



# Accreditation – Setting the standard for Ontario laboratory practice

In 2000, the Quality Management Program – Laboratory Services (QMP-LS) began developing an accreditation program to integrate accreditation standards with existing external quality assessment (EQA) provided by the Laboratory Proficiency Testing Program (LPTP). In 2003, the Ontario Laboratory Accreditation (OLA) program was implemented and QMP-LS/OLA began accrediting laboratories while continuing to conduct EQA. In less than three years, QMP-LS/OLA introduced consensus requirements for accreditation, established accreditation and surveillance processes, developed an assessor training program, certified assessors, conducted many educational focus sessions, and began laboratory assessments.

The objective of this article is to provide an update on laboratory accreditation in Ontario, including the involvement of laboratory professionals, laboratory performance, and new developments.

In Ontario, all medical laboratories are licensed by the government and QMP-LS is mandated by legislation, which means every licensed laboratory is accredited by QMP-LS/OLA and the ongoing proficiency is monitored by QMP-LS/EQA. Operated by the Ontario Medical Association for the government, QMP-LS' purpose is to promote quality improvement of laboratories for the public good and the benefit of health professionals, through collaboration and with integrity. A panel of nine Ontario laboratory professionals provides advice and counsel to QMP-LS/OLA. As an accreditation provider, QMP-LS/OLA declares that laboratories are competent when it issues accreditation certificates.

The standards of accreditation are described in QMP-LS/OLA requirements for accreditation. Version 4.1 of the requirements was recently released (July 2008). Requirements are based on three ISO standards (ISO 15189 for laboratory quality, ISO 15190 for laboratory safety, ISO 22870 for point-of-care testing quality), national standards (e.g., CAN/CSA Z-902 for blood safety), statutes and regulations, as well as consensus guidelines considered to represent the generally accepted principle of good practice in On-

tario (e.g. CLSI guidelines). Requirements are organized into 11 sections representing the path of workflow (**Table 1**). Altogether there are 513 requirements and three good practice recommendations. Accompanying the requirements is “what to look for” guidance information to explain the application of requirements at the bench - including specific guidance for distinct disciplines of practice. **Table 2** shows the evolution of requirements, which are reviewed and revised biennially, with sub-versions released when legislative changes occur. Some important changes were introduced in 2008, and are explained in **Table 3**. The most important of these changes is the addition of requirements for internal auditing, management review, and contract review. With these changes, the current version of OLA requirements includes all of the ISO 15189:2007 standard *Medical laboratories – Particular require-*

*ments for quality and competence*, which is also a Canadian national standard published by Standards Council of Canada as CAN-P-11. In the winter of 2007-2008, QMP-LS will offer education to explain these new requirements.

Assessment visits are conducted by peers – technologists, physicians, and scientists – who are pre-trained and certified according to international guidelines, and who volunteer their time. Each team of assessors is accompanied by a QMP-LS/OLA staff technologist. Ontario laboratory professionals have demonstrated their enthusiasm and commitment to the accreditation process. There are currently 276 certified active assessors available to QMP-LS/OLA. Assessor training is ongoing and new applicants are welcome. Certified assessors must conduct

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**Table 1** Number of Version 4.1 OLA Requirements and Good Practice Recommendations, by Section

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

**Table 2** Number of OLA Requirements for Accreditation and Good Practice Recommendations

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



**Table 3**

## Important Changes to OLA Requirements in 2008, By Section and Requirement Number

<p><b>I. Organizational Structure, Personnel Policies and Laboratory Management</b></p> <p><i>Six good practice recommendations revised to requirements:</i></p> <p><b>I.B.3</b> Need policies to ensure personnel are free from pressures that may adversely affect quality of work</p> <p><b>I.B.11.1</b> Include staff orientation in personnel training programs</p> <p><b>I.B.13.4</b> Record staff immunization status</p> <p><b>I.B.13.5</b> Record staff continuing education and achievements</p> <p><b>I.C.2</b> Lab director to be active member of medical/scientific staff in facilities served</p> <p><b>I.C.6</b> Management to provide and participate in education for personnel responsible for patient care</p>	<p><b>V. Pre-Analytical Process</b></p> <p><i>One requirement revised to reflect new legislation</i></p> <p><b>V.A.10</b> Effective September 1, 2008 safety engineered needles or needle-less systems are mandatory in hospitals, effective 2009 these are mandatory in laboratories and specimen collection centres (per Occupational Health and Safety Act O. Reg. 474/07)</p>
<p><b>II. Quality Management System</b></p> <p><i>Seven internal auditing good practice recommendations revised to requirements</i></p> <p><b>II.D.5.4</b> Internal audits to be triggered by non-conformities that cast doubt on compliance with the QMS</p> <p><b>II.D.7</b> Internal audits to be conducted to verify operations comply with the QMS</p> <p><b>II.D.7.1</b> Define internal audit processes and procedures to include main elements of the QMS</p> <p><b>II.D.7.2</b> Personnel not to audit own work</p> <p><b>II.D.7.3</b> Management to review internal audit results</p> <p><b>II.D.7.4</b> Corrective/preventive actions that result from internal audits to be documented and completed within a specified time frame</p> <p><b>II.D.7.5</b> Assess effectiveness of corrective actions from internal audit activities</p> <p><i>Four management review good practice recommendations revised to requirements</i></p> <p><b>II.E.1</b> Conduct management reviews</p> <p><b>II.E.2</b> Develop, document and implement action plans from management reviews</p> <p><b>II.E.3</b> Follow up on management review to ensure actions are taken</p> <p><b>II.E.4</b> Lab management to monitor effectiveness of actions resulting from management reviews</p> <p><i>Two referral laboratory management good practice recommendations revised to requirements</i></p> <p><b>II.G.3</b> Periodically review arrangements with referral laboratories</p> <p><b>II.G.3.2</b> Record reviews of referral laboratory arrangements and contract changes</p> <p><i>Five new contract review requirements</i></p> <p><b>II.H.1</b> Review contracts to provide services</p> <p><b>II.H.1.1</b> Keep records of contract reviews</p> <p><b>II.H.1.2</b> Include subcontracting in contract reviews</p> <p><b>II.H.1.3</b> Inform clients of contract deviations</p> <p><b>II.H.1.4</b> Initiate contract reviews when contracts require amending</p>	<p><b>VI. Analytical Process</b></p> <p><i>Two good practice recommendations revised to requirements</i></p> <p><b>VI.7.1</b> When determining reference intervals for quantitative methods, need a minimum of 120 reference values</p> <p><b>VI.7.2</b> When clinically useful, partition reference intervals by race, gender, and age</p> <p><b>VII. Quality Assurance of Laboratory Examinations</b></p> <p><i>One requirement revised.</i></p> <p><b>VII.9.1</b> Participate in PT/EQA for all tests on scope of accreditation, when available/feasible</p> <p><b>VIII. Post-Analytical Process (Reporting)</b></p> <p><i>One good practice recommendation revised to requirement.</i></p> <p><b>VIII.2.6</b> Include time of sample receipt by lab on patient report or lab record</p> <p><i>One requirement's guidance revised to reflect new legislation.</i></p> <p><b>VIII.2.10</b> Patient reports can also be issued to Chief Medical Officer of Health (per Health Protection and Promotion Act, 2007)</p> <p><i>One requirement revised to reflect new legislation.</i></p> <p><b>VIII.12.1</b> All positive findings indicating reportable diseases now reported to Chief Medical Officer of Health where patients reside (per Laboratory and Specimen Collection Centre Licensing Act O. Reg. 682)</p>
<p><b>III. Physical Facilities</b></p> <p><i>Three good practice recommendations revised to requirements</i></p> <p><b>III.3</b> Floor surfaces to be slip resistant, cleanable, carpet not allowed</p> <p><b>III.4</b> Consider ergonomic factors to reduce fatigue and repetitive strain injuries, in lab design</p> <p><b>III.12.2</b> Define and measure allowable temperature deviation in frost free freezers</p>	<p><b>IX. Laboratory Information System</b></p> <p><i>Three good practice recommendations revised to requirements.</i></p> <p><b>IX.D.4</b> Need an automated mechanism within LIS to check quantitative results against a predefined range of expected values (to detect absurd or impossible results)</p> <p><b>IX.D.7</b> LIS to allow individual computer-based examination results to be audited (even when share accession numbers)</p> <p><b>IX.D.10</b> LIS format and methods for disseminating data to be standardized</p> <p><b>X. Safety</b></p> <p><i>One new requirement.</i></p> <p><b>X.H.1.3</b> Need a pest control program</p> <p><i>Two good practice recommendations revised to requirements.</i></p> <p><b>X.K.2</b> Check electrical outlets for voltage, grounding and polarity on installation/modification</p> <p><b>X.L.5.3</b> Need explosion-proof lights and switches where flammable gases are stored</p>
<p><b>IV. Equipment, Reagents and Supplies</b></p> <p><i>Three good practice recommendations revised to requirements</i></p> <p><b>IV.5</b> Define and follow retention time for quality records of supplies and purchased products</p> <p><b>IV.10</b> Validate computer software built into equipment</p> <p><b>IV.12.1</b> Maintain records of the condition of equipment when received</p>	<p><b>XI. Point-of-Care Testing</b></p> <p><i>Four good practice recommendations revised to requirements</i></p> <p><b>XI.E.1</b> Periodically evaluate POCT program in terms of clinical need and utilization</p> <p><b>XI.E.2.1</b> Identify opportunities for improvement for POCT program</p> <p><b>XI.E.2.2</b> Lab director/designate and POCT management group to jointly make appropriate changes to POCT policies, processes, procedures</p> <p><b>XI.E.2.3</b> Need policy and procedures for resolution of complaints/feedback on POCT program</p> <p><b>General</b></p> <ul style="list-style-type: none"> <li>• Guidance provided on the number or sample size that assessors will look for.</li> <li>• Many pieces of guidance for specific disciplines added, revised, or deleted – the largest number in transfusion medicine to comply with CAN/CSA Z902-04, Blood and Blood Components.</li> <li>• Some guidance realigned between cytogenetics/clinical genetics and molecular diagnostics.</li> </ul>



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a minimum of one assessment and/or complete an on-line refresher exercise annually, and participate in a face-to-face refresher exercise once every three to five years. Every year, approximately 100 assessors volunteer nearly 400 days for QMP-LS/OLA assessment visits.

The initial assessment visits to Ontario laboratories began in January 2003. The schedule to initially assess all 230 Ontario laboratories spanned five years and will be complete in August 2008. Following the assessment visit, laboratories have 90 days to correct non-conformances (*see sidebar “Definitions: Major and Minor Non-conformances”*). The initial certificates of accreditation are valid for five years. Any laboratory that resolved all major non-conformances and addressed minor non-conformances was issued a five-year certificate. If not all major non-conformances were resolved, but the action plan to address major and minor non-conformances was acceptable, a two-year certificate was issued and when the outstanding major non-conformance(s) was resolved, an upgraded five-year certificate was issued. Laboratories conduct self-assessments at the mid-way mark between assessments and report their ongoing compliance with accreditation requirements to QMP-LS.

Conformance rates demonstrate that Ontario laboratories meet a high standard of practice. The average conformance per laboratory on initial assessment was 94%, based on an average of 444 applicable requirements. The majority of laboratories were assessed fewer than five major non-conformances and 20 minor non-conformances. Most non-conformances were assessed for point-of-care testing and safety issues.

In September 2008, QMP-LS/OLA will begin to re-assess laboratories prior to the expiration of their five-year accreditation certificates. Following assessment, the re-issued certificates will expire in four years. A four-year accreditation cycle meets international standards, and intensifies the surveillance of Ontario’s licensed laboratories – assessment visits will occur every four years and self-assessments will be conducted every two years. Improvements to the assessment process have been approved and laboratories will be canvassed in the fall of 2008 to identify additional opportunities for improvement.

Ongoing surveillance of PT/EQA participation and performance in accredited labo-

raries is a mechanism to ensure ongoing competence. Beginning September 2008, QMP-LS/OLA will require laboratories to demonstrate satisfactory performance in PT/EQA for all tests within the scopes of accreditation. Criteria for acceptable PT/EQA programs in addition to QMP-LS/EQA were recently approved and will be shared with laboratories along with criteria for acceptable performance when a new Web-based data entry system for submission of enrolment and performance data is introduced.

QMP-LS/OLA operations comply with ISO 17011:2004 *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies and the International Laboratory Accreditation Cooperation (ILAC) guidelines for accreditation bodies*. Through a partnership with the Standards Council of Canada (SCC), QMP-LS/OLA is recognized both nationally and internationally as a program of the highest standards. Ongoing evaluation by SCC and the Asia Pacific International Laboratory Accreditation Cooperation (APLAC) is required to maintain this recognition. SCC conducts periodic audits with assessment observation to ensure that QMP-LS/OLA is in compliance. Ontario laboratories may opt to receive a certificate issued by Standards Council of Canada (SCC) following their next QMP-LS/OLA assessment visit, which provides national recognition of competence to ISO 15189.

In summary, in a short period of three years, Ontario’s accreditation program was created in consultation with Ontario’s laboratory professionals, those professionals were engaged as assessors for laboratory assessment visits, the program was implemented, and Ontario laboratories demonstrated an ability to meet the accreditation standard. The standard set by QMP-LS/OLA is a high one, with a foundation in ISO 15189 – in fact, QMP-LS/OLA was the first accreditation program in North America and only the second in the

world to require laboratories to meet this international standard for medical laboratory quality and competence, and accreditation bodies in several countries have followed suit. The degree of conformance achieved by Ontario’s medical laboratories is remarkable (average conformance is 94%). Within Canada, QMP-LS/OLA is the only English-speaking accreditation program partnered with SCC to offer optional national certificates of accreditation to ISO 15189. Version 4.1 (July 2008) of the accreditation requirements, guidance information and reference sources is available to all Ontario licensed laboratories and identified stakeholders, and accreditation assessments conducted after September 1, 2008 will be based on it. Important changes to the accreditation process are: QMP-LS/OLA will issue four-year instead of five-year certificates, and laboratories must provide information on enrolment and performance in PT/EQA programs for all licensed tests. Your source of ongoing information is *QMP-LS News* published monthly and available at <http://www.qmpls.org>. ♦

### Definitions:

#### Major and Minor Non-conformances

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

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

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

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