QUALITY MANAGEMENT PROGRAM – LABORATORY SERVICES (QMP–LS)

Ontario Laboratory Accreditation Division (OLA)

# Guidance for Laboratory Quality Manuals



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# Introduction

An essential requirement of the Ontario Laboratory Accreditation (OLA) program is the design and implementation of a quality management system. Central to an effective quality management system is the creation of a laboratory quality manual, the top tier of a facility's quality system documentation.

This guide will help laboratories write a quality manual that meets the criteria defined by the OLA Program Requirements.

The guide:

- Provides necessary information on the structure and content of the quality manual
- Provides guidance on document control of the quality manual
- Includes sample tables of contents to illustrate how a quality manual can be organized
- Presents OLA criteria for participant self-assessment of their quality manual
- Clarifies what assessors will evaluate during an assessment visit
- Provides Internet links to examples of quality manuals
- Suggests resources for those needing further information

## Glossary of Terms

**Document**
Any information that provides direction (e.g. instructions including policy statements, textbooks, reference intervals and their origins, procedures, specifications, calibration tables, charts, posters, notices, memoranda, plans, software, drawings, regulations and standards).

**Document Control**
A system to regulate the handling and management (including archiving, storing and destruction) of documents containing information that communicates policies, processes, procedures as well as records. Usually pertains to documents that are part of the quality management system.

**ISO**
International Organization for Standardization. A network of standards institutes from 140 countries working in partnership with international organizations, governments, industry, business and consumer representation. The source of more than 13,000 international standards for business, government and society.

**CLSI**
Clinical and Laboratory Standards Institute. A global, voluntary organization that develops and disseminates consensus standards, guidelines and best practices. Formerly known as the National Committee for Clinical Laboratory Standards (NCCLS).

**Non-Conforming Examinations**
Non-fulfillment of any requirement in the performance of a laboratory examination or test. Identified from many sources, including audits, quality control, staff comments and clinician complaints.

**Policy**
Statement describing what is done and why.

**Process**
Series of inter-related steps involved in an activity or examination that uses resources and is managed to transform inputs into outputs.

**Procedure**
Written work instructions that specify a way to carry out an examination or step in a process.

**Quality Management System**
A program developed to support efficient and effective, high quality and appropriate laboratory services (e.g. accurate and precise results, appropriate test selection, timely reporting, correct interpretation of results, clinical usefulness, appropriate recommendations for further tests).

Comprehensive and coordinated efforts (policies, processes and procedures) designed to meet quality objectives, to direct and control an organization with regard to quality.

Encompasses quality (management) system, quality assurance and quality control.

**Quality System**
See "Quality Management System."

**Quality Manual**
A document describing the quality management system.

**Quality Manager**
An individual with delegated responsibility and authority to ensure compliance with the quality management system.

**Record**
Any information that produces evidence (e.g. requisitions, examination results and reports, instrument printouts, laboratory workbooks and worksheets, accession records, calibration records, quality control records, records of audits, complaints and action taken, external quality assessment records, instrument maintenance records, incident/accident reports, staff training and competency records, personnel records).

**SOP**

Standard Operating Procedure. See "Procedure".

## Quality Manual Basics

The purpose of the quality manual is to:

- Communicate information
- Provide evidence of conformity to the OLA program requirements
- Share knowledge
- Provide evidence of management's commitment to quality

The following points should be considered when creating a quality manual:

1. It is a document that describes a facility's quality management system through a series of policies.
2. It is the primary documentation of a quality system and must provide a thorough description of the system.
3. The expected length is from 30-70 pages although this could vary depending on the size and scope of the facility, and the amount of information a facility chooses to include.
4. It will usually include management processes, but does not usually include any technical procedures. Procedures are referenced where appropriate.
5. It is a road map to the rest of a laboratory's documentation, and will refer to a myriad of supporting documentation: procedures (work instructions), records, forms, charts, etc.
6. Some of the supporting documentation may be within the manual or included as appendices, but usually it will be kept elsewhere. The quality manual should indicate where supporting documentation can be found.
7. The medium can be either electronic or paper.
8. It must be easy for authorized personnel to update and easy for staff to access.
9. Typically, it is maintained and reviewed by a quality manager.
10. Everyone in the laboratory must be encouraged to provide input into the development of the quality manual.
11. It is essential that the entire staff is familiar with, and understands the contents of the manual and its related documentation

## International Organization for Standardization (ISO)

The International Organization for Standardization (ISO) was established in 1947 and since then as been developing voluntary technical standards over sectors of business, industry and technology. The work is conducted by a worldwide federation of national standards bodies from more than 140 countries.

With the exception of ISO 9000 and ISO 14000, the vast majority of ISO standards are highly specific and technical in nature. The ISO 9000 series was first published in 1987, and was the first ISO document to focus on management principles for a much wider business community. In 2000, the series was rewritten. It consists of three basic documents:

- ISO 9000:2000. Quality management systems—Fundamentals and vocabulary
- ISO 9001:2000. Quality management systems—Requirements
- ISO 9004:2000. Quality management systems—Guidelines for performance improvements

The concept of a quality management system is based on principles described in ISO 9001:2000, Quality management systems—Requirements. It describes eight quality management principles that can be applied to any business or service. Five hundred thousand organizations are already registered to ISO 9001.

ISO 17025:2005 (General requirements for the competence of testing and calibration laboratories) and ISO 15189:2003 (Medical laboratories—Particular requirements for quality and competence) are more technical documents written specifically for laboratories by international committees.

The OLA Program Requirements are based on both of the laboratory ISO standards: ISO 17025:2005 and ISO 15189:2003, which emphasize quality management system implementation. In addition, requirements were added based on Ontario law. Also included were requirements that represent generally accepted principles of good laboratory practice, usually consensus guidelines from professional societies and institutes.

## ISO Definition of a Quality Manual

"A document specifying the quality management system of an organization." NOTE: Quality manuals can vary in detail and format, in or to suit the size and complexity of an individual organization.[1]

ISO 9001:2000 contains the following clause (4.2.2) regarding the quality manual:
The organization shall establish and maintain a quality manual that includes

a) The scope of the quality management system, including details of and justifications for any exclusions;
b) The documented procedures or reference to them;
c) A description and interaction between the processes of the QMS.[2]

[1] CAN/CSA-ISO 9000-0 (ISO 9000:2000). Quality Management Systems—Fundamentals and Vocabulary. December 2000; 3.7.4:14.

[2] CAN/CSA-ISO 9001-00 (ISO 9001::2000) Quality Management Systems—Requirements. December 2000; 4.2.:2: 3.

# Structure and Contents of the Quality Manual

The exact format, structure and contents of the quality manual are at the discretion of each facility. You have the latitude to design your manual in keeping with your facility's size and complexity. Because of the large variance in facility types in the province, QMP-LS is unable to provide a "one-size fits all" quality manual template. Organize the manual as you wish, but be sure to divide it into manageable sections, and at minimum include the following:

- An introduction (overview of the manual),
- A description of the organization
- A quality policy statement
- A table of contents
- Cross references to other documents
- Definitions and/or glossary of terms
- Proper identification

In developing your quality manual contents, consider that your quality management system must encompass all management activities and processes relating to quality assurance. The following list of essential elements appears as part of OLA program requirement II.A.2:

*The quality management system shall encompass all management activities and processes relating to quality assurance*

- *organization*
- *personnel*
- *equipment*
- *purchasing and inventory*
- *process control (includes validation of processes, internal quality control and external quality assessment)*
- *documents and records*
- *information management*
- *investigation of non-conformities*
- *assessment (includes the use of quality indicators and internal audits)*
- *process improvement*
- *service and satisfaction*
- *facilities and safety*

# Structure and Contents of the Quality Manual: Suggestions

### Option 1: Follow ISO 15189:2003 Guidance

Table 1 presents a quality manual table of contents developed from the list included as part of OLA program requirement II.C.1. The list was developed in keeping with ISO 15189:2003, Medical laboratories—Particular requirements for quality and competence. It is also harmonious with the ISO 9000 family of standards for quality management systems.

### Option 2: Follow the Structure of ISO 9001:2000

Many quality manuals developed by facilities in industry will follow the structure of the ISO 9001:2000 requirements. Table 2 presents a table of contents developed in this fashion. This option would satisfy both OLA requirements and ISO 9000 principles. In this model, the ISO standard is transformed from a set of requirements, into the facilities commitment to those requirements in short and concise statements. The facility quality manual is in sync with the ISO standard and in the example; the numbering structure is the same as the ISO 9001:2000 standard.

### Option 3: Follow CLSI Guidance

The essential activities and processes listed on page 7 are based on the CLSI document GP26-A3 titled "Application of a Quality Management System Model for Laboratory Services Quality System Model for Health Care" and HS1-A2 titled "A Quality Management System Model for Health Care". The headings of this list could easily be used as the basis for a quality manual; a sample table of contents organized with this approach is presented in Table 3. An entire manual created with this format can be viewed at http://www.clsi.org/Content/NavigationMenu/AboutCLSI/QualityManual/Quality-Manual-Second-Edition-June2003-041102.pdf

### Option 4: Follow the Structure of OLA Program Requirements

Table 4 is an example of a table of contents that is structured to follow the OLA Program Requirements. In this model (as for Option 2), the OLA Program Requirements are transformed from a set of requirements into your laboratory's commitment to those requirements. The facility quality manual is in sync with the OLA Program Requirements and in the example; the numbering structure is the same as the OLA Program Requirements. Using this structure will make it easier for both the user and OLA assessors to read the manual, and will help you to ensure that you don't overlook anything.

### Option 5: Create Your Own Structure

You may choose to create your own structure. Keep in mind that the quality manual should address all of the key elements of the OLA Program Requirements, and that QMP–LS will use your quality manual to pre-assess your quality management system prior to the OLA peer assessment visit.

Table 1: ISO 15189:2003 Style Quality Manual Table of Contents

## Table 2: ISO 9001:2000 Style Quality Manual Table of Contents

## Table 3: CLSI Style Quality Manual Table of Contents

## Table 4: OLA Style Quality Manual Table of Contents

## The Introduction

In the quality manual, there should be an introductory section containing a brief overview of the quality manual and your facility. Consider including the following information:

- The name of the individual who reviewed and approved the quality manual
- The version status, and the date the current version was issued
- The overall scope and use of the manual
- Information about how revisions to the manual will occur
- Distribution information: i.e. internal only, external
- Information about your facility:
  - Name, address, FAX numbers, e-mail contacts etc
  - The scope of examinations offered
  - History
  - Vision, mission statement, values
- Definitions and/or glossary of terms
- A table of contents

## The Quality Policy Statement

The purpose of the quality policy statement is to define the intentions and direction of the quality management system. It demonstrates the facility's commitment to quality with clear leadership by top management. This is essential since the leaders shape the culture of the laboratory: their commitment is the key to success.

The following requirements appear in the OLA Program Requirements:

**II.B Quality Policy Statement**

II.B.1 Laboratory management shall define its quality management system in a quality policy statement.

II.B.2 The quality policy statement shall include the laboratory's commitment to good professional practice, the quality of its examinations, compliance with and continuous improvement of the quality management system.

II.B.3 The quality policy statement shall include the objectives of the quality management system.

II.B.4 The quality policy statement shall include the scope of the service the laboratory intends to provide.

II.B.5 The quality policy statement shall include a requirement that all personnel familiarize themselves with the quality management system and implement it at all times.

**QMP-LS Quality Policy:**

QMP–LS commits to provide high quality laboratory accreditation, assessment and education services, that:

- Meet all customers' requirements; applicable regulatory, statutory and contractual requirements; and relevant national/international standards;
- Evaluate and continually improve the effectiveness of the service;
- Ensure this policy is communicated to and understood by all employees;
- Provide a process for establishment, review and modification of quality objectives;
- Review and modify this policy annually for continued suitability.

## Document Control

Your quality manual must be considered a controlled document. As such, it is subject to all of the requirements for documents from Section II.F of the OLA Program Requirements:

### II.F Document and Record Control

II.F.1 Laboratory management shall define, document and maintain a policy, process(es) and procedures to control documents and records. Documents and records may be maintained and stored on any appropriate medium.

II.F.2 Authorized documents shall be available at all locations where operations essential to the effective functioning of the laboratory are performed.

II.F.3 All documents issued to laboratory personnel as part of the quality management system shall be reviewed and approved for use by the laboratory director or designate(s) prior to issue.

II.F.4 A list, also referred to as a document control log, that identifies the current valid revisions and their distribution shall be maintained.

II.F.5 All documents relevant to the quality management system shall have a unique identification.

II.F.6 Documents shall include the date of issue.

II.F.7 Documents shall include the edition and/or current revision date and/or revision number.

II.F.8 Documents shall designate the number of pages within.

II.F.9 Documents shall contain authority for issue.

II.F.10 Documents shall contain an electronic identification, if applicable.

II.F.11 Document control processes shall be adopted to ensure that obsolete documents are removed and only currently authorized versions of appropriate documents are available for active use at relevant locations.

II.F.11.1 A retention period for superseded documents shall be defined.

II.F.11.2 Retained or archived superceded documents shall be appropriately identified to prevent their inadvertent use.

## Example Headers and Footers

Figures 1-4 present a variety of headers/footers that meet the requirements for document identification specified in OLA Program Requirements II.F.5-II.F.10. Any of these could be adapted for your quality manual and for all of the related documentation in your quality management system. Note that pagination can be either continuous or sectioned.

**Figure 1: Example Header/Footer Combination**

*Header:*

| **Best Test Laboratories** | | |
|---|---|---|
| Quality Manual | Section 0.0<br>**TABLE OF CONTENTS** | Page 1 of 1 |

*Footer:*

| | | | |
|---|---|---|---|
| Prepared by<br>Approved by | William Jones<br>Dr Mary Smith | Issue Number<br>Issue Date | 2<br>Jan 21, 2002 |

**Figure 2: Example Header**

| | | |
|---|---|---|
| Section 0.0 | Date Issued: 21/01/02 | Pg 1 of 1 |
| Element: Table of Contents | Authorized by: William Jones | |
| Revision 2 | Approved by: Dr Mary Smith | |

**Figure 3: Example Footer**

| | | |
|---|---|---|
| 01/11/10, 02/01/21 (rev) | Qualitymanual.doc | Pg 1 of 42 |
| Authority for Issue: Dr Mary Smith | | |

**Figure 4: Example Header/Footer used internally at QMP-LS**

Header:

| | | |
|---|---|---|
| QMP-LS | Quality Manual Section 5.1 | Page **1 of 2** |
| **Status:** Approved | **Title**: Document and Record Management Policy | Version 1.0 |

Footer:

| | | |
|---|---|---|
| **Prepared by:** Jane Gun-Munro | **Approved by:** Dr. Harold Richardson | **Effective Date:** 2002 08 26 |

*NOTE: This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the server file version prior to use.*

## Maintaining the Manual

Ensure the quality manual:

- Is up-to-date
- Is required reading for all personnel
- Is reviewed annually

These points are covered in the following OLA Program Requirements contained in Section II.C:

> **II.C Quality Manual**
>
> II.C.2 The quality manual shall be maintained current under the authority of an individual appointed responsible by laboratory management (quality manager).
>
> II.C.3 The quality manual should be reviewed, signed and dated regularly, and at minimum annually by the quality manager or laboratory management.

It is advisable to include a "Record of Revisions" page within your quality manual. This could appear in the front material or as an appendix. Alternatively, include a revision history for each individual policy as part of a standard header or footer.

If your quality manual is primarily an electronic document wherein uncontrolled printed paper copies may exist, you should consider adding a footer at the bottom of printed pages:

NOTE: This is a CONTROLLED Document as are all management system files on this server. Any documents appearing in paper form are not controlled and should be checked against the server file version prior to use.

**Notice:** This Document hardcopy must be used for reference purpose only.
**The on-line copy must be used as the current documentation level.**

This type of warning reminds personnel to ensure that they are using the most up to date issued copy of any document.

## Review of Laboratory Quality Manual

Facilities will be requested to complete a self-assessment of their quality manual one month prior to each accreditation peer assessment visit. With the initial notification of an upcoming accreditation peer assessment, QMP–LS sends to each facility a form that outlines the criteria for the self- assessment. . You will be required to submit the completed form to QMP–LS for review by the OLA Staff Coordinator and copies will be provided to your peer assessment team. You are requested to have your quality manual available for the team to review on-site.

The purpose of the self-assessment is to:

- Review the general characteristics of the quality manual
- Pre-assess the facility's quality policies
- Expedite the on-site peer assessment of your quality management system
- Assist the assessment team in locating your quality policies

The list of policies included on the form (Table 5) are those for which QMPP–LS expects to see within the quality manual. Facilities are encouraged to include the indicated information in their quality manual to allow for an effective self-assessment and to expedite the accreditation assessment visit. However, non-inclusion of a policy in the quality manual will not constitute a deficiency if the information is documented elsewhere. For each of the criteria in Table 5, laboratories are instructed provide the page number in their quality manual or specify where documentation of this information can be found by OLA assessors.

## Table 5: Criteria for Self-Assessment of Laboratory Quality Manual

| Criteria | Requirement # * | Yes/No and Page No. or location ** |
|---|---|---|
| **General Criteria** | | |
| 1. Is the quality manual properly identified with the following? | | |
| a. Date of issue | II.F.6 | |
| b. Current revision date or version number | II.F.7 | |
| c. The page number and the number of pages therein | II.F.8 | |
| d. Authority for issue | II.F.9 | |
| e. Unique identifier or electronic file identification | II.F.10 | |
| 2. Was the quality manual approved by the laboratory director or designated responsible person prior to implementation and distribution? | II.F.3 | |
| 3. Do policies in the Quality Manual indicate that the Quality Management System encompasses all management activities and processes (in all areas of the laboratory)? | II.A.2 | |
| 4. Are there cross-references to related processes, procedures, and reports not included in the quality manual? | II.C.1 | |
| 5. Is the Quality Manual reviewed, signed and dated at minimum annually? | II.C.3 | |
| **Specific Policies/Processes or Statements** | | |
| 6. Is there an organizational chart? | I.A.4 | |
| 7. Is there a mission statement or statement of purpose? | I.A.3 | |
| 8. Are personnel policies defined (or a reference made to where they can be found)? | I.B.2 | |
| 9. Are there policies defined that address the confidentiality of patient information? | I.C.9 | |
| 10. Is there a quality policy statement? | II.B.1 | |
| 11. Does the laboratory have quality improvement programs in place? | II.D.1 | |
| 12. Have quality indicators been implemented? | II.D.3 | |
| 13. Is there a policy and process for non-conformities? | II.D.5 | |

| Criteria | Requirement # * | Yes/No and Page No. or location ** |
|---|---|---|
| 14. Is there a policy or process for the resolution of complaints? | II.D.6 | |
| 15. Does the laboratory have a defined policy and process to control documents and records? | II.F.1 | |
| 16. Is there a policy or process that describes the selection, use and monitoring of referral laboratories and consultants? | II.G.1 | |
| 17. Is there a policy for purchasing and inventory? | IV.1 | |
| 18. Are there policies/processes and/or procedures for calibration and verification programs for instruments, reagents and analytical systems? | IV.8 | |
| 19. Are computer policies, processes and procedures defined? | IX.B.1 | |
| 20. Is there a safety policy? | X.A.1 | |
| 21. Has the scope of POCT been defined by the Medical Advisory Committee or other appropriate body? | XI.A.3 | |

* Recommended best practice, not an essential requirement.

## The Peer Assessment Visit

OLA accreditation assessment visits will be conducted by a team of peers assembled from our pool of over 300 volunteer assessors. An OLA staff coordinator will accompany each team to ensure consistency and provide advice to the team as needed. Individual assessors will have specific expertise and will assess the scope of a laboratory they are familiar with. They will utilize checklists that guide them in what to look for in seeking objective evidence that the laboratory meets program requirements. They may ask to see specific documentation, may directly observe the physical conditions of the laboratory and practices in action, and may speak directly to all levels of staff to ensure that requirements are met.

The assessment team will ensure that policies, processes and procedures are implemented, that staff follow them as written, and that appropriate "checks and balances" are in place to ensure quality and allow for continual improvement. If a policy is documented and included in your quality manual, it must reflect your actual practice. OLA will review the quality manual and make note of items to be validated by observation of actual laboratory practice. The validation will be done at the time of the assessment visit.

Validation will be achieved through the following means:

- Interviews with laboratory director(s) and staff
- Observations of staff
- Review of laboratory records
- Review of additional documentation that the facility has not included as part of the quality manual

OLA assessors will conduct a process-based assessment, as opposed to a procedurally-based inspection. In other words, OLA assessors will concentrate on laboratory policies and processes. Each laboratory should provide evidence that its processes are effective in meeting the goals defined in its policies. OLA will assess the efforts of laboratory management to define its own criteria for quality according to the laboratory's unique circumstances and patient population served. OLA assessors will ask to see evidence that the laboratory's defined processes are followed by staff and are effective. The assessment will be as objective as possible, using checklists developed with emphasis on a process approach.

For example: One OLA program requirement (VIII.7) states that laboratory management, in consultation with the requesters, shall establish clinically appropriate turnaround times (TAT) for each of its examinations. A procedurally-based approach would likely lead assessors to look at the actual TAT of each examination and make a judgment on whether or not the TAT is acceptable. OLA's process-based assessment will direct assessors not to look at individual TATs but to review the process by which the laboratory has determined that its TATs are clinically appropriate. Thus, the specific "What to Look for" instructions for this requirement are:

A) Did the laboratory determine clinically relevant TATs for each examination in consultation with their clients?
B) Does the laboratory monitor the established TATs to ensure that they remain clinically relevant?

## Frequently Asked Questions

1. What is the difference between a policy, a process and a procedure?

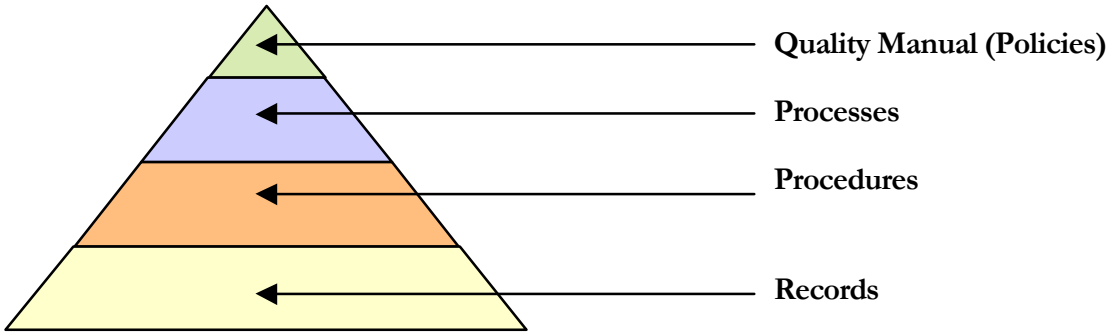
*A policy is a brief statement describing your intent, they describe what is done and why. Policies form the basis of the quality manual. Policies define your goals.*

*A process describes the inter-related steps involved in an activity and may involve a number of people. Processes are usually displayed as flowcharts and illustrate the path of workflow and who is responsible. Most processes will be linked to one another because the output of one process is often the input to the next. Rarely is there a process that is not linked to another.*

*A procedure is the written work instructions that specify a way to carry out an activity, examination or step in a process. Procedures describe in detail exactly how one individual should perform an activity. These should be written so that any individual who has a role in a process has detailed instructions to follow.*

2. Where in the typical document hierarchy does the quality manual fit in?

*The Quality manual is the top tier of the document hierarchy:*




3. Where do we put our process flow charts?

*Once you have created a process flow chart, it is a controlled document. Some may be included within the quality manual, such as your process for the investigation of non-conformities. Others will be more technical in nature and may be included as part of a procedure manual. For instance, a flow chart on the process for specimen reception and accessioning could be included in the procedure manual located in your specimen reception area.*

4. Is it better to use continuous pagination, or to number the pages within individual sections?

*OLA does not dictate how you must set up the pagination of your quality manual, but it may be easier to update individual polices and add/remove pages if the pagination is by section rather than continuous.*

5. Do we include procedures in the quality manual?

   *No, you may want to include some process flow charts, but step-by-step work instruction should generally not be included. However, you should indicate within the quality manual, a list of the procedures related to each policy and where they can be found.*

6. Do we write our quality manual according to what we actually do, or according to what we would like to do, or plan to do in the future?

   *It is essential that the quality manual reflects what you actually do. Each laboratory should be able to provide evidence that its processes are effective in meeting the goals defined in their policies. It is up to the laboratory to define what records and documentation are necessary to provide this evidence.i OLA assessors will ensure that policies, processes and procedures are implemented, that staff follow them as written, and that appropriate "checks and balances" are in place to ensure quality and allow for continual improvement.*

7. Should there be only one Quality Manual per license/facility? If we have laboratory sections not under Laboratory Medicine/Pathology (e.g. Genetics, molecular, MSS laboratories) should these departments have a separate quality manual?

   *Our intent is that there is ONE quality manual to represent the general administrative policies of all laboratory divisions. Differences between the types of programs listed and the rest of your laboratory should be limited to operational or technical details that need not be included within the quality manual.*

8. I have seen a quality manual from another organization that included reports of the outcomes of management review such as the results of internal audits, results of quality indicators, process improvement plans. Does OLA require this sort of information in the quality manual?

   *Management review reports such as these are not required to be included in the quality manual. However, we will ask to see these kinds of reports as part of our assessment visit and that is the rationale why some may choose to include them in the quality manual itself.*

## Sample Quality Manuals

**CLSI Quality Manual (US)**
http://www.clsi.org/Content/NavigationMenu/AboutCLSI/QualityManual/Quality-Manual-Second-Edition-June2003-041102.pdf

**Delta Environmental Consulting (Australia):**
http://www.deltaenvironmental.com.au/management/index.htm

**National Institute of Standards and Technology (US):**
http://ts.nist.gov/ts/htdocs/230/235/quality/d5802.htm

**NASA Quality Manual (US):**
http://nodis3.gsfc.nasa.gov/library/hq_list.cfm

**Quality Network (UK):**
http://www.quality.co.uk/example/manual.htm

## Resources

Canadian Standards Association. Plus 15189. The ISO 15189:2003 essentials—A practical handbook for implementing the ISO 15189:2003 Standard for medical laboratories. July 2004.

CAN/CSA-ISO 9000-0 (ISO 9000:2000). Quality Management Systems—Fundamentals and Vocabulary. December 2000.

CAN/CSA-ISO 9001-00 (ISO 9001:2000) Quality Management Systems—Requirements. December 2000.

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CLSI. Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition. CLSI document GP26-A3, 2004.

CLSI. A Quality System Model for Health Care; Approved Guideline—Second Edition. CLSI document HS1-A2, 2004.

ISO/TC 176/SC 2/N 525R. ISO 9000 Introduction and Support Package: Guidance on the Documentation Requirements of ISO 9001:2000.

ISO/TC 176/SC 2/N 544R. ISO 9000 Introduction and Support Package: Guidance on the Process Approach to quality management systems. May 2001.

International Organization for Standardization ISO 15189 Medical Laboratories-Particular Requirements for Quality and Competence. February 2003

Ontario Laboratory Accreditation Requirements and Guidance Information, Version 3, September 2005.

Richardson H. Medical Laboratories—Requirements for Quality and Competence: An ISO Perspective. Vox Sang 2002; 83:333-5.