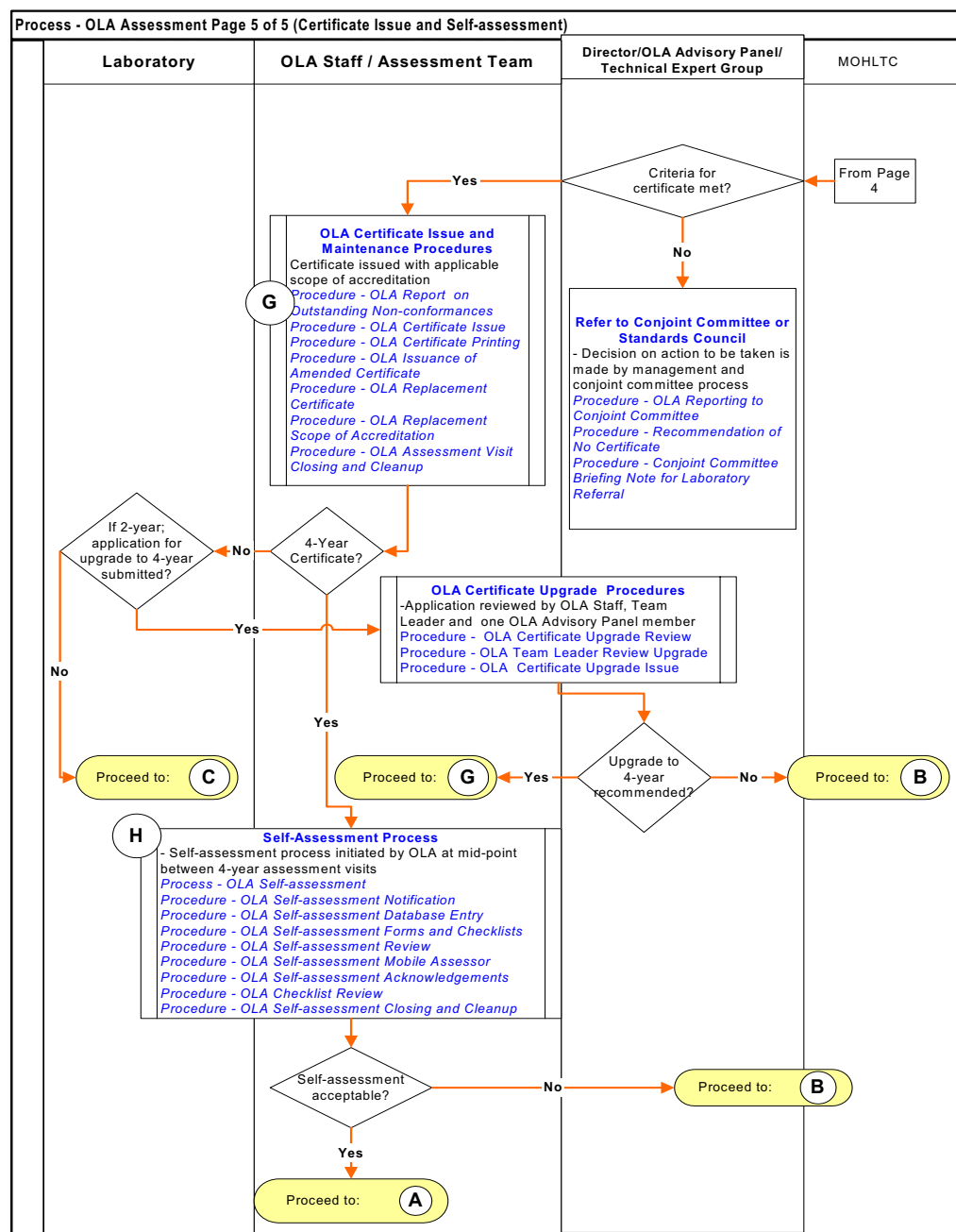
APPENDIX D

PROCESS – OLA ASSESSMENT



APPENDIX D

PROCESS – OLA ASSESSMENT



APPENDIX E

PUBLICATIONS AND EDUCATION

Scientific Communications

Cole DE, Webb S, Chan PC. Update on parathyroid hormone: New tests and new challenges for external quality assessment. *Clin Biochem.* 2007 Jun;40:585–590.

Crowther M, Bates S, Keeney M and Raby A. Human Derived D-dimer for External Quality Assessment: Results of Four Surveys in Ontario. *Am J. Clin Pathol* 2008. *In Press.*

Lafferty JD, Barth DS, Sheridan BL, McFarlane AG, Halchuk LM, Raby A, Crowther MA. A Multicentre Trial of the Effectiveness of ζ Globin Enzyme Linked Immunosorbent Assay (ELISA) and Hb H Inclusion Body Screening for the Detection of α^0 Thalassemia Trait *Haematologica.*

Invited Presentation and Talks

Coffey J and Crawford L. Steering a Course to Excellence – Driving Outside the Laboratory. OSMT 2007 Conference. OSMT. Toronto, Ontario. October 2007.

Coffey J and Crawford L. Steering a Course to Excellence – Driving Outside the Laboratory. OSMT 2007 Conference. OSMT. Toronto, Ontario. October 2007.

Coffey J and Crawford L. Steering a Course to Excellence – Driving Outside the Laboratory. OSMT 2007 Conference. OSMT. Toronto, Ontario. October 2007.

Gun-Munro J. External Quality Assessment – What's the Score? OSMT Annual Meeting. Toronto, Ontario. October 2007.

Petersons A. The ABCs of EQA. 2007 London Laboratory Services Group Academic Symposium Series. London, Ontario. November 2007.

Gun-Munro J. Introduction to QMP-LS. MEDEC Diagnostic Committee. Toronto, Ontario. February 2008.

Crawford L. 30 Years of Medical Technology. NORONT 2008. Timmins, Ontario. March 2008.

Crawford L. Looking Back – Peering Into the Future. NORONT 2008. Timmins, Ontario. March 2008.

Posters

Turner C and Crawford L. Ontario's Mandatory Accreditation to ISO 15189:2003. CSTM Conference. Calgary, Alberta. May 2007.

Crowther M, Raby A, Keeney M, Flynn G. Use of Human Derived Artificially Prepared D-dimer in External Quality Assessment (EQA). ISTH 2007. The International Society on Thrombosis and Hemostasis XXth Congress. Geneva, Switzerland. July 2007.

Raby A, Crowther M, Flynn G. D-dimer Reporting: A Problem for the Electronic Health Record? An Ontario Perspective. ISTH 2007. The International Society on Thrombosis and Hemostasis XXth Congress. Geneva, Switzerland. July 2007.

Julian C. Preparation, fixation and staining of cell blocks in cytology laboratories – 2005. American Society of Cytopathology (ASC). Houston, Texas. November 2007.

Webinars

Gun-Munro J. Performance Scores for Quantitative Chemistry and Hematology EQA Surveys. Toronto, Ontario. March 2008.