



DIAGNOSTIC ACCREDITATION PROGRAM

College of Physicians and Surgeons of British Columbia

300-669 Howe Street
Vancouver BC V6C 0B4
www.dap.org

Telephone: 604-733-7758 ext. 2635
Toll Free: 1-800-461-3008 (in BC)
Fax: 604-733-3503

2015 Laboratory Medicine Accreditation Standards FAQ

If you have questions about items in the standards please email them to:

laboratorymedicine@cpsbc.ca

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FAQ Quality Management Systems

With the inclusion of ISO 15189 *Medical laboratories — Requirements for quality and competence*, the 2015 laboratory medicine accreditation standards require organizations and facilities to implement and maintain a quality management system.

What is ISO?

ISO is the International Organization for Standardization, an independent, non-governmental standard setting body composed of representatives from various national standards organizations headquartered in Geneva Switzerland. ISO promotes worldwide standards. One of the documents developed and maintained by ISO is ISO 15189 *Medical laboratories — Requirements for quality and competence*. Based on feedback from BC laboratory medicine stakeholders, the 2013 Laboratory Reform Committee's Laboratory Services Plan recommended adoption of ISO 15189 and movement to an accreditation program that is ISO 15189 compliant. This recommendation was endorsed by the DAP Committee in 2014.

What is a quality management system?

Let's take one step back first. Quality management ensures that an organization and its products and services are consistent. There are four main components of quality management: quality planning; quality control; quality assurance; and quality improvement. A quality management system is the organizational structure, policies, processes and procedures needed to implement quality management.

What are the quality management system responsibilities of a laboratory?

Under the requirements of ISO 15189, laboratories must:

- establish, maintain and improve a quality management system
- define a quality policy
- appoint or select a quality manager
- establish a quality manual
- control documents
- control records
- establish procedures for the selection, evaluation and monitoring of referral laboratories and consultants
- establish procedures for purchased external services and materials
- manage nonconformities and potential nonconformities
- conduct internal audits
- conduct periodic management review

What references are available for the establishment of a quality management system?

- International Standards Organization. *Medical laboratories: Requirements for quality and competence*. ISO 15189. Geneva: International Standards Organization; 2012.
- Clinical and Laboratory Standards Institute (CLSI). *Quality management system: a model for laboratory services; approved guideline*. 4th ed. CLSI document QMS01-A4. Wayne (PA): Clinical and Laboratory Standards Institute; 2011.

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FAQ Quality Policy

With the inclusion of ISO 15189 *Medical laboratories — Requirements for quality and competence*, the 2015 laboratory medicine accreditation standards require organizations and facilities to define a quality policy.

What is a quality policy?

A quality policy is a formal expression by laboratory management of the overall intentions and direction of a laboratory related to quality.

How is a quality policy different from the mission, vision and values of the organization?

While an organization's mission, vision and value statements reflect the overall goals of the service, the quality policy defines the laboratory's overall philosophy with respect to quality and the expected outcomes from the quality management system.

Where is the quality policy addressed in the DAP standards?

The quality policy is addressed in QMS1.1 of the 2015 laboratory medicine accreditation standards which states:

- a quality policy has been defined for the quality management system
- the quality policy defines the intent of the quality management system and is appropriate to the purpose of the organization
- the quality policy includes a commitment to good professional practice, examinations that are fit for intended use and continual improvement of the quality of laboratory services
- the quality policy provides a framework for establishing and reviewing quality objectives
- the quality policy is communicated and understood within the laboratory
- the quality policy is reviewed for continuing suitability and revised as appropriate
- the quality management system provides for the integration of all processes required to fulfill its quality policy and objectives

What references are available for quality policy?

- International Standards Organization. Medical laboratories: Requirements for quality and competence. ISO 15189. Geneva: International Standards Organization; 2012.

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FAQ Quality Manual

With the inclusion of ISO 15189 *Medical laboratories — Requirements for quality and competence*, the 2015 laboratory medicine accreditation standards require organizations and facilities to develop and maintain a quality manual.

Where is the quality manual addressed in the standards?

The requirements for a quality manual are detailed in QMS 1.4 which states the laboratory has established and maintains a quality manual, that the quality manual is reviewed at defined intervals, and

that all laboratory personnel have access to and instruction on the quality manual. Furthermore the standards state that the quality manual includes:

- the quality policy
- a description of the scope of the quality manual
- a presentation of the organization and management structure of the laboratory and its place in any parent organization
- a description of the roles and responsibilities of laboratory management for ensuring compliance with ISO 15189
- a description of the structure and relationships of the documentation used in the quality management system
- documented policies for the quality management system

How is the quality manual different from a procedure manual?

The quality manual describes the quality management system using policies and management processes. Procedures are not included in the quality manual, but may be referenced when appropriate. Using the 2015 laboratory medicine accreditation standards as a guideline, a **suggested** table of contents might include (in addition to the bulleted items above):

- introduction
- scope of service
- document control
- management of quality and technical records
- management of instruments, supplies and consumables
- quality control, quality assurance and proficiency testing
- verification of comparability
- validation of examination procedures and results
- external resources
- nonconformities and potential nonconformities
- internal audits
- management review
- medical peer review
- communication with and handling feedback from users, patients and personnel

What references are available for the establishment of a quality manual?

- International Standards Organization. Medical laboratories: Requirements for quality and competence. ISO 15189. Geneva: International Standards Organization; 2012.

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FAQ Quality Manager

With the inclusion of ISO 15189 *Medical laboratories — Requirements for quality and competence*, the 2015 laboratory medicine accreditation standards require organizations and facilities to appoint or select a quality manager.

What does the quality manager do?

According to the 2015 laboratory medicine accreditation standards, the quality manager:

- ensures that processes needed for the QMS are established, implemented and maintained
- reports on the performance of the QMS and any need for improvement to the level of laboratory management where decisions are made on laboratory policy and resources
- promotes awareness of users' needs and requirements throughout the laboratory
- assumes responsibility for POCT, if no POCT quality manager has been identified
- reviews results of internal audits along with the medical director or designate

Who can be a quality manager and who does the quality manager report to?

The DAP standards refer to “a quality manager (or otherwise titled).” The quality manager does not require that specific title and the quality manager does not have to be a specific position within the laboratory. The duties of a quality manager can be fulfilled by a person in another position. The laboratory should select or appoint the best candidate available for the position of quality manager. Organizations are required to maintain an up-to-date organizational chart that includes the quality manager.

Does every laboratory need a separate quality manager?

There is not a requirement for a quality manager at every facility, but a quality manager should have responsibility for each and every facility.

The standards address a quality manager for POCT. Does this have to be the same person as the quality manager for the QMs?

The quality manager responsible for POCT can be a separate individual, and the duties for this position can be performed by someone in a different position. The quality manager for POCT may not even come from the laboratory.

What references are available for quality managers?

- International Standards Organization. *Medical laboratories: Requirements for quality and competence*. ISO 15189. Geneva: International Standards Organization; 2012.

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FAQ Measurement Uncertainty

What is measurement uncertainty?

Measurement uncertainty is a calculated parameter of quality for any measurement. This is often calculated using quantity values obtained by the measurement of QC materials under intermediate precision conditions that includes as many routine changes as routinely possible.

When samples are examined over and over again, there is often inconsistency in results. Random differences of the measuring conditions will lead to variable results if the measuring system is sensitive enough. That result variability must be quantified so those who produce the examination results and those who receive examination results have an objective estimate of the quality of results produced by the laboratory. Understanding measurement uncertainty allows meaningful comparison with the results of other similar measurements made at different times using the same measuring system and provides a framework estimating the reliability of results produced by a measurement system.

Where is measurement uncertainty mentioned in the DAP standards?

Measurement uncertainty is addressed within EXA3.2 of the 2015 laboratory medicine accreditation standards. The standards require laboratories to:

- determine measurement uncertainty for each quantitative measurement procedure
- define performance requirements for measurement uncertainty for each quantitative measurement procedure
- review estimation of measurement uncertainty at defined intervals
- consider measurement uncertainty when interpreting measured quantitative values
- provide measurement uncertainty to users upon request

What are the responsibilities of a laboratory in estimating and reporting measurement uncertainty?

Laboratories should become familiar with the concept of measurement uncertainty and create a practical approach to developing estimates of measurement uncertainty. There are a number of strategies that can be employed to estimate measurement uncertainty. Laboratories will need to verify the model used to calculate measurement uncertainty and understand when and how to report uncertainty of measurement.

What references are available for estimating and reporting measurement uncertainty?

- Clinical and Laboratory Standards Institute, Expression of Measurement Uncertainty in Laboratory Medicine; Approved Guideline, Wayne, PA: CLSI; 2012
- International Standards Organization, ISO/IEC Guide 98-3 Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995), Geneva, Switzerland: ISO; 2008

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FAQ Safety Inspections and Audits

What are safety inspections and audits and how do they differ?

A safety inspection is a routine, assessment of the general working conditions. Safety inspections often involve the use of a standardized checklist to assess the physical safety of the laboratory including items such as emergency eyewashes, spill kits, the storage of flammables, etc.

A safety audit is a review covering the basic elements and activities of safety within the facility. An audit often includes interviews, documentation review and first-hand observation. Examples of safety audits include hand hygiene, the use of PPE, environmental decontamination, etc. Safety audits may be comprehensive or may only cover a specific element of safety.

Where are safety inspections and safety audits mentioned in the DAP standards?

Safety inspections are mentioned in SAF2.1 of the 2015 laboratory medicine accreditation standards.

SAF2.1.1 **M** Safety inspections are conducted monthly.

WorkSafeBC states inspections must be carried out regularly, and will not define a required frequency of inspections given the vast range of work environments within the province of BC. However WorkSafeBC states that safety inspections are conducted at an interval that allows for timely reporting to the monthly joint occupational health and safety committee or health and safety representative.

Furthermore, WorkSafeBC states they provide minimum guidelines and encourage regulatory bodies to exceed these when appropriate. Finally, WorkSafeBC has identified that plumbed-in safety devices such as eyewashes and showers are required by regulation to be inspected and flushed monthly as a minimum, and that if this activity was to be considered by the regulatory body as part of the safety inspection, then inspections must be conducted monthly at a minimum.

Safety audits are mentioned in SAF1.1 and SAF2.1 of the 2015 laboratory medicine accreditation standards.

SAF1.1.17 The safety program includes an audit conducted at least annually.

Guidance: The audit should include the following: safety and health policy; written safe work practices; safety education and training; supervision of safety; regular inspections; hazardous materials; health surveillance; first aid services and equipment; accident and illness investigation; health and safety committee review; and records and statistics.

SAF2.1.6 **M** The laboratory has defined safety audits of work methods or practices to identify and resolve safety hazards (e.g. hand hygiene, use of PPE, decontamination processes).

What are the responsibilities of a laboratory in conducting safety inspections and audits?

Laboratories should identify what safety elements are to be inspected monthly, and then must conduct a monthly safety inspection. Safety elements subject to less frequent inspection should be identified and inspected at a frequency determined by the laboratory. Records of these safety inspections are to be retained for a time frame defined by the laboratory, facility or health authority.

With regard to safety audits, laboratories must comply with any specific safety audit requests from their facility, health authority, regulatory bodies or government. Records of these safety audits are to be

submitted as required and retained for a time frame defined by the laboratory, facility, health authority or requesting body.

As a best practice, laboratories may choose to undergo a comprehensive safety audit on an annual basis.

What references are available for laboratory safety inspections and safety audits?

- Worker's Compensation Board of BC. WorkSafeBC [Internet]. Worker's Compensation Board of BC; c2015 [cited 2015 Jun 30]. Available from: <http://www.worksafebc.com/>.
- International Standards Organization. Medical laboratories: requirements for safety. ISO 15190. Geneva: International Standards Organization; 2010.
- Clinical and Laboratory Standards Institute (CLSI). Clinical laboratory safety; approved guideline. 3rd ed. CLS document GP17-A3. Wayne (PA): Clinical and Laboratory Standards Institute; 2012.
- Clinical and Laboratory Standards Institute (CLSI). Assessments: laboratory internal audit program; approved guideline. CLSI document QMS15-A. Wayne (PA): Clinical and Laboratory Standards Institute; 2013.

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FAQ Evaluation of Supplies and Suppliers

The quality of the services a laboratory provides is determined by many elements. Supplies, including reagents and consumables should be carefully selected and subsequently monitored.

What are the responsibilities of a laboratory in the evaluation of supplies and suppliers?

Evaluation of suppliers is addressed in QMS3.3 of the 2015 laboratory medicine accreditation standards. The standards require laboratories to:

- have procedures for the selection and purchase of external services, equipment, reagents and consumables that affect the quality of examinations
- select and approve suppliers using established criteria based on the supplier's ability to provide external services, equipment, reagents and consumables in accordance with the laboratory's requirements
- maintain a list of selected and approved suppliers
- monitor the performance of suppliers to ensure that purchased products and services consistently meet the stated criteria

What are the differences between the 2010 and 2015 standards in regards to the evaluation of supplies and suppliers?

This is a completely new addition to the standards, and it is required by ISO 15189.

What if we have limited choice in the selection of suppliers within our regional system?

Limited input into supplier selection does not remove the laboratory's responsibility to establish the necessary characteristics for quality and to pass those along to purchasing departments or the requirement to evaluate and monitor supplies provided by vendors.

What references are available for the evaluation of supplies and suppliers?

- Clinical and Laboratory Standards Institute (CLSI). Quality management system: a model for laboratory services; approved guideline. 4th ed. CLSI document QMS01-A4. Wayne (PA): Clinical and Laboratory Standards Institute; 2011.
- International Standards Organization. Medical laboratories: Requirements for quality and competence. ISO 15189. Geneva: International Standards Organization; 2012.

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FAQ Verification of Comparability

What is verification of comparability and why is it important?

Verification of comparability is a process that ensures examination results produced by different measurement systems are equivalent and within acceptable criteria. Patients may present for laboratory examination at multiple locations within the health-care system. Laboratories may have multiple instruments within one location that may provide examination results for an individual patient. Continuity of medical care requires that the comparability of examination results produced by different measurement systems is verified periodically. Maintaining comparability involves standardization and calibration of instruments, forced agreement of results among different measurement systems through mathematical transformation, or adoption of different reference intervals and therapeutic or diagnostic cutoffs that are clearly indicated in the patient report. Regardless of the approach used, periodic verification of examination comparability is necessary to provide optimal patient care.

Where is comparability mentioned in the DAP standards?

Verification of comparability is addressed within QUA3.1 of the 2015 laboratory medicine accreditation standards. The standards require laboratories to:

- establish comparability of procedures, equipment and methods used, and establishing the comparability of results for patient samples
- apply comparability to the same or different procedures, equipment, different sites or all of these
- encompasses comparability for the entire range of clinically relevant values
- define acceptability criteria for comparability of procedures, equipment and methods
- document, record and act upon results from comparability
- check instruments and methods against each other at least twice a year for comparability of results

What are the differences between the 2010 and 2015 standards in regards to comparability?

The 2010 standards required comparability to be carried out only within a single facility. The 2015 standards now require that procedures, equipment and methods used are compared to the same or different procedures, equipment, different sites or **all** of these. This effectively means that comparability is required across all of the organizations analytical facilities.

What references are available for verification of comparability?

- CLSI EP31-A-IR Clinical and Laboratory Standards Institute, Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (Interim Revision), Wayne, PA: CLSI; 2012
- International Standards Organization. Medical laboratories: Requirements for quality and competence. ISO 15189. Geneva: International Standards Organization; 2012.

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FAQ Point-of-Care Testing (POCT)

What is considered point-of-care testing (POCT)?

POCT is defined by the location where a laboratory examination is performed. Any laboratory examination performed outside of the confines of the conventional laboratory is considered POCT irrespective of the person performing the examination, the examination method, the intent of the examination or the time of the examination.

Who can perform POCT?

The standards do not define any specific occupational groups that can or cannot perform POCT. However, for all POCT, the standards require:

- an appropriate theoretical and practical training program
- a competency assessment
- that POCT is performed by personnel who have completed training and demonstrated competence
- there is a procedure for dealing with non-compliant POCT operators

Should the individual performing POCT also be the person that performs QC?

In general, personnel performing laboratory examinations should also be the individuals performing QC. As stated in QUA 1.2.4 “QC is performed in the same manner as patient samples and rotated among all operators who perform the examination.”

What is “unauthorized POCT”?

Any POCT that is being performed without knowledge of the laboratory or the multidisciplinary POCT management committee is considered unauthorized. Unauthorized POCT represents a hazard since there is usually no laboratory consultation, formal training, competency assessment and QC oversight.

What references or source documents address POCT?

- ISO 22780 Point of care testing – Requirements for quality and competence, Geneva, Switzerland: ISO; 2006
- CLSI POCT04-A : Point-of-Care *In Vitro* Diagnostic (IVD) Testing. Clinical and Laboratory Standards Institute; 2006
- CLSI POCT07-A : Quality Management. Approaches to Reducing Errors at the Point of Care. Clinical and Laboratory Standards Institute; 2010
- CLSI POCT09-A : Selection Criteria for Point-of-Care Testing Devices. Clinical and Laboratory Standards Institute; 2010

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FAQ Referral Laboratories and Consultants

What are referral laboratories and referral consultants?

A referral laboratory is any laboratory that receives samples for examination from another laboratory. This includes laboratories where samples are submitted as required by regulations, regional structures such as the BC Centre for Disease Control and large hospitals within health authorities. A referral consultant is an expert laboratory physician or clinical doctoral scientist who provides diagnostic advice or services on submitted samples.

Where are referral laboratories and consultants mentioned in the DAP Standards?

Referral laboratories are addressed within ORG 2.2 and QMS 3.0 of the 2015 laboratory medicine accreditation standards.

For all referral laboratories the standards require referring laboratories to:

- maintain a register of all referral laboratories and referral consultants
- assume responsibility for reporting referral laboratory results to users, unless other arrangements have been made
- maintain records of samples sent to referral laboratories (**Note:** A collection site is not considered a referring laboratory and bears no responsibility for reporting results to users.)
- indication of results produced by a referral laboratory on reports
- develop a documented process for resolving discrepancies between referring laboratories and referral laboratories

For laboratories not in British Columbia or laboratories not accredited by the DAP, and for referral consultants working in laboratories not in British Columbia or not accredited by the DAP, the standards require:

- procedures for the selection, evaluation and monitoring of the quality and competence of referral laboratories and consultants

How does a laboratory select and monitor referral laboratories and consultants?

Major considerations for selection of a referral laboratory include licensure and accreditation status, the use of a quality management system, the types of laboratory services provided and cost. The referring laboratory is not expected to assess the quality of the referral laboratory or the referral consultant directly. The referring laboratory is required to maintain evidence from the referral laboratory or referral consultant that demonstrates competence, such as licensure, certification or accreditation status. The referral laboratory or consultant should be monitored to ensure the services provided meet the requirements of the referring laboratory for accurate and timely services.

The processes for selection, evaluation and monitoring of referral laboratories should be included in the quality management system.

What references or source documents address referral laboratories?

- ISO 15189 Medical laboratories – Requirements for quality and competence, Geneva, Switzerland: ISO; 2012
- CLSI QMS05-A2 Quality Management System: Qualifying, Selecting and Evaluating a Referral Laboratory. Clinical and Laboratory Standards Institute; 2012

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