



2006 REVIEW

Quality Management Program—Laboratory Services



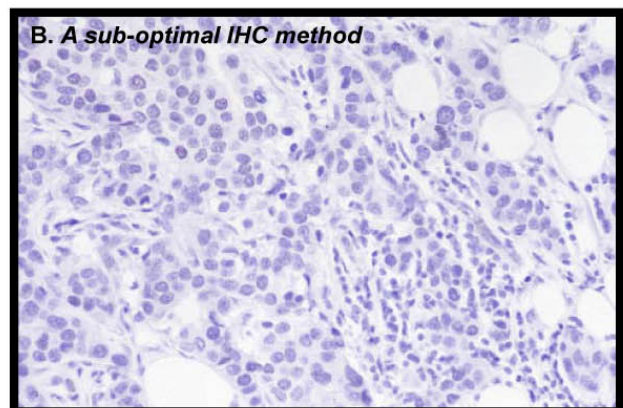
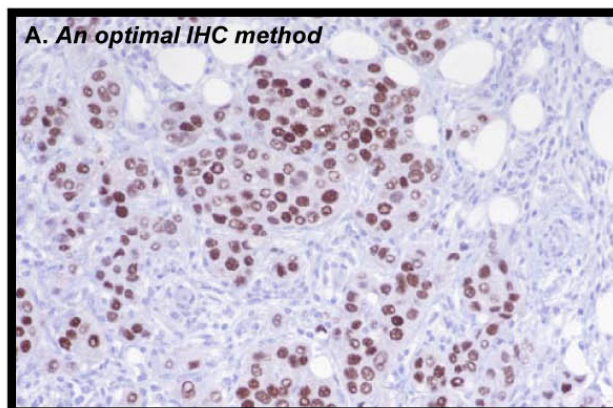


Cover image and images below generously provided by
Bryan Hewlett, QMP-LS EQA Consultant Technologist, Anatomic Pathology

COVER IMAGE: Photomicrograph of an invasive breast cancer stained for the presence of estrogen receptor protein (ER) by an optimized, calibrated and validated immunohistochemical (IHC) method. *ER positive cell nuclei—reddish-brown, ER negative cell nuclei—blue.*

Appropriate treatment for the patient relies on accurate, reproducible ER results.

The images below illustrate both good and poor results of IHC staining for ER on adjacent sections from another sample of breast cancer.



Quality Management Program—Laboratory Services

Traditionally, the QMP–LS *Review* reported on activities by the calendar year; however, to align with our strategic goals and objectives, the *2006 Review* presents fiscal year data. Information reported in the *2006 Review* is based on a 15-month period from January 1, 2006 to March 31, 2007. The content has also been streamlined to speak to a broader audience.

“Building quality through continual improvement.”

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

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:

- Meets all clients’ needs; applicable regulatory, statutory and contractual requirements; and relevant national/international standards;
- 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;
- Reviews and modifies this policy for continued suitability.

QMP–LS Vision, The Purpose/Mission, Values and Quality Policy	i	External Quality Assessment	11
Contents	ii	Introduction	11
Message from the Managing Director	1	Project Highlights	11
Acknowledgements	1	Revision of EQA Survey Analysis and Performance Evaluation Processes	11
Corporate Highlights	2	Revision of the 1999 Ministry of Health and Long-Term Care POCT Policy	12
Education	2	EQA Core Activities	14
Symposia and Workshops	2	Provision of EQA Services from January 2006–March 2007	13
Chronic Disease Prevention and Management Guidelines.....	2	Ontario Laboratory Accreditation	22
Information Services	2	Introduction	22
Customer Service	2	Highlights	22
Resource Management	3	Meeting International Standards.....	24
Service Realization	3	Partnership with Standards Council of Canada for Voluntary Accreditation	24
Measurement and Analysis	3	Achievements in the Implementation of Our Quality System.....	25
Quality Systems	4	Reaching Out to Participants, Stakeholders and Partners	27
Internal Audit.....	4	Acknowledgements	28
External Audit	4	Summary and Future	28
Performance Measures	4	Appendices	
Opportunities for Improvement	4	A. 2006–7 QMP–LS Committees	29
Annual Management Review.....	4	B. Volunteers who assisted QMP–LS in 2006/2007.....	31
Corporate Profile, Framework and Governance	4	C. QMP–LS Staff as at March 31, 2007	32
Profile	5	D. Publications and Education	33
Framework	5		
External Quality Assessment.....	5		
Ontario Laboratory Accreditation	6		
Oversight of OLA and EQA.....	7		
Support Services	7		
Senior Management Group	7		
External Liaison	7		
Collaboration with Other Jurisdictions	7		
Governance	8		
Relationship with the Ontario Ministry of Health and Long-Term Care	8		
QMP–LS Committees	8		

The reader is cautioned not to take any single item, or part thereof, of the 2006 Review out of context.

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Message from the Managing Director

The *2006 Review*, like the past year, reflects a significant change from previous *Reviews*. It is intended to be more accessible and readable to those who are not on the inside of the organization, and to be a useful document not only to the laboratory community, but also to other health care professionals who might wish to understand the nature of work at QMP-LS. Accordingly, it is more of a descriptive review aimed at a conceptual level than a detailed review of the various divisional and corporate work of the past year.

QMP-LS has a long and proud history of accomplishments in laboratory quality management. Working with peers in the field of laboratory medicine, QMP-LS has evolved to be an international leader in external quality assurance and accreditation to international standards. The staff work creatively and diligently to adapt to changes in technology, delivery and regulation of laboratory testing.

QMP-LS delivered a customer-focused product to its provincial, national and international clients in 2006. Supported by leading edge Information Services and well-subscribed Educational activities, QMP-LS has provided great added value to the laboratories and communities they serve.

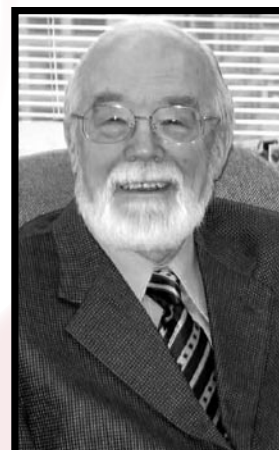
During 2006 the organization underwent a significant change in leadership. For 11 years the program was guided by a great friend and visionary, Dr. Harold (Harry) Richardson. His tenure was marked by the maturation of the External Quality Assessment (EQA) division to a stage where we are able to offer truly best in class proficiency testing materials and more rigorous methods for laboratories to assess their performance on individual surveys, and over time.

Dr. Richardson's vision was international in scope. Through his efforts, Canada played an important and formative role in the development of the ISO 15189 standard for medical laboratory testing. This standard, on which the Ontario Laboratory Accreditation's (OLA) requirements are based, has been embraced by more laboratory regulatory bodies than any other.

Central to the running of a laboratory, or any other complicated activity, is the need for a quality management system (QMS). Embedded in the ISO 15189 standards is the need to find evidence of such a system to manage risk, ensure quality indicators are in use, and to ensure that opportunities for improvement are recognized and acted upon.

So with Harry's retirement it is a good time to reflect on that legacy. He was also a team builder, and he retired with a strong management team and an internationally recognized program. Harry passed away in February 2007 shortly after his retirement. He will be greatly missed.

For the immediate future, QMP-LS will continue its work in mandated areas of laboratory testing. We will consider our management and governance structure and strategically plan our future.



*Harold Richardson,
BSc, MBBS, MD, FCCM,
FRCPC 1939-2007*

ACKNOWLEDGEMENTS

QMP-LS continues to provide world-class external quality assessment, accreditation and education services, with the tireless support of many expert individuals who serve as committee members ([Appendix A](#)) and volunteers ([Appendix B](#)). We acknowledge their commitment and dedication to our program.

We thank the following committee members who retired during 2006/2007 year:

Dr. Robert Barr	Dr. Joanna Dolling	Dr. Doug W. McPherson	Dr. Peter Ray
Dr. Vipin Bhayana	Ms. Linda Evelyn	Mr. Chris Meier	Dr. Brian Rudrik
Mrs. Linda Borycheski	Mrs. Viola Freeman	Mr. Gaman Modi	Dr. Brian Sheridan
Mr. David Carson	Dr. Geoffrey W. Gardiner	Dr. David Murray	Dr. Anne M. Summers
Dr. Nancy Carson	Dr. Joel Goodman	Mrs. Andrea O'Donnell	
Ms. Anna Chan	Dr. Linda Kapusta	Dr. Ken Onuska	
Dr. Christine Collier	Dr. Denis Macdonald	Ms. Wendy Owens	

Our sincere gratitude to the Ontario laboratories and institutions that allow their staff to serve on our committees. We also thank Mr. Jim Moran, our Ontario Laboratory Accreditation (OLA) assessor trainer, and Mr. Dan Tholen, our statistical consultant, for their invaluable expertise, advice, and guidance.

Mrs. Linda Crawford was awarded the 2006 Trillium Award by the Ontario Society of Medical Technologists in recognition of her significant contribution to medical laboratory technology in Ontario through her work with QMP-LS/OLA. Mr. Bryan Hewlett received the Elisabeth Pletscher Award at the World Congress of Biomedical Laboratory Science in September 2006. Congratulations to both for their outstanding work and dedication!

Staff at QMP-LS ([Appendix C](#)) are commended for their continual support. Mrs. Colette Caruso, Communications Assistant, and Mrs. Betty Waltenberry, Data Officer left during 2006/2007. We wish them well.

EDUCATION

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 (Appendix D). In addition, specific educational activities are detailed in the EQA and OLA reports.

In 2006, we published articles on significant developments in the medical and scientific literature (Appendix D). Two invited presentations were made at international meetings and nine at local and Canadian national meetings (Appendix D). *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' document server, QView™.

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

- Health Canada, Tier 1 Training Program
- Cancer Care Ontario, Pathology Project
- National Center for Infectious Diseases, Centers of Disease Control and Prevention, Virtual Microscopy Project
- Canadian Network for Public Health Intelligence, Breast Cancer and Virtual Microscopy Projects

New tools will be developed to enable on-line Internet-based training.

SYMPOSIA AND WORKSHOPS

QMP-LS continued its collaboration with the College of Medical Laboratory Technologists of Ontario (CMLTO) and the Ontario Society of Medical Technologists (OSMT) to deliver a hematology travelling workshop across Ontario. Over 140 registrants participated at the seven regional workshops in Ontario.

A national Flow Cytometry workshop was conducted on June 24 and 25 in collaboration with Becton Dickinson and Beckman Coulter. The two-day meeting attracted 180 participants.

CHRONIC DISEASE PREVENTION AND MANAGEMENT GUIDELINES

A process was developed to provide education to physicians and health care providers regarding guidelines for laboratory services in the prevention and management of chronic diseases. The initial guidelines to be developed include:

- Diabetes (HbA_{1c}, Lipids and eGFR)
- Cardiac Markers (Myoglobin, Troponin and BNP)

QMP-LS continued to provide education and professional development to its staff. Processes are being developed to facilitate distribution of resources for staff travel and education.

INFORMATION SERVICES

In 2006, Information Services achieved a number of significant operational objectives whilst striving for continual improvement:

CUSTOMER SERVICE

We replaced the existing document server with QView™, our Web-based document server and data collections server. There are now more than 1800 laboratory professionals with their own site-specific QView™ accounts.

Electronic Data Collection

We began electronic data collection development. Our initial applications were questionnaires for the former Management Committee* and an internal QMP-LS staff survey. The responses will be used to improve client and staff satisfaction.

* The Management Committee was restructured in 2006 and became the Advisory Council.



Cumulative EQA Performance Reporting

We improved the presentation of a number of survey reports and began development of cumulative EQA survey performance reports. These will be implemented in 2008.

RESOURCE MANAGEMENT

We replaced several critical pieces of equipment including obsolete file and print servers, staff workstations, the network backup hardware and software, and our obsolete phone system. In addition, the existing photocopier/printers were replaced with newer, cost-effective machines that will provide annual savings greater than \$11,000 commencing 2007/2008. We also acquired a film scanner with a medical slide holder to capture images for Web-based surveys.

SERVICE REALIZATION

OLA Accreditation Software Application Enhancements and Support

We developed and deployed a revised Mobile Assessor component of the Q-Accredit!™ application. This version was used by assessors on assessment visits during a pilot that will be extended through 2007 to evaluate whether efficiencies can be improved by making the transfer of assessment data easier and quicker, and also if the data quality can be improved by reducing manual transcription.

Migration of EQA Surveys from Ingres to SQL-Server based LEQA application

Hewlett Packard discontinued support for its proprietary HP3000 computer in 2007. In 2006, we completed the move of all EQA surveys from the Ingres® relational database on the HP3000 onto a SQL-Server based application we call LEQA (Lab-EQA).

EQA Survey Data Collection, Analysis and Reporting

Information Services also performed data entry and analysis, and generated participant survey reports for 114 Ontario challenge surveys, 2 questionnaires and 6 pattern-of-practice surveys.

MEASUREMENT AND ANALYSIS

In 2006, we began utilizing the information captured via the Client Contact form into the QMP-LS Help Desk application to effectively make decisions on quality improvement opportunities.

QMP-LS
1510-250 Bloor Street East
Toronto, Ontario M5W 1B6
Tel: (416) 323-9540
Fax: (416) 323-9324

Management Committee Questionnaire

Please Return to QMP-LS by:
January 8, 2007

Please Enter Your Name

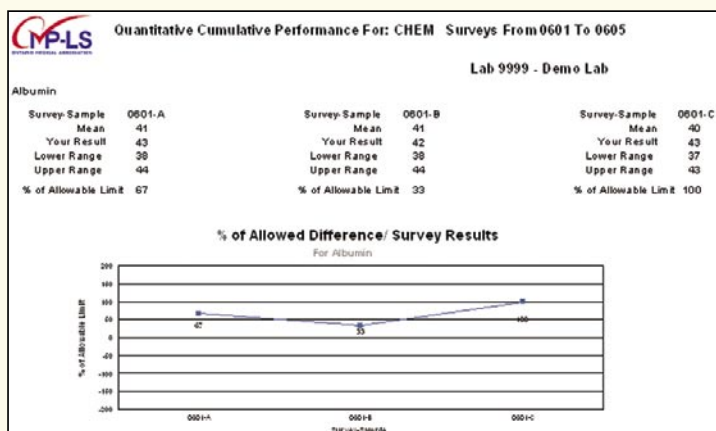
2. From which areas of your work as a Committee member do you get the most satisfaction?

The organisation stands for a worthwhile cause ☒

Seeing the organisation develop ☒

Ensuring the organisation meets the needs of its participants/stakeholders ☒

Providing help/guidance in my own area of expertise ☒



Q-Accredit! Mobile Assessor

1 Clives Memorial Hospital

Requirements

Guidance

Num

Eval

II. A

II. A.1

Minor

II. A.2

Met

2004 SURVEY PARAMETERS

HEMA 6705 CBC AND LEUKOCYTE DIFFERENTIAL

Test Name	Num	Mand	Stat	Anal	Dc	Resp	Zero	Dups	Semi	Anal	Dc	Style	Add	Results	Expected	A	B	C
1 Leukocyte Cnt			Active	1-SN	1	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
2 Erythrocyte Cnt			Active	1-SN	2	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
3 Hemoglobin			Active	1-SN	0	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
4 Hematocrit			Active	1-SN	2	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
5 MCV			Active	1-SN	0	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
6 Thrombocyte Cnt			Active	1-SN	0	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
7 LYMPHOCYTES			Active	1-SN	1	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
8 MONOCYTES			Active	1-SN	1	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
9 GRANULOCYTES			Active	1-SN	1	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
10 EOSINOPHILS			Active	1-SN	1	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
11 BASOPHILS			Active	1-SN	1	Numeric				0-AB		Flagg	Key By Lab	0	All Samples			
12 Material OK			Active	3-FC	0	Code				0-AB		Flagg	Key By Lab	0	Question Response			
13 Comments			Active	3-FC	0	Code				0-AB		Flagg	Key By Lab	0	Question Response			
14 Comp. Blood Cl			Active	1-SN	0	Numeric				0-AB		No An	No Result Ke	0	Undefined			

Division - LS.

HelpDesk Client Contact Cases From 2006/10/01 To 2006/12/31

Request #	Subject	Requested By	Request Date Status	Completion Date Assigned To
Request -	Hello QMPLS people:			
Comments	I cant seem to find recent worksheets sent to you. They used to be scanned and available for review on line. Have you stopped doing this?			

QUALITY SYSTEMS

In 2006, the quality focus of QMP–LS was on continual improvement, a key component of quality. In particular, the organization concentrated on monitoring and measuring the success of processes and taking the actions necessary for improvement. It implemented several processes and procedures both to measure progress and to identify further opportunities for improvement. They are:

- internal audit
- external audit
- performance measures
- opportunities for improvement
- annual management review of the system.

INTERNAL AUDIT

Internal audits are one of the most important means by which QMP–LS ensures improvement. In 2006, it developed a process and detailed procedures for conducting regular annual audits of its programs. The audits are an opportunity to:

- identify potential problems
- streamline activities
- be more critical than a third party
- learn more about each other's work.

The audits check QMP–LS' conformance to international standards and its compliance to its own procedures. Processes and procedures are documented and the audit is carried out by staff trained in auditing who are independent of the activity being audited.

The audit process consists of four phases, similar to those carried out in OLA assessments:

- preparation
- performance
- report
- follow-up and closure.

The audit identifies each non-conformance and defines corrective actions that include those responsible and a timeline for completion. In addition, the QMP–LS Quality Manager must verify the effectiveness of the actions taken, using a specially designed measurement process.

EXTERNAL AUDIT

On January 31–February 2, 2007, the Standards Council of Canada (SCC) conducted an external audit of the OLA division to assess its conformance to *ISO 17011:2004*. This formal audit covered all aspects of the quality system, with a large emphasis on continual improvement activities. The internal audit process and results received intense scrutiny, as did the system for the management of occurrences. It was important to demonstrate how processes are measured and that all opportunities for improvement are suitably addressed with concrete plans to implement changes.

PERFORMANCE MEASURES

As one of its methods of measuring performance, QMP–LS conducted a series of satisfaction surveys with scientific committees, QMP–LS staff and OLA assessors.

Senior management and staff regularly monitor a number of internal performance measures, such as the issuance of OLA certificates. In addition, the OLA division seeks evaluation of performance from every facility undergoing peer assessment and every team leader. The feedback, which is discussed by staff and the OLA Advisory Panel, has led to implementation of several improvements.

OPPORTUNITIES FOR IMPROVEMENT

An in-house software program (HelpDesk) enables staff to record a variety of opportunities for improvement. These include complaints, suggestions and questions from clients and staff. Division directors and supervisors review all opportunities for improvement and record implementation of corrective actions where necessary.

The Quality Manager verifies the effectiveness of the corrective actions and completes a monthly review of all occurrences for the Senior Management Group. By analyzing errors, QMP–LS can design improved systems and processes and build in controls to catch errors before they reach participants.

ANNUAL MANAGEMENT REVIEW

Rather than being a post-mortem of the year's activities, the annual management review is an opportunity to uncover further opportunities for improvement. Divisions share reports on all aspects of the quality systems and management reviews their success in meeting operating objectives of the past year. If objectives were not met, management develops a future plan of action to ensure that they will be.

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 focused on problem areas identified through assessment or accreditation.

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

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

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

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

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.

A piece of QMP–LS history...

In the late 1960s the Ontario Medical Association (OMA) Section on Laboratory Medicine organized voluntary program for inspection and certification of medical laboratories, however, it soon became apparent that an objective method of determining the proficiency of laboratories had to be established. By the end of the decade, the OMA had established proficiency testing programs in chemistry, microbiology and hematology.

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. Pattern-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 was developed from several sources:

- the International Organization for Standardization's ISO 15189:2003 for medical laboratories;
- 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;
- Ontario government legislation and regulations;
- association guidelines;
- input from laboratory stakeholders.

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

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

Ontario's 231 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 Assessment Process

A laboratory undergoes a peer assessment 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 peer assessments.

Laboratories are given four months' notice of the peer 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 peer 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 OLA AND EQA

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, and maintain and manage the QMP-LS Web site including 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, Information Services, Quality Manager, Manager, Business Development and Education, and Supervisor, Communications and Documents is supported by the Corporate Administrative Assistant 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, and Technical Group on Laboratories; Canadian Association of Environmental Analytical Laboratories; International Laboratory Accreditation Cooperation; and 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 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 partnered with the British Columbia Clinical Microbiology Proficiency Testing program. In 2006, under a pilot study, the program supplied QMP-LS with testing material for an EQA survey for *Clostridium difficile* toxin detection.

Alberta

Since 1997, QMP–LS has been providing the College of Physicians and Surgeons of Alberta with its cytology EQA program. 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 Alberta program, 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. In addition, several current and retired QMP–LS staff work with various Caribbean countries as advisers.

A piece of QMP–LS history...

In 1974, the Ontario government passed legislation requiring quality assurance oversight of the laboratories that it licensed. In response, the OMA developed the Laboratory Proficiency Testing Program (LPTP).

As it developed, LPTP became a multi-disciplinary program whose primary emphasis was on support and education. Peers helped each other to improve their work in laboratory medicine by providing feedback on their performance, in this way expanding the knowledge base of technologists and laboratory physicians.

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 the 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 QMP–LS programs and operations. Specifically, it is responsible for advising the former Management Committee on the implementation of all policies and directives, and assists in the preparation of reports, policy options and recommendations to the QMP–LS Advisory Council.

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 peer 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 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, as required by legislation, the current Ministry of Health and Long-Term Care/OMA Memorandum of Agreement and the accountability framework for action;
- 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
- cytology
- endocrinology and immunology
- genetics
- hematology
- maternal serum screening
- microbiology
- mycology
- point-of-care testing
- 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.

A piece of QMP–LS history...

In 1992, the Ontario government initiated a Laboratory Services Review. The evaluation, published in 1994, revealed that while the quality of Ontario laboratories met a high standard, their competence was not formally recognized. It recommended establishment of a province-wide quality management program.

Accountable to the Advisory Council, the Scientific Committees 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 EQA director 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 the QMP–LS Consultant Technologist 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 and the former Management Committee;
- receiving reports from the Ministry of Health and Long-Term Care (MOHLTC) via the former Management 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 OLA director.

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.

A piece of QMP-LS history...

In 2000, the provincial Ministry of Health and Long-Term Care asked the OMA to develop a quality management program for laboratory services that would assure the highest standards of laboratory services. The result was the establishment of the Quality Management Program—Laboratory Services (QMP-LS).

QMP-LS was to oversee both the accreditation and the quality assessment of Ontario laboratories. The original Laboratory Proficiency Testing Program (LPTP) program expanded to become External Quality Assessment and a new Ontario Laboratory Accreditation program was instituted.

In 2003, after preparing comprehensive accreditation standards, and assessment processes consistent with international guidelines, QMP-LS began accrediting Ontario laboratories.

INTRODUCTION

The External Quality Assessment (EQA) division is building quality through continual improvement of the EQA survey model designs to meet international guidelines and standards. Timing is everything, and undergoing transition at this time has presented many exciting opportunities for improvement. These include involvement with the following projects:

- Revision of EQA survey analysis and performance evaluation processes to conform to *ISO/IEC 13528: Statistical methods for use in proficiency testing by interlaboratory comparisons*, just released in 2005;
- Revision of the 1999 Ministry of Health and Long-Term Care (MOHLTC) policy on point-of-care testing (POCT) to align with *ISO/IEC 22870: Point-of-care testing (POCT)—Requirements for quality and competence*, just released in 2006.
- Participation in standards development working groups at an international level to revise current standards and guidelines for proficiency testing (EQA) providers, to be released in 2007–10.
- Development of a new database and reporting application for EQA that can support and sustain the necessary redesign of survey-related processes, to be completed in 2008 (for more information, see the Information Services report on pages 2–3).

These activities were, of course, in addition to our core responsibility of providing EQA surveys to Ontario laboratories throughout the year.

PROJECT HIGHLIGHTS

REVISION OF EQA SURVEY ANALYSIS AND PERFORMANCE EVALUATION PROCESSES

Statistical Analysis Procedures

A robust statistical algorithm recommended in *ISO/IEC 13528 Statistical Methods for Interlaboratory Comparisons* was implemented in 2006 surveys, following a rigorous validation process during 2005. This had an impact on the majority of chemistry or hematology surveys where statistics form the basis for performance evaluation. All such surveys now comply with international standards.

Development of Scoring Schemes

The current error system of performance assessment has served Ontario laboratories well for more than 20 years. Presently, scientific committees assess laboratory performance in EQA surveys by review of results and assignment of error, with subsequent notification to participants by correspondence. Significant limitations are inherent in this system and include:

- requirement for significant manual intervention by QMP–LS staff for review and identification of outlying results;
- dependency upon technologist expertise and committee deliberation for performance evaluation;
- dependence of participants on receipt of correspondence from QMP–LS prior to implementation of corrective action.

A project to transform laboratory results into quantifiable score systems that would replace the current error system was initiated in 2005 to minimize these issues and build sustainability of the program.

While there are no perfect scoring systems, the evolving design is anticipated to provide:

- objective and consistent assessment;
- tangible and ‘definable’ measures for committees and laboratories;
- rapid feedback to participants to allow prompt corrective action;
- a tracking tool for cumulative performance;
- a computer programmable system;
- measurement systems that meet or exceed international standards;
- reduction in manual analysis and assessment, saving time for both staff and committees;
- standardization of processes within the EQA disciplines and reduced opportunity for error.

Providing the score information to laboratories as part of the survey report will enable them to react to discordant EQA results promptly. This improvement is consistent with good laboratory practice embedded in the Ontario Laboratory Accreditation

(OLA) Requirements. Scoring systems for most surveys were developed in 2006–7 and are undergoing validation during 2007. Rollout is targeted for 2008 surveys.

REVISION OF THE 1999 MINISTRY OF HEALTH AND LONG-TERM CARE POINT-OF-CARE TESTING (POCT) POLICY

In 2005, the MOHLTC requested that QMP–LS facilitate a project to review the existing quality requirements for POCT in Ontario healthcare institutions and recommend changes to align them with newly introduced national and international standards. To accomplish this, QMP–LS convened an advisory committee that comprised leaders and stakeholders from all relevant sectors. [Appendix B](#) lists the committee membership for the POCT Advisory Committee.

Major findings from the POCT questionnaire were published as a summary document in QMP–LS' password-protected document server, QView™ (Summary - POCT 0601 Questionnaire. <https://home.qmpls.org/qview/MainForm.aspx?dl=72750>).

The first step was to issue a questionnaire to all Ontario hospitals (with and without licensed laboratories) as well as long-term care homes. The objective of the questionnaire was to establish a baseline of POCT in healthcare facilities together with an understanding of the corporate knowledge of and conformance with current provincial requirements and international standards for POCT. These requirements documents included the 1999 MOHLTC Policy on POCT in Ontario healthcare facilities, the OLA Requirements for POCT and the newly released ISO standard, *ISO/IEC 22870: Point-of-care testing (POCT)—Requirements for quality and competence*.

The committee also recommended revisions to the 1999 MOHLTC policy together with guidelines on how to implement this revised policy. The guidelines were specific for hospitals with licensed laboratories, hospitals without licensed laboratories and long-term care homes. Ontario hospitals with licensed laboratories received a copy of the policy and associated guidelines in April 2007.

Development of Standards and Guidelines for Proficiency Testing (EQA) Providers

There are currently three major guidance documents that apply to the operation and use of proficiency testing (EQA) providers:

- *CLSI: GP27-A2: Using Proficiency Testing to Improve the Clinical Laboratory*
- *ISO/IEC Guide 43 Parts 1 and 2.1997, Proficiency testing by interlaboratory comparisons*
- *ILAC Guide 13: 2000: Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes*

There has been rapid growth and development of proficiency testing practices globally in the past decade as increasing numbers of laboratories in all industries seek accreditation or certification against external standards. This prompted the need to revise all of the above documents. During 2006, QMP–LS was privileged to participate in working groups closely involved with revision of these documents. Participation in the development of standards and guidelines at an international level benefits the organization by provision of many opportunities such as:

- ensuring the relevancy and appropriateness of standards to PT/EQA providers of medical laboratories;
- rapidly identifying improvements for QMP–LS and its users;
- sharing the strengths of QMP–LS with peer organizations
- clarifying and problem-solving common difficult issues;
- participating in knowledge growth and transfer within the PT/EQA community.

CLSI: GP27-A2: Using Proficiency Testing to Improve the Clinical Laboratory

This revised document was published in February 2007. The target audience includes clinical laboratories, laboratory accreditation/regulatory bodies and PT/EQA providers. The document provides an overview of the PT/EQA process with valuable guidance for interpreting and acting on survey results. Included is an investigation process based on the one developed by QMP–LS for Ontario participants.

ISO/IEC Guide 43 Parts 1 and 2. 1997, Proficiency testing by interlaboratory comparisons

This document has been widely used globally by PT/EQA providers and their accreditation bodies to establish competence. The international community recommended revision of this guide to become a standard that accommodates progress in the field of proficiency testing and incorporates requirements for the providers to operate within a quality management system. To this end, an ISO working group WG 28 was formed to produce a new standard *ISO/IEC 17043 Proficiency testing by interlaboratory comparisons*. Work on this standard is in progress. Development of a new ISO standard typically takes several years. QMP–LS sits on this working group to represent Canada's interest, and also to represent the specific interests of PT/EQA providers for medical laboratories, which are not well defined in the existing documents. It is anticipated that QMP–LS EQA division will be accredited against this standard, once finalized.

This document is also undergoing revision. Required updates include a review of the management system requirements, a revision of requirements that were considered to be ambiguous or redundant and addition of new requirements to reflect changes in the field of practice. The revision process is occurring through consensus within a wide international forum of PT/EQA providers. QMP-LS has been an active participant in the revision of this document, once again representing the specific interests of PT/EQA providers for medical laboratories.

EQA CORE ACTIVITIES

PROVISION OF EQA SERVICES FROM JANUARY 2006–MARCH 2007

Activities for EQA have traditionally been reported by calendar year. However, this year QMP-LS moved to fiscal year reporting for the *Review*. To accommodate this, most of the information reported in this year's *Review* is based on 15 months of activity, from January 1, 2006 to March 31, 2007.

Planned 2006–7 EQA Survey Activities

Provision of EQA surveys is the primary function for this division. Planning is largely an activity of the scientific committees, which review the outcome of the current year's surveys and plan the survey models for the following year. During this process, each committee considers the following in the selection and recommendation of challenges:

- strengths and weaknesses of previous year's program;
- opportunities for improvement and education;
- current scientific or medical issues relevant to laboratory practice;
- design of survey model in accordance with accepted standards and;
- reliable supply of high quality testing material.

Plans for the various discipline surveys are reviewed and endorsed by the Professional Advisory Committee, the senior EQA advisory committee that comprise all scientific committee chairpersons. The QMP-LS Senior Management Group approves availability of resources for the survey plans.

QMP-LS Scientific Committees and Volunteers

In 2006–7, we hosted more than 54 committee meetings involving 66 committee members to plan and assess performance in EQA surveys. We are grateful for the dedication and commitment of our scientific committee members who bring a wealth of knowledge and understanding of laboratory discipline issues to our program. As representatives of the Ontario laboratory community, these professionals reinforce the relevance of our surveys and advocate on behalf of peer laboratories in the assessment of performance for this mandatory program. In addition to review of survey information during 2006–7, the scientific committees assisted in the development of scoring schemes as alternatives to the current error-based schemes for performance evaluation. The names of individuals who served on committees or volunteered their time to our program are listed in Appendices A and B. Their contribution to the program is invaluable.

Provision of EQA Services

During the 15-month period from January 2006 to March 2007, we administered 139 challenge surveys, 5 dry or Web-based surveys, 7 patterns-of-practice surveys and 3 questionnaires. The parameters monitored within the EQA surveys are listed by discipline in [Table 1](#). The scope of EQA surveys provided in 2006–7 is shown in [Table 2](#). The number and types of laboratories required to participate in the program are shown in [Table 3](#). The testing material suppliers for each discipline and the reference laboratories are shown in [Table 4](#).

Table 1. Parameters Monitored by QMP–LS, by Discipline—2006 (continued on page 15)

CHEMISTRY

Chemistry-General

Albumin
Albumin Excretion Rate (AER)
Bicarbonate
Bilirubin, Total
Blood (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
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)

Enzymes, Cardiac Markers and Lipids

Alkaline Phosphatase (ALP)
Alanine Aminotransferase (ALT)
Amylase
Aspartate Aminotransferase (AST)
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)
Antimicrobial 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 (μE₃)
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, μE₃, 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 and IX
D-dimer

Thrombophilia Investigation:

Activated Protein C (APC) Resistance
Antithrombin
Protein C
Protein S
Factor V Leiden
Prothrombin Gene Mutation
Russell Viper Venom (dilute and confirm)
Anticardiolipin Antibody (ACA)

Flow Cytometry

Lymphocyte CD3/CD4/CD8 quantitation by immunophenotyping
Leukocyte immunophenotyping in the investigation of hematological disorders (lymphoma/leukemia)
CD34⁺ Stem Cell Enumeration

Red Cell Disorders

Hemoglobin S Screen
Hemoglobin Fraction Quantitation
Fetal Maternal Hemorrhage
Glucose-6-phosphate Dehydrogenase (G6PD)

Morphology

Peripheral Blood Film:
Differential Leukocyte Count
Descriptive Morphology
Diagnosis

Table 1. Parameters Monitored by QMP–LS, by Discipline—2006 (continued from page 14)

Routine Hematology

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

Transfusion Medicine

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

MICROBIOLOGY

Bacteriology

Isolation and identification of aerobic/anaerobic organisms from:
Blood
Genital specimens
Throat swabs
Urine
Body fluids
Other swabs/pus
Sputum
Stool samples
Serological grouping and identification
Quantitative urine cultures
Interpretation and reporting of cultures
Antimicrobial susceptibility testing
Interpretation and reporting of susceptibility findings
Gram stain interpretation
Special stains
Detection of *Clostridium difficile* toxin
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:
Cytomegalovirus
Hepatitis A, B, and C
HIV
Rubella
VZV
Antigen Detection:
Chlamydia trachomatis
Respiratory Syncytial Virus
Influenza A virus
Influenza B virus
Parainfluenza virus

GENETICS

Cytogenetics

Blood
Bone Marrow
Tumour
Tissue
Amnion Cells

Molecular Diagnostics of Inherited Diseases—Suspended for 2005

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 2. 2006–7 EQA Surveys for Ontario

Class of Test	Survey	Challenge	Dry	Pattern of Practice	Questionnaire
Bacteriology	Bacteriology	8	...	1	2
	Acid Fast Stain	2	...	...	...
Biochemistry	Routine Chemistry	17	...	1	...
	Drugs	9	...	...	...
	Enzymes	8	...	...	...
	Lipids	4	...	...	...
	Blood Gases	2	...	...	...
Cytogenetics	Cytogenetics	5	...	...	...
Cytology	Cytology	4	...	1	...
Hematology	Routine Hematology	8	...	...	...
	Coagulation	15	...	...	...
	Red Cell Disorders	4	1	...	...
	Morphology	4	1	...	...
	Bone Marrow	3	1	...	...
	Flow Cytometry	9	1	...	...
Immunoassays	Endocrinology	5	...	1	...
	Immunology	4	...	...	...
Immunohematology	Transfusion Medicine	7	1	3	...
Immunology	Virology	13	...	...	...
Mycology	Mycology	2	...	...	...
Parasitology	Intestinal Parasites	2	...	...	...
Pathology	Histotechnology	2	...	...	...
POCT	Glucometers	2	...	...	1
Total Surveys		139	5	7	3

Table 3. Comparison of Types of Ontario Laboratories Participating in QMP–LS

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

Table 4. Testing Material Suppliers and Reference Laboratories (continued on page 18)

Testing Material Suppliers	Reference Laboratories
<i>Chemistry Disciplines</i>	
<u>Chemistry-General</u>	
Bio-Rad Laboratories (Canada) Ltd. Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario The Credit Valley Hospital, Mississauga, Ontario	Reference Laboratory, Ortho Clinical Diagnostics Inc., Rochester, New York Diabetes Diagnostic Laboratory, University of Missouri-Columbia, Columbia, Missouri
<u>Drug Monitoring</u>	
Centre for Addiction and Mental Health, Toronto, Ontario The Credit Valley Hospital, Mississauga, Ontario	Centre for Addiction and Mental Health, Toronto, Ontario
<u>Endocrinology</u>	
Consolidated Technologies, Inc, Austin, Texas Toronto General Hospital, University Health Network, Toronto, Ontario	
<u>Enzymes, Cardiac Markers and Lipids</u>	
Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario Kingston General Hospital, Kingston, Ontario The Credit Valley Hospital, Mississauga, Ontario	Wadsworth Center for Laboratories and Research, New York State Department of Health, Albany, New York Reference Laboratory, Ortho Clinical Diagnostics Inc., Rochester, New York Northwest Lipid Research Core Laboratory, University of Washington, Seattle Canadian External Quality Assessment Laboratories Inc. (CEQAL), Vancouver, British Columbia
<u>Maternal Serum Screening</u>	
United Kingdom National External Quality Assessment Service (UK NEQAS)	
<u>Point-of-Care Testing (Glucose Meters)</u>	
Bio-Rad Laboratories, Benicia, California	
<i>Hematology Disciplines</i>	
<u>Hematology-Routine</u>	
Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario R&D Systems, Inc., Minneapolis, Minnesota	Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario
<u>Hematology-Red Cell Disorders</u>	
Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario	Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario
<u>Hematology-Flow Cytometry</u>	
London Health Sciences Centre, London, Ontario R&D Systems, Inc., Minneapolis, Minnesota	
<u>Coagulation</u>	
Affinity Biologicals Inc., Ancaster, Ontario Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario Somagen Diagnostics Inc., Edmonton, Alberta South Manchester University Hospitals, Manchester, U.K.	Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario

Table 4. Testing Material Suppliers and Reference Laboratories (continued from page 17)

Testing Material Suppliers	Reference Laboratories
<u>Morphology and Hematology-Bone Marrow</u> Various laboratories throughout the province	London Health Sciences Centre, London, Ontario The Ottawa Hospital – General Site Huron Perth Healthcare Alliance – Stratford Site
<u>Transfusion Medicine</u> Immucor/Gamma, Houston, Texas London Health Sciences Centre/Canadian Blood Services, London, Ontario	The Credit Valley Hospital, Mississauga, Ontario Royal Victoria Hospital, Barrie, Ontario
Microbiology Disciplines	
<u>Bacteriology</u> London Health Sciences Centre, London, Ontario AFB Smears Central Public Health Laboratory, Toronto, Ontario <i>Clostridium difficile</i> Toxin	Central Public Health Laboratory, Toronto, Ontario London Health Sciences Centre, London, Ontario Mount Sinai Hospital, Toronto, Ontario The Credit Valley Hospital, Mississauga, Ontario The Ottawa Hospital, Ottawa, Ontario Hamilton Regional Laboratory Medicine Program, Hamilton, Ontario MDS Laboratories, Etobicoke, Ontario Clinical Microbiology Proficiency Testing (CMPT), Vancouver, BC
<u>Mycology</u> Sporometrics Inc., Toronto, Ontario – Purchased from culture collections: University of Alberta Microfungus Collection and Herbarium, Edmonton, Alberta (UAMH); 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.	Central Public Health Laboratory, Toronto, Ontario Wadsworth Centre for Laboratories and Research, Laboratoire de Santé Publique du Québec, Ste-Anne-de-Bellevue, Quebec
<u>Parasitology</u> Various participating laboratories (distributed by London Health Sciences Centre)	
<u>Virology</u> London Health Sciences Centre, London, Ontario ZeptoMetrix Corporation, Franklin, Massachusetts	Central Public Health Laboratory, Toronto, Ontario National HIV Reference Laboratory, Health Canada, Ottawa, Ontario
Anatomic Pathology Various participating laboratories	
Cytology Various participating laboratories	
Genetics Various participating laboratories	

Survey Highlights

The majority of relevant survey information is contained in the Committee Comments (available through QMP-LS' password-protected document server, QView™). Details below describe any relevant changes to the routine survey model, any new initiatives not previously described or any significant findings from the 2006–7 surveys.

Challenge surveys

- **Introduction of body fluid cell count as a routine challenge survey**

The pilot survey for body fluid cell counts conducted in 2005 as a Hematology survey provided insight into the lack of standardization around the performance of this important test. This resulted in the development of a routine body fluid cell count survey for 2006. Two surveys were conducted, each containing two samples.

- **Provision of additional coagulation surveys for D-dimer and Thrombophilia**

An additional survey for D-dimer and Thrombophilia was added to the EQA testing schedule, bringing the number of surveys for each parameter to two, each with two samples. This was done to ensure laboratories were able to participate in our stated minimum frequency of two challenges required to satisfactorily assess performance in these parameters.

- **Provision of EQA testing for *C. difficile* toxin assays**

Analysis of *C. difficile* toxin assays is a critical test performed by many microbiology laboratories in acute care settings, since appropriate management of positive patients has significant epidemiological/infection control implications in hospital settings. Historically, this assay has not been assessed through EQA, largely due to the lack of availability of suitable testing material. This pilot challenge survey assessed the suitability of the testing material used, assessed the capability of different laboratory methods to correctly estimate the presence of *C. difficile* toxin and confirmed the need for *C. difficile* toxin assay EQA in Ontario. One survey was performed containing two samples. Based on the results of this survey, a decision was made to continue to offer this survey as a routine challenge survey. Two surveys are scheduled for 2007; one was conducted in January 2007.

- **Training of pathology assessors**

A pool of assessors, in addition to the scientific committee members, is required to facilitate the prompt evaluation of stained tissue sections received from participants of the histotechnology surveys. An additional five assessors were trained during 2006–7, bringing the total number of trained assessors to 16. Training time is significant, requiring 15 hours to complete.

- **Status of lipid testing in Ontario**

Use of single donor serum samples and reference laboratory target values in the survey for lipid (LIPS) analytes assures commutability with patient specimens and allows the Chemistry committee to identify any system bias issues that may exist. This is not possible in PT/EQA programs that use lyophilized sera, which exhibit matrix effects. In 2006, it became obvious that two triglyceride methods had a substantial negative bias in comparison to the reference target value. QMP-LS contacted the manufacturers regarding the bias. While both manufacturers indicated that no complaints had been received from other PT/EQA programs, they reviewed the results from the lipid surveys and agreed there was indeed a calibration problem. This has now been corrected for Ontario laboratories.

- **Improved performance in transfusion medicine**

The inclusion of samples demonstrating mixed-field agglutination (MF) in either the ABO or Rh group has historically been responsible for a marked increase in errors on transfusion medicine surveys. Mixed-field agglutination is typically seen in blood grouping tests when there is a mixed population of cells present. These reactions occur most frequently as a result of a recent transfusion of either ABO or Rh mismatched red cells. Less frequently encountered are mixed cell populations due to bone marrow transplant with subsequent engraftment. In each case, identification and clarification of the underlying cause of the MF is critical to ensure the transfusion of appropriate blood products. Patients whose red cells exhibit MF may be more commonly seen in trauma centres, transplant centres and neonatal settings; however, with the rapid transition from the tertiary centres into the community setting, it is important that technologists in all transfusion services learn to recognize these reactions and understand their significance. In 2005 an educational survey was presented that provided participants with an opportunity to view mixed-field agglutination in the various testing platforms. This led to marked improvement in performance on survey TMED-0505 with 90% of Set A and 89% of Set B participants detecting this phenomenon in the ABO group. Performance continues to be good, with 100% of Set A and 90% of Set B participants detecting mixed-field agglutination in the ABO group on survey TMED-0702.

Patterns-of-Practice Surveys

Pattern-of-practice surveys are paper-based surveys that assess pre- and post-analytical phases of laboratory workflow in addition to the analytical phase. Results of these surveys are published electronically as Committee Comments and are available for review in the QView™ folders. Surveys conducted in 2006–7 included the following:

- Antimicrobial susceptibility reporting practices;
- Use of precision goals in chemistry quality control practice;
- Linearity methods in endocrinology assays;
- Disaster planning in transfusion medicine laboratories;
- Management of blood component replacement in massive transfusion;
- Status of practice of cytology.

Questionnaires

- Status of point-of-care testing in Ontario healthcare facilities
- Antimicrobial Resistance in Common Hospital Pathogens in Ontario

Laboratory Performance

The scientific committee evaluation of survey results includes 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 the participating laboratories regarding the discordant findings, requesting feedback on the cause and corrective action. Unacceptable or incomplete participant responses may prompt further communication, continuing to monitor performance and/or an offer of an on-site consultation.

Two on-site consultations were conducted during 2006, one in bacteriology and one in clinical chemistry. No laboratory was declared non-proficient.

Reports to Participants

Reports provided to participants include preliminary reports of the reference or consensus results, summary information of all participant results 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 2006–7, the following were provided to participant laboratories:

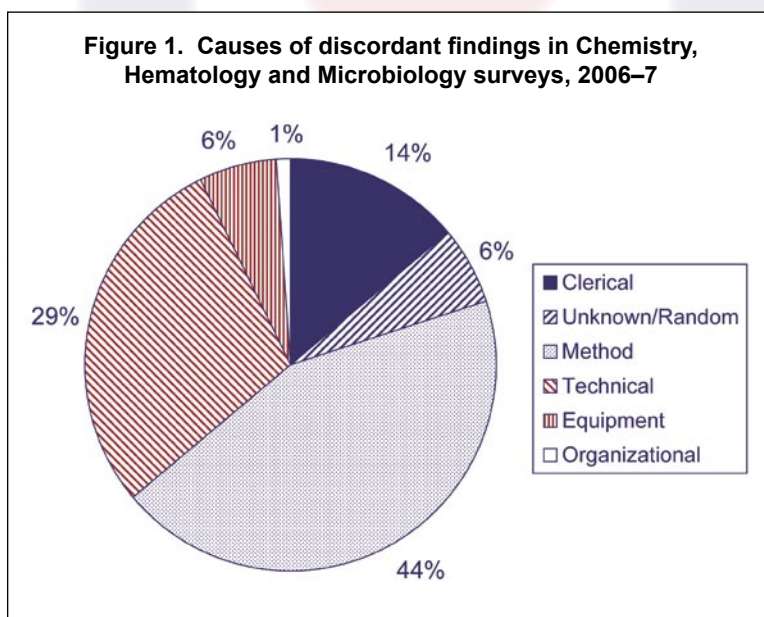
- 121 Provisional Reports
- 117 Survey Reports
- 98 Committee Comments
- 7 Broadsheets

The titles for the Broadsheets published this year are:

- Extended-Spectrum β -Lactamases and AmpC Resistance in Gram Negative Bacilli
- Critical Values for Chemistry
- Parathyroid Hormone
- Laboratory Interpretation and Reporting of Lipid Values
- Lipid Update
- Reference Intervals and Calculation of Mean Values for Coagulation Laboratories
- Verification and Validation of Hematology Methods

Investigation of Discordant Findings

Participants that report discordant results as part of the EQA process are requested to investigate and report a summary of the investigation and corrective actions to QMP–LS. The overall discordance rate for the 15-month period between January 2006 and March 2007 was 1.3%, the same as for the calendar year 2005. Summary information of causes for discordance in Chemistry, Hematology and Microbiology surveys is included in [Figure 1](#).



The most common categories of discordance were associated with methodology related issues (44%) and technological causes (29%). The method-related issues involved problems with automated systems, inadequate or inappropriate quality control programs and use of inadequate or out-dated procedures or reporting protocols. Technical issues included inadequate response to quality control results, failure to follow written procedures, and sample handling issues.

For more information on root cause analysis see Root cause analysis of EQA discordances—looking for “golden eggs”? QMP–LS News, No. 95 October 2005 (http://www.qmpls.org/pub_resources/publications/qmpls_news/pdf/qmplsnews095.pdf).

It is interesting to note that the nature and contributing causes of discordant results have not changed significantly over the past four years. This is likely due to the fact that laboratories have not identified the real root causes of these discordances in the majority of cases. The “what” and “how” the discordance happened are addressed in investigations but not the “why”. Laboratories often do not get to the underlying reason for why procedures are inadequate or not followed, why quality control programs are inadequate or why QMP–LS samples are handled incorrectly. It is only when these underlying causes are identified and corrective measures are put in place to prevent them from recurring that significant improvement will be achieved.

Almost 14% of discordances were associated with clerical errors. These included errors in transcription of either results or codes as well as use of incorrect reporting units or misplaced decimals. Early in 2008, manual transcription of results to hard copy Analysis Worksheets will be replaced by direct data entry of results electronically through QView™. It is hoped that this will facilitate reduction of clerical error associated with EQA surveys.

For more detailed discussion regarding causes of discordant findings, see the discipline-specific supplementary Committee Comments that will be posted on QView™.

Services to Other Jurisdictions

In addition to services provided to Ontario laboratories, we provide services to other jurisdictions on a cost-recovery basis. The surveys most commonly provided are listed in Table 5. In addition, we provide separate microbiology surveys to 22 member countries of CARICOM and separate cytology surveys to Alberta laboratories.

Table 5. Number of Participating Ontario Laboratories in 2006 vs. Out-of-Province

Discipline	Ontario	Out-of-Province
Anatomic Pathology	76	1
Chemistry-General	195	3
Drug Monitoring	163	1
Endocrinology	131	1
Enzymes, Cardiac Markers	191	2
Lipids	129	0
Immunology	62	2
Maternal Serum Screening	NA*	NA*
Hematology-General	203	4
Flow Cytometry	23	14
Red Cell Disorders	78	2
Coagulation	195	0
Hematology-Morphology	200	0
Transfusion Medicine	163	0
Bacteriology	107	0
Mycology	21	2
Parasitology	18	0
Virology	82	3
Genetics	11	9
Cytology	78	0
Point-of-Care Testing	192	1

* No surveys conducted in 2006

INTRODUCTION

This report captures activities of the Ontario Laboratory Accreditation (OLA) program for the 15-month period beginning January 1, 2006 and ending March 31, 2007. During this time, implementation of the mandatory program for Ontario's 231 licensed medical laboratories continued, surveillance activities were implemented, and the program became available voluntarily to other laboratories.

OLA's principle function is to help laboratories deliver high-quality, efficient laboratory services. The purpose of accreditation is to determine if appropriate laboratory processes are in place, and to ensure those processes are effective through ongoing surveillance activities.

HIGHLIGHTS

Conceived in 2000, Ontario Laboratory Accreditation (OLA) has raised the standard for delivery of quality medical laboratory services in Ontario by combining comprehensive requirements with a thorough, peer-driven assessment process. A QMP-LS accreditation certificate is recognized as a symbol of key accomplishments and competence.

By adopting the Organization for International Standardization's standards for medical laboratories as the foundation for its accreditation requirements (*ISO 15189:2003 Medical laboratories—Particular requirements for quality and competence* and *ISO 22870:2006 Point-of-care testing (POCT)—Requirements for quality and competence*), OLA has guaranteed that every Ontario medical laboratory has a quality management system in place to foster continual improvement through risk management, deployment of quality indicators, and demonstration of effective corrective action—all under the watchful eye of laboratory management (see [Figure 2](#)). In addition to management requirements, this standard also addresses key technical components associated with pre-analytical, analytical and post-analytical phases of laboratory examinations, to assure the accuracy and reliability of test results. Two other important Canadian national standards embedded into OLA requirements are *CAN/CSA Z15190 Medical laboratories – Requirements for safety* and *CAN/CSA Z902-04 Blood and Blood Components*. These provide safety frameworks for medical laboratories and transfusion services. By utilizing these documents to set the criteria for medical laboratory accreditation, and augmenting them with law and consensus guidelines that represent generally accepted principles of good practice, OLA has set a high standard for Ontario's medical laboratories.

Laboratories have responded by demonstrating outstanding conformance to accreditation requirements. For the review period from January 1, 2006 to March 31, 2007, conformance ranged from 79.5%–100%, with an average conformance of 94.4% (58 peer assessments). Since assessments began (January 1, 2003) overall conformance ranged from 74.8%–100%, with an average conformance of 93.9%. Year-by-year, conformance at peer assessments has equaled or surpassed that reported on self-assessments ([Tables 6A and 6B](#)).

Any laboratory has the right to submit an error of fact if laboratory personnel believe an identified non-conformance is in error. In the 58 peer assessments occurring between January 1, 2006 and March 31, 2007, only two errors of fact were received.

Table 6A. Per cent Conformance at Peer Assessments, by Year (January 1, 2003–March 31, 2007)

Year	Average Conformance (%)	Range of Conformance (%)	Number of Peer Assessments
2003	86.6	79.5–97.7	6
2004	93.8	82.1–100.0	55
2005	94.4	74.8–100.0	53
2006	94.5	79.5–100.0	49
2007 (to March 31)	94.0	86.1–99.3	9

Table 6B. Per cent Conformance Reported on Self-Assessments, by Year (January 1, 2003–March 31, 2007)

Year	Average Conformance (%)	Range of Conformance (%)	Number of Self-Assessments
2003	90.1	80.5–99.1	19
2004	88.2	51.2–99.8	209
2005	85.7	46.0–99.5	27
2006	95.5	80.8–100.0	73
2007 (to March 31)	95.6	89.0–99.3	15

OLA's peer assessments are conducted by certified assessors who are physicians, scientists and technologists from within Ontario's laboratory community. In addition to being trained in accreditation assessment techniques, they are familiar with Ontario laboratory practices and Ontario's accreditation requirements. Two hundred seventy-two certified assessors currently constitute the active assessor pool. These dedicated individuals give freely of their time and report that assessing is a rewarding and enriching experience. Over the 15-month period from January 1, 2006 to March 31, 2007, 110 individuals provided 385 assessment days. Forty-seven new candidates participated in three assessor training courses. Ontario laboratory professionals are in short supply, and QMP-LS gratefully acknowledges the commitment of its OLA assessors (Appendix B). OLA's peer assessment process is detailed and comprehensive, and assessors put in long hours preparing for and conducting assessments. Table 7 shows the numbers of volunteers serving OLA as peer assessors, and their commitment, over time.

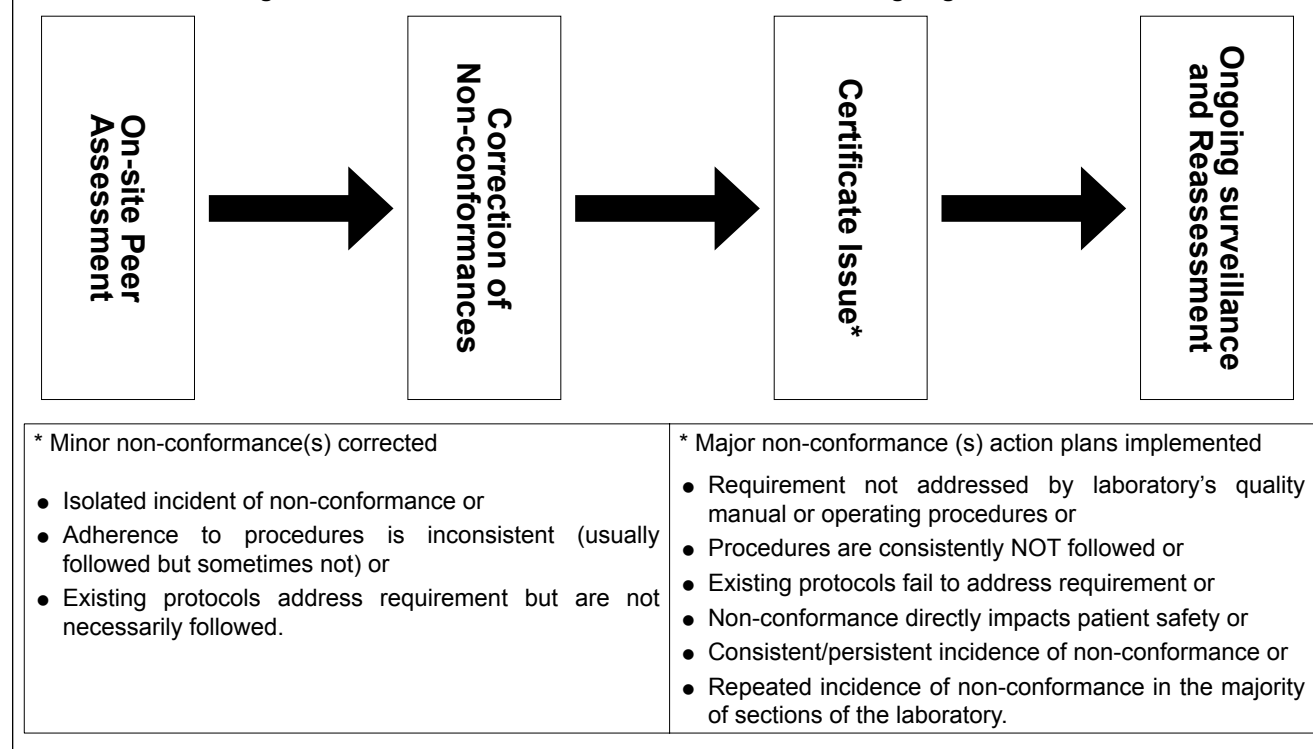
Following a two and a half-year development phase, OLA accreditation assessments began in 2003. Initial assessment of Ontario's licensed medical laboratories will take until August 2008 to complete. Laboratories that successfully correct any major non-conformances and implement corrective action to address minor non-conformances receive certificates of accreditation good for up to five years (see Figure 2). During the five-year period, ongoing surveillance (monitoring of PT/EQA [proficiency testing/external quality assessment] participation and performance along with coordinated self-assessment at the two-and-a-half-year mark) ensures continued competence. Between January 1, 2006 and March 31, 2007, 83 self-assessments were completed. At March 31, 2007, 69% of Ontario's medical laboratories held accreditation certificates. Assessments had occurred in 172 of the 231 Ontario medical laboratories.

OLA's achievements have received international attention. In January 2007, representatives of the American Association for Laboratory Accreditation (A2LA) participated in assessor training and studied OLA's assessment processes as A2LA embarks

Table 7. Volunteer Assessment Activity, by Year (January 1, 2003–March 31, 2007)

Year	No. of Peer Assessments	No. of Volunteers Serving as Team Leaders	No. of Volunteers Serving as Assessors (Total)	No. of Assessment Days (Total)
2003	6	4	20	58
2004	55	29	108	386.5
2005	53	29	90	315
2006	49	27	95	318.5
2007 (to March 31)	9	7	24	66.5

Figure 2. Accreditation conformance assessment and ongoing surveillance



on ISO 15189-based medical laboratory accreditation within the United States. In February 2007, representatives of the College of American Pathologists (which has operated a clinical Laboratory Accreditation Program for many years) visited QMP–LS to learn about OLA operations (the assessment process and its facilitation tools, ISO 15189-based requirements for accreditation, additional surveillance activities, our education curriculum, and assessor training) and to observe the assessment process. In March 2007, a poster titled *Ensuring Excellence in Canadian Laboratories* was presented at the “Quality in the Spotlight” international conference in Belgium.

MEETING INTERNATIONAL STANDARDS

Just as OLA requires laboratories to meet ISO standards, its operations comply also with international standards. During the development of the accreditation program, operations were designed to meet one ISO standard and two guidelines from the International Laboratory Accreditation Cooperation (ILAC):

- *ISO/IEC 17011:2004 Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies*
- *ILAC-G11:07/2006 ILAC Guidelines on Qualification and Competence of Assessors and Technical Experts*
- *ILAC-G3:1994 ILAC Guidelines for Training Courses for Assessors Used by Laboratory Accreditation Schemes*

These operating standards distinguish the OLA medical laboratory accreditation program from others available in North America in the following ways:

- A comprehensive assessor training program, consisting of 18 hours of self-study, 2½ days of classroom training, formal examination and annual refreshers to maintain certification. OLA assessors are all pre-trained and certified.
- All OLA peer assessment teams are accompanied on-site by a QMP–LS Staff Technologist. This ensures consistency in the assessment process, that impartiality is maintained, and that confidentiality is observed. Assessment teams contain technical experts in all areas covered under the scope of accreditation.
- Key competencies for assessors were identified in 2006, and performance evaluations revised to reflect adherence to them (see [Achievements in the Implementation of Our Quality System, and Assessor Competency](#) page 25).
- A complete Quality Management System facilitates consistency in processes, identification of non-conformities, corrective and preventive actions, complete and controlled documentation and records, and integration with the External Quality Assessment (EQA) division for ongoing surveillance in accredited laboratories.

In October 2006, OLA conducted its first internal audit to determine its conformance to *ISO/IEC 17011:2004 Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies*. The audit team noted twenty-one non-conformances, and only two remain unresolved. These relate to the fact that QMP–LS does not make publicly available information on accredited laboratories, nor maintain a list of appropriate PT/EQA programs, nor describe its complaint procedure to the public. Corrective actions are ongoing to address these non-conformances.

On January 31 to February 2, 2007, the Standards Council of Canada (SCC) conducted an external audit of OLA to assess its conformance to *ISO 17011:2004*. This formal audit was conducted to formalize a partnership in delivery of accreditation (see “Partnership with Standards Council of Canada for Voluntary Accreditation” next section). The audit consisted of two components: a two-day office review of processes, procedures and records and a three-day “witness audit” to observe an actual laboratory peer assessment (thanks to the gracious approval of the recipient laboratory). A mere five non-conformances were noted. The auditors commended OLA for its staff commitment, assessor training program, the planning process for peer assessments and the well-developed information and document control systems. In particular, the auditors were impressed with the creation of customized checklists to match laboratories’ scopes of testing. Three non-conformances have been closed and corrective actions to address two are nearing completion. The unresolved issues relate to inconsistency in the assessment of laboratory compliance with traceability requirements and application of SCC accreditation guidelines (e.g. uncertainty of measurement, traceability). It is anticipated these will be resolved by December 31, 2007 with the release of version 4 of OLA’s requirements and revised guidance information, and the publication of updated program information.

PARTNERSHIP WITH STANDARDS COUNCIL OF CANADA FOR VOLUNTARY ACCREDITATION

In August 2005, the Ontario Medical Association (OMA) and Standards Council of Canada (SCC) signed a partnership agreement for joint delivery of voluntary accreditation in medical laboratories. Standards Council of Canada is a Crown corporation with the mandate to promote efficient and effective standardization in Canada. It coordinates the National Standards System and offers a variety of standards and accreditation programs and services. Its Program for Accreditation of Laboratories – Canada (PALCAN) has accredited hundreds of laboratories in a variety of general testing and specialty areas. SCC is a signatory to the International Laboratory Accreditation Cooperation mutual recognition arrangement. In this partnership, OLA will conduct the assessment and SCC will issue the accreditation certificate, which will provide national recognition of competence to ISO 15189. Ontario’s licensed medical laboratories may choose this option on reassessment.

Since January 2006, three laboratories have applied for voluntary accreditation, and 22 inquiries have been received.

QMP-LS and SCC are finalizing the logistics of the assessment review and accreditation approval processes. Ongoing projects include the refinement of surveillance activities in accredited laboratories (e.g. criteria for participation and performance in PT/EQA activities for all classes of tests included on the scope of accreditation), establishing criteria for acceptable PT/EQA programs and publishing a list of available programs that meet these criteria, publication of additional program information and the application of key concepts included in accreditation requirements).

The Director, OLA serves on SCC's TG Labs Committee, and its PALCAN Partners Advisory Group, and attended three meetings between January 1, 2006 and March 31, 2007.

ACHIEVEMENTS IN THE IMPLEMENTATION OF OUR QUALITY SYSTEM

Quality Indicators

A cornerstone of any quality system is the "Plan, Do, Check, Act (PDCA)" cycle (Figure 3). OLA receives feedback from laboratory personnel, team leaders and staff coordinators on the peer assessment process, and identifies improvements from these evaluations. For example, comments that assessments were "rushed" with inadequate time allowed for the summation meeting resulted in a re-evaluation of assessment agendas and the lengthening of peer assessments by approximately one day. Two key performance indicators are monitored quarterly: turnaround time from peer assessment to issue of accreditation certificates; and (introduced late in 2006) turnaround from receipt of laboratory self assessment to issue of summary reports. During the review period from January 1, 2006 to March 31, 2007, on average peer assessment summary reports were distributed to laboratories within 12 days and certificates were issued is less than five months. Turnaround of self-assessment reviews averaged one and a half months. OLA staff completed "crosswalk" spreadsheets that map OLA's requirements to ISO 15189:2003 and CAN/CSA Z902-04, to make sure OLA requirements for accreditation cover all aspects of these standards.

In excess of 150 document-controlled processes and procedures guide OLA staff and assessors through the complicated steps associated with the accreditation model. By categorizing procedures according to the process they support (e.g. peer assessment, self assessment, surveillance, assessor certification, administration) individuals can access clear instructions for a single step in each process. An additional 160 master templates and forms are in use. These foster consistent communication (master letters), direction, and record keeping (master forms).



Assessor Competency

In 2006, a competency profile for assessors was developed. These competencies provide the framework for assessor training, certification exams, and evaluation of performance.

Seven competencies

1. Familiarity with the OLA Requirements and Guidance Information
2. Knowledge of the peer assessment process and procedures
3. General knowledge of quality management systems
4. Specific laboratory knowledge of the appropriate disciplines
5. Assessment information gathering techniques
6. Ability to identify, record and classify the degree of conformance to the OLA Requirements
7. Interpersonal skills

This competency profile influences the assessor certification process. Following peer assessments, assessors now receive evaluations of their performance. The evaluation areas of assessor performance are shown in Table 8.

Mobile Assessor

In the fall of 2006, QMP-LS/OLA engaged in a pilot to explore expanded use of computer notebooks during peer assessments. Essentially, assessors used electronic checklists to assess laboratory conformance to accreditation requirements, instead of paper checklists. The proprietary software in use ("Mobile Assessor") is similar to that already used by staff coordinators on-site.

Table 8. OLA Assessor Competency Profile Introduced in 2006

Competency	Evaluation
1. Familiarity with the OLA Requirements and Guidance Information	Did the assessor appropriately interpret and apply the requirements to his or her assigned area?
2. Knowledge of the peer assessment process and procedures	- Did the assessor conduct his or her assignments according to established protocol? - Did the assessor maintain confidentiality?
3. General knowledge of quality management systems	Did the assessor understand the principles of quality management systems?
4. Specific laboratory knowledge of the appropriate disciplines	Did the assessor demonstrate sufficient knowledge of technical aspects to make objective decisions?
5. Assessment information gathering techniques	- Did the assessor assess evidence objectively? - Did the assessor commit his or her full attention to the assessment process? - Was the assessor able to distinguish crucial or essential points from less important ones?
6. Ability to identify, record and classify the degree of conformance to the OLA Requirements	- Did the assessor demonstrate sound judgment and analytical skills? - Was the assessor decisive – did he or she reach timely conclusions? - Did the assessor remain true to a conclusion despite pressure to change that may not have been on objective evidence? - Was the assessor self-reliant – did he or she function independently while interacting effectively with others? - Was the team leader able to make decisions and lead the team to reach conclusions? - Was the team leader able to present non-conformances in a clear, understandable manner?
7. Interpersonal skills	- Was the assessor diplomatic and tactful? - Was the assessor open-minded, flexible, adaptable and willing to consider alternative ideas or point of view? - Was the assessor sensitive of the effects of his or her activities? - Did the assessor react effectively to stressful situations? - Was the assessor impartial, non-discriminatory and respectful? (fair, truthful, sincere, honest and discreet) - Can the team leader effectively prevent and resolve conflicts? - Did the team leader communicate effectively during the opening and summation?

About a dozen assessors participated in the pilot during seven assessments encompassing 10 laboratories. It was hoped that efficiencies could be achieved with the use of electronic checklists. Unfortunately, this was not the case. Consensus is that it takes more time to ready computers for assessors' use than to prepare paper checklists, and there was no evidence that the use of computers during the assessment streamlined the process, especially at the stage where conformance information is compiled into a master conformance report. To the contrary, assessors found that using computers impeded the "process approach" to assessment and that they instead reverted to reciting the "what to look for" guidance questions during the assessment. Some assessors reported the computers to be a burden and even a barrier between them and laboratory personnel. The pilot has been extended into 2007, to ascertain if computer use can enhance the quality (accuracy) of data by reducing manual data entry while compiling non-conformances and directly transferring the data into OLA's database. Team leaders and members assessing the areas of laboratory management, quality management systems, laboratory information systems and safety will use computer checklists, and submit evaluations.

Ongoing Laboratory Surveillance

On September 1, 2006, OLA commenced surveillance activities in accredited laboratories with the provision for a surveillance on-site visit when changes to a laboratory's scope, service, ownership, location or existing accreditation status occur (Table 9). Surveillance on-site visits are additional peer assessment visits conducted prior to regularly scheduled reassessment visits, and they do not affect the expiry of accreditation certificates. Surveillance on-site visits focus on one sector or aspect of laboratory service and therefore are less comprehensive than full assessments. As shown in Table 9, the following changes automatically prompt the scheduling of a surveillance on-site visit:

- new laboratory ownership (in conjunction with a licence number) or laboratory address (possibly along with a new licence number);
- reinstatement of a laboratory previously declared non-proficient by the Conjoint Committee;
- request for a visit due to a potential threat to patient safety (from the facility or government regulator).

The following changes may prompt the scheduling of a surveillance on-site visit, at the discretion of the OLA Advisory Panel:

- adding a class of tests to the testing menu;
- self-assessment findings that demonstrate no intent to implement corrective actions or raise other concerns regarding patient care;
- the imminent expiry of a two-year accreditation certificate.

Additional surveillance activities (such as the monitoring of participation and performance in PT/EQA described above) will follow.

Table 9. Criteria for OLA Surveillance Activities

Event	Event Description	Triggers Accreditation Surveillance On-site Visit?	Alternate/Additional Action
1.	Changes in laboratory ownership, location or menu of tests		
	a. Change of name, owner and/or operator, licence # does not change	No	Issue revised certificate if name of laboratory changes
	b. Change of owner and/or operator, licence # changes	Yes	Issue revised certificate/scope
	c. Changes in Laboratory Location (Civic Address)	Yes	Issue revised certificate/scope
	d. Addition of a class of tests in a single laboratory or within a corporate grouping (moving from one laboratory licence to another within the corporate grouping)	No, except at the discretion of Advisory Panel	• Send questionnaire • Possible surveillance on-site visit • Issue revised certificate/scope
	e. Voluntary deletion of a class of tests in a single laboratory or laboratory within a corporate group	No	Issue revised certificate/scope
	f. Addition of tests with no change in licensed class of tests	No	None
	g. Deletion of tests with no change in licensed class of tests	No	None
2.	Self-assessment findings demonstrate no intent to implement corrective actions or raise other concerns regarding patient care (if holding a current certificate or not)	Yes, at discretion of Advisory Panel	Rapid response protocol
3.	Declaration of non-proficiency	Yes, within 6 months of reinstatement notification by MOHLTC	Issue revised certificate/scope
4.	Imminent expiry of a 2-year certificate	Yes, depending on receipt of certificate upgrade application and at discretion of Advisory Panel	Issue revised certificate/scope (Certificate Upgrade)
5.	Other concerns regarding a threat to patient safety (e.g. request from facility or MOHLTC)	Yes, at discretion of Advisory Panel	• Self-assessment to confirm change to previous findings • Rapid response

REACHING OUT TO PARTICIPANTS, STAKEHOLDERS AND PARTNERS

OLA's communication program was improved in August 2006 with the introduction of a regular "Eye on OLA" column in the monthly *QMP-LS News*. That column provides a focused look at the OLA accreditation process and its requirements. It improves the understanding of OLA requirements and their application in the laboratory, and provides conformance updates. In addition, lead articles appeared in *QMP-LS News* on the following topics: OLA's first internal audit, surveillance activities, expectations for corrective actions submitted by laboratories. Program information (for mandatory and voluntary participants) was updated on the QMP-LS Web site.

A complete list of OLA Educational Activities and Tools can be found on the QMP-LS Web site at http://www.qmpls.org/ola/ola_educational.html.

In May 2006, OLA staff condensed the previously offered five-day course on ISO 15189 to a one-day workshop and delivered it at the Canadian Society for Medical Laboratory Science Congress in Winnipeg. The session was fully subscribed with interested individuals from across Canada.

In March 2007, two national initiatives included OLA. OLA staff attended a meeting convened by Health Canada. Its purpose was to gather information about Ontario's regulatory oversight of hospital blood banks including accreditation, and to seek a mechanism of enforcing federal safety regulations without duplicating provincial activities. At the root of this issue is the Krever Commission and the resulting seed funding Health Canada provided CSA to develop and maintain CAN/CSA Z902-04 Standard for Blood and Blood Components. Health Canada plans to harmonize blood safety practices by regulating the distribution of blood and blood components under the Food and Drugs Act. Provincial and territorial governments are responsible for regulating the practice of transfusion medicine including the delivery of blood supply and transfusion services in hospitals. With new federal regulations anticipated in the fall of 2008, hospital blood banks will be federally regulated for the first time. Health Canada is seeking partnerships with existing provincial accreditation bodies like OLA, to ensure that hospital transfusion services comply with Health Canada's regulations without duplication of inspection/assessment. QMP-LS/OLA is now working with Ontario's Blood Programs Coordinating Office and Ontario Hospital Association. A poster showing Ontario's accreditation experience was presented at the Clinical Microbiology and Infectious Diseases meeting in Halifax.

The Director, OLA is the president-elect of the Canadian Coalition for Quality in Laboratory Medicine, which provides a national structure for quality management in medical laboratories for provinces and territories; pursues issues of common concern and interest; shares, considers and develops positions on such matters; develops/promotes national standards where appropriate; and promotes communication and collaboration among the member organizations.

QMP-LS' affiliate status in ILAC affords it the opportunity to improve OLA's operations as international guidelines are released. The Director, OLA serves on its Accreditation Issues Committee and Proficiency Testing Consultative Group, and serves as the ILAC liaison between the two. Members represent accreditation bodies worldwide. QMP-LS was represented at two sets of ILAC meetings between January 1, 2006 and March 31, 2007.

ACKNOWLEDGEMENTS

The OLA Advisory Panel provides guidance and counsel regarding the operation of OLA, in addition to reviewing corrective actions and recommending the issue of accreditation certificates. It met on 16 occasions between January 1, 2006 and March 31, 2007. Due to improved technology and the preparation of explicit briefing notes, the majority of meetings are convened by teleconference.

An increased assessment workload necessitated the hiring of an additional Staff Technologist in March 2007, which brings the staff complement to one Senior Administrative Assistant, four Staff Technologists (3.8 FTE), and one Director. They managed a heavy workload with aplomb.

OLA's quality management initiatives have attracted interest within the Province of Ontario. In 2006, the Ontario Quality Health Council conducted interviews to gather information on existing healthcare quality management initiatives, and the Director, OLA participated. In early 2007, the Diagnostic Services Committee (a joint venture between the Ministry of Health and Long-Term Care and the Ontario Medical Association to plan and coordinate diagnostic services province-wide) asked OLA to give a presentation on the design of its accreditation program according to quality management principles.

SUMMARY AND FUTURE

The 15-month period from January 1, 2006 to March 31, 2007 was a very busy one for OLA. Fifty-eight peer assessments and 83 self-assessments occurred, surveillance activities were implemented, three assessor training courses were modeled on new assessor competencies, and two audits of operations conducted. With improvements to its quality system and other enhancements to meet ISO 17011:2004 *Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies*, OLA's reputation has attracted international attention. Through a partnership with SCC, OLA became available voluntarily to additional laboratories and offers national recognition of competence to ISO 15189. OLA's national and international connections foster continual improvement and assisted in the building of a world-class accreditation body.

OLA has set a high standard for medical laboratories, and laboratories have responded with a remarkable average conformance rate of 93.9% at peer assessment. Personnel in laboratories are commended for their competence, and OLA will continue its education curriculum to assist laboratories in the application of requirements. In 2007, the current version 3 of the OLA requirements, "what to look for" guidance information, and references will be revised into version 4.

Appendix A: 2006–7 QMP–LS Committees as at March 31, 2007

CONJOINT

MOHLTC Representatives:

Ms. Marnie Cooper
Mrs. Patricia Anderson
Ms. Leela Prasaud

OMA Representatives:

Dr. Harold Richardson
Dr. Gregory J. Flynn
Dr. Michael Thoburn
Dr. Virginia Walley

MANAGEMENT†

(March 31, 2006 to April 1, 2007)

Dr. Gregory J. Flynn
Ms. Marnie Cooper
Dr. Daniel Klass
Dr. Denis Macdonald
Ms. Kathryn Snell
Dr. Virginia Walley
Mrs. Kathy Wilkie

Mrs. Patricia Anderson (observer)
Ms. Leela Prasaud (observer)
Dr. Harold Richardson (ex-officio)
Dr. Michael Thoburn (ex-officio)

ADVISORY COUNCIL

Ontario Society of Clinical Chemists
Dr. Lynn Allen
Ontario Hospital Association
Mr. Glen Dietz
Ontario Association of Medical Laboratories
Mr. Donald W. Kerr
College of Physicians and Surgeons of Ontario
Dr. Daniel Klass
Ontario Society of Medical Technologists
Mrs. Blanca McArthur
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
OMA Section on Laboratory Medicine
Dr. John Doucet
Quality Management Program—Laboratory Services
Dr. Gregory J. Flynn
Dr. Harold Richardson

PROFESSIONAL ADVISORY COMMITTEE

Dr. Denis Macdonald
Dr. Sheila Boss
Dr. Margaret Fearon
Dr. Karen Harrison
Mrs. Laura J. Harrison
Dr. David Murray
Dr. Golnar Rasty or Dr. Linda Kapusta
Dr. Anne M. Summers
Dr. Baldwin Toyé
Dr. Pui-Yuen Wong
Mrs. Patricia Anderson (ex-officio)
Ms. Leela Prasaud (ex-officio)

ONTARIO LABORATORY ACCREDITATION ADVISORY PANEL

Ms. Kathryn Snell
Ms. Ruth C. Jaeger
Dr. James Kerry MacDonald
Ms. Cathie McCallum
Dr. Anna G. Morris
Dr. Godfrey Moses
Ms. Janice Nolan
Dr. Brian Rudrick
Mr. Barry Vermeersch
Ms. Marnie Cooper (ex-officio)
Mrs. Linda Crawford (ex-officio)
Dr. Gregory J. Flynn (ex-officio)
Dr. Harold Richardson (ex-officio)
Ms. Leela Prasaud (ex-officio)

TEST REVIEW COMMITTEE

Dr. Robert Moore
Dr. Kenneth Arnold
(OMA Representative)
Mrs. Patricia Anderson
Ms. Marnie Cooper* or
Ms. Leela Prasaud*
Dr. Frank E. Thompson
Mr. Sam Thomson
Dr. Gregory J. Flynn (ex-officio)
Dr. Harold Richardson (ex-officio)

* Ex-officio member with voting rights

† Management Committee was restructured in 2006 and became the Advisory Council.

Note: Names in Italics identify Chairs

Appendix A: 2006–7 QMP–LS Committees as at March 31, 2007

CHEMISTRY-GENERAL AND ENZYMES

Dr. Sheila Boss
Dr. Stephen A. Hill
Dr. Lynn Allen
Mr. David Carson
Dr. Douglas Gornall
Dr. Ken Newell
Dr. Alex Romaschin

Advisor, Drug Monitoring

Dr. Edward Dunn

ENDOCRINOLOGY AND IMMUNOLOGY

Dr. Pui-Yuen. Wong
Dr. David E.C. Cole
Mr. Mark Donahoe
Ms. Linda Evelyn
Dr. Lois E. Shepherd
Dr. S. Tokmakejian

MATERNAL SERUM SCREENING

Dr. Anne M. Summers
Dr. Nathalie Lepage
Dr. Alan Dennis
Dr. Barry Hoffman
Ms. Shamim Rashid

Ontario Maternal Serum Screening Database

Ms. Ellis Chow

HEMATOLOGY

Dr. Denis Macdonald
Mr. Michael Keeney
Dr. Ian H. Chin-Yee
Dr. Mark Crowther
Dr. Adam Ninos
Dr. Ruth Padmore
Mr. Jeffrey Sumner

TRANSFUSION MEDICINE

Mrs. Laura J. Harrison
Mrs. Debbie Lauzon
Mr. Jeff Kinney
Dr. Alan Tinmouth
Dr. Kathryn Webert

MICROBIOLOGY

Dr. Baldwin W. Toye
Dr. Alicia Sarabia
Mrs. Linda Borycheski
Ms. Helen Meaney
Dr. Susan Poutanen
Ms. Candy Rutherford

Advisor, Microbiology

Dr. Frances B. Jamieson

Parasitology Advisory Group

Ms. Rose McQueen MLT ART

Mycology Advisory Group

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

VIROLOGY

Dr. Margaret Fearon
Mr. John Nishikawa
Dr. Astrid Petrich

ANATOMIC PATHOLOGY

Dr. David Murray
Dr. Virginia Walley
Ms. Cathie Crukley
Dr. Geoffrey W. Gardiner
Dr. Ola A. Kassim
Ms. Laurie Mason
Mr. William R. Parks
Ms. Sue Seguin

CYTOLOGY

Dr. Linda Kapusta
Dr. Golnar Rasty
Ms. Sharon Crafter
Mr. Marvin K. MacLean
Dr. Caroline Rowlands
Dr. Michelle Sapp

GENETICS

Dr. Karen Harrison
Dr. Ron Carter
Dr. Kathy Chun
Dr. Diane Allingham-Hawkins
Dr. Jean McGowan-Jordan
Ms. Michelle Wood

POINT-OF-CARE TESTING ADVISORY

Mrs. Patricia Anderson
Ms. Mary Bayliss
Ms. Anne-Marie Case
Mrs. Linda Crawford
Dr. JG Donelly
Ms. Jane Gun-Munro
Ms. Norma Layno
Ms. Cathie McCallum
Dr. Daylily S. Ooi
Ms. Christine Opsteen
Ms. Astrid Petersons
Ms. Leela Prasaud
Dr. Harold Richardson
Dr. Alex Romaschin
Ms. Kathryn Snell
Mrs. Rose Tompkins
Dr. Murray Treloar
Mrs. Kathy Wilkie

Note: Names in Italics identify Chairs

Appendix B: Volunteers Who Assisted QMP-LS in 2006-7

EXTERNAL QUALITY ASSESSMENT

Ms. Wendy Brown	Ms. Lai Ling Wat
Ms. Laura Burton	Mr. Scott MacDonald
Ms. Alison Carey	Ms. Theresa Mahony
Ms. Jessica Carson	Ms. Anne Maki
Ms. Ping Chao	Ms. Laurie Malloch
Mrs. Patti Cheatley	Ms. Barrie Malloch
Ms. Pam Chedore	Mr. Sam Nagra
Ms. Gladys Chen See	Mrs. Connie Pletch
Dr. Dennis Delaney	Dr. Russell Price
Ms. Karen DeRuiter	Ms. Kalijinder Purewal
Ms. Kathleen Eckert	Mr. Prasad Rawte
Ms. Jacky Fok	Dr. Michael J. Raymond
Dr. John Freedman	Ms. Gwen Rosenfield
Dr. Richard Garceau	Ms. Debra Saunders
Ms. Esther Geisbrecht	Mr. Vito Scalia
Mr. Gordon Hawes	Ms. Heather Siebert
Ms. Darlene Henrickson	Mr. Glen Small
Ms. Jennine Kafka	Ms. Carol Swantee
Dr. John Kim	Ms. Lynn Towns
Ms. Tina Kozlowski	Ms. Liese Walchuk
Dr. Wendy Lau	Ms. Carol Wenzel

ONTARIO LABORATORY ACCREDITATION

Dr. Vina Alexopoulou	Ms. Debbie Lauzon
Ms. Marjorie Allen	Ms. Susan Leask
Ms. Beate (BJ) Anding	Mr. Albert Lee
Ms. Janice Archer	Mr. Victor Leung
Ms. Jeanine Baker	Ms. Jean Lew
Ms. Jane Barry	Ms. Pauline Lo
Mr. David Beal	Mr. Al Lupish
Ms. Alison Bear	Mr. Dave MacDonald
Mr. Conrad Jr Begin	Ms. Shelley MacIntyre
Ms. Fran Belsito	Ms. Christine Mackay
Ms. Deborah Benson	Ms. Lorraine MacLean
Ms. Johanne Bietola	Mr. Marvin MacLean
Mr. Paul Birch	Ms. Carol Major
Dr. Michel Bonin	Ms. Ellen Mak-Tam
Ms. Idelta Coelho	Ms. Debbie Maki
Ms. Diana Booth	Mr. Rick Mancini
Dr. Sheila Boss	Ms. Laurie Mason
Ms. Patti Boyd	Ms. Judy Maxwell
Ms. Mary Breadner	Dr. Tony Mazzulli
Dr. Peter Bunting	Ms. Marion McChesney
Ms. Pamela Calverley	Ms. Patricia McGillis
Ms. Johanna Campbell	Ms. Heather McMullen
Ms. Bessie Carydis	Ms. Chee-Yuen (Helen) Meaney
Dr. Peter Catomeris	Ms. Shawne Milne
Mr. Robert Cheslo-Trengrove	Mr. Dennis Miskie
Ms. Betty Anne Clark	Mr. Gaman Modi
Ms. Sandra Comand	Ms. Pauline Monks
Ms. Rose Costa	Mr. Jim Moran
Mr. James Crumb	Mr. David More
Ms. Brenda Cutting	Mr. Doris Neurath
Mr. Glen Dietz	Ms. Jean Neville
Ms. Louise Dwyre	Ms. Cindy O'Neill
Mr. Doug Ems	Dr. Kenneth Onuska
Ms. Kemi Erhiaganoma	Mr. Wayne Ozanne
Ms. Susan Evans	Ms. Bonnie Page
Ms. Louise Farrar	Ms. Claudine Pelaggi
Ms. Robert Fitz-James	Ms. Anne Marie Phillips
Ms. Mary Fountas	Mr. Robert Poulin
Ms. Rosanne Frassetto	Ms. Susan Pugh
Dr. Douglas Gornall	Dr. Karam Ramotar
Ms. Margaret Grabowski	Ms. Susan Randell
Ms. Karen Harrison	Ms. Rena Retallick
Ms. Laura Harrison	Dr. Alicia Sarabia
Ms. Lorraine Hart	Ms. Judy Sherman-Jones
Ms. Susan Hemmerling	Ms. Marilyn Spagnoli
Ms. Gina Hendrick	Ms. Tracy Stockley
Dr. Robert Hill	Ms. Laurie Sweeting
Ms. Chin Ho	Ms. Connie Thurber
Mr. Gary Holly	Ms. Linda Turner-Smith
Ms. Vi Jewitt	Ms. Marsha Ward
Ms. Gayle Johnson	Mr. Kevin Webb
Ms. Tanya Jorden	Ms. Laura White
Mr. Robert Kendrick	Mr. Tony Wong
Ms. Peggy Kerk	Ms. Michelle Wood
Ms. Pam Kirwan	Dr. Deborah Yamamura
Mr. Ivan Lam	Mr. Greg Young
Dr. Robert Lannigan	

Appendix C: QMP–LS Staff as at March 31, 2007

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

Appendix D: Publications and Education

PUBLICATIONS

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.

Lafferty J, Gill K, Raby A, Richardson H, Crowther M. Proficiency Testing of Reticulocyte Counting in Ontario. *Lab Hematol*. 2005;11(3):185–9.

Raby A, Clarke G, Crawford L, McBride E, Marsh V. Blood Film Morphology External Quality Assessment Surveys: A Canadian Quality Assurance Initiative. *Blood Film Morphology External Quality Assessment Surveys: A Canadian Quality Assurance Initiative*. *Can J Med Lab Sci* 2006; 68(5):178–187.

EDUCATION

INVITED PRESENTATIONS AND TALKS

Richardson H. George Frank Memorial Lecture—Managing Quality in Ontario Labs. Residents' Research Day. McMaster University, Laboratory Medicine Residency Training Program. Hamilton, Ontario. March 2006.

Fleming CA, Rutherford C, Jamieson F, Toye B, L. Borycheski, S. Poutanen, A. Sarabia, J. Gun-Munro, H. Richardson. Laboratory Practices for Prenatal Group B Streptococcus (GBS) Screening in Ontario. CACMID/AMMI Conjoint Meeting. Victoria, British Columbia March 2006.

Crawford L. Impact of ISO 17011 on QMP–LS Operations. QMP–LS Forum. QMP–LS. Toronto, Ontario. May 2006.

Crawford L and Unger B. Accreditation for Medical Laboratories: Three What's, a Who and a How. Joint Congress of Medical Laboratory Science. CSMLS/Manitoba College of Medical Laboratory Technologists (MSMLT). Winnipeg, Manitoba. May 2006.

Crawford L. Coming Out and Speaking Up: Empowerment Tips for Technologists. Joint Congress of Medical Laboratory Science. CSMLS/Manitoba College of Medical Laboratory Technologists (MSMLT). Winnipeg, Manitoba. May 2006.

Gun-Munro J. Standards for EQA and Proposed Changes to Committee Function. QMP–LS Forum. QMP–LS. Toronto, Ontario. May 2006.

MacFayden D. Information Systems Solutions. QMP–LS Forum. QMP–LS. Toronto, Ontario. May 2006.

Richardson H. QMP–LS: The Coming of Age—30 Years On. QMP–LS Forum. QMP–LS. Toronto, Ontario. May 2006.

Raby A, Clarke G, Crawford L, McBride E, Marsh V. Blood Film Morphology External Quality Assessment Surveys: A Canadian Quality Assurance Initiative. Joint Congress of Medical Laboratory Science. CSMLS/Manitoba College of Medical Laboratory Technologists (MSMLT). Winnipeg, Manitoba. May 2006.

Gun-Munro J. Secrets for Quality in the Laboratory. Gamma DynaCare. Mississauga, Ontario. September 2006.

Crawford L. Before the Testing Begins...Understanding Pre-analytic Accreditation Requirements. Ontario Society for Medical Technology Annual Convention. Niagara Falls, Ontario. September 2006.

Hewlett B. Ontario EQA for histotechnology update. Ontario Society for Medical Technology Annual Convention. Niagara Falls, Ontario. September 2006.

Gun-Munro J. Use of EQA for Improvement of Laboratory Performance. Canadian Association for Clinical Microbiology and Infectious Diseases (CACMID). Port of Spain, Trinidad. October 2006.

Petersons A. Pretransfusion Testing for Emergencies in the Small Hospital. University of Toronto Transfusion Medicine Rounds. Toronto, Ontario. November 2006.

Fleming CA. Root Cause Analysis of Discordant Results on QMP–LS Microbiology Surveys. Toronto Invasive Bacterial Disease Network Education Day. Toronto, Ontario. November 2006.

Hewlett B. Challenges in providing an IHC service. National Society for Histotechnology Annual Convention. Phoenix, Arizona. September 2006.

POSTERS

Raby A, Clarke G, Crawford L, McBride E, Marsh V. Blood Film Morphology External Quality Assessment Surveys: A Canadian Quality Assurance Initiative. Joint Congress of Medical Laboratory Science. CSMLS/Manitoba College of Medical Laboratory Technologists (MSMLT). Winnipeg, Manitoba. May 2006.

Appendix D: Publications and Education

Fleming CA, Sarabia A, Toye B, Borycheski L, Jamieson F, Meaney H, Poutanen S, Rutherford C, Gun-Munro J, Flynn G. External Quality Assessment of *Clostridium difficile* Toxin Detection in Ontario Laboratories—Results of a Pilot Survey. Canadian Association for Clinical Microbiology and Infectious Diseases (CACMID). Halifax, NS. March 2007.

Bishop J, Ramotar K, Crawford L. Mandatory Accreditation to ISO 15189:2003—The Ontario Experience. Canadian Association for Clinical Microbiology and Infectious Diseases (CACMID). Halifax, Nova Scotia. March 2007.

Coffey J, Crawford L. Ensuring Excellence in Canadian Laboratories—Assessor Training. Quality in the Spotlight Conference. Antwerp, Belgium. March 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 XXIIth Congress. Geneva, Switzerland. July 2007.

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

SYMPOSIA

Canadian Flow Cytometry Meeting

Topic	Location	Date	Presenter
Instrumentation Setup and Calibration	Toronto, Ontario	June 24, 2006	Mike Keeney
Paroxysmal Nocturnal Hemoglobinuria—Clinical and Laboratory Insights	Toronto, Ontario	June 24, 2006	Ian Chin-Yee
Flow Crossmatch and HLA Antibody Screening: Gateway to Kidney Transplant	Toronto, Ontario	June 24, 2006	Dennis Snider
Zap-70 Protein Expression in Chronic Lymphocytic Leukemias	Toronto, Ontario	June 24, 2006	Vincent Shankey
CD34+ Enumeration, Past Present, and Future	Toronto, Ontario	June 24, 2006	Rakesh Nayyar
Rare Event Detection in Solid Cancers	Toronto, Ontario	June 24, 2006	Alison L. Allan
Platelets	Toronto, Ontario	June 24, 2006	John Freedman
Lymphoma	Toronto, Ontario	June 24, 2006	Jeannine Holden
Acute Leukemia	Toronto, Ontario	June 24, 2006	Brent Wood
QMP–LS Quality Assurance Programs in Flow Cytometry	Toronto, Ontario	June 25, 2006	Mike Keeney
Flow Cytometric Investigation of Immunodeficiencies	Toronto, Ontario	June 25, 2006	Joanne Luider
Lymphoma	Toronto, Ontario	June 25, 2006	Jeannine Holden
Acute Leukemia	Toronto, Ontario	June 25, 2006	Brent Wood
Pediatric Leukemia	Toronto, Ontario	June 25, 2006	Mohamed Abdelhaleem
Current and Innovative Uses of Flow Cytometry in HIV Vaccine Development	Toronto, Ontario	June 25, 2006	Chris Tsoukas
CD4 T-Cell Counting Past, Present and Future	Toronto, Ontario	June 25, 2006	Frank Mandy

WORKSHOPS

Topic/Event	Location	Date	Presenter
Joint QMP–LS/College of Medical Laboratory Technologists (CMLTO)/Ontario Society of Medical Technologists (OSMT):	Windsor, Ontario	May 13, 2006	Aruna Kolhatkar
<i>Hematology Workshop: Case Studies and Quality Assurance/Quality Control</i>	Kingston, Ontario	June 10, 2006	Kim Hartill-Dadson
	Thunderbay, Ontario	June 24, 2006	Aruna Kolhatkar
	Hamilton, Ontario	September 9, 2006	Kim Hartill-Dadson
	Barrie, Ontario	October 28, 2006	Kim Hartill-Dadson
	Sudbury, Ontario	November 4, 2006	Aruna Kolhatkar
	Ottawa, Ontario	November 18, 2006	Kim Hartill-Dadson
Canadian Society for Medical Laboratory Science National Congress:			
<i>The Meaning of Life, the Universe and Everything to the Histotechnologist</i>	Winnipeg, Manitoba	May 2006	Bryan Hewlett
<i>Histological Staining: The Good, the Bad and the Ugly</i>	Winnipeg, Manitoba	May 2006	Bryan Hewlett
<i>Understanding the Canadian Accreditation Standard Z15189—Medical Laboratories Particular Requirements for Quality and Competence</i>	Winnipeg, Manitoba	May 2006	Linda Crawford and Julie Coffey