

Hear ye, hear ye! QMP-LS rings in 2008 with new Ontario Laboratory Accreditation (OLA) Requirements

by: Linda Crawford



PURPOSE AND PROCESS OF REVIEW

Every other year, QMP-LS conducts a complete review and revision of its Ontario Laboratory Accreditation (OLA) requirements. In this way, QMP-LS ensures that its requirements for accreditation reflect current standards, are reasonable and achievable, and meet the expectations for high quality patient care. Included in this review are requirements, good practice recommendations, “what to look for” guidance information, and referenced documents.

Lasting approximately nine months, this review begins with requests for feedback from personnel within Ontario’s laboratories, OLA assessors and stakeholder organizations. While awaiting feedback, staff begin the detailed task of checking each and every reference source to identify any newly released documents and what impact they may have on the wording of requirements. Once feedback is received from laboratories, assessors and stakeholders, it is collated with that received during the last two years, and vetted by QMP-LS scientific advisors. Draft changes to requirements, good practice recommendations, guidance information and references undergo a thorough review by the OLA Advisory Panel and staff. The OLA Advisory Panel approves all changes prior to release.

The resulting new version of OLA requirements is version 4 (December 2007), and it replaces the previous version 3 released in September 2005.



EFFECTIVE DATE

Version 4 of the OLA requirements will be used to assess laboratories’ conformance on peer assessments and self assessments conducted after September 1, 2008. The introduction of this new version coincides with the first reassessments in Ontario’s licensed medical laboratories. Therefore, all Ontario medical laboratories will hold certificates of accreditation prior to being assessed against this or subsequent new versions. Laboratories who voluntarily submit to accreditation after the release of requirements will need to demonstrate compliance to version 4 by April 30, 2009.



IMPORTANT CHANGES CONTAINED IN VERSION 4

Version 4 contains 514 requirements and three good practice recommendations. Changes reflect generally accepted principles of good practice and clauses from reference sources, and they are detailed in Table 1. Changes by discipline are shown in Table 2. An important change in the guidance for molecular diagnostics is that eight pieces of guidance information were re-classified under cytogenetics because they applied to clinical genetics. The molecular diagnostics guidance items now apply to the technology applied in microbiology and hematology.

The numbering system for requirements exists of roman numerals followed by alphabetical categories and sequential numbers. In order to retain the existing number for each requirement, there may now be gaps in the numbering system where requirements were deleted. Likewise, new requirements were assigned the next available number. No numbers were reassigned.



There is nothing so useless as doing efficiently that which should not be done at all.

~ Peter Drucker

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If you have any questions or comments regarding the QMP-LS News, please e-mail feedback@qmpls.org or contact Marite Koerner at the number above.

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Table 1: Changes Reflected in Version 4

Number	Version 4
Requirements	514
Good Practice Recommendations	3
Updated References	685
New Requirements	8
Deleted Requirements	37*
Revisions that may "impact" laboratory practice	25
Good Practice Recommendations now requirements	36

* Of the 37 deleted requirements, 36 were duplicates and therefore combined or relocated, and 1 was deleted altogether.

Table 3: Acceptable Reference Sources

Canadian Statutes and Regulations
Ontario Statutes and Regulations
Health Canada Guidelines
Standards and Guidelines achieved through consensus by international, north American, Canadian and provincial professional associations, federations, organizations, and regulatory bodies.

Table 2: Changes to Guidance Information Reflected in Version 4

Discipline	No. of New Guidance	No. of Revised Guidance	No. Deleted or Moved
Anatomic Pathology	1	4	–
Chemistry	–	6	3
Cytogenetics	7	3	–
Cytology	1	6	2
Hematology	1	15	–
Flow Cytometry	8	18	–
Maternal Serum Screening	–	2	–
Microbiology	–	5	1
Molecular Diagnostics	–	2	6
Transfusion Medicine	30	59	7

HOW TO ACCESS VERSION 4



The new requirements, guidance information and reference listings are available on QView™, the password protected document server available at www.qmpls.org, by selecting "Participant Login" then "QView Login." You will need the username and password previously provided by QMP-LS. A folder for version 4 is located under General OLA/OLA Accreditation Requirements.

Several files are posted to QView™, all of them in PDF format. The largest file contains the complete requirement checklist, good practice recommendations and "what to look for" guidance information. Smaller files contain requirements only, and requirements with guidance information applicable to selected laboratory disciplines. Two important files are those titled "Revisions That May Impact Laboratory Practice V4" (which contains a listing of key changes to version 3 that are reflected in version 4), and "Requirements Deleted for V4" (which summarizes things no longer required for accreditation).

REFERENCE DOCUMENTS



No OLA requirement exists without a supporting reference document, and many OLA requirements have more than one reference. National and international standards are augmented by generally accepted principles of good practice. For a description of what reference documents are acceptable sources, see Table 3. Version 4 is based on the following national and international standards:

- International Organization for Standardization. ISO 15189:2007(E) Medical Laboratories – Particular Requirements for Quality and Competence
- Canadian Standards Association. CAN/CSA-Z15189-03 Medical Laboratories – Particular Requirements for Quality and Competence
- International Organization for Standardization. ISO 15190:2003(E) Medical Laboratories – Requirements for Safety
- Canadian Standards Association. CAN/CSA-Z15190-05 Medical Laboratories – Requirements for Safety
- International Organization for Standardization. ISO 22870:2006(E) Point-of-care testing (POCT) – Requirements for quality and competence.
- Canadian Standards Association. CSA Standard Z902-04. Blood and Blood Components March 2004

Two separate lists of supporting references are posted to QView™ – one for requirements and the other for guidance information. These files contain lists of reference documents that support requirements and guidance information. They are valuable resources to laboratory personnel in understanding the intent of requirements and their application within the laboratory.

FURTHER INFORMATION



Further information highlighting important changes reflected in version 4 will be included in the "Eye on OLA" over the coming months. Laboratories will be notified after June 1, 2008, that their peer and self assessments will be based on version 4. Other questions may be directed to ola@qmpls.org.

QMP-LS Releases Version 4 of OLA Requirements



Version 4 (December 2007) of the OLA requirements is now available on www.qmpls.org, by selecting "Participant Login" then "QView Login." You will need the username and password previously provided by QMP-LS. A folder for version 4 is located under General OLA/OLA Accreditation Requirements.

Version 4 of the OLA requirements will be in place for all peer assessments and self assessments conducted after September 1, 2008.

The introduction of version 4 coincides with the first reassessments in Ontario's licensed medical laboratories. Therefore, all Ontario medical laboratories will hold certificates of accreditation prior to being assessed against version 4 or subsequent versions.

Key changes to version 4 require a complete working quality management system for laboratories, in which internal audits, management reviews and contract reviews are ongoing.

Table 1: Number of Requirements and Good Practice Recommendations

Stat	Version 4	Version 3
Requirements	514	506

Knowledge Transfer: Quality Management in Action is a column in *QMP-LS News* featuring a series of quality-related articles to showcase examples where laboratory individuals or teams have successfully used quality management principles to lead projects outside the walls of their laboratories in pursuit of integrated health care. The articles are intended to inspire and assist laboratory personnel in becoming leaders within their workplaces in the quest for quality services.

The success stories used in this series are all reprinted with permission from the author(s).

Knowledge Transfer: Quality Management in Action

Laboratory team implements point-of-care testing (POCT) program in 90 days

Submitted by Mary Breadner, Laboratory Manager, Grey Bruce Health Services, Owen Sound

OPPORTUNITY FOR IMPROVEMENT

The laboratory team at Grey Bruce Health Services led the implementation of a complete POCT program in seven facilities within 90 days. They developed standard templates for nursing and laboratory POCT documents, created self-directed learning tools for re-certification, and established a solid inventory system together with materials management.



ROADBLOCKS

- The program had to be implemented in 90 days to address major non-conformances.
- There were 644 POCT operators to train.
- Number of committee meetings to identify needs, and the cycles of review and approvals (Nursing Practice Council, Nursing Leadership Council, Professional Practice Council and Medical Advisory Committee)
- Scheduling training posed difficulty due to timing (Christmas and New Year holidays)
- There were seven facilities involved, and each of these had to review and approve all processes.

TIPS FOR SUCCESS

- Foster strong ties with cross-functional partners
- Set up committee meetings so that approval cycle goes in the "correct direction"
- Committees included cross corporate representation
- Information and training scheduled for new employees at orientation
- Self-directed learning tools created and available on Intranet for re-certification. This enabled self-directed learning and testing. Nursing staff could work it into their day (trainers, rooms, staff etc didn't have to be booked).

FUTURE PLANS

- Interfacing for POCT into information system
- Eye towards broadening menu at remote sites

Preparing for QView™ Data Collection

In 2008, QMP-LS will be implementing electronic data collection for:

- EQA Survey Results
- EQA Change of Method Information
- EQA Discordant Findings Responses
- OLA Laboratory Self-Assessment Responses
- OLA Peer Assessment Evaluations

The benefits of electronic data collection are significant and include improved data quality and accuracy by eliminating transcription and interpretation errors, automatic filing of electronic records that are readily available to each site's authorized users, and quicker turnaround for computer-assisted data analysis and reporting.

VALUABLE FEEDBACK FROM PARTICIPANTS IN THE 2007 PILOT PROJECTS

In 2007, pilot projects were conducted with **electronic Analysis Worksheets** for EQA surveys **GENE-0706-CG and GENE-0710-CG** and **electronic Discordant Finding Response** forms for the **BACT-0708** EQA survey. We thank the individuals and organizations involved in these pilots. Your valuable feedback identified opportunities for improvement in the QView™ data collection application, and brought forward potential problems that other sites and QView™ users could encounter when they first attempt to submit their responses.

We ask all QView™ sites and their authorized users to review the following known issues and take the appropriate steps to ensure the computers you use to access QView™ are capable of problem-free electronic responses:

1. Old versions of Adobe® Reader®

Participants in the pilots who did not have **version 6.0 or higher of Adobe® Reader®** installed on their computer could not use the submit functionality to send us their approved responses. Once their workstations were provided with the free upgrade to the most recent version they were able to use the submit function.

1a. Users without authority to download software

A subset of the participants who needed their Adobe® Reader® upgraded did not have sufficient permission to download the software upgrade and required their I.T. department to do this which caused their submission to be delayed.

2. Multiple versions of Adobe® Reader® installed on the same workstation

This problem may not be apparent right away, and might need some investigation from the site's I.T. department. A few participants had an older version of the Adobe® Reader® installed on their workstations, together with the current version. This caused conflicts between the versions when the "Save" function was attempted, which resulted in either a lengthy delay or an inability to save data. QView™ could not identify this error so participants were not informed there was a problem. Once the older version was uninstalled participants were able to submit but, again, this often required the involvement of the site's I.T. department.

3. Insufficient QView™ permission to approve and submit responses

Our participating sites have advised us that our electronic forms should only be approved and submitted by users who have been authorized to do so. Some pilot participants who attempted to submit their site's final responses were unable to do so because they had not been given "write all and approve" permission by one of their site's QView™ administrators. This caused the site's submission to be delayed until a QView™ site administrator could be contacted to make the appropriate changes.

GETTING READY: NEXT STEPS

The problems identified above can be avoided if appropriate steps are followed in advance to ensure your site's workstations and staff have the required software versions and QView™ permission levels.

To help you get ready, use the simple form on QView™ called the "Data Collection System Test" to check your computer's version of the Adobe Reader and your user permission levels:



Data Collection System Test

This System Check is designed to ensure your computer system is configured to work with the QMP-LS web data collection forms.

Please perform the following steps to ensure you can successfully save and submit data to QMP-LS using the on-line forms.

The minimum requirement for QMP-LS web data collection is **Version 6 of Adobe Acrobat Reader**.

The test page will confirm whether you are able to submit approved data:

VIEW **Data Received Successfully**

Event Message: Your data has been successfully saved on QMP-LS server.

Form: Data Collection System Test

Or, if you do not have sufficient permission to submit an approved response:

VIEW **Insufficient Permissions**

Event Message: Your data has been saved BUT you are not authorized to approve this form submission. Please contact one of the designated approvers that may be listed below. If no approvers are defined please contact your Site Administrator.

If either of these messages is not displayed, please contact QMP-LS Information Services Technical Support (Alex Lesniara 416.323.9540 ext. 225), and we will work with you to determine the problem and its solution.

Important: To avoid potential technical issues and other problems, please take a few moments, at your earliest convenience, to ensure you will be able to successfully submit your responses.

If you have any questions or comments regarding QView™ Data Collection please contact Dan MacFayden at 416.323.9540 ext. 240 or e-mail macfayden@qmpls.org.

Call for QMP-LS Scientific Committee Members

QMP-LS is seeking volunteers from Ontario laboratories to sit on its scientific committees, as of April 2008. Membership of the scientific committees consists of a three-year term of office, renewable once. Committees meet an average of four times a year for full-day meetings.

QMP-LS considers the following criteria for membership:

- Membership will reflect the geography of the province and the laboratory community, including hospital and community-based representation.
- Members shall be laboratory professionals of stature who have broad knowledge of laboratory operations, quality assurance practices and their chosen laboratory medicine discipline.

Responsibilities of the scientific committees include:

- advice on the design and content of External Quality Assessment (EQA) surveys;
- review of EQA survey results and evaluation of laboratory performance;
- preparation of educational Committee Comments for each EQA survey, including a review of the medical and scientific literature, commentary on discordant results, and recommendations for improved practice;
- review standards of practice in laboratory medicine and recommend guidelines to the Ontario Laboratory Accreditation program.

Expectations of committee members are that they are able to:

- regularly attend committee meetings and important related activities;
- make serious commitment to participate actively in committee work;
- volunteer for and willingly accept assignments and complete them thoroughly and on time;
- stay informed about committee matters, be well-prepared for meetings and review and comment on minutes and reports;
- build a collegial working relationship with other committee members that contributes to consensus;
- be active participants in the committees' annual evaluation and planning efforts.

We are seeking members for the following committees at this time:

Scientific Committee	Member	Facility Type	Additional Information
Cytology	Medical Laboratory Technologist	Community Laboratory	Broad experience in cytology
Hematology	Medical Laboratory Technologist	Community Laboratory	Expertise in routine hematology
Hematology	Medical Laboratory Technologist	Hospital Laboratory	Expertise in specialized coagulation
Mycology	Clinical Scientist	Community or Public Health Laboratory	Broad experience in mycology
Mycology	Medical Laboratory Technologist	Community or Public Health Laboratory	Broad experience in mycology
Pathology	Pathologist	Hospital Laboratory	Expertise in anatomic pathology
Pathology	Pathologist	Hospital Laboratory	Expertise in breast pathology

For more information, please contact Jane Gun-Munro at gunmunro@qmpls.org.

Interested parties should complete the committee-specific nomination form located in the QView™ General – EQA folder and forward, together with a resume/curriculum vitae, by February 15, 2008, to the address below:

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