

LifeLabs
Medical Laboratory Services

Coordinating Quality for a Multi-Site Community Laboratory

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1

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Today's Objectives

- Overview of LifeLabs Ontario integrated laboratory system
- Ontario Laboratory Accreditation (OLA) – History and Progress
- How did we do it – Lessons Learned along the path to accreditation
- Quality Management System

2

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Ontario – Locations

- 11 Licensed Diagnostic Testing Laboratories
- 122 Licensed Specimen Collection Centres
- 1 Quality Management System

3

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Ontario – Testing Locations

Largest laboratory located in Toronto

- 24/7 operation
- Employs 360 lab staff
- Plus 75 sample sort staff
- ~50,000 specimens daily
- ~90,000 tests per day
- Full-service laboratory
- 24 hour centralized Call Centre
- Support staff:
 - IT
 - HR
 - Supply Chain Management
 - Quality & Regulatory Affairs

4

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Ontario – Testing Locations

Large lab in St. Catharines

- Days/Evenings operation
- Employs 60 lab staff
- Plus 30 sample sort staff
- ~7,500 specimens daily
- ~24,000 tests
- Smaller test menu

5

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Ontario – Testing Locations

Smaller test menu at the other locations

6

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Ontario – Locations

122 Specimen Collection Centres

7

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Development of Provincial Government Quality Management Program for Laboratory Services (QMP-LS)

- November 1999 – “*To Err Is Human*” report published by the US Institute of Medicine
- September 2000 – Ontario Medical Association asked by the provincial Ministry of Health and Long Term Care to set-up a ‘quality’ program for clinical laboratories

8

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Quality Management Program – Laboratory Services

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graph TD
    QMP-LS[QMP-LS] --> OLA[Ontario Laboratory Accreditation (OLA Division)]
    QMP-LS --> EQA[External Quality Assessment (EQA Division)]
  
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9

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Development of OLA Ontario Laboratory Accreditation Program

- Requirements based on ISO 15189 ‘*Medical laboratories - Particular requirements for quality and competence*’
- In 2002, our Toronto lab volunteered to be one of 4 pilots sites; representative of a community laboratory
- First on-site peer accreditation visit in February 2003
 - Opportunity to participate and influence the process
 - Opportunity to provide feedback on the wording of the requirements
 - 3 days, 9 assessors

10

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Ontario Laboratory Accreditation Program

- Began on a 5-year cycle, now 4-year cycle
- On-site peer assessment (trained volunteers)
 - Assessment teams contain technical experts in all areas covered under the scope of accreditation
- Mid-cycle self assessment
- Surveillance assessments possible for EQA non-conformance
- Mandatory for all licensed laboratory sites in Ontario
- Process based assessment
- Covers entire path of workflow

Pre analytic → Analytic → Post analytic

11


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Ontario Laboratory Accreditation Program

- Program Director (Ms. Linda Crawford)
 - Reports to QMPLS Managing Director (Dr. Greg Flynn)
- 4 Staff Technologists
 - Coordinate the program
 - OLA technologist accompanies each assessment team
- Program overseen by OLA Advisory Panel
 - Selected volunteer laboratory professionals
- Non-conformances are identified as Major or Minor
 - Major non-conformances must be resolved prior to issue of a 4-year certificate
 - Minor non-conformances require an acceptable action plan for resolution

12

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Ontario Laboratory Accreditation Program

- The principal function of accreditation is to help laboratories deliver high-quality, efficient laboratory services
- Laboratories are required to provide objective evidence of quality goals, management commitment, communication within and outside the laboratory, client satisfaction, continual improvement through effective QC/QA/quality management and sound reporting practices
- Accreditation assessment will ensure that laboratories meet explicit quality management criteria and will recognize the laboratory's competency and integrity.
- Accreditation requirements define quality expectations, set the desired standards of best practice, and serve as the benchmark against which laboratory quality and competency are assessed

¹³ • The assessment process will be non-discriminatory and impartial

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Ontario Laboratory Accreditation Program

- Accreditation processes are aligned with ISO 17011:2004 *Conformity Assessment – General requirements for accreditation bodies* and
- International Laboratory Accreditation Cooperation (ILAC) guidelines for assessor qualifications, training and competence
- For further information visit www.qmpls.org

¹⁴

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Quality System Essentials

1) Organization	7) Information management
2) Personnel	8) Investigation of non-conformities
3) Equipment	9) Assessment
4) Purchasing and inventory	10) Process improvement
5) Process control	11) Service and satisfaction
6) Documents and records	12) Facilities and safety

¹⁵

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What is a Quality Management System?

□ **Quality Management System (QMS)** can be defined as: a set of **policies, processes** and **procedures** required for **planning** and **execution** (**production / development / service**) in the core business area of an organization. QMS integrates the various internal processes within the organization and intends to provide a process approach for project execution. QMS enables the organizations to identify, measure, control and improve the various core business processes that will ultimately lead to improved business performance.

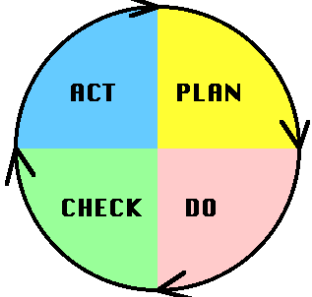
□ Wikipedia

¹⁶

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The Deming Cycle



¹⁷

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Quality Management System


Includes a complete set of policies, processes and procedures that allow laboratory management to:

- Define all activities
- Monitor them
- Measure their effectiveness and
- Improve at every opportunity

Where have we heard that before?


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What Are Assessors Looking For?

- Objective evidence of compliance to the requirements
- Do what you say you do, and be able to prove it with records



19

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Control Your Organization's Path of Workflow

- Determine the actual sequence of activities
- Identify 'who does what and when'
- Document 'how it happens here'
- Train to the process and procedures
- Measure, monitor and improve

20

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How Does Lean/Sigma Fit?

- Lean and Six Sigma provide a disciplined and proven methodology for the investigation and resolution of defects
- This approach includes a variety of tools that are proven to provide answers
- DMAIC
 - Define
 - Measure
 - Analyse
 - Improve
 - Control



21

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Lessons Learned

- Start now
- Involve all layers of your facility
- Be familiar with the requirements
- Develop and maintain a Quality Manual
- Involve all departments
- Educate staff
- Control your documents
- Embrace the QSE's
- Build 'Quality' into every process


22

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Challenges?

- Document Control
- Internal Audit
- Management Review
- Annual Review of Documents
- Provision of evidence




Excellent Resource: CLSI guidelines

GP26-A3 – *Application of a Quality Management System Model for Laboratory Services*


HS01-A2 – *A Quality Management System Model for Healthcare*

23

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Questions?



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24