



QUALITY MANAGEMENT PROGRAM – LABORATORY SERVICES (QMP-LS)

Ontario Laboratory Accreditation Division (OLA)

Ontario Laboratory Accreditation (OLA) Program Information

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Preface

This booklet describes the Ontario Laboratory Accreditation (OLA) program, which is part of the Quality Management Program–Laboratory Services (QMP–LS) operated by the Ontario Medical Association. It provides information about the accreditation program and describes the rights and duties of accredited laboratories.

What is Accreditation?

Laboratory clients know the importance of reliability when it comes to diagnostic medical laboratory examinations. The industry demands rigour and the users of a laboratory service depend on the laboratory to deliver credible results. Laboratory accreditation is a process by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks (detailed in a scope of accreditation) in a reliable, credible, and accurate manner. Accreditation assesses both the quality system and technical competence of the organization on the basis of a pre-defined standard. For medical laboratories, the fundamental standard is *ISO 15189:2007 Medical Laboratories – Particular requirements for quality and competence*.

To meet national and international demand for formal accreditation to ISO 15189, QMP–LS offers accreditation to ISO 15189 under its Ontario Laboratory Accreditation (OLA) division. This accreditation program is mandated by two provinces in Canada (Ontario and Newfoundland & Labrador), and subscribed to voluntarily by other laboratories. If desired, ISO 15189 accreditation certificates can be issued in conjunction with our partner, Standards Council of Canada (SCC). A certificate issued by QMP–LS or SCC provides recognition of medical laboratory competence and underscores the laboratory’s experience, superior technical competence and reliability. Further benefits of accreditation are:

- An effective quality system will reduce risk and improve patient safety through the implementation of tools that eliminate variability in processes.
- A quality system provides a solid base and the infrastructure on which to add cost-savings projects such as LEAN and Six Sigma initiatives. To refine processes, they must first be defined. To measure progress, tools such as internal audits, management reviews and occurrence management must be established.
- A quality system can foster needed healthcare reform in order to provide an environment in which staff can perform their best, staff contribution and involvement and professionalism are encouraged, and morale is improved.
- The clear documentation of processes and procedures results in improved communication and reduced variability.
- Accreditation increases competitiveness and assists private sector laboratories in expanding their business model.

Accreditation to ISO 15189 provides assurance that an effective quality management system is in place, and also ensures technical competence. A medical laboratory’s fulfilment of the requirements of ISO 15189:2007 means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid test results. Medical laboratories accredited to ISO 15189 are recognized as meeting the management systems principles of ISO 9001:2008 *Quality management systems – Requirements*.

Information About QMP-LS

OLA is operated by the Quality Management Program – Laboratory Services, a department of the Ontario Medical Association.

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.

Mission

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 that:

- Is customer focused;
- Meets applicable regulatory, statutory and contractual requirements; and relevant national/international standards referenced below;
- 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;
- Ensures annual review of this policy for continued suitability.

Purpose

QMP-LS is operated by the Ontario Medical Association (OMA).

QMP-LS identifies, designs and delivers external quality assessment (EQA), accreditation and education services and related products that meet international standards, client and stakeholder requirements. QMP-LS has been issuing accreditation certificates since 2003.

Clients in Canada and other countries may voluntarily apply for accreditation and/or participate in EQA surveys. In Ontario, Canada the OMA serves as an agent of the Ministry of Health and Long-Term Care (MOHLTC) to carry out a quality management program for licensed medical laboratories according to the *The Laboratory and Specimen Collection Centre Licensing Act, R.S.O. 1990, c.L.1, s. 14*, and its *Laboratories Regulation 682, R.S.O. 1990, s. 14*. In Newfoundland & Labrador, Canada the QMP-LS accreditation program is mandated by the Health and Community Services, Government of Newfoundland & Labrador for all medical laboratories.

Accreditation processes are aligned with ISO 17011:2004 *Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies* and International Laboratory Accreditation Cooperation (ILAC) guidelines for assessor qualifications, training and competence.

EQA surveys are conducted in accordance with ISO/IEC 17043: 2010 *Conformity assessment – General requirements for proficiency testing* and ILAC guidelines for competent proficiency testing schemes. For more information on EQA surveys, see “Program Information” at <http://www.qmpls.org/eqa/eqa.html>.

Governance and Financial Support

QMP-LS is governed in accordance with the terms and conditions of agreements between the OMA, Ontario’s MOHLTC, and the Standards Council of Canada (SCC). QMP-LS policies, processes and procedures are developed with the advice of a stakeholder Advisory Council, a Professional Advisory Committee and an Accreditation Advisory Panel. Infrastructure is funded by Ontario’s MOHLTC and operating costs are obtained from clients. Policies are approved by a Senior Management Group.

Organizational Structure

QMP-LS has three operating divisions:

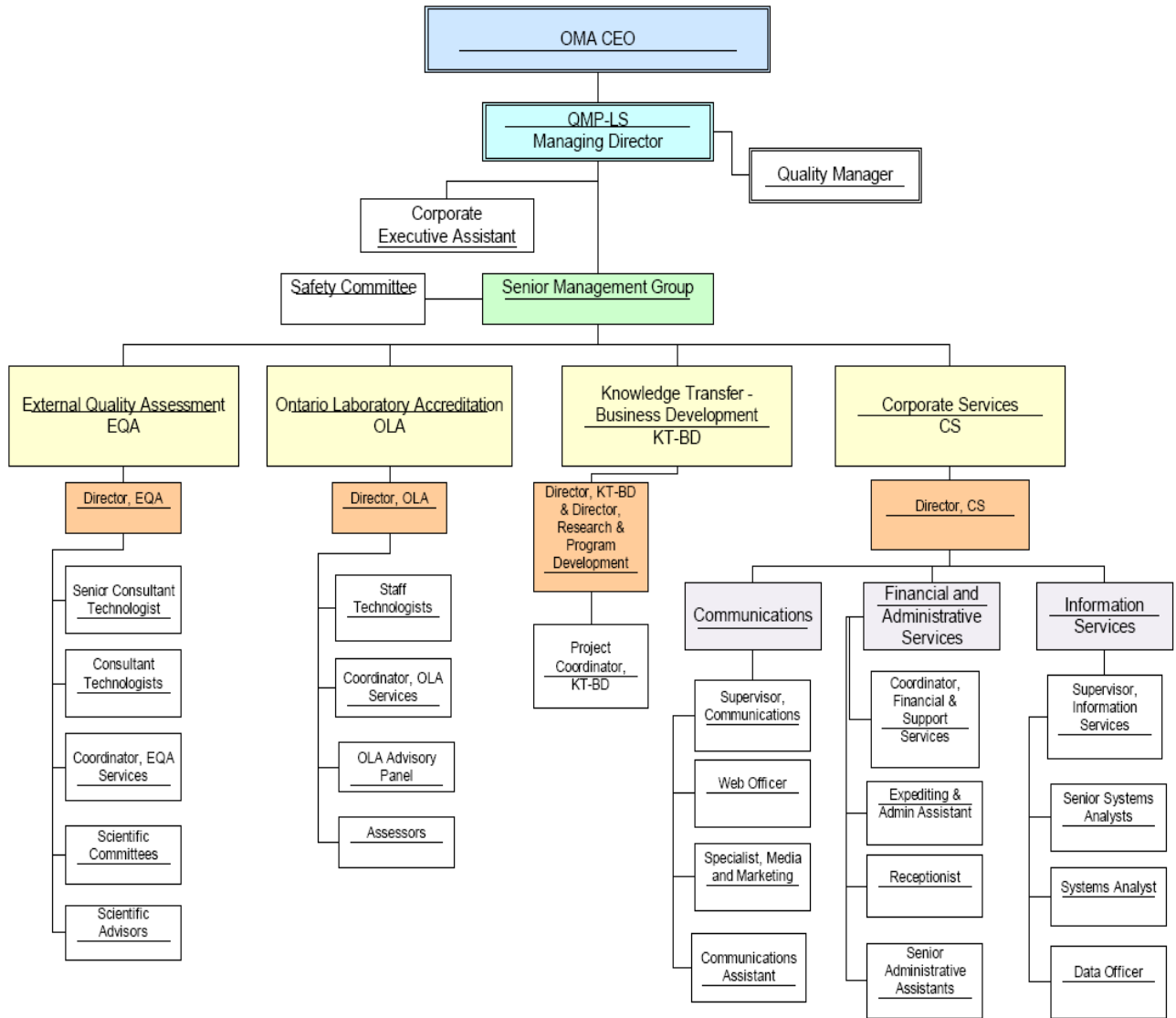
1. External Quality Assessment (EQA)
2. Ontario Laboratory Accreditation (OLA)
3. Knowledge Transfer and Business Development

These divisions are supported by a Corporate Services division that includes: Information Services (IS), Communications, Financial and Support Services, Expediting, and Office Administration (Figure 1).

Management and Staff Responsibility

The Managing Director has overall responsibility for QMP-LS, and is supported by a Director, EQA, a Director, OLA, a Director, Corporate Services, a Director, Research & Program Development, a Director, Research and Program Development, and a Quality Manager in accordance with OMA Human Resources policies. Staff includes medical technologists dedicated to EQA or OLA, and administrative, secretarial and clerical staff who are multi-tasked across the divisions. A current listing of staff names, telephone numbers and e-mail addresses is available at http://www.qmpls.org/about/about_staff.html.

Figure 1: QMP-LS Organizational Chart



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Operations and Subcontracting

QMP-LS provides its own EQA and accreditation services. QMP-LS conducts its OLA accreditation assessments using its own trained and certified assessors.

Confidentiality and Impartiality (Conflict of Interest)

QMP-LS does not disclose confidential information about a particular laboratory to outside parties without written consent from the laboratory, except where the law requires such information to be disclosed without such consent.

Impartiality is ensured with the self-declaration of any conflicts of interest by all staff, assessors, consultants and advisors. Advisors consist of laboratory professionals of stature who have broad knowledge of laboratory operations, quality assurance practices, management skills, and who represent a cross-section of practitioners. No single party predominates.

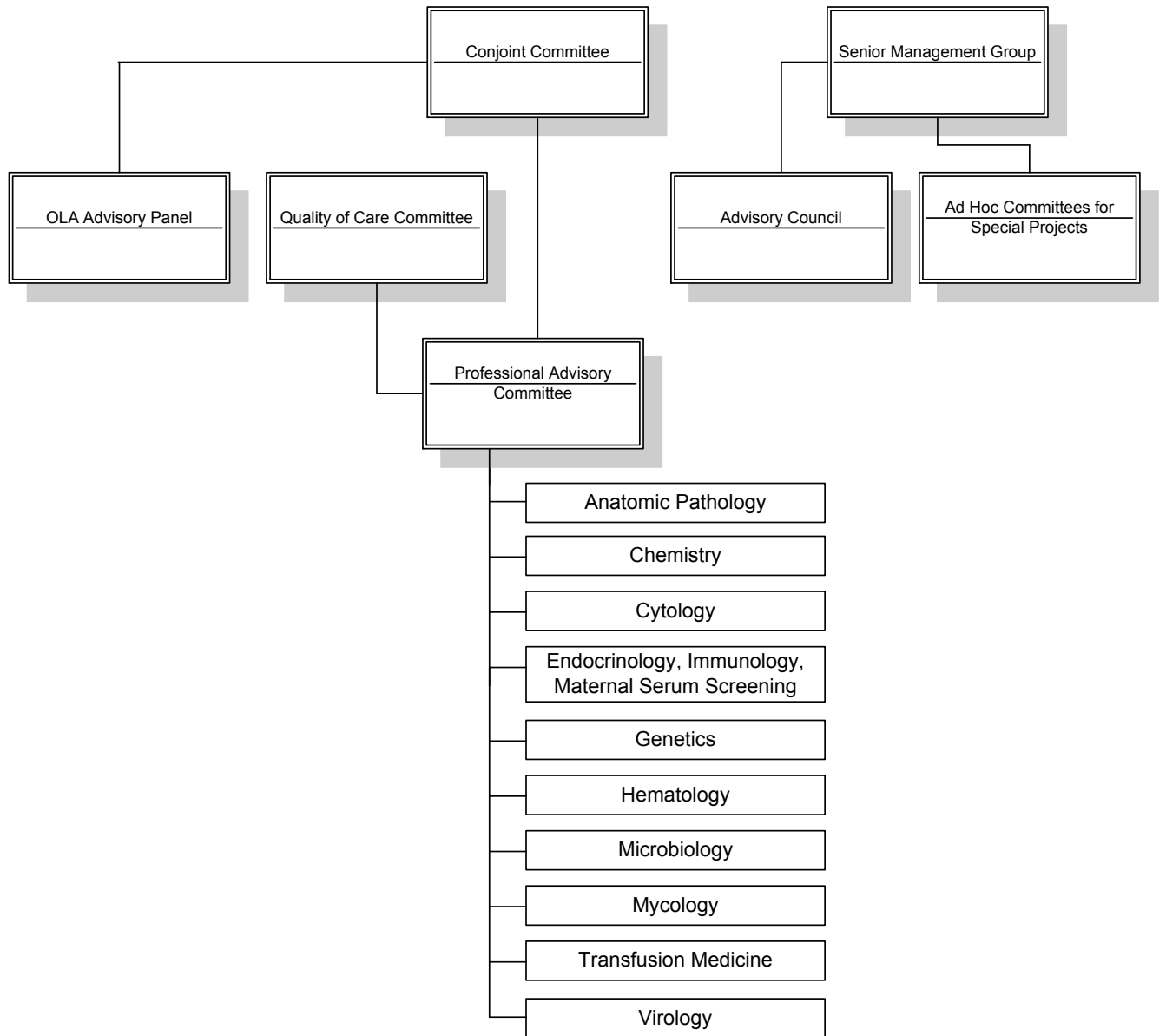
On an ongoing basis, key communications are sent to stakeholder groups, and they are encouraged to provide advice and counsel. A stakeholder committee called the QMP-LS Advisory Council exists to advise QMP-LS on policies and operations from a stakeholder perspective (see “Accreditation Program Stakeholders”).

QMP-LS Committees

QMP-LS selects the best available consultant expertise to support credibility and excellence of its programs (Figure 2).

The terms of reference, nomination process, terms and conditions of appointments, membership, roles and responsibilities of committees and members are in a Committee Handbook that is readily available through QMP-LS staff. OLA has an Advisory Panel and utilizes the expertise of the EQA Scientific Committees (Figure 2).

Figure 2: QMP-LS Committee Structure



Information About OLA

Background

Development of OLA began on September 15, 2000. Accreditation assessments began in 2003.

Accreditation services are provided to licensed Ontario medical laboratories under agreement with Ontario's MOHLTC, to Newfoundland & Labrador medical laboratories under agreement with the Health and Community Services, and to laboratories from other jurisdictions in Canada and other countries. Applicant laboratories for voluntary accreditation are assessed by QMP-LS and issued ISO 15189 certificates by the Standards Council of Canada (SCC) under a partnership agreement (see "Partnership with Standards Council of Canada").

Operations comply with the following international standards and guidelines:

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

This standard, guidelines and the resulting operating principles distinguish the OLA medical laboratory accreditation program from others in the following ways:

- Volunteer assessors are pre-certified through 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.
- All OLA accreditation 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 assessor competencies form the basis of performance evaluations.
- A QMP-LS 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 EQA division for ongoing surveillance of accredited laboratories.
- Certificates to ISO 15189 are issued by SCC (conditions apply – see "Agreement with Standards Council of Canada").

Operating Principles and Values

The principal function of accreditation is to help laboratories deliver high-quality, efficient laboratory services. Our accreditation program:

- Provides assessment of mandatory participants within Ontario leading to the issuance of an Ontario Laboratory Accreditation certificate as a condition of licensure.
- Offers assessment leading to the issuance of an Ontario Laboratory Accreditation certificate to medical laboratories not under the jurisdiction of the Ontario Laboratory and Specimen Collection Centre Licensing Act that apply for and purchase this option;

- Offers assessment leading to accreditation to ISO 15189:2007 in partnership with Standards Council of Canada to medical laboratories that apply for and purchase this option;
- Appoints expert laboratory physicians, scientists and technologists to advise on the accreditation model and accreditation status of participating medical laboratories;
- Selects, orientates and trains laboratory physicians, scientists and technologists as assessors, and monitors their competence;
- Designs, develops and validates accreditation requirements according to ISO 15189:2007. In Canada, federal laws are incorporated, and in Ontario provincial laws;
- Provides information to participants on the accreditation process, the obligations of the laboratory, the obligations of the accrediting body and the use of accreditation symbols;
- Services diagnostic medical laboratories within available resources and does not sub-contract its services to other providers;
- Prepares for assessments by appointing a competent assessment team, defining assignments, pursuing a mutually agreeable date, and providing the team with relevant working papers;
- Performs on-site assessments according to established procedures;
- Prepares an assessment summary report for the laboratory;
- Reviews the responses of the laboratory to resolve non-conformances in an impartial manner to determine if the actions taken by the laboratory are sufficient and effective;
- Grants accreditation and issues certificates based on defined criteria, and in partnership with the Standards Council of Canada, where applicable;
- Conducts regular monitoring of laboratory self-assessments, licence changes, and proficiency testing performance and conducts surveillance on-site assessments according to defined criteria;
- Maintains confidential records on laboratories to demonstrate that requirements for accreditation have been fulfilled.

OLA is committed to upholding the following values in the delivery of the accreditation program:

Responsible:

- We will ensure that operations comply with ISO standard 17011 *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*.
- We will ensure that our requirements are consistent with international and national standards, national, regional or local consensus guidelines, government regulations and generally accepted principles of good practice.

Objective:

- We will ensure our requirements are vetted by stakeholders, that a reference source is identified for each, and that requirements, reference source and guidance information are reviewed regularly.
- We will ensure that assessors and Advisory Panel members are free from any commercial, financial or other pressures that could compromise impartiality, and that they have not provided consultancy to the participating laboratory.
- We will ensure our assessments are impartial and based on the factual evidence presented.

- We will ensure that decisions on accreditation status are made by persons different from those who carried out the assessment.

Consistent:

- We will ensure that our assessors are trained and certified, that they are provided with guidance information for each requirement, and current assessment procedures.
- We will ensure that standard processes are applied with each accreditation assessment.

Transparent:

- We will communicate our requirements, guidance information and assessment processes with participants.
- We will communicate the agenda, checklist, and names of the assessment team members in advance of an assessment.
- We will communicate assessment findings with participants throughout the assessment visit.

Open-Minded:

- We will ensure that assessment team members strive to understand the participating laboratory's unique needs and that they consider those needs in decisions on conformance.

Respectful:

- We will treat every person with dignity and courtesy.

Staff, Consultants and Advisors

OLA permanent staff consists of a Director, four Staff Technologists, a Staff Coordinator and a Senior Administrative Assistant.

Accreditation Advisory Panel

The accreditation Advisory Panel consists of laboratory professionals of stature who have broad knowledge of laboratory operations, quality assurance practices, management skills, and who represent a cross-section of practitioners (Figure 3). Further advice is sought from additional experts as necessary. The panel reviews and approves operational policy, accreditation requirements, and recommends the issue of accreditation certificates.

Partnership with Standards Council of Canada

QMP-LS has an agreement with Standards Council of Canada for accreditation of medical laboratories outside the Province of Quebec.

The Standards Council of Canada (SCC) is a crown corporation established by an Act of Parliament in 1970, amended in 1996, to foster and promote efficient and effective voluntary standardization in Canada. The mandate of SCC is to promote the participation of Canadians in voluntary standards activities, promote public-private sector cooperation in relation to voluntary standardization in Canada, coordinate and oversee the efforts of the persons and organizations involved in the National Standards System, foster quality, performance and technological innovation in Canadian goods and services through standards-related activities, and develop standards-related strategies and long-term objectives.

Certain portions of the SCC accreditation program are provided in partnership with other organizations that are qualified and monitored on a regular basis by the SCC. In these cases, the partner organization receives the application and conducts the assessment of the applicant as well as the maintenance and surveillance activities. The

partner forwards a recommendation for accreditation to SCC.

Voluntary applicant medical laboratories are assessed by QMP–LS for recommendation to SCC for an ISO 15189 accreditation certificate. Licensed Ontario medical laboratories may choose to have the SCC issue certificates. (See “Agreement with Standards Council of Canada”).

Figure 3: Accreditation Advisory Panel Membership

Ms. Janice Nolan LifeLabs Toronto, Ontario	Dr. Godfrey Moses Gamma-Dynacare Medical Laboratories Toronto, Ontario	Mr. Tim Burns Ministry of Health and Long- Term Care Toronto, Ontario
Ms. Ruth C. Jaeger Eastern Ontario Regional Laboratory Association Ottawa, Ontario	Dr. William Brien Hospital for Sick Children Toronto, Ontario	Mr. Leo Tse Ministry of Health and Long- Term Care Toronto, Ontario
Ms. Mary Fountas University Health Network Toronto, Ontario	Dr. James Kerry MacDonald Lake of the Woods District Hospital Kenora, Ontario	Mrs. Linda Crawford QMP–LS Toronto, Ontario
Ms. Brenda Cutting Norfolk General Hospital Simcoe, Ontario	Mr. Richard Bedard Alexandra and Marine General Hospital Goderich, Ontario	Dr. Gregory Flynn QMP–LS Toronto, Ontario
Ms. Cathie McCallum St. Joseph's Hospital Hamilton, Ontario		

The Relationship between EQA and OLA

Accreditation is valid provided the laboratory demonstrates ongoing competence in EQA surveys conducted by QMP–LS and other appropriate proficiency testing (PT) or EQA bodies. OLA requires laboratories to participate in inter-laboratory comparisons, where available and appropriate, for all examinations included in the scope of accreditation.

QMP–LS offers extensive EQA that is mandatory for all Ontario medical laboratories and available to others. EQA is the determination of laboratory performance by means of inter-laboratory comparisons. QMP–LS’ EQA programs are designed to provide regular, objective and independent assessment of a laboratory’s ability to provide an acceptable standard of service by comparison with peers. It is meant to complement the laboratory’s quality control and quality assurance programs.

The EQA division of QMP–LS routinely provides the OLA division with records of Ontario laboratory participation and performance in EQA surveys as part of surveillance.

Laboratories holding accreditation certificates must provide OLA with evidence of participation and satisfactory performance in PT/EQA programs from other providers, as part of ongoing surveillance. (See “PT/EQA Surveillance”).

Accreditation Program Stakeholders

On an ongoing basis, key communications are sent to stakeholder groups, and they are encouraged to provide advice and counsel. A stakeholder committee called the QMP-LS Advisory Council exists to advise QMP-LS on policies and operations from a stakeholder perspective. The identified OLA stakeholders are:

- Canadian Society for Medical Laboratory Science
- Clinical Laboratory Management Association Trillium Chapter
- College of Medical Radiation Technologists of Ontario
- College of Medical Laboratory Technologists of Ontario
- College of Physicians and Surgeons of Ontario
- College of Respiratory Therapists of Ontario
- College of Nurses of Ontario
- Coroner of Ontario
- Ontario Association of Medical Laboratories
- Ontario Association of Pathologists
- Ontario Hospital Association
- Ontario Medical Association Section on Laboratory Medicine
- Ontario Society of Clinical Chemists
- Ontario Society of Medical Technologists
- Standards Council of Canada

Information About the Accreditation Process

Overview

OLA's assessment process uses peer volunteers to ensure that laboratories meet explicit quality management criteria, in order to provide formal recognition that the laboratory is competent to carry out examinations. Standards for accreditation are identified in advance. OLA's accreditation requirements translate the standards into explicit criteria for accreditation. Accreditation assessment visits determine if laboratories conform to requirements, for all examinations performed for diagnosis, prophylaxis and treatment of humans. Applicant laboratories designate the applicable scope under assessment. Ongoing surveillance (e.g. self assessment, PT/EQA monitoring) ensures that accredited laboratories continue to meet the requirements for accreditation. In Ontario and Newfoundland & Labrador, all activities and all premises associated with the scope of testing proposed for accreditation (classes of tests), are subject to accreditation assessment.

Agreement with Standards Council of Canada

In August 2005, an agreement was signed with the Standards Council of Canada (SCC) for the joint delivery of a national program for medical laboratory accreditation outside of Quebec. Under this agreement, SCC will impart national recognition of conformance and issue an accreditation certificate to ISO 15189. ISO 15189:2007 *Medical laboratories – Particular requirements for quality and competence*, is available from SCC as CAN-P-11. (See "Partnership with Standards Council of Canada").

A licensed Ontario medical laboratory wishing to have the SCC issue it an ISO 15189 certificate needs to inform QMP-LS when notified of its pending accreditation assessment visit. Additional conditions and fees will apply.

Eligibility

OLA accreditation is mandated for medical laboratories in Ontario and Newfoundland & Labrador. Medical laboratories from other jurisdictions in Canada and other countries are eligible to voluntarily apply for accreditation as long as applicants agree to the following conditions for attaining and maintaining accreditation:

1. Cooperate as is necessary to enable OLA to verify conformance with the requirements for accreditation. This includes providing access to information, documents and records as necessary for determination of impartiality, assessment and maintenance of accreditation. It also includes arranging witnessing of services during assessment.
2. Comply at all times with the criteria, requirements (including participation in proficiency testing as required), and conditions for accreditation.
3. Authorize full exchange of laboratory and assessment information between QMP-LS and SCC, for the purpose of granting accreditation.
4. Claim accreditation only in respect to the testing scope accompanying the certificate, which pertains to the scope of assessment.
5. Pay such fees as shall be determined by OLA and SCC. Costs associated with assessments are variable depending on the scope of assessment and the travel needs of the team members.
6. Not use its accreditation in such a manner as to bring OLA or SCC into disrepute and not make any statement relevant to its accreditation which OLA may consider misleading or unauthorized.
7. Upon suspension, withdrawal or expiration of its accreditation, discontinue its use of all advertising matter that refers to the accreditation status, and when requested, return any certificates of accreditation.

8. Inform OLA without delay and in writing of changes or pending changes in the:
 - legal, commercial, ownership or organizational status;
 - organization, top management or key personnel;
 - main policies;
 - resources and premises;
 - testing scope; and
 - miscellaneous matters that may affect the ability to fulfill accreditation requirements.

Enrolment Procedure

Licensed Ontario Laboratories

In Ontario, all licensed medical laboratories are required to meet accreditation requirements as a condition of licensure. When an Ontario laboratory applies to the MOHLTC for addition or deletion of classes of tests under *The Laboratory and Specimen Collection Centre Licensing Act*, this information is automatically downloaded to the OLA database.

Newfoundland & Labrador Medical Laboratories

OLA accreditation is mandated for medical laboratories in Newfoundland and Labrador, and registration is coordinated by regional health authorities.

Applicants for Voluntary Accreditation

Staff in a laboratory interested in voluntary accreditation should first acquire and become familiar with the OLA requirements. These are available through the Institute for Quality Management in Healthcare (IQMH). Visit IQMH online at www.IQMH.org to order. When ready, laboratory administration formally requests voluntary accreditation by OLA. OLA sends program information and an application, which requires payment of a non-refundable application fee. (see “Fees”).

Upon receipt of the application fee and completed application, OLA issues customized assessment checklists and requests that the laboratory conduct a formal self-assessment using the customized checklists and submit to OLA the resulting self-exception report. (See “The Self Assessment”).

NOTE: For voluntary accreditation, up to one year is allowed to transpire between the request for the initial self-assessment and receipt of the laboratory's self-exception report, until the application expires.

Upon receipt of the initial self-exception report, OLA reviews it to determine the laboratory's readiness for accreditation assessment. Generally, conformance to requirements of at least 85% must be met. The applicant laboratory is requested to submit its quality manual and demonstrate that it meets the quality management system requirements. When satisfied that the laboratory is ready, OLA initiates formal notification of the accreditation assessment visit, to be conducted within four months. If the voluntary laboratory prefers, a pre-assessment visit may be arranged.

Fees

- Voluntary applicants pay a non-refundable \$200.00 CAD application fee to cover the administrative costs associated with opening of the laboratory file and preparation of the customized checklist.
- Voluntary applicants pay all direct costs associated with accreditation assessment visits (inclusive of travel plus staff and volunteer labour associated with set-up, on-site assessment, insurance premiums and follow-up).

- For voluntary applicants, a 30% administration fee is added to assessment visit costs, to cover staff and volunteer labour associated with file reviews and self-assessment reviews, office supplies and postage/courier charges incurred by OLA.
- Upon issue of the ISO 15189 accreditation certificate by SCC, accredited laboratories pay an annual maintenance fee of \$1100. This annual fee is invoiced on the anniversary date of certificate issue, until such time that the certificate expires or is withdrawn.
- Accredited laboratories pay for surveillance visits (some exceptions apply).

QMP-LS Laboratory Identification Code

On enrolment, each laboratory is given a unique OLA identification code, which remains associated with that laboratory indefinitely.

Assessment Scope

OLA assesses medical laboratories against requirements based on the ISO 15189:2007 *Medical Laboratories – Particular requirements for quality and competence* and ISO 15190:2003 *Medical laboratories – Requirements for safety* standards. If point-of-care testing is included in accreditation, the ISO 22870:2005 *Point-of-care testing (POCT) – Requirements for quality and competence* standard also applies.

OLA's accreditation process includes regular accreditation assessment visits and self-assessments that occur mid-way between visits (and may result in a focused surveillance assessment visit).

Regular accreditation assessment visits and self-assessments encompass all aspects of laboratory practice. Program requirements are comprehensive and process-based. They focus on the management of quality to reduce errors. They require laboratories to implement inter-related processes that create a failure-resistant system in which it is difficult to do the wrong thing and easier to do the right thing. If mistakes occur, the root cause is determined and the process re-defined. Assessments validate that quality management processes are in place. Depending on the size and scope of the laboratory, an accreditation assessment visit will be 1–4 days in length.

Initial accreditation assessments, reassessments and self-assessments encompass all activities and all premises associated with the scope of testing proposed for accreditation (in Ontario, licensed classes of tests). A focused surveillance on-site visit may be conducted due to changes in laboratory ownership, location or menu of tests, self-assessment concerns, removal of Ontario licensed laboratories from the non-proficient list, imminent expiry of a 2-year certificate, or due to other concerns regarding a threat to patient safety. In these instances, the exact focus of the assessment is identified in advance. (See “The Surveillance Assessment Visit”).

Assessment Frequency

Regular accreditation assessment visits occur at minimum once every four years.

In those laboratories issued an ISO 15189 certificate from SCC, a surveillance assessment visit is conducted to examine the quality management system and status of previous non-conformances, one year after the initial certificate is issued.

Laboratories are required to complete a self-assessment mid-cycle and submit their report to OLA. Within two years of certificate issue, laboratories receive notification of self-assessments. Detailed results of the self-assessment must be documented along with deficiencies and corrective actions. Ongoing follow-up to address non-conformances assessed at the last accreditation assessment must also be reported. Results of the self-assessment are reviewed at OLA on receipt. A focused surveillance assessment visit is conducted if necessary, but usually findings are reviewed during the next scheduled accreditation assessment. (See “The Surveillance Assessment Visit”).

Corresponding with Laboratories

Official correspondence between participating laboratories and OLA is considered confidential and is conducted in writing. The individual named by the laboratory as designated correspondent receives all official communication, although technical correspondence may be delegated to the laboratory director(s), regional consultant, and/or site coordinator. When accreditation may be in jeopardy, the chief executive/owner/operator is informed. Summarized performance data is presented to committees and in publications with laboratory identification removed. When this is not possible (as is the case for accreditation assessment teams and corrective action review), all parties receiving the information are bound by confidentiality agreements to maintain confidentiality of information.

Assessment Visit Notification

Laboratories receive written notification (120 days) of each pending accreditation assessment visit and self-assessment. This includes reassessment visits and focused surveillance visits. (See “The Surveillance Assessment Visit”). OLA staff and directors set mutually agreeable dates for visits. Laboratories receive the names of all team members prior to visits and have the opportunity to reject members based on defined conflict of interest guidelines.

Notification of an upcoming accreditation assessment visit includes a pre-visit questionnaire. The completed pre-visit questionnaire assists OLA staff in coordinating the visit.

Quality Manual Review

Notification of an upcoming accreditation assessment visit includes a self-assessment form for the laboratory quality manual. The completed form is returned to OLA prior to the visit, with a copy of the quality manual. The quality manual is returned during the accreditation assessment visit.

Accreditation Team Members

Accreditation assessment teams consist of a team leader, an OLA staff technologist, and additional assessors as dictated by the size and scope of the laboratory. Teams are balanced to include physicians, scientists and medical laboratory technologists and to provide expert technical coverage for all disciplines involved. Teams include peers with the knowledge of laboratory operations and quality assurance practices, and who possess management skills and specialty technical expertise. All assessors receive advance training and certification.

Training, certification and recertification of assessors are based on the following seven competencies.

1. Familiarity with the OLA Requirements and Guidance Information and values
2. Knowledge of the accreditation 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 to conduct assessments according to OLA values

For each assessment visit, one member of the team is engaged to serve as the team leader. The Team Leader has the following duties (but may also serve as a technical assessor):

- Leading the assessment team
- Conducting the opening and summation meetings
- Making decisions relating to the assignment of non-conformances
- Representing the assessment team with the laboratory’s management
- Assisting in the drafting of the final report, approval of the report
- Review of corrective actions
- Review of errors of fact

- Preventing and resolving conflicts
- Providing guidance to technical assessors

To qualify as a team leader, an individual must:

- a) Meet the basic selection requirements for technical assessors
- b) Have completed at least three assessment visits
- c) Possess demonstrated knowledge of quality management systems; i.e., demonstrated during previous three assessments as a team member.
- d) Demonstrate the following interpersonal skills, through three positive assessment evaluations:
 - Diplomacy
 - Open- mindedness
 - Ability to reactive effectively to stressful situations
 - Communication and public speaking
 - Respectfulness

The Accreditation Assessment Visit

The team leader conducts an opening meeting with laboratory staff to review the accreditation assessment visit purpose and agenda. Accreditation team members assess the laboratory according to pre-assigned tasks (e.g. interviews, observation, document review) and each member completes the appropriate assessment tools (checklists) to determine conformance to program requirements. This process is detailed and comprehensive. At the conclusion of the visit, the team leader facilitates a summation meeting to review the findings and conclusions with administration, laboratory management and additional laboratory staff included by laboratory management. This verbal report outlines commendations and major/minor non-conformances.

Sampling and the Agenda

The visit agenda is created after a comprehensive review of the scope of testing of the laboratory and a pre-visit questionnaire. Particular attention is paid to hours of operation. Visits encompass all activities and all premises associated with the scope of testing proposed for accreditation (with the exception of some surveillance assessment visits).

The guidance provided to each assessor includes suggested sample sizes to ensure the assessor views a representative number of examples.

Multi-site Assessment Visits

Multi-site corporations may qualify for a single assessment, in which the application of shared management services and the quality management system are verified at each site. Team members visit all premises of the laboratory from which one or more key activities are performed and which are covered by the scope of accreditation. Some conditions apply to address travel and duration of the visit(s).

Assessment Report

A formal report of the accreditation assessment visit is issued to the recipient facility within 14 days of the accreditation assessment visit, with a spreadsheet on which the laboratory may submit any corrective action. It summarizes conformance and provides commentary to explain all incidences of non-conformance with the program requirements. Within two weeks of its receipt, the facility may dispute findings based on errors of fact.

Non-conformances are classified as either minor or major. (See “Decision Making and Granting Accreditation” for an explanation of their significance).

Minor non-conformance

- 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.

Major non-conformance

- 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.

Note: If on a subsequent assessment visit, a repeated non-conformance occurs for exactly the same reason, then that repeated non-conformance is categorized as a major.

Corrective Action

The facility must submit corrective actions to OLA with supporting documentation within 90 days of the accreditation assessment visit. OLA reviews the corrective actions and corresponds with laboratory staff if further clarification/documentation is required. Laboratory corrective action documentation is shared with the staff coordinator, team leader and Advisory Panel. The appropriate QMP–LS Scientific Committee(s) may be consulted for advice and determination of satisfaction in addressing outstanding technical issues.

Falsification of Documents or Records

Falsification of documents and records on the part of a participating laboratory may include misrepresentation or fraudulent altering of a document or record when submitted as evidence to support conformance to an accreditation requirement. This may occur during an accreditation assessment visit, or during the corrective action review following an assessment visit, or during review of self-assessment reports from laboratories. All suspected cases of falsification are investigated. The laboratory is informed in writing and no pending accreditation certificate will be issued until the dispute is resolved.

Decision-making and Granting Accreditation

The process for recommending accreditation is shown in the “Process – Accreditation Recommendation – OLA Decision Path” (See “Appendix B”). Decisions on accreditation are taken by competent persons different from those who carried out the assessment. OLA staff coordinators, team leaders, OLA Advisory Panel members review and assess the acceptability of corrective actions. Advisory Panel members and the Director, OLA recommend certificate issue to the QMP–LS Managing Director or SCC (Figure 4). Three options may result.

1. 4-year accreditation certificate issued
2. 2-year accreditation certificate issued
3. Intent to withdraw accreditation declared

Initial accreditation certificates are issued only after conducting an initial accreditation assessment visit encompassing all activities and all premises associated with the scope of testing proposed for accreditation. Corrective action is required. To maintain certificates of accreditation, laboratories must submit to all assessment visits described under “Assessment Frequency” and to ongoing surveillance of PT/EQA, and conduct a self-assessment on all activities conducted in conjunction with the scope of testing in each discipline subject to accreditation. (See “The Surveillance Assessment Visit” and “PT/EQA Surveillance”).

All major non-conformances must be resolved prior to issue of a 4-year certificate. If any major non-conformance is outstanding but there is a satisfactory action plan to address it, a 2-year certificate may be issued. Acceptable action plans to address minor non-conformances must be submitted prior to certificate issue, and ongoing follow-up reported at the next self assessment. If a minor non-conformance is still outstanding upon reassessment, it will be classified as a major non-conformance to ensure it is subsequently resolved.

Figure 4: Accreditation Recommendation, Based on Accreditation Assessment Findings and Follow-up

Scenario:	QMP-LS Action:	Follow-up
Laboratory submits a response within 90 days of assessment. All major non-conformances are resolved and action plan to address minor non-conformances is acceptable.	Issue 4-year Accreditation Certificate	Regularly scheduled self-assessment, applicable surveillance and accreditation assessment visit occur.
Laboratory submits a response within 90 days of assessment. Not all major non-conformances are resolved, but the action plan to address major and minor non-conformances is acceptable.	Issue 2-year Accreditation Certificate	Within the two years, a laboratory may apply to have a 2-year certificate replaced with a 4-year certificate, provided evidence is submitted substantiating all major non-conformances have been resolved. In some cases, a repeat accreditation assessment visit may be necessary.
Assessment findings adversely affect patient care and/or laboratory does not resolve all major non-conformances and/or does not submit an acceptable action plan for all major and minor non-conformances and/or there is conclusive evidence that the generally accepted standard cannot be met.	Recommend Intent To Not Issue Certificate or To Withdraw Accreditation	File referred to Conjoint Committee/government regulator, and/or Standards Council of Canada if applicable.

Dispute Resolution

Laboratories have the right to appeal accreditation assessment and associated decisions regarding accreditation status. Appeals must be submitted in writing, and are reviewed by a multi-disciplinary and impartial panel.

Certificate of Accreditation and Accompanying Scope of Accreditation

An accreditation certificate is issued with a scope of accreditation, which lists the classes of tests, the number of tests, and testing details. The accreditation certificate includes the name and logo of the accreditation body*, laboratory name, address(es), unique identifier(s), assessment date(s), issue date and expiry date with reference to the applicable version of the OLA requirements, ISO standards, scope and conditions of accreditation. The Managing Director of QMP-LS (or in the case of ISO 15189 certificates, the Chairman of SCC) signs the accreditation certificate.

A change in the laboratory name (in Ontario ownership without a change in the licence number) prompt issue of a revised accreditation certificate and a revised scope without reassessment. Addition of classes of tests may prompt reassessment before a new certificate and scope can be issued. Other changes in laboratory ownership and location may require a surveillance assessment visit before a new certificate and scope can be issued. (See “The Surveillance Assessment Visit”).

* OLA and if applicable, SCC

Use of Logos and Claims of Accreditation Status

Accredited laboratories are reminded that the certificate of accreditation applies only to the scope of testing at the time of assessment. Claims that accreditation extends to additional testing or other unauthorized references to accreditation may result in withdrawal of accreditation, or other legal sanctions.

Once accredited, a laboratory may wish to make reference to its accreditation status on reports or for promotional purposes, on stationary or on work proposals. The following conditions govern the use of accreditation logos or references:

- Accreditation logos are provided on request
- Accreditation logos or references to accreditation can not be used by a laboratory’s subcontractor which is not accredited
- Accreditation logos or references to accreditation can not be used by applicants for accreditation
- Accreditation logos or references to accreditation can be used only under the name in which the laboratory holds accreditation
- Where examinations outside the scope of accreditation are included on a report, they must be clearly identified as such with a clear disclaimer (e.g. “This laboratory is not accredited for the examinations marked *)
- There should be nothing in any report, certificate, attachment or other material which implies, or may lead any user of the results or any interested party to believe, that the work is accredited when in fact it is not.

List of Accredited Laboratories

OLA maintains a list of all laboratories that are granted accreditation, along with the current status of accreditation and the applicable scope of testing. This list is publicly available on the QMP-LS Web site at http://www.qmpls.org/ola/ola_accruited.htm.

Surveillance

Surveillance of accredited laboratories involves the monitoring of:

- changes in laboratory ownership, management and location (See “The Surveillance Assessment Visit”)
- interlaboratory comparison (PT/EQA) participation and performance (See “PT/EQA Surveillance”); and
- complaints.

Complaints are investigated promptly and the laboratory is informed of any complaints.

The Surveillance Assessment Visit

A surveillance assessment visit (focused) occurs one year after the initial issue of an ISO 15189 certificate by SCC, and otherwise may be initiated upon:

- New laboratory ownership or laboratory address
- Issues with ongoing competency/proficiency
- Request due to a potential threat to patient safety (from the facility or government regulator)
- Addition of a class of tests to the test menu
- Self-assessment findings that demonstrate no intent to implement corrective actions or that raise other concerns regarding patient care
- Imminent expiry of a 2-year certificate

Surveillance assessment visits will occur within six months of the change or request. The direct costs associated with a surveillance assessment visit will be billed to the laboratory (some exceptions apply).

For voluntary accreditation laboratories, a surveillance assessment visit (focused) may occur to verify self assessment findings submitted two years following the accreditation assessment, and the laboratory is invoiced for costs.

PT/EQA Surveillance

Participation in and performance on formal inter-laboratory comparison, i.e., proficiency testing/external quality assessment (PT/EQA), are monitored on an on-going basis. Laboratories holding accreditation certificates must participate in formal inter-laboratory comparison schemes, where available and appropriate, for all examinations included in the scope of accreditation.

Laboratories holding accreditation certificates must provide OLA with evidence of participation and satisfactory performance in PT/EQA programs from other providers, as part of ongoing surveillance. OLA provides a form on which accredited laboratories submit this information. Satisfactory performance is defined as acceptable results on the majority of samples in a single survey. Over time, satisfactory performance is defined by satisfactory performance in the majority of surveys.

Formal inter-laboratory comparison programs (PT/EQA) must provide challenges of undisclosed assay value or content, and also provide evaluation of the laboratory performance on submitted results, e.g., provide comparison of results for like methods and different methods with a score and/or judgement of performance. Formal interlaboratory comparison programs shall provide a minimum of four sample challenges in a 12-month period. It is the responsibility of the laboratory director to ensure that the testing schedule adequately challenges test performance. Formal programs known to OLA that meet the above criteria are published on the QMP-LS Web site at http://www.qmpls.org/ola/ola_list_of_approp_PT_EQA_providers.html. Additional programs that meet these

criteria should be submitted by e-mail to ola@qmpls.org and will be added to the list.

When formal inter-laboratory comparison programs are not available, accredited laboratories are expected to find an alternative such as split sample testing. The alternative shall occur at least twice per year with a minimum of two samples each time. Examples of alternatives can be obtained in the following Clinical Laboratory Standards Institute document: *Assessment of Laboratory Tests when Proficiency Testing is Not Available*; Approved Guideline, NCCLS Document GP29-A December 2002.

Laboratories must also demonstrate that corrective actions identified through these activities are carried out when necessary.

The Self Assessment

Self-assessments are intended to assist laboratories in determining the degree to which they meet accreditation requirements. Self-assessments ensure that:

1. Laboratories continue to monitor their own conformance to accreditation requirements.
2. QMP-LS can identify the degree to which laboratories meet requirements and monitor corrective action plans.
3. QMP-LS can determine requirements that may be difficult to achieve.

OLA formally coordinates the self-assessment process by requiring that laboratories perform self-assessments and report their findings in exception reports. Ongoing follow-up to address non-conformances assessed at the last accreditation assessment must also be reported. Detailed instructions and a customized checklist are provided with the 120-day notification. Self-assessment exception reports are reviewed by OLA. Following review, laboratories receive correspondence that confirms receipt of reports and provides a summary of conformance.

For voluntary accreditation, a focused surveillance assessment visit may be conducted to verify the findings. Submitted reports are retained in accreditation files, and details of self-assessments are reviewed during the next scheduled accreditation assessment visits.

The Surveillance Questionnaire

A surveillance questionnaire is sent to laboratories issued an ISO 15189 certificate by SCC on the years when there is no self-assessment or surveillance assessment visit.

Information About the OLA Requirements and Guidance Information

Accreditation Requirements and Guidance Information

Program requirements are based on the following International Organization for Standardization (ISO) standards:

ISO 15189:2007 Medical laboratories — Particular requirements for quality and competence

ISO 15190:2003 Medical laboratories – Requirements for safety

ISO 22870:2006 Point-of-care testing (POCT) – Requirements for quality and competence

In addition, these Canadian national standards are also fully addressed:

CAN/CSA-Z15190-05 Medical Laboratories – Requirements for Safety

CSA Z902-04 Blood and Blood Components March 2004

Requirement development was aided by cross-referencing these standards to generally accepted principles of good practice in Ontario. As a result, additional documents are also referenced:

- Canadian Statutes and Regulations (for laboratories located outside Canada, local regulations apply)
- Provincial Statutes and Regulations
- Health Canada Guidelines
- Standards and guidelines achieved through consensus by international, North American, Canadian and provincial associations, federations, organizations and regulatory bodies.

Each accreditation requirement has an accompanying reference source. Additional good practice recommendations are included with the requirements.

Accompanying each requirement and good practice recommendation is “What To Look For” guidance information that explains the intent of the requirement and provides insight into its application. Usually, this guidance information is phrased as a question, and may include an indication of documents and records required to meet the requirements. Discipline-specific technical detail is incorporated within the requirements as “What To Look For” guidance, and represents application of the requirements to individual discipline practice. This discipline specific information encompasses key details that the peer assessors will consider, but it should not be considered all-inclusive. Individual assessors apply their own knowledge and expertise when assessing whether a laboratory meets requirements.

The Ontario Laboratory Accreditation (OLA) Requirements and Guidance Information are available to accreditation applicants and accredited laboratories through QView™. The posted files may be accessed with a username and password by logging into QView™ at www.qmpls.org. Assistance with login may be obtained by contacting ola@qmpls.org. Other parties may purchase them through the Institute for Quality Management in Healthcare (IQMH). Please visit IQMH online at www.IQMH.org to learn more.

Revisions/Review of the Requirements

A review of requirements occurs every year. Supporting reference sources are reviewed, updated and their impact (if any) on the wording of requirements is assessed to determine the necessity for a new version of the requirements. At minimum, a new version of the requirements is released once every three years. Any laboratory may offer suggestions regarding the suitability of a requirement at any time, ongoing feedback is recorded and reviewed regularly. The OLA Advisory Panel investigates and addresses challenges as needed.

List of Accredited Laboratories

Visit http://www.qmpls.org/ola/ola_accredited.htm for OLA accredited laboratories. This list of accreditation certificates granted includes information and reports showing laboratory information, laboratory location, owner information, certificate issue date and scope of testing.

Information For Ontario Laboratory Accreditation (OLA) Assessors

Visit http://www.qmpls.org/ola/ola_assessors.html for Assessor General Information.

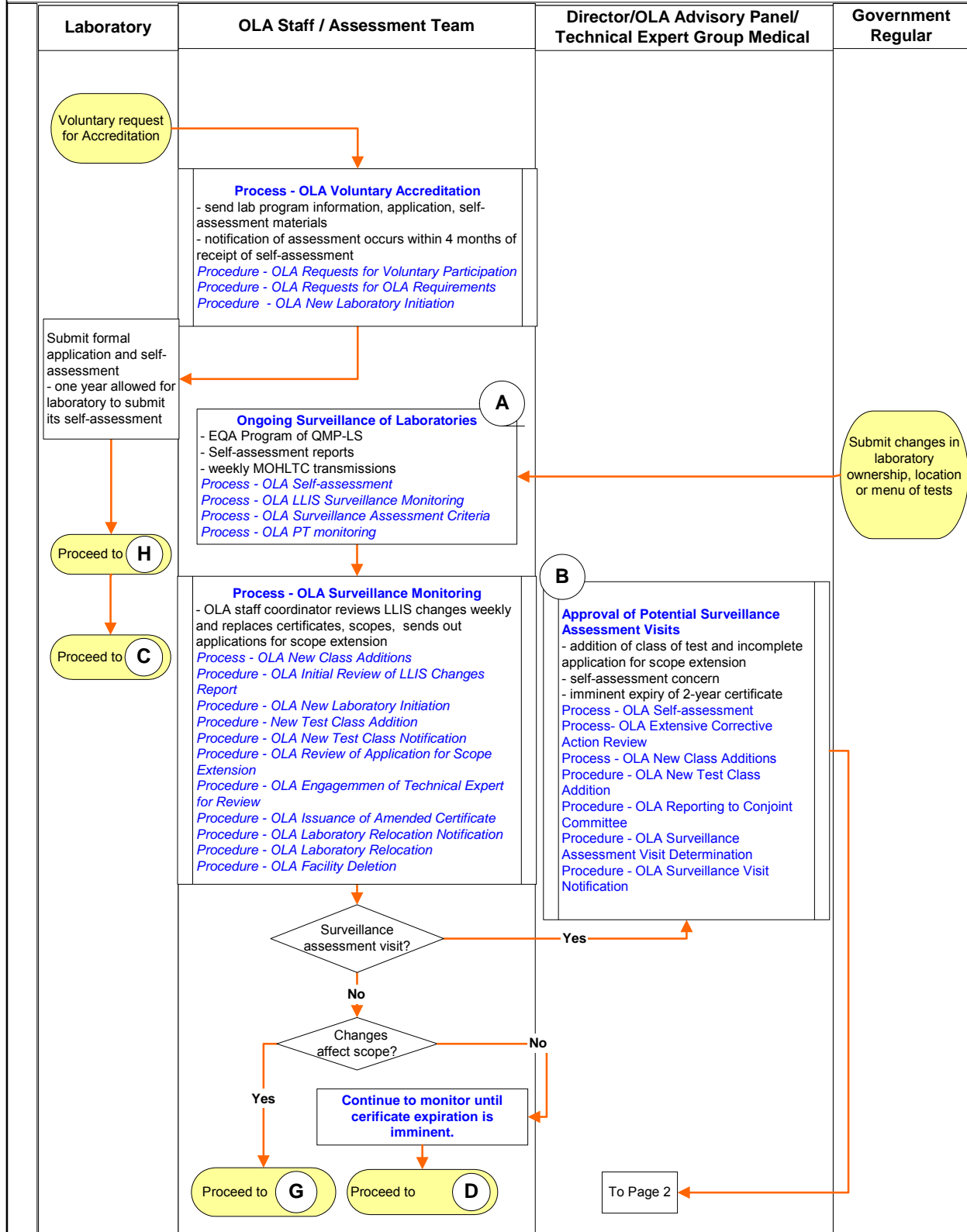
Information About Educational Activities and Tools

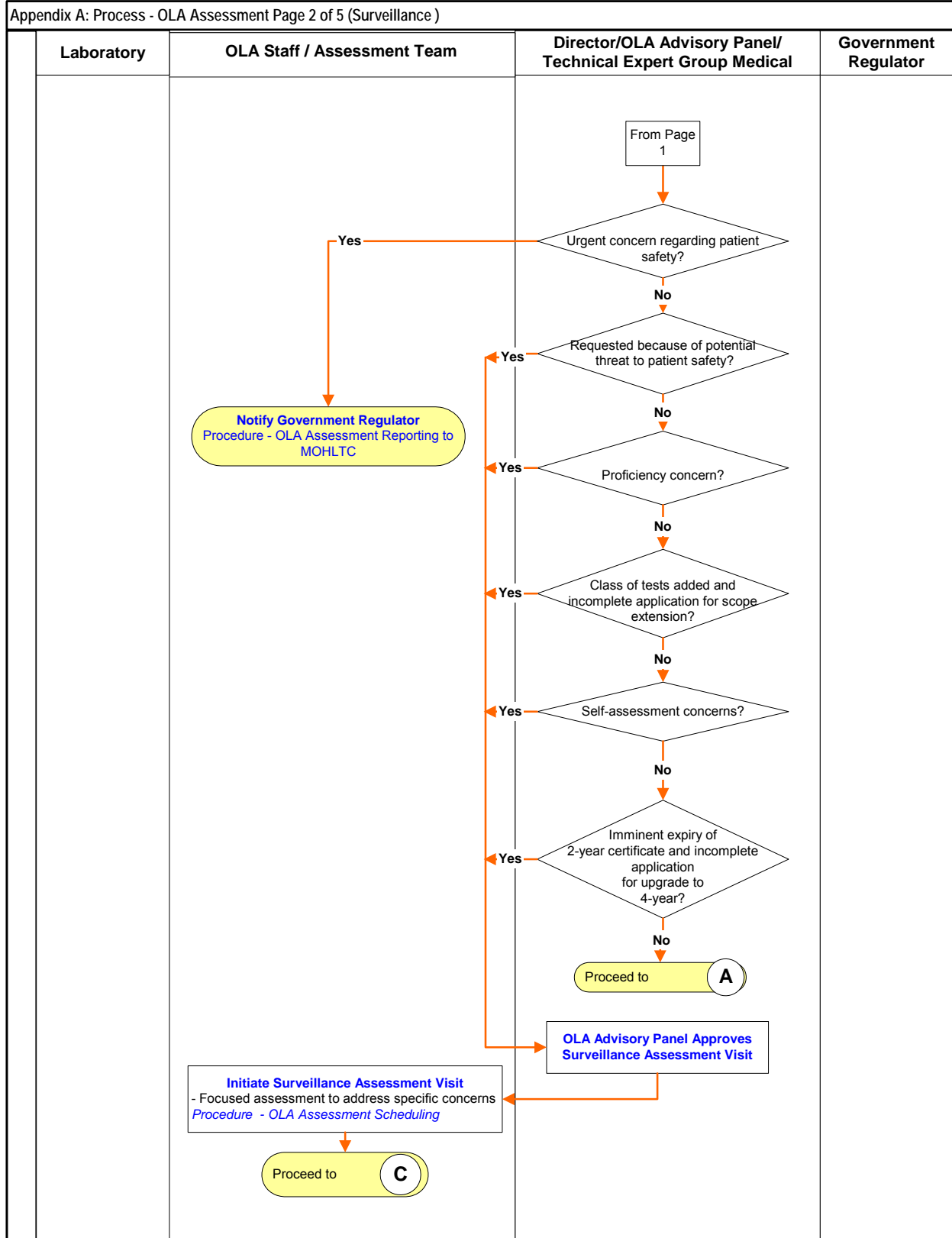
Visit http://www.qmpls.org/ola/ola_educational.html for current information on Educational Activities and Tools.

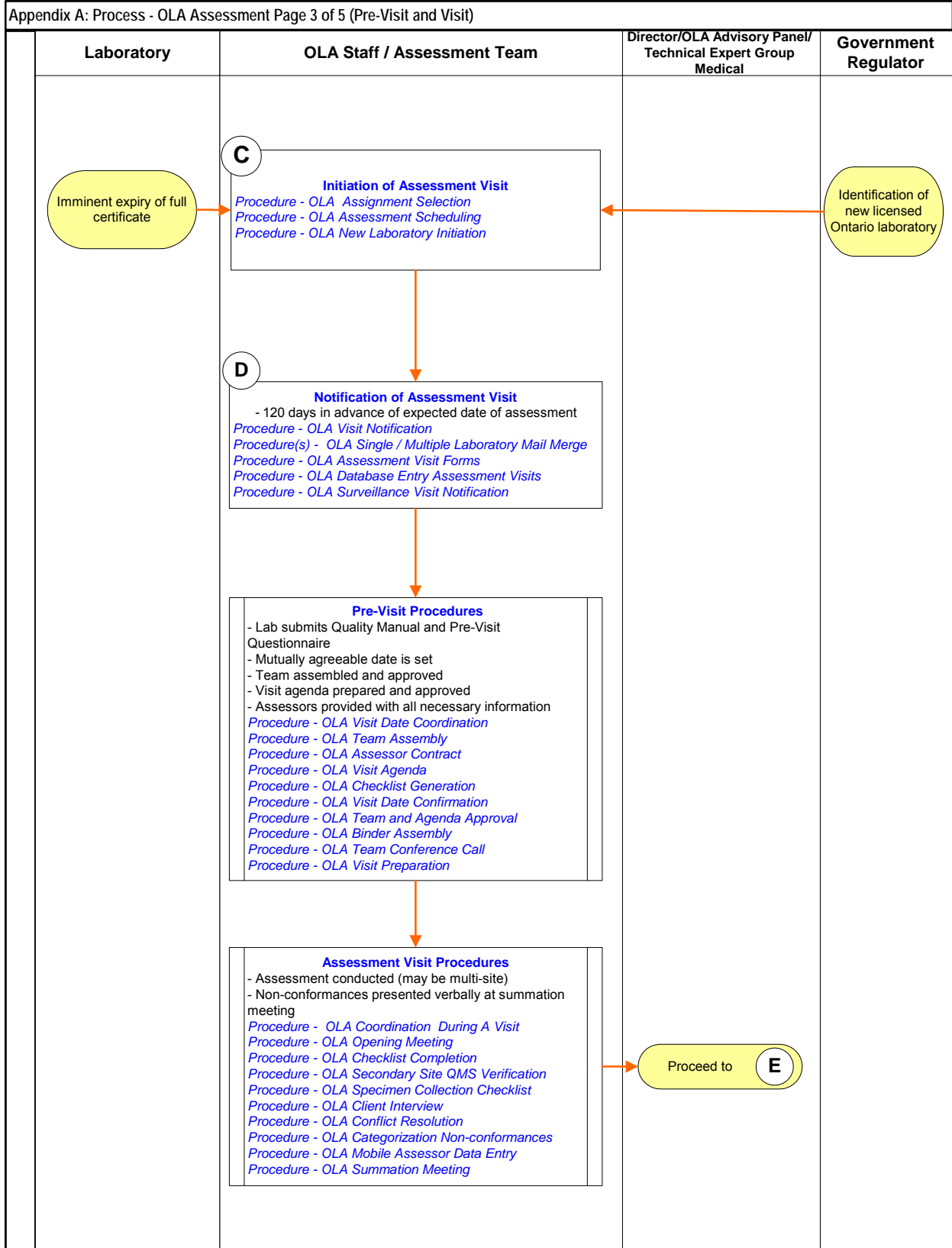
Frequently Asked Questions

Visit http://www.qmpls.org/ola/ola_frequently_asked.html for Frequently Asked Questions

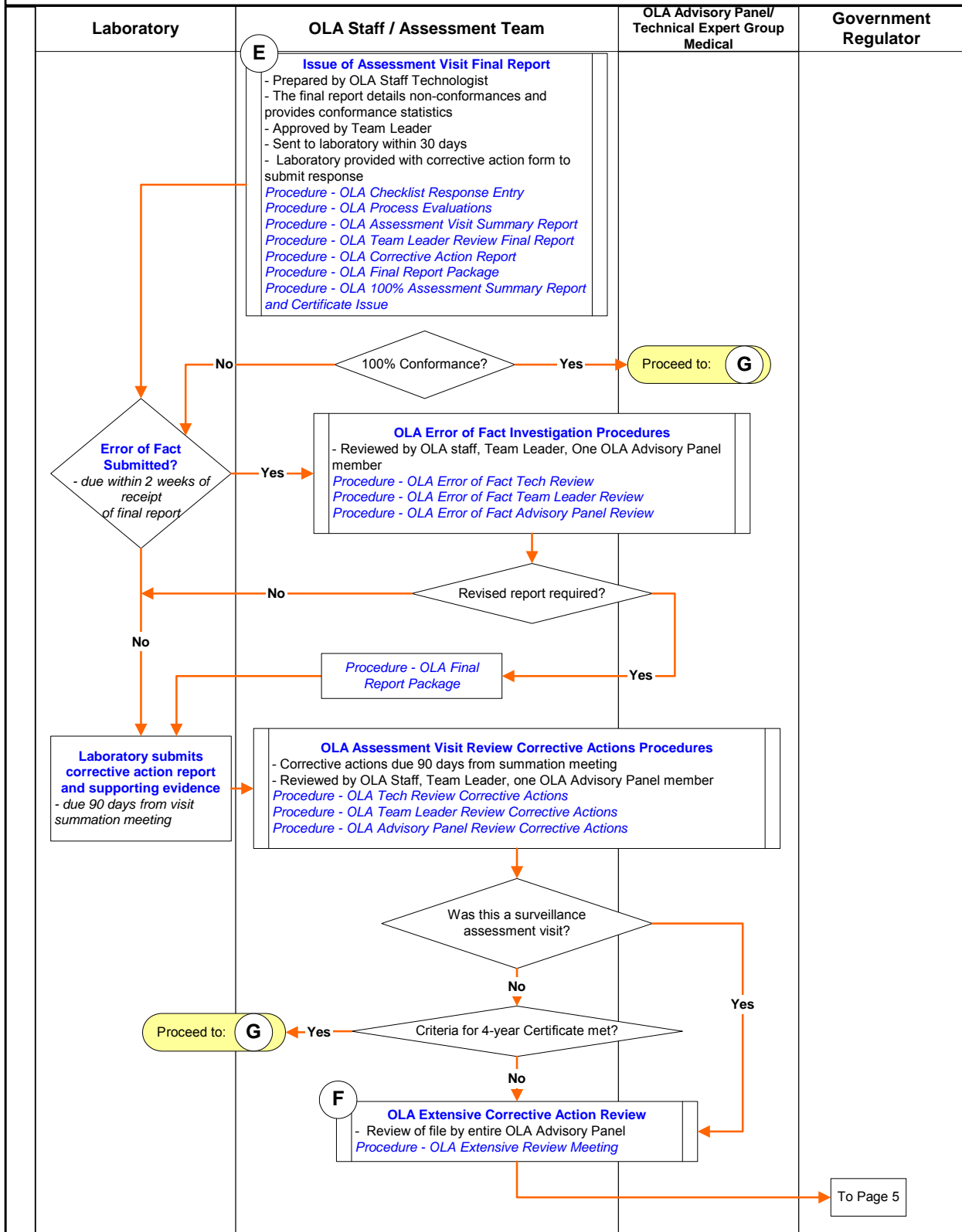
Appendix A: Process - OLA Assessment Page 1 of 5 (Surveillance)



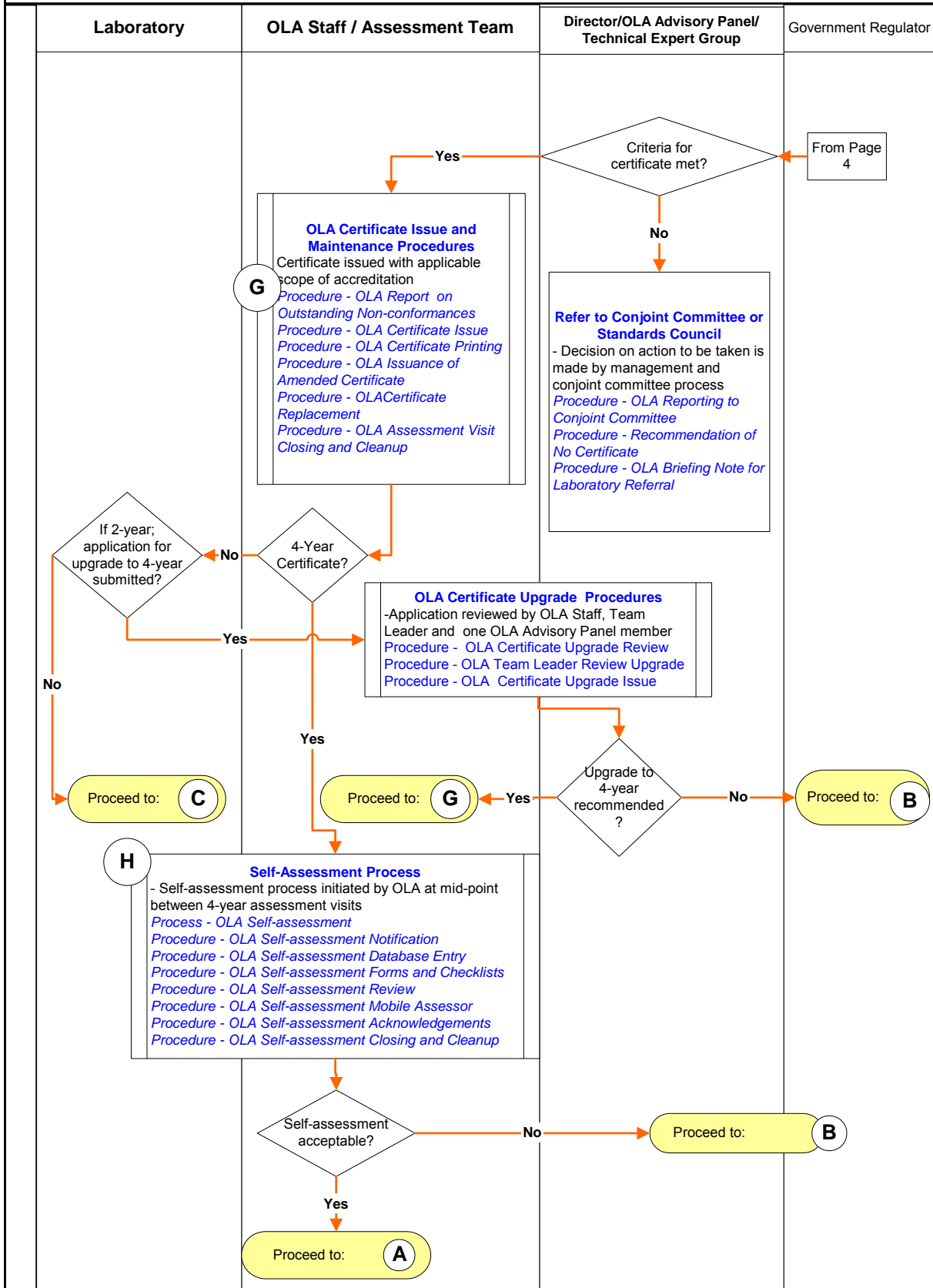




Appendix A: Process - OLA Assessment Page 4 of 5 (Final Report and Corrective Actions)



Appendix A: Process - OLA Assessment Page 5 of 5 (Certificate Issue and Self-assessment)



Appendix B: Process - OLA Certificate Issue & Recommendation of Withdrawal of Accreditation

