



*ORDRE PROFESSIONNEL DES
TECHNOLOGISTES MÉDICAUX
DU QUÉBEC*

QUALITY MANAGEMENT GUIDE IN BIOMEDICAL LABORATORIES



QUALITY MANAGEMENT GUIDE IN BIOMEDICAL LABORATORIES

Ordre professionnel des technologistes médicaux du Québec
281 Laurier Ave. East, Montreal, Quebec H2T 1G2
Tel. 514-527-9811 – 1-800-567-7763 Fax 514-527-7314
E-mail info@optmq.org Web site www.optmq.org

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Readers should consult the original French document for the official text if needed.

FOREWORD

This document is the English translation* of the OPTMQ (Ordre professionnel des technologistes médicaux du Québec) guide with regard to quality management in biomedical laboratories. This guide replaces the second edition of the rules of practice of the OPTMQ titled *Quality in Biomedical Laboratories*, published in 2010. This document was revised according to the periodic document revision process of the standards of practice committee and was adopted by the Board of Directors of the OPTMQ on October 28, 2017. Only minor modifications were made pending a full review of this document. These modifications are presented following this foreword.

In order to carry out its mandate of protecting the public, the OPTMQ oversees the practice of the profession through its general oversight as well as through the education of its members. The OPTMQ ensures that its members maintain their competencies and have access to appropriate tools to guide them as they carry out their duties.

Medical technologists must have the necessary competencies to practice their profession. These competencies include knowledge, know-how and knowing how to be and act. Although his role, his involvement and his responsibility varies from among institutions, the medical technologist must know the policies and procedures in effect in his workplace and comply with them. The exercise of professional judgment also includes the capacity to apply established policies and procedures with the necessary diligence and adaptability required by the circumstances.

The document entitled *Les normes de pratique du technologiste médical* sets forth the general competencies which must be mastered by medical technologists. The present guide indicates the competencies pertaining to activities performed in the biomedical laboratory. It aims to complete the knowledge and to improve the practice of medical technologists. Its goal is to collect the information currently available in order to reinforce quality and safety criteria as they apply to testing conducted in biomedical laboratories with the objective of giving priority to the well-being of patients and to the quality of the services dispensed. This guide covers not only the duties of medical technologists but all the tasks performed in biomedical laboratories—tasks that require the collaboration of several types of interacting participants. The activities of the various fields of practice vary, and although we have attempted to deal with all areas, the requirements of an area may go beyond the recommendations of this document.

This document does not intend to create any new obligations that are not prescribed by law. The information it contains is not exhaustive and does not replace the regulations in effect. Given that technology continues to evolve, it will be subject to revision, and any suggestion likely to improve its content will be considered with interest. All OPTMQ documents subsequently published will prevail on the requirements stated in this document.

We sincerely thank the following individuals who collaborated in the scientific review of the previous version of this document: Louise Beauséjour, T.M., Daniel Boutin, T.M., Patrick Cantin, T.M., Sophie Carbonneau, T.M., Julie Désautels, T.M., Marie-France Gionet, T.M., Maureen Jalbert, Reine McGrath, Rose-Marie Moreno, T.M., Jasmine Perron, France Pouliot, Heidi Salib, and Regina Zver, T.M.

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We thank the following individuals and acknowledge their exceptional expertise in reviewing the previous version of this document : Sergine Lapointe of the Institut national de santé publique du Québec, Dominique Lapointe, Microbiologist, and Mireille Blouin, Microbiologist, of the Bureau de normalisation du Québec, Dr Gaston Lalumière, Clinical Biochemist, of the Société québécoise de biologie clinique in collaboration with Dr Marie-Josée Champagne, Clinical Biochemist, of the Ordre des chimistes du Québec (including the collaboration of the OCQ's clinical biochemistry committee).

We thank the members of the Subcommittee on Quality, who prepared the previous version of this document: Lynda Godue, T.M., Arleen Jacques and Suzanne Deschênes Dion, F.T.M.

For undated references undated and cited in this document, the references of the most recent edition of the document apply. The hypertext Internet links in the text were operational at publication time.

In this document, the term “laboratory” designates an entity that includes medical technologists and laboratory managers, among others.

* In the event of any discrepancy between the English and French versions, the French version shall prevail.

Members of the standards of practice committee:

Julie Désautels, T.M.
Suzanne Deschênes Dion, F.T.M., President
Stéphanie Lemay, T.M.
Michèle Pellerin, T.M.
Carolle Robert, T.M.
Anne-Marie Martel, T.M., Scientific Coordinator

Modifications

The following modifications were made during the course of the review of this document:

- Modification of the title, the foreword, and all references to rules of practice. Consequently to the new orientations of the standards of practice committee, rules of practice are replaced by guides.
- Modification of the terms *shall*, *should* and *can* in clause 2.0.
- The term “standard operating procedure” is replaced by “procedure” throughout the document.
- The term “double identification” is replaced with “presence of two identifiers” throughout the document.
- The term “personalized identification number” is replaced by “patient-specific identification number” throughout the document.
- The requirement for the annual revision of documents is replaced by the requirement to revise documents according to current regulatory requirements in clause 3.6.2
- Modification of the prescription section in clause 10.1.
- Modification of the validity period for prescriptions in clause 10.1.5.
- The text concerning the sample identification is replaced by the instruction to consult the OPTMQ document titled *Prélèvement de sang par ponction veineuse pour fins d'analyse* in clause 10.7.
- The requirement for the record of the person who received the samples is replaced by a recommendation in clause 10.9.1.
- Modification of the frequency of calibration of thermometers in clause 11.2.4.1.
- Modifications of the requirements for verification and documentation of the temperature of refrigerators, freezers, and incubators for storage of whole blood and labile blood components as well as for access to an emergency power source in clause 11.2.4.2.
- A requirement to advise the prescriber of the correction of errors in reports has been added in clause 12.10.
- Modification of Appendix 10 in regards to the 2015 edition of the CAN/CSA-Z902 Standard *Blood and blood components*.
- The procedure for illumination adjustment in Appendix 11 was revised.
- The bibliography, the hypertext Internet links and most references were updated.

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1.0 Introduction

Since the first publication of this document, the Ministère de la Santé et des Services sociaux (MSSS) of Quebec committed to improving the quality of services provided by health and social services institutions in Quebec. In December 2002, amendments were made to the *Act respecting health services and social services* as regards the safe provision of health services and social services.

Since 2005, the Ministère de la Santé et des Services sociaux requires all biomedical laboratories to seek an accreditation⁽¹⁾ of their services by a recognized accreditation body. The accreditation body relies on different recognized standards, such as ISO 15189: *Medical laboratories — Requirements for quality and competence*.

The International Organization for Standardization, designated by the initialism ISO, is a global federation of national standards bodies whose purpose is to promote the development of standards that ensure that a product or service meets certain requirements. Laboratories can apply for ISO 15189 accreditation⁽²⁾ as an additional assurance of quality for their institution.

This guide presents particular requirements from the ISO 15189 standard to notify the reader of the applicable clauses relating to quality management. However, it does not intend to be an interpretation of this standard; to find out more, the reader must refer to the current edition of the standard as well as to all requirements of the laboratory accreditation⁽¹⁾ process. Additional requirements were added to reflect the positions taken by the OPTMQ in order to fulfill its mandate of protecting the public.

As well, institutions operating a blood bank laboratory, an autologous blood donation program, or an ambulatory blood donation program shall also comply with the requirements of CAN/CSA Standard Z902³ *Blood and blood components*, developed by CSA Group.

The specific requirements relating to quality in medical biology target all phases of testing (preanalytical, analytical, and postanalytical) inside or outside a laboratory. The complete process begins with the medical prescription for the test and ends with the sending and archiving of the test results report. The quality system targets all stages of the process.

This guide was developed taking into account all these elements in compliance with generally recognized laboratory standards and with standards such as those of the Clinical and Laboratory Standards Institute (CLSI) and the International Organization for Standardization (ISO). The objective is to offer tools for implementing procedures that target maintaining and improving the quality of service in biomedical laboratories, and ensuring the safety of personnel and patients.

2.0 Definitions

Accident	An action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, a professional involved, or a third person. RLRQ, chapter S-4.2, section 8 ⁵
Accreditation ⁽¹⁾	Recognition by a competent external authority (accreditation body) of the fact that an institution is engaged in a process of continuous improvement of the quality of its services. ⁷
Accreditation ⁽²⁾	Formal recognition that an organization is competent to carry out specific tasks. ISO 15189 ²
Audit	Systematic, independent examination of a situation with regard to a product, a process, or an organization in relation to quality, conducted with the cooperation of the interested parties so as to verify compliance of the situation with pre-established provisions and the matching of these provisions with the targeted objective. ⁸
Conformity	Fulfillment of all established requirements. ⁴
Corrective action	Action to eliminate the cause of a detected nonconformity or other undesirable situation. ⁴ This action is followed by a process of inquiry that either leads or does not lead to the implementation of preventive action.
Incident	An action or situation that does not have consequences for the state of health or welfare of a user, a personnel member, a professional involved, or a third person, but the outcome of which is unusual and could have had consequences under different circumstances. RLRQ, chapter S-4.2, section 183.2. ⁵
Nonconformity	Non-fulfillment of an established requirement. ⁴
Policy	A statement or written document that clearly defines the organization's position and values with regard to a given topic. ⁹
Preventive action	Action taken after an evaluation, the objective of which is to reduce the probability of the occurrence of a potential nonconformity or other undesirable potential situation. ⁴
Procedure	Documentation and technical instructions explaining all the stages of a procedure. ³ The expressions Standard operating procedure and Documented procedure may also be used.

Process	Set of interrelated or interacting activities that transform inputs into outputs. ⁴
Process mapping (flowcharts)	Graphic representation of one or more processes of all connected and sequential stages and activities.
Quality	The degree of excellence or the measurement whereby an organization meets clients' needs and surpasses their expectations. ⁹
Quality assurance	Part of quality management focused on providing confidence that quality requirements will be fulfilled. ISO 9000:2015, 3.3.6 ⁴
Quality control	Strategies enabling verification that a product, process, or service meets the appropriate quality requirements. ⁹
Quality management system	A management system enabling setting the direction of and monitoring an organization with regard to quality ⁴ .
Record	Document stating results achieved or providing evidence of activities performed. ISO 9000:2015, 3.8.10 ⁴
Traceability	Ability to trace the history, application, or location of that which is under consideration ⁴ .
Transfusion accident	Any event or error (including deviation from standards) found after the beginning of the transfusion, even if there is no transfusion reaction or consequence on the state of health of the recipient. ⁶
Transfusion incident	Any event or error during the process that may have had consequences on the state of health of the user, had it not been detected before the transfusion. ⁶
Meaning of the terms: “shall” “should” and “can”	
Shall	In this document, this verb form designates the obligation to comply with or apply the prescribed requirements, either because they are required by the current legislation or because they relate to a competency that the medical technologist must have. The expression <i>needs to</i> has the same meaning.
Should	In this document, this verb form means that the rule described is based on scientific facts and that compliance with the rule or application of it is recommended.
Can	In this document, this verb form means that the statement is considered to be valid and that its application is desirable.

Part 1 Administrative Requirements of the Quality Management System

The first part of this document presents the general requirements of a quality management system. It has been drafted in accordance with the generally recognized requirements of ISO standards, CLSI publications, and the publications of laboratory accreditation bodies in Canada.

The administrative requirements of a quality management system include the infrastructure required for managing an organization's operations whether the organization offers products or services.

The administrative requirements of a quality management system include, but are not limited to, the following elements:¹

- the organization and management of services;
- quality management system processes;
- monitoring of processes;
- continuous improvement;
- purchasing and inventory management;
- documentation management;
- mechanisms for communication and the dissemination of information.

3.0 Quality Management System

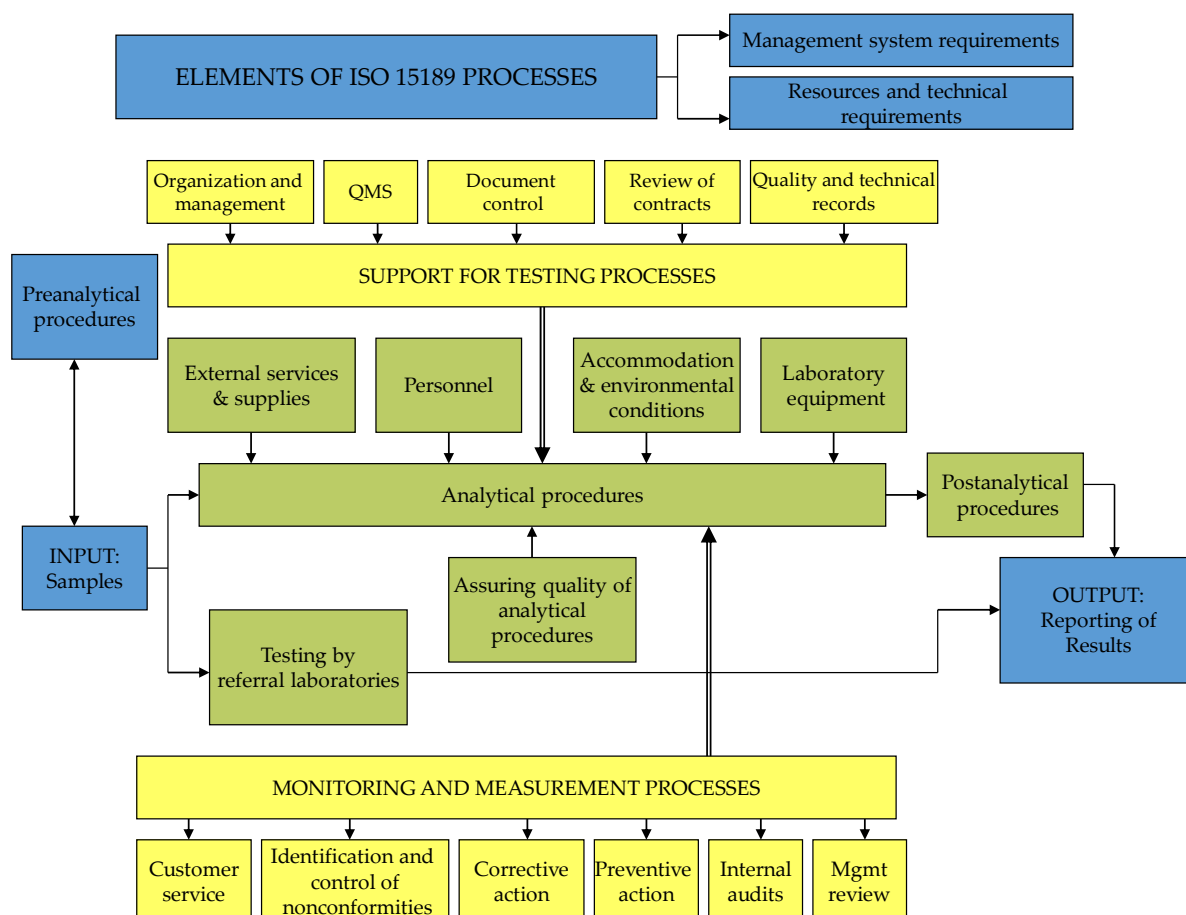
The objectives of implementing a quality management system in a biomedical laboratory are to meet the requirements of quality criteria, to ensure the monitoring of these criteria, and to implement a continuous improvement process so as to provide services that meet the needs of patients, professionals, physicians, and legal and regulatory authorities.

The laboratory, with the support of management of the institution, shall designate at least one person to be in charge of quality. This person shall oversee the application, monitoring, and updating of requirements defined in the quality management system.^{1,12}

All personnel shall take specific quality assurance and quality management training for the services provided.¹ They should participate in all stages of developing the quality management system.

The quality concept adapts to each situation. Appendix 1 presents, in flowchart form, an example of a quality management system and the essential elements of its infrastructure.

The essential elements of this system constitute the infrastructure necessary for managing its operations.^{12,13} The diagram that follows illustrates these elements.



Source: Translated from a presentation given by Sergine Lapointe of the Centre de toxicologie of the Institut national de santé publique du Québec.

Legend: QMS: Quality Management System

3.1 Organization and management of services

Planning of services and the organizational structure shall be implemented to ensure the satisfaction of clients (patients, professionals, physicians, clinics, and CLSCs).

3.1.1 Commitment of management of the organization

As prescribed by the ISO 15189 standard: “Laboratory management shall have responsibility for the design, implementation, maintenance, and improvement of the quality management system.”¹ This responsibility includes the appointment of a quality manager who will ensure the monitoring, continuous improvement, and document management of the quality management system. It also includes the appointment of assistants for all the key functions.

As well, in order to coordinate the quality management system, management should form a standing committee that may, for example include the following members:

- head of the biomedical department;
- medical specialist in the laboratory;
- manager of the quality system in the laboratory (chief technologist, administrative laboratory coordinator, etc.);
- technical and clinical transfusion safety officer;
- quality coordinator;
- medical technologists who are responsible for writing the procedures in each of the laboratory’s areas of activity;
- nurse;
- biomedical engineering representative;
- user.

3.1.2 Establishment of a quality policy and of the objectives of the quality management system

A quality policy is a precise statement that describes the direction and the intentions of the laboratory for meeting the needs of the population as well as the means implemented to do so. The quality policy shall be readily accessible to the personnel concerned.¹

As prescribed by the ISO 15189 standard, the policy shall include the following fundamentals:

- the field of services the laboratory intends to offer;
- the statement by laboratory management of the level of laboratory services provided;
- the objectives of the quality management system;

- the requirement of all personnel involved in testing to familiarize themselves with quality documentation and to apply the policy and procedures at all times;
- the commitment of the laboratory to comply with good professional practice, to conduct quality analyses, and to comply with the quality management system;
- the commitment of laboratory management to comply with standards required by current legislation.

The quality management system objectives should be measurable and should be reviewed periodically and allow for continuous improvement of the quality management system and of the quality policy.¹

3.2 Quality management system processes

During the implementation of a quality management system, the processes that represent all the activities to be carried out to produce the targeted results shall be described. The organization shall determine the necessary processes, the process sequence, and interaction between processes, and the criteria and methods to ensure the effective functioning and control of all processes.

3.2.1 Process categories

Processes can be divided into four main categories:

- Management processes including in particular the organization's vision and mission, management activities, financial management, management of resources, communication and information services, etc.;
- Realization support processes including in particular control activities (quality and technical records), document control, maintenance, information systems, purchasing, infection prevention, etc.;
- Continuous improvement processes including in particular corrective and preventive action, nonconformities, internal and external audits, quality indicators, data analysis, client service assessment, etc.
- Realization processes including all the activities connected to providing laboratory services, namely activities connected to the preanalytical, analytical, and postanalytical phases. In the laboratory, the process begins with the medical prescription and ends with the provision of the test results report.¹²

The process also draws on the contribution of all those who intervene at one stage or another. It is therefore important to ask for the suggestions and participation of all the people involved in the various stages of the process to properly define each activity to be carried out to produce the targeted results.

3.2.2 Process mapping (flowcharts)

Process mapping is a means of graphic presentation of processes that provides a clear illustration of activities and the essential elements of the quality management system and their interrelation.

In the laboratory, flowcharts of the preanalytical, analytical, and postanalytical phases are intrinsic to the laboratory test production system.

This mode of presentation is extensively used in quality management because it provides a rapid visual overview of all operations to be carried out and enables determining the procedures to be defined to ensure quality.

Appendices 2, 3, and 4 present examples of preanalytical, analytical, and postanalytical processes in flowchart form.

3.3 Process control

The organization shall permanently improve the effectiveness of the quality management system by using the quality policy, the quality management system objectives, audit results, data analysis, corrective and preventive action, and management review.

The laboratory shall put in place and maintain a mechanism that allows anyone participating in a process to report and record any organizational or technical problem in a register.¹² A **policy** and **procedures** shall.^{1,12}

- establish the reporting method;
- determine the documentation to be used (for example, a form);
- designate the person or people responsible for solving the problems;
- define the measures to be taken (for example, corrective action or preventive action);
- establish a decision-making process to interrupt noncompliant testing and to retain reports as required and to make corrections to reports already transmitted;
- allow for determining whether the noncompliance, the incident, or the accident has clinical repercussions on the patient and if so, to inform the prescriber;
- allow for follow-up to determine the cause of the problem for the purpose of improving the quality of service.

The laboratory quality management system shall include the implementation of control measures at every stage of the analysis process.^{1,12} The following subpoints deal with control measures.

3.3.1 Nonconformities

The laboratory shall define what is considered to be a nonconformity. A nonconformity is a deviation from a particular point of a standard in the quality management system. Some nonconformities directly affect the reliability of the analysis result, others indirectly affect the reliability of the analysis result.

Laboratory personnel should receive training to help them to recognize nonconformities and to guide them in managing nonconformities.¹⁴

3.3.1.1 Recording nonconformities

The purpose of recording nonconformities is to describe and objectively index the problems encountered that may have an incidence on the service provided to patients or on the safety of the public or personnel. Its purpose is also to record the cause and to note the immediate action taken or the corrective action to be taken.¹⁴

Analyzing the information recorded allows for evaluating the nature of problems and makes it possible to improve the quality of service provided as part of a continuous improvement process over the long term.

Appendix 5 presents an example of a form for recording nonconformities.

3.3.1.2 Problem solving in the event of nonconformities

Problem solving requires that medical technologists use their clinical judgment and their knowledge to ensure the quality of the product or service they dispense when nonconformities occur.¹¹

Action taken to correct a nonconformity shall be recorded on a nonconforming event report form.¹⁴

3.3.2 Incidents and accidents

The laboratory shall define what is considered to be an incident and what is considered to be an accident. The laboratory shall ensure that reporting incidents and accidents is part of the institution's risk management process established by the risk management committee. (See point 3.3.8.)

The *Act respecting health services and social services*⁵ defines “incident” as “an action or situation that does not have consequences for the state of health or welfare of a user, a personnel member, a professional involved, or a third person, but the outcome of which is unusual and could have had consequences under different circumstances.” The Act defines “accident” as “an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, a professional involved, or a third person.”

The medical technologist shall, without delay, take the necessary means to rectify the situation.

3.3.2.1 Recording an incident or an accident

The purpose of recording an incident or an accident is to objectively describe the problems encountered that have an impact on the service provided to patients or on the safety of the public or personnel. Its purpose is also to record the cause and to note the immediate correction made or the corrective action to be taken.

A monitoring system shall be put in place and include the creation of a local register for incidents and accidents.¹⁵ Analyzing the information recorded allows for evaluating the nature of problems and makes it possible to improve the quality of service provided over the long term.

3.3.2.2 Retrospective review of an incident or an accident

A retrospective review shall be carried out to determine the cause or causes of the incident or accident by encouraging the cooperation of all those involved. The review may include checking software, instrumentation, data, personnel training, established procedures, and it may include interviews with personnel.¹⁴

3.3.2.3 Reporting incidents and accidents

According to section 8 of the *Act respecting health services and social services*⁵, the medical technologist shall officially report any accident or incident that occurs when he or she is performing his or her duties that may have consequences for a patient or a colleague.¹¹ This statement is mandatory whether the medical technologist contributes to the accident or incident, witnesses it, or whether someone brings the accident or incident to his or her attention.

The forms used in public institutions are the incident or accident report form (AH-223) or the transfusion incident/accident report (RIAT AH-520).

Private institutions shall also record incidents and accidents on a form. Appendix 5 presents an example of a record of an incident or accident form that can be used for private institutions.

3.3.2.4 Disclosure

For any accident likely to result in consequences to the patient's state of safety or well-being, the medical technologist shall as quickly as possible advise his or her superior or a physician to enable the superior or physician to disclose the accident to the patient in accordance with the institution's policy in effect.

3.3.2.5 Reporting transfusion accidents

For any transfusion accident likely to result in consequences to the patient's state of safety or well-being, the medical technologist shall as quickly as possible advise his or her superior or a physician to enable the superior or physician to disclose the transfusion accident to the patient or the patient's family in accordance with the institution's policy in effect.

The transfusion accident shall also be reported to Héma-Québec in the event of severe transfusion reactions so as to withdraw products by the same donor before their use.

3.3.3 Corrective and preventive action

Corrective and preventive action are part of the quality assurance process. They shall be reviewed when a management review is conducted. (See point 3.3.7.)

3.3.3.1 Corrective action

Procedures for corrective action shall include an investigative process to determine the underlying cause or causes of the problem.¹ Laboratory management shall record and monitor the results of any corrective action taken,¹⁶ in order to ensure that they have been effective in overcoming the identified problems.¹ See the example of a corrective action form in Appendix 6.

3.3.3.2 Preventive action

The laboratory shall have procedures for preventive action that allow for identifying needed improvements and potential sources of nonconformities, either technical or concerning the quality management system.¹ If preventive action is required, action plans shall be developed, implemented, and monitored to reduce the likelihood of the occurrence of such nonconformities.¹ Preventive action shall be recorded.¹⁶ See the example of a preventive action form in Appendix 6.

3.3.4 Quality indicators

Quality indicators allow for systematic monitoring and assessment of the test production process and the laboratory's contribution to patient care.¹ Quality indicators should be tied to quality management system objectives and the laboratory's quality policy on continuous improvement. They allow for the identification of the areas requiring special attention to maintain a system at the defined service levels.¹⁷

3.3.4.1 The role of indicators¹⁸

- to follow up on quality improvement activities;
- to assess daily activities;
- to set strategic direction;
- to compare performance with an established standard (comparative analyses, accreditation criteria);
- to reflect the implementation of measures that guarantee favourable results.

3.3.4.2 Characteristics of indicators¹⁹

- in agreement with quality management system objectives;
- simple and relevant (indicate where action shall be taken);
- focused on high-volume or critical problems or processes;
- relatively easy to control;
- can be audited;
- sensitive (shall reflect the variabilities of the process to examine);
- specific (shall only reflect what shall be measured);
- reproducible;
- measurable.

3.3.4.3 Stages of implementation of indicators¹⁷

- define the indicators (according to characteristics in point 3.3.4.2);
- determine the frequency of data analysis;
- prepare the benchmark or acceptable standard for the indicator;
- perform data collection over a specific period;
- assess the indicators;
- interpret the results of the indicators and the data;
- implement an action plan.

3.3.4.4 Examples of indicators

The table that follows gives an overview of possible indicators for the preanalytical, analytical, and postanalytical phases.

Examples of indicators ¹⁷	
Preanalytical phase	• Delay in sample transport time • Number of unidentified or improperly identified samples • Rate of sample acceptability • Number of errors entering computer data • Waiting time at the sample collection centre
Analytical phase	• Internal and external quality control results • Follow-up on quality control of point-of-care testing (POCT) • Downtime of information system • Equipment breakage rate and downtime • Number of power failures and information system failures • Percentage of expired reagents • Correlation of test results, for example, between cytology and biopsy results, frozen section, and the final diagnosis • Units of outdated blood • Blood culture contamination rate • Delay in performing the analysis
Postanalytical phase	• Urgent or critical result turnaround time • Number of times the physician could not be reached in the event of critical/urgent results • Delay between end of testing and transmission of results • Report error correction rate

3.3.5 Client satisfaction

The laboratory is encouraged to obtain both positive and negative feedback on the quality of its client service by means of surveys of its clientele.¹

The laboratory shall have a policy and procedure for processing complaints from its clientele.¹ These complaints shall be processed as quickly as possible and recorded in a register. They may lead to corrective or preventive action.¹ The complaint register and survey results shall be part of laboratory management review.

3.3.6 Audits

3.3.6.1 Internal audits

In order to verify the compliance of operations with quality management system requirements, internal audits of all elements of the system shall be conducted at intervals defined by the system itself.¹

The quality manager or designated qualified personnel shall formally plan, organize, and conduct audits. Personnel shall not audit their own activities. The laboratory shall define and document its audit procedures and include the types of audits conducted, frequency, methodologies, and required documentation. When nonconformities or opportunities for improvement are noted, the laboratory shall undertake appropriate corrective or preventive action which shall be documented and carried out within an agreed-upon time.¹

3.3.6.2 External audits

External audits are also necessary, for example, as part of the accreditation process or when applying for certification. Several bodies may be called upon to act as auditor: Health Canada, the Laboratoire de santé publique du Québec, Héma-Québec, and other recognized bodies. As part of the laboratory accreditation process, the audit of compliance with identified standards is conducted by an internationally recognized accreditation body such as Accreditation Canada or the Bureau de normalisation Québec (mandated by the Conseil québécois d'agrément).

3.3.7 Management review

Laboratory management shall review the laboratory's quality management system and all of its medical services, including testing and advisory activities, to ensure their continuing suitability and effectiveness in support of patient care and to make any necessary changes or improvements. The results of the review shall be incorporated into a plan that includes objectives and action plans. A typical frequency for conducting a management review is once every year, or over a shorter period when the quality management system is being developed.¹

3.3.7.1 Personnel involved in management review

The personnel involved in management review should include, but not be limited to:

- The biomedical department head or laboratory specialist;
- the laboratory manager;
- the technical and clinical transfusion safety coordinators;
- the designated quality coordinator;
- the risk manager;
- any other person involved connected to the laboratory, when relevant.

3.3.7.2 Points taken into account in management review

Management review shall take into account, but not be limited to, the following points:¹

- follow-up of previous management reviews;
- quality indicators;
- nonconformities;
- the results of corrective and preventive action;
- complaints received and the appraisal of client service;
- the results of internal audits;
- reports from managerial and supervisory personnel;
- assessments conducted by external bodies (external audits or external quality control);
- any changes in the volume or type of work undertaken;
- the evaluation of suppliers (including manufacturers and suppliers of external services).

Findings and the actions that arise from management reviews shall be recorded, and laboratory staff shall be informed of these findings and the decisions made as a result of the review. Laboratory management shall ensure that arising actions are carried out within an appropriate and agreed-upon time.¹

3.3.8 Risk management

Risk management is a regular, continuous process coordinated with and integrated into all the organization's systems and sub-systems allowing for the identification, analysis, control, and evaluation of risks and situations deemed to be a risk that have caused or that could have caused damage to users, visitors, or staff, or to their property or the institution's property.²⁰

The four stages of risk management include:²⁰

- identifying risks and situations deemed at risk;
- analyzing risks and situations deemed at risk;
- controlling risks and situations deemed at risk;
- evaluating risk management activities.

3.3.8.1 Risk management committee

The *Act respecting health and social services*⁵ requires every institution to form a risk management committee responsible for seeking, developing, and promoting means to ensure the safety of users and to reduce the incidence of adverse effects and accidents related to the provision of health services and social services.⁵

The composition of the committee shall ensure a balanced representation of the employees of the institution, of users, and of the people practising in a centre operated by the institution.⁵

3.4 Procurement and inventory management

Procurement and inventory management includes, without being limited to, the purchasing process, the selection of suppliers, contract review, the receiving and inspection process, and the inventory management process.

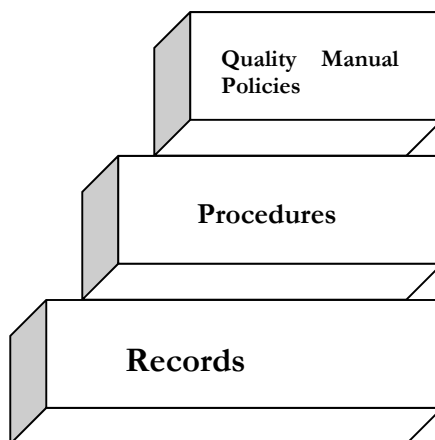
The procedures and technical requirements with regard to laboratory materials are described in the second part of this document in point 11.2

3.4.1 Evaluation of suppliers

The laboratory shall evaluate suppliers (of reagents, supplies, and critical services) and shall maintain records of these evaluations. Suppliers shall be selected and evaluated based on their ability to meet the requirements defined by the laboratory. A list of approved suppliers shall be established and reviewed at the time of management review.¹

3.5 Document and record hierarchy

Documentation in a quality system varies according to the needs of a particular department. Nevertheless, generally speaking, the following hierarchy is used for documents and records:



The quality manual is at the top of the hierarchy; it presents all the policies that establish the guidelines, and what shall be done to manage all the laboratory production processes.

The procedures define the “Who,” “When,” “Where,” and “How” of laboratory activities.

Records are evidence of activities performed.

A designated document coordinator should be responsible for keeping a consultable original of all documents in a specific location.^{1,21}

All policies, processes, and procedures shall be recorded on an appropriate support media (paper or electronic).

3.5.1 Quality manual

The quality manual includes all the points defined in the quality management system.

It includes, among others:

- the quality policy and the objectives of the quality management system;
- planning of services concerning client needs and satisfaction;
- the resources of the biomedical department;
- information on the laboratory's organizational structure;
- the role and responsibilities of technical management and of the quality coordinator;
- the overall process (preanalytical, analytical, and postanalytical);
- the documentation structure;
- the quality management system.

The quality manual shall describe or refer to the processes and to the procedures and to the resources required for the overall implementation of the quality management system in the laboratory including POCT activities.^{1,12} It shall be kept up to date under the authority of the quality coordinator designated by laboratory management.¹

Note: Appendix 7 presents an example of a table of contents of a quality manual.

3.5.2 Policies

Policies are statements or writings that clearly indicate the organization's position and values on a given topic.⁹ The policies shall be documented and communicated to all personnel concerned.¹

3.5.3 Procedures

The laboratory shall have procedures that describe all the activities of the preanalytical, analytical, and postanalytical phases of the production process.²¹

Depending on the organization of laboratory documentation, procedures may include technical instructions that describe the stages of execution of a specific activity. The procedures can also refer to documents containing this information.

All activities shall be recorded (paper or electronic media) and be available at the workstation for relevant staff.¹

The criteria for management of laboratory documentation are defined in Section 3.6 of this document.

3.5.4 Records

All records shall be legible and stored such that they are readily retrievable.¹ The institution shall define the length of time various records pertaining to the quality management system and test results are to be retained. (See point 3.6.4.)

3.6 Documentation management

A documentation management procedure shall establish a documenting hierarchy and define the guidelines for responsibilities with regard to creating, reviewing, and approving any document from internal or external sources.^{1,21} Documentation management system procedures shall be controlled to avoid using obsolete, incomplete, or invalid documents. Appendix 8 presents an example of the document management process.

The documentation shall be available in a language commonly understood by the staff in the laboratory.

3.6.1 Identification of documentation

Standardization of the writing and presentation of laboratory documentation is an integral part of the quality management system.

The form of presentation of laboratory documentation shall include, without being limited to, the following information:^{1,3,21,22}

- the title and the objective;
- the name of the institution (for example, the hospital logo);
- coding (shall be uniquely identified). All documents shall be coded in accordance with a system eliminating any possible confusion between two different documents;
- the effective date;
- the version number and the revision date;
- the page number and the total number of pages;
- a clear description of the steps and instructions to follow;
- clear responsibilities with regard to the measures that require verification, examination, and approval.
- identification of sources (works cited or consulted);
- the signature of the person(s) who gave authorization and the date of signature.

It is also useful to include the following:

- history of changes made to the procedure so as to more readily follow how the document evolves;
- the filename and document location;
- the identity and signature of the author(s) and revisor(s).

3.6.2 Revision of documentation

Each document shall be revised according to current regulatory requirements, dated, and signed by the authorized person(s).^{1,2,3,21,23} The laboratory shall determine the list of amendments that require the creation of a new version of the document.²¹

3.6.3 Withdrawal of documentation

When a document is withdrawn, the withdrawal date shall be recorded. All copies shall promptly be removed from all points of use. Retained or archived superseded documents shall be appropriately identified to prevent their inadvertent use.¹ The original of obsolete documents shall be kept for the period provided for by the institution's retention schedule and in accordance with legal and regulatory requirements. See appendices 9 and 10.

3.6.4 Documentation retention schedule

Biomedical laboratories shall have a retention schedule that defines the length of time documents, laboratory files, and test results are to be retained. Retention time shall be defined according to the nature of the analysis or document and shall comply with the laws and regulations in force.^{1,24}

Archiving and the retention period of obsolete documents shall be defined in accordance with legal and regulatory requirements.^{1,21}

Appendix 9 lists in a non-exhaustive way the various documents for which the retention period should be defined.

Appendix 10 provides the retention periods recommended by various bodies.

3.6.5 Communication and dissemination of documentation

The laboratory shall establish a formal mechanism for the communication and dissemination of documentation. A procedure shall provide for the dissemination to all personnel involved of any amendment to documentation.^{1,21} It is the medical technologist's responsibility to be aware of and to read updates to documentation.¹¹

A process for confirming that all new information has been read shall be established and followed up on.^{1,22} This process shall include a section for each medical technologist concerned to confirm having read the new information by initialling and dating the reading.¹¹

Laboratory documentation shall be readily accessible to personnel. If these documents are in electronic format, a method shall exist allowing access to them at all times as well as in the event of an information system failure.

Part 2 Technical Requirements of the Quality Management System

The second part of this document presents the technical requirements of a quality management system. It has been drafted in accordance with the principles set forth in ISO Standard 15189 (*Medical laboratories—Requirements for quality and competence*¹), CAN/CSA Standard Z902 (*Blood and blood components*³), and in accordance with the generally recognized requirements of good laboratory practice, CLSI publications, and the laboratory accreditation bodies in Canada.

4.0 Accommodation and environmental conditions

With regard to environmental conditions, the work premises shall be adapted to the activities of each laboratory area and shall comply with Health Canada guidelines (lighting, temperature, ventilation, relative humidity, equipment, work surfaces, floors, etc.). These requirements are described in the *Canadian Biosafety Standard* and the *Canadian Biosafety Guidelines* at:

<https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines.html>

Laboratory premises shall be organized and environmental conditions designed so as to:^{1,26}

- protect patients, personnel, and visitors from recognized hazards;
- define the zones of confinement according to risk categories and define the people having access to these zones;
- regarding physical areas for sample collection, provide accommodation that is appropriate, comfortable, secure, respectful of the patient's privacy, with optimal conditions for collecting samples from patients experiencing loss of autonomy.
- ensure that the environmental conditions in which testing is done are appropriate and in no way affect the quality of the analytical process;
- ensure that an effective barrier is set up between neighbouring zones where incompatible activities take place. Measures shall be taken to avoid any cross-contamination;
- ensure that workspaces are clean, well maintained, and ergonomic;^{23,27}
- ensure that the facilities for storing documentation, samples, reagents, supplies, slides, and any other item provide a suitable environment to prevent damage, deterioration, loss, or unauthorized access.
- control room settings such as relevant humidity and temperature. A register shall be kept to record these settings;^{1,28}
- eliminate hazardous materials in compliance with regulations in effect. There shall be compliance with *The Regulation respecting biomedical waste*.²⁹

Premises shall be clean and work surfaces shall be cleaned every day with a recognized disinfectant or germicidal agent according to an established procedure. In the event of an accidental spill, or if at any time surface contamination is visible or suspected, the work surface shall be disinfected according to an established procedure.^{25,30}

5.0 Personnel

Personnel are an essential element of the quality management system.³¹ The laboratory shall have sufficient personnel with adequate training.¹ Laboratory management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel.¹ A register shall be kept of the signature, identification, and initials of each employee.³

Laboratory management shall authorize personnel to perform specific tasks as stipulated in the institution's organization plan.³²

The following information shall be readily available to all laboratory personnel:¹

- a written description of the laboratory's organizational structure;
- a description of the competencies, roles, and duties of personnel.

This information shall be included in the quality manual. (See point 3.5.1.)

5.1 Duties and responsibilities

Protection of the general public is fundamental to the professional system in Quebec. Professional orders exercise oversight to ensure that members practise with competence.

As members of a professional order, medical technologists have professional duties to perform. They shall practise their profession in compliance with their *Code of Ethics*¹⁰ and regulations, the *Normes de pratique du technologiste médical*,¹¹ and in accordance with guidelines and generally recognized requirements of good laboratory practice.

5.1.1 Confidentiality

Medical technologists shall respect professional secrecy and shall maintain the confidentiality of information regarding patients.^{1,5,11,33,34,35}

5.1.2 Collaboration

Medical technologists will be able to instill a sense of belonging in the team and will have the communication skills required for quality work.^{11,36}

5.2 Training and maintenance of competencies

The laboratory shall have a training program to ensure that medical technologists maintain their competencies.

The laboratory shall promote the participation of medical technologists in continuing education. Training taken by medical technologists shall be recorded.¹

5.2.1 Training in cardiopulmonary resuscitation

Medical technologists who perform interventions on patients shall take and maintain training in cardiopulmonary resuscitation.³⁷

5.2.2 Training in pharmacology

Medical technologists who administer medications or other substances, including intravenously from a peripheral site, for the purpose of prescribed analyses or tests, shall hold an attestation issued by the OPTMQ following training in pharmacology.³⁵

5.2.3 Training for collecting samples via an artificial opening in the human body

The Regulation respecting certain professional activities that may be engaged in by a medical technologist allows medical technologists to insert a catheter into an artificial opening in the human body:

1° via an ileal conduit stoma, except in the presence of ureters;

2° via a tracheostomy, except when the patient is under ventilator assistance.

The regulation sets forth the specific terms and conditions that allow medical technologists to perform these activities including holding an attestation issued by the OPTMQ certifying that they have completed at least four hours of theoretical and practical training, and that they have, at least once, successfully performed the activity under the immediate supervision of a physician, nurse, or respiratory therapist.³⁸

5.2.4 On-the-job training

The on-the-job training program shall include an initial orientation session for new employees and continuing education activities.^{1,31}

Medical technologists shall be entitled to have a training period before a new procedure takes effect in their field of activity.

5.2.5 Continuing education

Medical technologists shall keep their knowledge up to date in their field of practice and shall regularly participate in continuous education activities.^{10,31} Medical technologists shall comply with the continuous training program of the OPTMQ in effect.

5.2.6 Evaluation of competencies

The laboratory shall establish a competency evaluation program.¹ This program is part of any quality management system.³¹ This program shall be designed with the objective of continuous improvement of quality. A distinction shall be made between the evaluation of competencies and performance review.

A competency verification process shall validate the acquisition of knowledge subsequent to the initial orientation session of a newly hired medical technologist, training on the coming into effect of a new procedure, and during periodic re-assessment of competencies in a medical technologist's field of practice.^{1,31}

6.0 Teaching and reference material

To perform their daily work and for orientation and continuing education sessions, medical technologists shall have access, on the spot, to the materials required for the performance of their functions, including:

- the most current versions of standards and guidelines;
- the good practice guides and guidelines of recognized bodies;
- recent reference volumes;
- charts, atlases, or software;
- a collection of slides for identifying cells or other elements, depending on the test;
- the sample collection manual (see point 10.6.1);
- laboratory procedures;
- any other relevant sources of information (for example, the Internet).

7.0 Information system management

When a laboratory uses an information system to collect, record, and store data, it shall establish procedures that are recorded in the information system procedures manual. These procedures may also be integrated into analytical procedures.

All personnel shall be trained to use the information system, and their competencies shall be evaluated. Computer software shall be documented and suitably validated as adequate for use in the facility. There should be provision for an uninterruptible power supply (UPS).¹

7.1 Access code responsibility

Every user shall have their own access code.¹ Each person is responsible for his or her access code and the operations performed under that code.¹¹

Users shall under no circumstances allow other people to access their code and they shall end their session when they leave their workstations.³⁹ The system should be equipped with an automatic logoff mechanism and/or automatic locking system.⁴⁰

To ensure information system security and to protect the confidentiality of data, a policy shall define authorized computer users and the level of data they have access to.¹

7.2 Information system procedures manual

The information system procedures manual shall include the following points without being limited to them, or shall refer to another procedure that includes the following:¹

- technical instructions for all stages of computer processes, from data capture of an inquiry to the archiving of results. If applicable, a directory of the various computer codes necessary to data entry (tests, names of physicians, etc.) should be available and kept up to date;
- the measures to be taken to protect the confidentiality of patient information;
- the measures to be taken to protect data integrity at all times;
- the measures ensuring that the set of correction factors are correctly updated and that calculations performed on patient data by the computer are periodically reviewed;
- procedures allowing for periodic comparison of patient data on reports with original input in order to ensure the integrity of data transfer at defined intervals by detecting errors in data transmission, storage or processing;
- procedures to be followed in the event of partial or complete information system failure (see section 8.2);
- the retention schedule and the method for storing data;
- the contact information of the designated people who must be advised in the event the information system malfunctions.

Authorized computer users shall have access to this manual.

8.0 Procedures in the event of disruption of service

Standard operating procedures shall establish the measures to take in the event of disruption of service, whether due to a minor or major defect in laboratory equipment, a power failure or an information system failure, for each laboratory service.¹

When the length of a disruption of service is likely to compromise patient care, the client shall be advised of the possible delay and the disruption of service shall also be reported to the designated people in the institution.¹

8.1 Power failure

The laboratory shall describe the procedure to follow in the event of a power failure. This procedure should include the following information, among others:

- the presence of an emergency power system;
- record of the situation and the corrective measures taken;
- the possible use of a support device;
- sample management;
- client communication plan;
- system restart.

8.2 Information system failure

The laboratory shall describe the procedure to follow in the event of a planned or unplanned information system stoppage.¹ This procedure should include the following information, among others:

- the description of the recovery plan (from the test requisition to result transmission);
- record of the situation and the corrective measures taken;
- data storage;
- client communication plan;
- system restart.

9.0 Laboratory safety

This section provides a summary overview of the most important points with regard to laboratory safety. The laboratory shall also comply with the requirements of the following references:

Canadian Society for Medical Laboratory Science: Laboratory Safety Guidelines

The Canadian Biosafety Standard and the *Canadian Biosafety Guidelines* from the Public Health Agency of Canada

9.1 Risk categories

The existence of many risk categories forces us to develop policies and procedures relating to occupational health and safety risks.^{27,30,41} These policies and procedures shall describe the measures to take to manage:

- **Chemical hazards:** flammable liquids, toxic gases.
- **Biological hazards:** bacteria, viruses, parasites, or fungi which are capable of causing disease in humans.
- **Physical hazards:** the environment, radiation, noise, thermal stress, and mechanical hazards.
- **Ergonomic hazards:** elements related to the design of a workplace which stress the human organism physically or mentally.
- **Psychosocial hazards:** working conditions which cause psychological stress.

9.2 Legislation

Many laws govern occupational health and safety in our laboratories.²⁷ Here, without limitation to these, are some of those laws and regulations:

- Laws and regulations relating to hygiene and safety at work.
- The *Act respecting industrial accidents and occupational diseases*.
- Environmental legislation.
- The Workplace Hazardous Materials Information System (WHMIS).
- Regulations respecting the disposal of biomedical waste.
- Transport of Dangerous Goods regulations.
- Municipal fire prevention code.
- The *Building Code*.

9.3 General

The laboratory shall designate a person to be in charge of occupational health and safety in the laboratory.^{13,23,25,30,41}

Procedures are necessary so as to ensure a secure environment in compliance with good practices and the regulations in force.^{27,30,41} Policies and procedures should include detailed instructions concerning the potential hazards encountered during the procedure and the means to use to minimize risks. These potential hazards shall be recorded in a safety manual and reviewed annually.^{27,28,30,41}

Medical technologists shall know the occupational health and safety measures and shall put them into practice in their work environment.¹¹

9.4 Safety manual

The safety manual shall **in the very least** address the following points:^{30,41,42}

- 1) Policies and procedures on standard (universal) precautions and the prevention of infections

The wearing of personal protective equipment (PPE) shall be established based on established and observed risks (gloves, lab coats, aprons, protective glasses, appropriate masks, visors, appropriate shoes).^{27,30,41}

It is strongly recommended that gloves be worn in the laboratory for any handling of biological specimens.^{13,25,43,44,45,46}

For more information on requirements related to handling of samples suspected of containing pathogens, consult the *Canadian Biosafety Standard* and the *Canadian Biosafety Guideline* from the Public Health Agency of Canada.

- 2) Prevention measures to follow when handling, transporting, and storing potentially hazardous materials.

- **Biological specimens**

When handling biological specimens, the practices set forth in Health Canada's documents *Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care Settings*⁴⁸ and with *Hand Hygiene Practices in Healthcare Settings*⁴⁷ should be respected.

These documents can be consulted at:

<http://publications.gc.ca/site/eng/440707/publication.html>

<http://publications.gc.ca/site/eng/430135/publication.html>

- **Chemicals**

WHMIS is a pan-Canadian information system designed to reduce the frequency of occupational illnesses and accidents due to the use of hazardous materials. The three key elements of WHMIS are training on the safe use of controlled hazardous materials, labelling, and material safety data sheets.

Technologists must be able to understand the information provided by WHMIS (or any other classification or labelling system depending on the regulations in effect).

A reference manual with regard to WHMIS requirements pursuant to the *Hazardous Products Act*⁴⁹ and *Controlled Products Regulations*⁵⁰ can be found at this link:

<https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/occupational-health-safety/reference-manual-whmis-requirements-hazardous-products-act-controlled-products-regulations.html>

As well, the Commission de la santé et de la sécurité du travail (CSST) has a Service du répertoire toxicologique accessible in French at the following link:

<http://www.reptox.csst.qc.ca/>

[With some English content here:](#)

<http://www.reptox.csst.qc.ca/Documents/SIMDUT/IntroAng/Htm/IntroAng.htm>

Material safety data sheets (MSDS) governed by WHMIS legislation shall be available, accessible at all times (7 days a week, 24 hours a day) and shall be known by all laboratory personnel.

▪ **Pathogenic agents**

The MSDS are also designed to be a quick reference tool with regard to safety from infectious microorganisms. They contain information on health hazards such as infectious doses, dissemination, viability (including decontamination), information on medical aspects, hazards to laboratory personnel, recommended precautions, information with regard to handling, and procedures to follow in case of spills.

Material Safety Data Sheets are accessible on the Website of the Public Health Agency of Canada under Laboratory Biosafety and Biosecurity:

<https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html>

The *Human Pathogens and Toxins Act* aims to ensure the safe and secure handling of human pathogens and toxins. Laboratories that handle pathogenic agents and toxins must register with the Public Health Agency of Canada and comply with the requirements of the Act.⁵¹

- 3) Measures to take in an emergency situation that endangers the health and safety of laboratory personnel (outside disaster, laboratory accident, explosion, fire).^{27,30,41}
- 4) Procedures to follow in the event of a hazardous chemical or biological spill in the laboratory or in an instrument, including decontamination procedures for the environment or instruments.^{27,30,41}
- 5) Regular verification schedule of equipment such as fire extinguishers, emergency shower, eye wash, and the certification period of safety equipment such as biological safety cabinets, and fume hoods or other equipment.^{27,30,41}
- 6) Procedures describing the elimination of biological or chemical waste pursuant to the *Regulation respecting biomedical waste*²⁹ or any other laws or regulations. The institution's waste management policy shall comply with the regulations in effect.
- 7) A management system that provides for recording and reporting laboratory health and occupational incidents and accidents as well as the corrective measures taken.³⁰

9.5 Occupational health and safety training

A health and safety program shall be established for newly hired personnel and a continuous training for personnel on staff.^{13,25,30,41} The continuous training in occupational health and safety shall be given on an annual basis.^{30,41,52}

Training on WHMIS is mandatory for laboratory personnel.⁵²

Training for activities linked to the transport of dangerous goods is also mandatory. For more information, consult the OPTMQ document *Transport et conservation des échantillons dans le domaine de la biologie médicale*.⁵³

9.6 Medical monitoring program

The laboratory shall establish a monitoring program for the health of all laboratory personnel including for vaccination and medical post-exposure monitoring.^{1,30,41} This monitoring program shall be recorded.

All personnel should be strongly encouraged to receive adequate immunization to prevent infections related to the micro-organisms to which they are exposed.^{13,25,30,41}

The hepatitis B vaccination must be made available to all personnel with occupational exposure to body fluids or human tissue.³⁰

9.7 Internal health and safety audit

The laboratory shall establish an internal occupational health and safety inspection system (audit).^{30,41}

This procedure makes it possible to verify compliance with all the established health and safety measures by all laboratory personnel and to make the necessary recommendations to improve safety in the laboratory.

The inspection shall take place and be reviewed at least annually by appropriately trained personnel.^{30,41}

For more information, consult the following documents:

CANADIAN SOCIETY FOR MEDICAL LABORATORY SCIENCE *Laboratory Safety Guidelines*.²⁷

CANADIAN STANDARDS ASSOCIATION. A National Standard of Canada. Medical laboratories—*Requirements for safety (Laboratoires de médecine – Exigences pour la sécurité)*, CAN/CSA-Z15190³⁰

PUBLIC HEALTH AGENCY OF CANADA. *Canadian Biosafety Standard* and the *Canadian Biosafety Guideline*

10.0 Preanalytical phase

10.1 Prescription

Section 39.3 of the *Professional Code* of Quebec defines “prescription” as “a direction given to a professional by a physician, a dentist, or another professional authorized by law, specifying the medications, treatments, examinations, or other forms of care to be provided to a person or a group of persons, the circumstances in which they may be provided, and the possible contraindications. A prescription can be individual or collective.” The *Professional Code* of Quebec and other laws governing professional practice specify which professionals are authorized to prescribe tests. Professional bodies whose members can prescribe tests and exams have adopted regulations that specify the elements that must be included on an individual prescription.^{34,54,55,56,57}

The prescription starts the preanalytical process. A prescription can also be requested after the preanalytical phase, when tests are being added or in the event of a request for blood components for a sample already collected.

The medical technologist shall ensure that he or she properly understands the prescription before collecting the sample. In the event of any doubt, the prescription shall be verified with the prescriber or an authorized person.

Among others, the *Regulation respecting the standards relating to prescriptions made by a physician*⁵⁴ specifies the elements that must be included in an individual prescription:

- the name of the physician, typed or printed;
- his permit number
- the name of the facility or the clinical setting, the phone number and address of correspondence where he wants to be reached relative to this prescription;
- the patient’s name;
- the patient’s date of birth or his Régie de l’assurance maladie du Québec number;
- the date the prescription was written;
- the prescription’s validity period, when justified by a patient’s condition;
- where appropriate, any contraindication or other information required by the patient’s condition;
- his signature;
- if the prescription is for an examination or a laboratory test, the nature of the examination as well as the clinical information necessary for conducting the test or for its interpretation.

The Collège des médecins du Québec has produced an exercise guide: *Les ordonnances individuelles faites par un médecin*.⁵⁸ The document is available free of charge at:

<http://www.cmq.org/publications-pdf/p-1-2016-10-03-fr-ordonnances-individuelles-faites-par-un-medecin.pdf>

10.1.1 Test prescription

A prescription can also be a test requisition form, the content of which is established by the laboratory.

10.1.2 Blood component prescription

The blood bank and transfusion services shall ensure that the blood component prescription complies with CAN/CSA Standard Z902 (*Blood and blood components*).³

10.1.3 Verbal prescription

The prescription can also be transmitted verbally. The laboratory shall define a policy¹ and procedure concerning verbal test prescriptions and shall define who can receive a verbal prescription and how the information is to be recorded in the laboratory. The prescriber shall provide the same elements as for a written prescription.

10.1.4 Collective prescription

A collective prescription can be written by one or more physicians to prescribe laboratory tests, among others. The collective prescription allows a skilled professional to perform certain activities without having to obtain an individual prescription from a physician. This means that the person for whom the prescription is made has not had a prior visit with the physician. This type of prescription is particularly useful in emergency or frequent, even routine situations.⁵⁸ The laboratory personnel and sample collection centre personnel shall be informed of the existence of such a prescription. As a general rule, the test result is sent to the physician identified as the responsible physician, based on the procedure described in the collective prescription.

10.1.5 Validity period

An individual prescription's validity period is not limited in time unless otherwise indicated by the prescriber.⁶⁰

10.2 Out-patient with or without an appointment

A patient's waiting period from the time of arrival to the point of service and sample collection shall comply with ministerial requirements.⁶¹ The quality coordinator shall follow up on patient waiting times.

The response time from the time of sample collection and the prescriber's receipt of the result shall also be determined and verified on a continuous basis so as to improve client service.

10.3 Patient identification

The medical technologist shall unequivocally determine the identity of the patient before sample collection or any other intervention.^{62,63}

For more information on patient identification, consult the OPTMQ's document *Prélèvement de sang par ponction veineuse pour fins d'analyse*.⁶³

10.4 Patient consent

10.4.1 Consent to tests

It is the medical technologist's duty to advise the patient of his or her rights and of ensuring the patient understands the procedures for sample collection and consents to them.^{11,34} According to the *Civil Code of Québec*, 14 is the legal age for consenting to health care. The medical technologist shall know the provisions of the *Civil Code* with regard to consent. Consent can be implicit when a patient arrives at the sample collection centre with a prescription and voluntarily submits to standard sample collection procedures such as presenting his or her arm for a blood sample to be taken.

The patient can withdraw consent at any time. A procedure shall be set up to document patient refusal and to advise the prescriber.^{32,62}

Consent to medical care is not required in case of emergency if the life of the person is in danger or his or her integrity is threatened and his or her consent cannot be obtained in due time.³⁴

For more information, consult the OPTMQ document *Prélèvement de sang par ponction veineuse pour fins d'analyse*.⁶³

10.4.2 Free and informed consent to transfusion

With the medical bodies concerned, the blood bank and transfusion services shall ensure the implementation of a procedure to obtain the free and informed consent to blood component transfusion.³

10.5 Administration of medications or other prescribed substances for analyses and tests

The medical technologist may administer, including intravenously from a peripheral site, prescribed medications or other prescribed substances for analyses and tests, provided an attestation has been issued to the member by the OPTMQ subsequent to training in pharmacology.³⁵

A procedure shall be established and readily available for the administration of medications or other prescribed substances for medical biology analyses or tests, including instructions in the event of adverse reactions.

Medications can be administered via the following routes, among others:

- oral
- intravenous
- subcutaneous
- intramuscular
- intradermal (allergy tests)
- topical (for example, the administration of pilocarpine on the skin in a sweat test).
- via the mucosa (anal, ocular, nasal, bucal, etc.)

The medical technologist shall apply the established procedures placing priority on patient safety.

10.5.1 Preparation of medications for analyses and tests

Procedures shall be developed for the preparation of medications for analyses and tests.

10.5.2 Storage of medications

In compliance with the recommendations of the manufacturer of the medication, a procedure shall define the criteria for storing and handling medications used to conduct analyses and tests.

10.5.3 Administration of medications

The administration of medications or other substances for analyses and tests is a procedure that requires special knowledge and a set of competencies. As part of their duties, medical technologists shall know and verify the following criteria before administering medications:⁶⁴

- The patient's identity
Before administering a medication or other substance, the medical technologist shall unequivocally determine the identity of the patient and verify whether the patient has allergies.
- The required medication
Medical technologists shall ensure they are administering the appropriate medication or substance by comparing the label of the container with the medication or substance's card record, and the prescription. They shall also ensure that the label of the container corresponds to its prewrapped packaging when it is prewrapped.
- The medication's expiry date.
- The appropriate dose to administer.
- The recommended route of administration.
- The appropriate time of administration.

10.5.4 Recording in patient's file

The medical technologist shall record on the appropriate form in the medical file:⁶⁵

- the name of the medication administered;
- the lot number of the medication administered;
- the dose administered;
- the date and time of administration;
- the administration route;
- the duration of administration;
- the adverse effects, if applicable;
- the signature of the medical technologist.

10.6 Sample collection for analyses

Obtaining a quality sample is fundamental to any reliable analysis result. All inadequate procedures relating to sample collection, from identification, to handling, to sample transport, may result in erroneous results. Sample collection tasks are not exclusive to medical technologists. The tasks can be shared with several healthcare professionals, for whom collection is part of their reserved activities.

10.6.1 Sample collection manual

As prescribed by the ISO 15189 standard, specific instructions for the proper collection and handling of samples shall be documented and implemented by laboratory management and made available to those responsible for sample collection. These instructions shall be contained in a sample collection manual.¹

These instructions should in addition include the following elements:

- the test's IT code (mnemonic);
- eating restrictions (if applicable);
- possible interference;
- whether or not the patient must take his or her medication before the test;
- testing time interval;
- tests that can be requested on an urgent basis;^{1,2}
- routine tests and tests conducted upon special request;
- the criteria for accepting or rejecting samples;
- any other information or directive relevant to the test or sample collection.

The sample collection manual shall be part of the document control system.¹

The laboratory shall provide these written directives to any person or institution submitting samples for testing.^{1,12}

10.6.2 Sample collection procedures

The standard operating procedures relating to samples and sample collection shall comply with recognized standards. These procedures shall be available at the sample collection centre.^{1,28}

- **Venous sample:** the procedures for venous blood collection shall be documented and shall be carried out in compliance with the OPTMQ document *Prélèvement de sang par ponction veineuse pour fins d'analyse*.⁶³
- **Capillary sample:** the procedures for capillary blood collection shall be documented and carried out in compliance with the OPTMQ document *Prélèvement de sang par ponction capillaire aux fins d'analyse*.⁶⁶
- **Cytology sample:** the procedures for cytology sample collection shall be documented and carried out in compliance with the *Guidelines for Practice and Quality Assurance in Cytopathology* of the Canadian Society of Cytology.⁶⁷
- **Histopathology sample:** the procedures for histopathology sample collection shall be documented and carried out in compliance with the OPTMQ document *Guide d'anatomopathologie*.⁶⁸
- **Microbiology sample:** the procedures for microbiological sample collection shall be documented and carried out in compliance with the OPTMQ document *Microbiologie*.⁶⁹
- **Other samples for biomedical testing:** The procedures for sample collection for all other types of testing shall be documented and carried out in accordance with recognized standards.
- **Tests for point-of-care testing (POCT):** See point 13.0

A procedure shall define the means to take when a sample could not be taken. This procedure shall provide for recording the reason for not obtaining the sample and the process for advising the prescriber and for ensuring traceability.

10.7 Sample identification

Sample identification is an important step in the preanalytical phase. The requirements in the OPTMQ document *Prélèvement de sang par ponction veineuse pour fins d'analyse* must be respected.⁶³

10.7.1 Anonymized sample

In some specific cases, when confidential clinical studies or tests require patient anonymity, a sample can be submitted with an anonymized identification. In this case, the prescriber shall assign a code to the sample and shall keep in his or her files the identity of the patient corresponding to this code. Information allowing for biological validation of the results (sex and date of birth) shall be available.

The data required in the event of a notifiable disease shall be available upon request.

The identifiers required on a sample consists of the code assigned by the prescriber and the date of birth (or other identifier).

10.7.2 Patient whose identity cannot be determined

A procedure shall be implemented for the temporary identification of a patient whose identity cannot be determined. For more information, consult the OPTMQ document *Prélèvement de sang par ponction veineuse pour fins d'analyse*.⁶³

10.8 Sample storage and transport

The laboratory shall ensure that samples:¹

- are transported within an appropriate timeframe;
- are kept at the recommended temperature interval and with the designated preservatives to ensure their integrity;
- are transported in a manner that ensures safety for the carrier and the receiving laboratory.

The procedures shall be documented and established in accordance with the regulations in force and with recognized laboratory practices.

For more information, consult the OPTMQ document *Transport et conservation des spécimens dans le domaine de la biologie médicale*⁵³ and the *Transportation of Dangerous Goods Regulations*.⁷⁵

10.9 Sample reception

10.9.1 Recording sample reception

The receipt of a sample in the laboratory shall be recorded either on a paper or electronic medium before testing.¹

This record, which can take the form of a copy of the test requisition, shall contain all the information with regard to the identity of the patient, of the prescriber, of the prescribed tests, of the time and date the sample was collected, of the person who collected the sample, of the nature of the sample, and of the time and date of receipt at the laboratory. The record should also mention the name of the person who received the samples.¹ The record shall be kept in compliance with the institution's documentation retention schedule.

10.9.2 Processing urgent tests

The laboratory should determine, in collaboration with the medical bodies in charge of the institution, the list of analyses and tests that can be subject to an urgent request. These analyses and tests require priority processing.

The laboratory shall draft a procedure for the receipt, labelling, processing method, and transmission of the results report for these urgent analyses and tests.¹

10.10 Sample acceptance and rejection criteria

The medical technologist shall ensure that the sample received complies with the quality criteria determined for the test before carrying out the test.¹¹

Sample acceptance and rejection criteria shall be established in each laboratory, working closely with the laboratory specialists. A procedure shall be established to describe the means of rejection and shall include a derogation process if the patient's clinical condition requires it (e.g., life threatening).

This procedure shall also take into account the following conditions:^{53,63,76}

10.10.1 Adequate sample identification

There shall be compliance with adequate sample identification and the presence of two identifiers (family name, first name, and patient-specific identification number).⁶³ If patient identification is not in compliance, the sample shall be rejected.

10.10.2 Unique sample

If on exceptional grounds connected to the patient's well-being a **unique sample** is not in compliance (CSF, surgical parts, etc.), this sample may nevertheless be tested. The test report shall note the noncompliance of the sample and the fact that the result has not been validated. If applicable, it shall include an *addendum* containing all the information likely to influence clinical interpretation of the results by a physician.¹

The report shall not be issued until confirmation is obtained from the prescriber or the person in charge of the sample that he or she assumes responsibility for identification and will provide the necessary information. The signature of the person confirming the identification shall be recorded on the requisition or be appended. If, for some reason, this requirement is not respected, the name of the person in charge shall be written in the test results report.¹

While sample acceptance criteria shall be established to this effect, medical technologists shall use their clinical judgment in applying these criteria and shall do everything possible to avoid refusing the unique sample, the objective being the patient's safety.

10.10.3 Sample quality

There shall be compliance with the requirements of the sample collection method, the stabilizing conditions, and the transportation timeframe for the test requested.

The integrity of the sample (hemolysis, lipemia, fill volume, etc.) shall be in compliance with the test method requirements. If the quality of the sample is not acceptable, the sample shall be rejected.¹

10.10.4 Processing the request in the event of rejection

When a noncompliant sample is rejected, a report indicating that the test was not conducted due to sample noncompliance shall be drafted and the person who applied for the test advised.

Traceability shall be maintained at all times: the request must never be cancelled, whether electronically or by paper. (See point 12.10.) If there was a mix-up between two patients, new samples shall be obtained and processed based on a new requisition.

The laboratory shall record in a (paper or electronic) register, the origin and the reason for noncompliance of the rejected sample. This data should be periodically analyzed to detect the causes of errors and to recommend corrective action and to thus improve service. (See points 3.3.1 and 3.3.3.)

11.0 Analytical phase

11.1 Procedures related to analytical activities

The procedures related to analytical activities shall clearly define the steps involved in all testing techniques used in the laboratory.

The procedures shall be accessible to all personnel. They should include the following or refer to another procedure that includes the following, as required:

- The principle, the purpose, and the clinical relevance of the test.
- The policies and processes that govern the procedure.
- The scope of the document.
- The particular sampling requirements (examples: patient preparation, special diet, conditions for storage and transport, conditions for rejection, procedures for preparing samples to be sent out for analysis in another centre).
- Mode of preparation of samples for analysis. Each step in the mode of preparation shall be described. Manufacturer's recommendations shall be taken into considerations at all times.
- Technical instructions for the analysis.
- The nature, mode of preparation, and the storage time of reagents used.
- Equipment or materials to be used.
- Special safety precautions involved in performing the procedure.
- Calibration.
- Preventive maintenance.
- Quality control.
- Calculations.
- Interpretation of results.
- Reference intervals and clinical values.
- Critical values and reference to the procedure to be followed in these cases.
- Performance specifications (for example, linearity, precision, accuracy expressed in terms of measurement uncertainty, detection limit, extent of measurement, trueness of measurement, analytical sensitivity, and analytical specificity).
- Interferences and cross reactions. Possible interferences shall be identified and described. It is important to evaluate these in all categories, for example, interference related to sample collection, medications, and the patient's clinical state.
- Bibliographical references.
- Effective date and review date.
- Identity of the author, revisor, and the person authorizing the procedure.
- Reference to the document detailing the procedure to follow for entering and transmitting results along with the steps to follow when there is a power failure or information system failure.

Adapted from Clinical Laboratory Standards Institute: QMS02, *Quality Management Systems: Development and Management of Laboratory Documents; Approved Guideline*.²¹

11.1.1 Equipment procedure manuals

All laboratory instruments and equipment shall be accompanied by an operating procedure manual.

The manufacturer's procedure manual, which gives specific information for the equipment, can also serve as the operation procedure if it contains all the points listed above, if it describes laboratory procedures that are in use, and if its language is easily understood by all medical technologists.

Equipment operation procedures can also be integrated into the analytical procedures.

11.1.2 Product inserts

Requirements as specified in product inserts for commercial kits, reagents, specimen collection tubes, and any other element shall be checked with each lot change.¹ The product insert shall be read, dated, signed and retained. As well, relevant changes shall be integrated into the procedure.

11.2 Laboratory equipment

Laboratory equipment includes instruments, equipment, reagents, reference materials, and consumables, without being limited to these.

The laboratory shall be furnished with all items of equipment required for the provision of services.¹ The laboratory shall define and document its policies and procedures for the selection and use of purchased external services, equipment, and consumable supplies that are likely to affect the quality of its service. Purchased items shall consistently meet the laboratory's quality requirements. Any laboratory equipment that affects the quality of the services shall not be used until it has been verified as complying with standard specifications or requirements defined for the procedures concerned.¹

There shall be an inventory control system for the supplies in place. Each item of material shall be uniquely labelled, marked, or otherwise identified.¹

11.2.1 Instruments

11.2.1.1 General requirements

Instrumentation is an important component of the analytical process. Despite the improved performance of instruments, the medical technologist must understand how they function and remain vigilant when using them.¹¹

Instrument management includes the processes of selection, inventory, installation, calibration, maintenance, annual certification, and the withdrawal of the instrument.

The laboratory shall have measures in place in order to verify that instruments in use comply with their specifications, that they are kept in good condition, that they are operated safely, that they respect the environment, and that there are a sufficient number of them. Compliance verification will be carried out before purchase, during set-up, and during normal operation.^{1,22}

All instrument parts directly or indirectly involved in analytical processes shall have associated with them an identification number, an operation procedure, and a schedule of preventive maintenance and function checks. (See points 11.1 and 11.5.)^{22,77}

Records shall be retained for the time specified by the laboratory, while respecting legal and administrative requirements. (See point 3.5.4 and Appendix 10.)

11.2.1.2 Inventory

A complete inventory of instruments shall be established and updated with each instrument purchase or withdrawal. The inventory shall include the following information:^{1,77}

- a unique inventory number for each component of the instrument;
- the location;
- the manufacturer's name, model number, and serial number;
- the date of receipt as well as condition upon receipt (for example, new, used, or reconditioned);
- the implementation date;
- the list of manufacturer's manuals and their location;
- the list of all versions of software.

Each instrument shall be identified with a label that includes its inventory number, calibration schedule, date of its latest operational verification, and the date of the next planned verification. Labels used shall be water resistant, humidity resistant, and heat resistant; and they shall be placed on the instrument so as to be clearly visible.⁷⁷

An instrument inventory coordinator should be named to keep the instrument inventory up to date.⁷⁷

11.2.1.3 Implementing a new instrument

The laboratory shall establish a protocol for implementing a new instrument.⁷⁸ The protocol should include:

- comparative study of new reagents in routine use;
- establishing reference intervals as well as disseminating any changes to the various health professionals;
- establishing new calibration curves, linearity curves, and detection limits;
- establishing or verifying target values and limits for quality control;
- evaluating sample precision, accuracy and remanence, and reagent cross-contamination;
- connecting the interface with the information system in place;
- personnel training;
- establishing maintenance procedures.

The manufacturer's manual can be used if it contains all elements necessary to instrument implementation.

Instrument records shall be stored for the retention period determined by the laboratory, while respecting legal and administrative requirements.⁷⁹

11.2.1.4 Instrument operation

The medical technologist shall have knowledge of the following elements:¹¹

- unique identifier of each instrument and its software (if applicable);
- manufacturer identification, supplier contact person and telephone number;
- implementation date;
- materials required;
- principle;
- linearity;
- limits of the instrument;
- interferences;
- corrective measures;
- applicable calibration and quality control and the intrinsic records (results, interpretation, calculations, etc.);
- preventive maintenance and intrinsic records;

- error sources;
- troubleshooting guide;
- biological, chemical, and physical risks associated with handling as well as the precautions to be taken to avoid these risks;
- decontamination procedure.

11.2.2 Reagents

Reagents include all products used during an analysis, for example, colorants, chemical products, commercial kits, control solutions, etc.

A reagent management process shall be established and should include:^{22,80}

- An inventory of reagents used.
- Manufacturer's storage instructions.
- Preparation, verification, and storage conditions of reagents.
- Recording of expiry dates and lot numbers of commercial solutions.
- Appropriate labelling of reagents that includes:
 - date of receipt (if applicable);
 - date opened (if applicable);
 - date prepared (if applicable);
 - expiry date;
 - concentration;
 - storage conditions;
 - initials of the medical technologist who did the preparation;
 - the relevant WHMIS labels.
- A product description that meets the requirements of WHMIS. A material safety data sheet or a health and safety technical specifications sheet shall accompany each product. The sheet shall include the name of the person who has prepared the product as well as the preparation date.²⁷
- Modes of preparation of laboratory reagents, which shall be described in the analytical techniques and procedures manual.

11.2.3 Water used in laboratories

Water is the most commonly used laboratory reagent. The laboratory shall ensure that the water used in its activities meets the intended quality criteria or specifications. These criteria are chosen mainly in terms of the specificities of various instrument applications and specifications. Water quality is crucial and can influence tests in various ways, for example:

- preparation of culture media;
- preparation of reagents;
- reconstitution of lyophilized matter.

The 4th edition of *Preparation and Testing of Reagent Water in the Clinical Laboratory* (GP40-A4), 2006, *Clinical and Laboratory Standards Institute* (CLSI)⁸¹ gives six categories of purified water:

- clinical laboratory reagent water (CLRW);
- special reagent water (SRW);
- instrument feed water;
- water supplied by a method manufacturer;
- autoclave and wash water;
- commercially bottled, purified water.

For its part, the Laboratoire de santé publique du Québec (LSPQ) provides a water quality analysis service for Quebec biomedical laboratories. Based on the CLSI GP40 standard, it has established specifications for microbiological and physical–chemical parameters as presented in the table below.⁸²

Comparative characteristics of parameters analyzed by the LSPQ in relation to the CLSI:

Parameter	LSPQ Type I	LSPQ Type II	LSPQ Type III	CLSI CLRW
Microorganism count (CFU/mL) ⁽¹⁾	< 10	< 100	N/A	< 10
Endotoxins (EU/mL)	< 0.25	< 1,0	N/A	N/A
Resistivity (MΩ.cm) ⁽²⁾	> 10	> 1.0	> 0.1	> 10 ⁽²⁾
Conductivity (μS/cm) ⁽²⁾	< 0.1	< 1.0	< 10.0	< 0.1 ⁽²⁾
pH	N/A	N/A	5.0–8.0	N/A
Silicates (mg/L)	< 0.05	< 0.1	< 1.0	N/A
Total organic carbon (μg/L)	< 100	< 500	N/A	< 500
Particulates (end-of-line filter blocking particulates ≥ 0.22 μm) ⁽³⁾	Yes	Yes	N/A	Yes

⁽¹⁾ filtering membrane technique with a 0.45 μm filter

⁽²⁾ obtained with a closed circuit

⁽³⁾ non-analyzed parameter

The new CLSI standard (GP40-A4) replaces the categories commonly referred to as Type I, Type II, and Type III, under the designation *Clinical Laboratory Reagent Water* (CLRW). A CLRW purified water has essentially the same properties as Type I water under the previous standard. LSPQ results for external requests for water analysis will be reported with mention of conformity under the new CLRW designation. However, upon client request, water quality for the former CLSI categories Type I, II, and III, will from now on be reported with the LSPQ designation Type I, II, or III depending on the parameters to be analyzed.⁸²

11.2.3.1 Use of the various water types

Water that meets specifications under the new CLRW designation is pure enough for most of the tests carried out in a biomedical laboratory and possesses essentially the same properties as Type I water under the former standard. Some analyses, like nucleic acid (DNA, RNA) analyses and analyses for traces of metal require special reagent water (designated SRW by CLSI). In such cases, additional parameters and limits different from CLRW criteria are established by the laboratory.⁸¹

11.2.3.2 Commercial laboratory water

Values for resistivity, microbial content, and total organic carbon shall be determined by the manufacturer at the time of production. These values will appear on the manufacturer's label with the lot number and the expiry date. It is recommended that each new lot be verified in order to ensure the desired quality.⁸³

11.2.3.3 Validation of criteria

A laboratory that establishes specific quality criteria for water to be used shall verify that the criteria meet expectations.⁸¹ Various methods of validation can be used (e.g., use of water as a blank sample, evaluation of quality control elements, comparison with a water that has an established purity, etc.).

11.2.3.4 Validation of the water purification system

The water purification system shall also be checked so as to demonstrate that it is able to provide water in accordance with the expected criteria. Validation should include installation qualification, operational qualification, and performance qualification. Any existing water purification system can be subjected to a retrospective validation based on historical data.⁸¹

11.2.3.5 Quality control of water

Once validation has been completed, the water purification system shall be verified periodically. A record of operations and maintenance enables documentation of the various functional checks. Analyses of targeted parameters shall be carried out according to an established schedule so as to assure water quality. In addition, these analyses make it possible to detect deviations from specifications or trends alerting the user to plan equipment maintenance.⁸¹

11.2.3.6 Quality control of glassware washing

Glassware washing with quality water can prevent a number of testing problems. A process shall be established so as to ensure that glassware and non-disposable plastic instruments are cleaned and sterilized in a manner that eliminates all traces of metals, residues, detergents, or other contaminants.²³

A visual spot check of washed glassware is recommended as well as a chemical pH check adding 0.04% bromothymol blue to a glassware item that has gone through all washing and rinsing cycles. A change of colour to yellow or dark blue indicates the possible presence of, respectively, acidic or alkaline residues.⁸³

11.2.4 Requirements for specific instruments

It is recommended that some instruments (among others, thermometers, refrigerators, balances, centrifuges) be calibrated by an organization accredited by the Standards Council of Canada in partnership with the Calibration Laboratory Assessment Service (CLAS).

Other instruments not mentioned in this section shall also be checked if they affect the quality of results. The electrical cord of each device should be inspected annually.⁸⁴

11.2.4.1 Refrigerator, freezer, water bath, and incubator

The medical technologist should verify temperature during each use. Temperature recording frequency shall be noted, in compliance with the standards for that area of activity. If the instrument is equipped with a device for continuous recording of temperature, the laboratory shall have a procedure defining the monitoring mode, including frequency of graph changes, according to instrument specifications. At least once a day but **ideally during each work shift**, the medical technologist shall record, date, and initial the temperature of each of these instruments.⁸⁵⁻⁸⁷ Accuracy of thermometers in use shall be performed regularly, in accordance with the manufacturer's instructions.³

Tolerance limits shall be determined for each instrument based on its methodology. For some instruments, tolerance limits are provided by the manufacturer.

11.2.4.2 Refrigerator, freezer, incubator for storage of whole blood and labile blood components

This equipment shall have a validated continuous system for monitoring temperature and with an alarm system with signals that are audible. The alarm warning shall signal in a location that is continually monitored or staffed.⁸⁸ A regular temperature verification procedure (for example, every eight hours) should be in place to prevent loss of blood.³

If these devices do not have a continuous temperature-monitoring system, the temperature shall be checked and documented every four hours.³

There shall be access to an emergency power source for critical equipment in the event of a power failure.³

11.2.4.3 Autoclaves

The effectiveness of decontamination by steam autoclaving depends upon various loading factors that influence the temperature to which the material is subjected and the contact time.^{13,25,89}

Record of a cycle as well as the use of a sterilization indicator tape shall be included in each use. Effectiveness shall be checked weekly with a biological indicator (or each time it is used, when used less than once a week).^{13,22,25,89,90}

11.2.4.4 Balances

Balances are sensitive instruments and should be installed in a location where factors of influence as specified by the manufacturer are controlled.

An analytical balance should be installed in an area free of vibrations and air currents.^{22,90} The balance must be clean and perfectly levelled. Should it be necessary to move a balance, it should be recalibrated.

The balance shall be calibrated with traceable weights.^{22,90} These weights shall be accessible, well maintained (no corrosion), and calibrated regularly.²² Calibration results shall be recorded, dated, and initialled.²²

11.2.4.5 Centrifuges and cytocentrifuges

At the minimum, the laboratory shall include the manufacturer's specifications when it establishes a preventive maintenance procedure for centrifuges and cytocentrifuges, one that includes a schedule of maintenance operations.

Maintenance shall include, among other aspects, an annual verification (or more often if necessary) of centrifugation speed, usually with a tachometer, as well as annual verification of the temperature of refrigerated centrifuges.^{84,90}

Maintenance operations can be carried out with participation of the medical engineering department or of another qualified person, provided that operating specifications are supplied by the laboratory. All interventions shall be recorded, dated, and initialled.²²

11.2.4.6 Biological safety cabinets

- Installation and certification of biological safety cabinets

Selection of the proper class of biological safety cabinet shall be in compliance with the level of confinement related to the risk group of the microorganisms being handled. Biological safety cabinets should be installed in compliance with the requirements stated in the *Canadian Biosafety Standard* and the *Canadian Biosafety Guidelines* from the Public Health Agency of Canada.

Among others, these requirements include:

- A biological safety cabinet should be located away from high traffic areas, doors, and air supply/exhaust vents that could interrupt air flow patterns.

- A minimum unobstructed distance of 40 cm should be provided between the exhaust outlet on top of the cabinet and any overhead obstructions. Whenever possible, a 30 cm clearance should be provided on each side of the cabinet to allow for maintenance access.^{13,25}
- The provision of natural gas to biological safety cabinets for purposes of sterilizing inoculation instruments is not recommended. Micro-incinerators must be used.^{13,25}
- Correct operation of biological safety cabinets shall be verified by an accredited organization before they are used, and then annually, and after any repairs or relocation.^{25,27} A copy of the certification report shall be provided to the user, who shall keep it on file.²⁵ A label shall be affixed to the cabinet exterior indicating the date of certification and the date of the next certification.²⁵
- Use of the biological safety cabinet

The procedure for the use of biological safety cabinets shall be in compliance with the procedures described in the *Canadian Biosafety Standard* and the *Canadian Biosafety Guidelines* from the Public Health Agency of Canada.

Verify inward airflow with a strip of paper (e.g., paper towelling) attached to the base of the protective viewing panel of the cabinet.²⁵ This verification shall be carried out daily before use and recorded.^{13,25}

It is recommended to avoid moving around behind someone using the cabinet.

- Decontamination.

Use a non-corrosive disinfectant to disinfect the interior surfaces of the cabinet.

11.2.4.7 Fume hoods

A fume hood shall be equipped with a visual and audible alarm system that signals when frontal air velocity has passed below a pre-established point.

A fume hood should be located away from high traffic areas, doors, and general ventilation devices that could interfere with air flow patterns.

The unobstructed work area in front of the fume hood should extend at least 1.5 m.⁹¹

A preventive maintenance program shall be established. Daily maintenance should include cleaning the work surfaces and checking the sashes and the alarm. Fume hood operation shall be verified by a qualified organization before commissioning, after each repair or relocation, and annually.

Calibration, inspection, and preventive maintenance reports shall be on file in compliance with the established retention schedule.⁹¹ (See point 3.6.4.)

For more information, consult the CSA Group Standard Z316.5, *Fume hoods and associated exhaust systems*.⁹¹

11.2.4.8 Microscope

An adjusted and optimally maintained microscope is an element essential to the precision and accuracy of any microscopic examination.

The medical technologist must have a basic knowledge of the principles and components of the microscope.¹¹

The microscope operating procedure should:

- describe adjustment and daily maintenance;⁹⁰
- establish a preventive maintenance schedule;
- provide for annual inspection by a specialist;
- provide for the obligation to record, date, and initial preventive maintenance operations.

The lighting adjustment procedure, in accordance with the Köhler method, shall be described and performed by the medical technologist before using the microscope.^{92,93} (See Appendix 11)

The Köhler lighting adjustment enables a total and uniform illumination of the microscopic field, thereby presenting a clear and precise image of the object observed.⁹⁴

11.2.4.9 Automated pipettes and dilutors

The medical technologist shall verify the accuracy and precision of each new automated pipette and each new dilutor before first use, after each preventive or corrective maintenance in compliance with user-defined run lengths, and minimally once a year.¹⁰³ The laboratory shall establish a calibration verification procedure that includes a schedule of maintenance procedures in compliance with the manufacturer's recommendations or with any other recognized standard. The medical technologist shall record, date, and initial all interventions.

11.3 Choice and validation of an analytical method

An analytical method shall be selected in terms of the needs of laboratory clientele and type of analysis.¹ Any change of analytical method (or in the method itself) that might cause a significant change in results or in the interpretation of results shall be communicated in writing to users of laboratory services before making the changes.¹

It is advisable to opt for analytical methods featured in publications recognized by experts in the area or for methods recommended in regional, national, or international directives.

Any other analytical method shall be supported by complete documentation and validated as being in compliance with its intended use.¹ Evaluation results shall be compiled and found to be satisfactory for the targeted medical test. Furthermore, results shall meet clinical requirements and be approved by the laboratory specialist.^{1,95} When possible, method validation will include a comparison of results with a recognized reference method.⁹⁶

The validation procedure as well as its results shall be recorded and kept on file in compliance with the period determined by the institution's retention schedule and by applicable regulations.¹

Note: Reference intervals shall be re-established when there has been any change in a method or a change of method. See point 11.4.

11.3.1 Correlation between a main device and a support device

Correlation between a main device and a support device shall be carried out according to an established frequency, as part of a continual process of quality control, and during installation, repair, or calibration.¹

Every intervention shall be recorded, dated, and initialled.

The difference between results obtained on the main device and those obtained on the support device shall not be clinically significant.⁹⁶ Reference intervals should be the same for both devices.

External quality control makes it possible to monitor the trends of each device and to verify the correlation between the two systems.

11.4 Reference intervals

A reference interval is defined as the interval between and including two numbers, an upper and lower reference limit, which are estimated to enclose a specified percentage (usually 95%) of the values for a given population. The lower limit and upper limit are estimated as the 2.5th and 97.5th percentiles of the distribution of reference values, respectively.⁹⁷

Reference intervals are calculated from reference values obtained in a reference population study for a particular analysis. Reference values should be obtained locally in each laboratory. The laboratory can also decide to validate reference intervals established by manufacturers or those found in the literature.⁹⁷

The population of individuals whose values serve to establish reference intervals shall be representative of the population to be analyzed.⁹⁷ In some cases, reference values typical of a pediatric population, for example, shall be obtained.

Reference intervals shall be reviewed periodically. A review shall also be carried out with any change in a preanalytical or analytical procedure.¹

The elements that are most important in determining a reliable reference interval are the following:⁹⁷

- appropriate selection of reference individuals;
- analysis of a sufficient number of reference individuals;
- elimination of preanalytical and analytical error sources.

Written consent shall be obtained from reference individuals.³⁴

Establishing reference intervals requires additional knowledge, not dealt with here. Please consult the reference literature and laboratory specialists.

More information on reference intervals is provided by the CLSI document EP28 *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline*.⁹⁷

11.5 Preventive maintenance

A laboratory shall develop and implement a regular monitoring program that will ensure the proper functioning of all laboratory instruments, materials, reagents, and analytical systems.¹

The preventive maintenance program shall be documented and recorded, and shall at least minimally comply with manufacturers' recommendations or any other recognized standard.¹ The medical technologist records, dates, and initials all preventive maintenance interventions.

Records related to a preventive maintenance program should be kept for the useful life of the equipment, plus three years.⁷⁹

11.6 Calibration

Calibration is defined as a set of operations that establish the mathematical relationship between values of quantities indicated by a measuring instrument or measuring system and the corresponding values realized by standards. This mathematical relationship is then used to determine the concentration of the analyte in the test sample.⁷⁸ Calibration must not be confused with quality control.

11.6.1 Calibration solutions

Calibration solutions shall be used and stored in rigorous compliance with the manufacturer's recommendations.

11.6.2 Calibration procedure

A calibration procedure specific to each analytical system used by a laboratory shall be described in the operational procedure manual or in the analytical procedure of this system. Calibration results shall be recorded, dated, and initialled.

Written procedures and technical instructions should specify what follows, or refer to another procedure or to other technical instructions that specify the following:

- requisite calibration frequency and situations that require calibration;
- maintenance or updating of the analytical system before calibration, if required;
- verification of the validity of calibration of the analytical system at the end of the procedure;
- measures to be taken in the event of calibration nonconformity.

11.7 Quality control program

The quality control program encompasses measures taken to assure the accuracy and precision of the result of each analysis performed. The ultimate goal is to provide high-quality analyses, and consequently, to support physicians in the care of their patients.

The laboratory specialist shall ensure that each analysis method is accompanied by a recognized and adequate quality control system.¹ The vigilance, expertise, and judgment of the medical technologist are essential to the application of any quality control approach to analytical systems.

The laboratory should designate a quality control coordinator to process data, to document sources of errors, to ensure recording and follow-up of data, and to suggest corrective measures.^{22,80}

The following section places special emphasis on quality control of blood tests.

For more information on quality control for other areas of activity in medical biology, consult the following documents:

- CSA Group, CAN/CSA Z902: *Blood and blood components*³
- OPTMQ, *Anatomopathologie*⁶⁸
- OPTMQ, *Hématologie*⁹⁹
- OPTMQ, *Hémostase*¹⁰⁰
- OPTMQ, *Microbiologie*⁶⁹

11.7.1 General criteria

The laboratory shall implement and maintain a quality control system for analytical procedures in accordance with the following requirements:

- The quality control program shall be adapted to the complexity of each analytical system, complying with manufacturer's requirements and recognized standards.

- An internal quality control system shall assure the precision of results obtained.¹
- An external quality control system and interlaboratory comparison scheme or a conformity assessment procedure shall be implemented.¹ (See point 11.7.8.)
- Verification of quality control results shall be recorded, dated, and initialled.
- Preparation of control materials and reagents used to perform controls shall be documented. Internal and external control results shall be recorded, dated, and initialled. They shall be subject to assessment and periodic follow-up by the coordinator. This information shall be conveyed to personnel.²³
- When the quality control result is noncompliant, corrective action shall be taken, documented, and reviewed.¹

11.7.2 Internal quality control

Internal quality control shall ensure that analytical phase processes are in compliance with the quality criteria established for each analysis carried out in the laboratory.

There shall be a process in place to standardize microscopic observations between users.¹⁰¹

Daily control includes regular use of materials and control methods, as well as continual statistical analysis of them.

Statistical analysis of controls shall enable identification and differentiation of a random error from a systematic error throughout the analytical process.

11.7.3 Control samples

Control samples shall be selected according to the characteristics of the measurement method and the patient sample. The laboratory should obtain stable control materials (appropriate expiry date) in a quantity sufficient to ensure long-term use of a single lot (for at least one year).¹⁰²

There are two kinds of control materials: commercial control solutions and control solutions prepared in-house.

11.7.3.1 Use of commercial quality control materials

The primary function of commercial control solutions is daily monitoring, continually and more-or-less long term, of the performance and level of precision of an analytical procedure.

The laboratory shall note and record all lot numbers corresponding to each commercial solution being used, and it shall retain these records in compliance with the institution's retention schedule.

Modes of reconstituting commercial lyophilized controls as well as defrosting frozen commercial controls shall rigorously comply with manufacturer's instructions. Commercial quality control solutions for a device shall not be identical to the calibration solutions for that device.⁸⁰

11.7.3.2 Controls prepared in-house

For control materials prepared internally, the laboratory shall have a procedure for verifying stability, establishing an expiry date, and defining storage conditions.¹⁰² This procedure shall also ensure compliance with the additional security measures required by the internal preparation of such control materials.

11.7.3.3 Control stability and storage

The medical technologist shall respect manufacturer's instructions with regard to the stability period, expiry date, and storage conditions of commercial quality control materials.

Once reconstituted or defrosted, control solutions shall not be refrozen, unless there is notice to the contrary by the manufacturer.

11.7.3.4 Control levels

The number of levels or concentrations of quality control materials shall be sufficient to verify the analytical performance over the measuring range of the technique.¹⁰²

Controls for normal and abnormal levels shall be used for each analysis carried out, and concentrations shall correspond to clinically significant values.¹⁰²

Control levels shall be representative of the clientele being served.

Commercial control solutions shall be treated in the same way as patient samples.

11.7.4 Frequency of quality control

The frequency of quality control measurement shall be established by the laboratory specialist based on the laboratory testing conditions and manufacturer's recommendations. Quality control samples shall be analyzed at least once during each analytical run length. An analytical run is the time or number of measurements for which the measurement procedure is stable.¹⁰²

Quality control shall also be conducted after a calibration and after a preventive maintenance or a repair.

A normal control concentration and an abnormal concentration shall be included in each analytical run for semi-automated devices, for manual methods, and for specialty tests.

11.7.5 Statistical treatment of quality control

11.7.5.1 Target value and control limits

Each laboratory shall establish a target value and control limits for each control level. Ideally, the target value and the limits correspond to the observed mean value and to plus or minus three times the observed standard deviations of a distribution made up of a minimum of 20 readings over a period of 20 days.¹⁰²

11.7.5.2 Validation of new control lots

A procedure shall be implemented that will compare the values of a new control lot to the former lot so as to establish the target value and limit values of each new lot.

11.7.5.3 Assessment and follow-up of control results

If technical conditions are respected and remain unchanged, control results shall respect the limits defined by the laboratory specialists. The Westgard rules of 1_{3s} (a result of plus or minus three standard deviations from the mean) or 2_{2s} (two consecutive results of plus or minus two standard deviations from the mean) can be used to determine control acceptability. If these rules are followed, results of patient analyses will be acceptable and validated. Other Westgard rules can apply. A result of plus or minus two standard deviations from the mean (1_{2s}) is generally considered as a warning.^{102,103}

If control results are beyond acceptable ranges, the laboratory shall implement a procedure that defines corrective action to be taken in order to solve the problem before producing an analytical result for a patient.

11.7.5.4 Reproducibility

Reproducibility is the measurement of imprecision; it expresses the degree of variation (dispersion) of results with multiple analyses of control materials of the same value carried out according to a method of analysis.

Reproducibility is expressed by the coefficient of variation (CV), which is calculated by dividing the standard deviation by the mean and multiplying it by 100; it thus defines the imprecision of a method.

The intra-assay CV (CV calculated over a period of 20–30 days) shall not exceed the imprecision limits specified by the manufacturer.

11.7.5.5 Charts

Automated instruments as well as laboratory information systems are usually equipped with an integrated system for processing quality control values, which allows for control interpretation and follow-up.

The quality control coordinator shall use the quality control charts to interpret the results and closely monitor quality control.

Levey-Jennings charts and Westgard multiple rules are most commonly used in biomedical laboratories, but these are not the only ones that are scientifically valid.

The laboratory shall be able to trace the identity of the medical technologist who verified quality control compliance and corrective action, where applicable.

11.7.6 Quality control of qualitative analyses

Quality control materials shall be used to ensure the quality of qualitative tests. Commercial solutions provided by a manufacturer should be used in compliance with requirements involving storage, reconstitution (if applicable), and expiry date.

The procedure shall provide for the use of a positive control and a negative control for each qualitative analyses run, when controls are available. On the condition that manufacturer's instructions are followed, some tests can be controlled by the daily use of a positive control and a negative control.¹⁰⁴

The laboratory should have confirmatory testing to confirm positive screening results.¹⁰⁴

11.7.7 Quality control of analyses without control materials

For some analyses, there are no appropriate or readily accessible control materials. In such cases, the laboratory shall prepare its own controls by referring to established and recognized standards. (See point 11.7.3.2.)

If preparation of these controls is impossible, accuracy and precision shall be assured by establishing procedures, method validation, reproducibility, and continuing education of medical technologists.^{1,92}

11.7.8 External quality control

The laboratory shall participate in an external quality assessment program that addresses all types of analyses it performs.¹ The main purpose of an external quality control program is to detect systematic errors (bias). Such a program thus makes it possible to perform an accuracy check of the analysis method and to compare laboratory accuracy performance with that of other laboratories.¹⁰⁵

For those analyses performed at different sites, there shall be a defined mechanism for verifying the comparability of results for the range of observed values in clinical practice.¹

Where there is no external quality assessment program in place for one type or several types of analysis, the laboratory shall establish a conformity (accuracy) assessment procedure.¹ In such a case, the laboratory can send an aliquot of a sample of a known patient to another laboratory or assess a sample from a former clinically known patient so as to assess conformity of analytical procedures.¹⁰⁶

For more information on quality assessment where there is no external quality assessment program in place, consult Clinical and Laboratory Standards Institute (CLSI) document GP29—*Assessment of Laboratory Tests When Proficiency Testing is not Available*.¹⁰⁶

Samples provided by an external quality assessment program shall be analyzed and processed in the same way as patient samples.¹

The external quality control and interlaboratory comparison scheme are useful tools for continuing education of personnel. Personnel from the various work shifts should participate in such training.

The laboratory should adopt a written procedure for handling and processing control materials as well as for recording and follow-up of results. Analysis and follow-up of external quality control results shall allow for detecting current or potential problems and to take the necessary corrective action when results are not acceptable.¹⁰⁵ Records of external quality control shall be retained in compliance with the institution's retention schedule.¹

The Clinical and Laboratory Standards Institute document GP27—*Using Proficiency Testing to Improve the Clinical Laboratory* explains in detail how to use external assessment to improve analysis quality.¹⁰⁵

11.8 Sending out analyses to referral laboratories

11.8.1 Selection and evaluation procedures

The referring laboratory is responsible for assuring the quality of analyses sent to the referral laboratory. It shall thus have available a procedure for selecting and evaluating the referral laboratory.¹

This procedure should allow for verification of the following points:¹

- Is the analysis method chosen by the referral laboratory appropriate for the intended use?
- Do turnaround times meet the needs of the referring laboratory and its users?
- Are the required preanalytical and postanalytical conditions clearly defined and documented?

11.8.2 Contract review

If the laboratory offers client services in medical biology (referring laboratory, pharmaceutical company, and medical clinic, etc.), it shall establish and maintain contract review procedures. Such reviews shall ensure that requirements, including the methods to be used, are adequately defined and documented and that the laboratory has the capability and resources to meet the requirements. Clients shall be informed of any deviation from the established contract.¹

11.8.3 Register for samples sent out to a referral laboratory

When samples are sent out to a referral laboratory for analysis, the referring laboratory shall keep a record in a register, with information related to each sample, and it is responsible for following up on the results.¹

Whether paper or electronic, this register should include as a minimum the following information:²²

- name of the analysis;
- patient's first and last name;
- patient-specific identification number;
- date and time of collection;
- name of referral laboratory;
- name or initials of person preparing the referral;
- date referral was sent;
- date result was received.

The referring laboratory shall maintain a register of all referral laboratories that it uses.¹

11.8.4 Documentation to be provided to a referral laboratory

The requisition form shall provide enough space to enter the following minimal elements:¹

- unique identification of the patient (first and last name, personalized ID number, sex, date of birth);
- identification of the referring laboratory as well as its address or name of clinician if the report is to be sent directly to him or her;
- type of sample and anatomic site, where applicable;
- clinical information relevant to the patient and the sample;
- date and time of sample collection.

This documentation can be a copy of the original request, a form provided by the referral laboratory, or a request form prepared by the referring laboratory.

Packaging of samples shall be in compliance with regulations in force. Conditions of transport shall maintain the appropriate constant temperature interval until the sample is processed by the referral laboratory. For further information, consult the OPTMQ reference *Transport et conservation des échantillons dans le domaine de la biologie médicale*.⁵³

The name and address of the laboratory that performed the analyses shall be supplied by the referring laboratory to the users of its services. The referring laboratory is responsible for conveying the analysis results to the prescriber. If the referring laboratory prepares the report of the analysis results, it shall include the essential elements of the result reported by the referral laboratory, without any changes that might affect clinical interpretation.¹

The laboratory shall establish a procedure that checks the accuracy of transcription of analysis results.¹

12.0 Postanalytical phase

Competence and judgment are called upon when ensuring that the transmitted analysis result reflects the clinical state of the patient whose sample was provided. Furthermore, care shall be taken to communicate the result in a timely fashion and by an appropriate mode of transmission that respects the legislation and regulations with regard to confidentiality.

12.1 Verification of the validity of the analysis result

Before accepting the result, the medical technologist shall:

- ensure that preventive maintenance has been performed, if applicable;
- ensure that quality control results are in conformity;
- check alarm signals and error messages generated by the instruments.

12.1.1 Interventions related to alarm signals and error messages

Many analytical systems are equipped with two criteria systems to alert the medical technologist to a potential problem. One of these alarm systems is set by the manufacturer while the other, usually quantitative, is determined by the laboratory.

Each laboratory shall:

- determine interventions, corrections, or corrective action by which to verify or validate a result identified by an error code before issuing the final result;
- together with the laboratory specialist, establish a procedure for determining situations (error message or client type) where a medical specialist shall check results.

Each laboratory should:

- in the section of the device instruction manual dealing with quality control, note and describe the various alarm signals and error messages emitted by the analyzer;
- with the laboratory specialist, define the clinically significant values in relation to the parameters analyzed and establish the corresponding error messages.

12.2 Biological validation of an analysis result

Biological validation of a result guarantees the reliability of a patient's analysis result in a given clinical context. It ensures the compatibility of a set of analyses performed for the same patient at different times, taking into account the variations in the patient's clinical state, the treatment received, and previous results.¹⁰⁷

Before reporting a result, the medical technologist shall:^{1,11,12}

- check the priority of requests;
- check the validity of each result located outside of the reference interval or any result attaining critical values;
- where available, check the correlation between the current result and the preceding result (delta check), clinical information, diagnosis, and the patient's treatment;
- where applicable, check the correlation between the result and other laboratory analyses;
- look for the cause of an unlikely result (preanalytical errors: hemolysis, lactescence, contamination by a solute, presence of clots, etc.).

Some analyses involve numerous parameters of which some are counted while others are measured or calculated. The medical technologist shall understand the nature of these parameters in order to be able to interpret and validate the results.

12.3 Management of alert and critical results

The laboratory, in agreement with clinicians working with the laboratory, shall determine a list of the critical properties and their alert/critical intervals well as their limits, which indicate a clinical state that puts the patient's life in danger.¹

A procedure shall define the measures to be taken for processing and forwarding an alert or critical result. It shall include the following elements:¹

- list of critical results requiring rapid intervention with the patient;
- a check of result validity;
- the professional who is responsible for transmitting a critical result;
- the professional who is authorized to receive a critical result;

- the mode of transmission for sending the result (e.g., telephone);
- information to be transmitted along with the critical result (e.g., name and file number of the patient);
- person to advise who is available after regular hours and on weekends or holidays;
- the specific procedure to follow when it is not possible to reach the professional in charge of patient care;
- a record of measures taken to transmit the critical result or, where applicable, a record of any difficulties encountered during transmission;
- record retention period.

The process shall provide for a record of the name of the person who transmitted the result as well as the name of the person who received, it shall record the date and time, and it shall initial the steps taken up to the final transmission of the result to the physician or health professional responsible for medical follow-up with the patient, or, where applicable, it shall record any difficulties encountered in meeting the transmission requirements.¹ The medical technologist is **responsible** for the transmission of results that he or she has issued.¹¹

12.4 Automated validation

In an automated validation process, the results that are within the parameters established by the laboratory specialist are validated electronically and transmitted electronically without further action.

There must be continuous follow-up of quality control when results within the parameters established by the laboratory specialist have only been validated electronically.

Safety precautions shall be part of the analysis procedure, for example:

- validation of any one sample cannot be performed automatically more than once on the same day so as to prevent any accidental change in a result already validated or issued;
- a delta check of the patient result shall be integrated into quality control where the information system allows it.

12.5 Report signatures

The *Regulation respecting the keeping of records by medical technologists*⁶⁵ and *Normes de pratique du technologiste médical*¹¹ make it mandatory for the medical technologist to sign all reports he or she issues.¹¹

12.5.1 Electronic signature of reports

The first source of information a patient will use with regard to laboratory analysis results is his or her medical file. It is thus essential that the patient be able to identify the professional who issued the results.

Section 2.07 of the *Regulation respecting the keeping of records by medical technologists*⁶⁵ stipulates that “The medical technologist must sign or initial each entry or report that he puts in a record of his partnership or employer.”

Traceability of the medical technologist in the laboratory information system (LIS) must not be confused with the obligation of the medical technologist to identify himself or herself on each report placed in a patient’s file.

The official position of the OPTMQ is as follows:

“Therefore, the Order considers that the signature of the medical technologist must appear on all results and reports that he or she issues, including those validated electronically. This signature can be handwritten, in the form of an initial, or it can be an electronic signature.”¹⁰⁸

This position includes those results issued by automated validation.¹⁰⁸

12.6 Format of the analysis report

The test results report is the ultimate outcome of the analysis process. The report shall be legible and without transcription mistakes.¹ The laboratory shall standardize the terminology and format of reports.

The report shall include, but not be limited to the following:¹

- the patient’s first and last name and patient-specific identification number;
- the name or other unique identifier of the prescriber and the prescriber’s address;
- the date and time of sample collection;
- sample origin or type, as well as comments on characteristics of the sample that may have compromised the result;
- clear, unambiguous identification of the analysis;
- identification and address of the laboratory issuing the report along with the identification and address of the referral laboratory, if applicable;
- test results, including measurement units and reference intervals, if applicable;
- interpretation of results, where appropriate;
- date and time of release of the report;
- any other comments (e.g., results or interpretations from referral laboratories, use of a developmental procedure, etc.);
- signature or initials, which can be electronic, of the person or persons validating the results or releasing the report.

In addition, date and time of laboratory receipt shall appear in the report.¹²

12.6.1 Addition of comments to the report

Any information that may have an influence on the result shall appear in the test results report. For example:

- The report of a test performed despite noncompliance with a preanalytical condition shall include detailed comments when issuing the result subject to reservations (e.g., hemolysis, icteric aspect, hyperlipemia, tube fill volume, etc.);¹⁰
- Any patient's clinical state, if available, that may interfere with the result shall be in the report.

All comments shall be signed or initialled.⁶⁵

12.7 Issuing the test results report

The medical technologist shall use his or her competence and judgment in order to produce quality results.

Policies and procedures related to issuing the results report shall contain, without being limited to, the following elements:^{1,13}

- timeliness of sample receipt and the release of the result in relation to the urgency of the analysis;¹
- steps to follow to inform the prescriber in case of a delay in issuing the report that may have an impact on the care provided to the patient;¹
- directives relating to amending reports (paper or electronic format).

The laboratory information system shall be able to reproduce the archived analysis results, including the reference interval that was first linked with this analysis, along with the footnotes or interpretative comments associated with the results.^{1,28}

For provisional results, the final report shall always be forwarded to the prescriber.¹

12.8 Transmission of the report

The laboratory shall determine, in agreement with the users of its services, the persons authorized to receive a result, the format of the analysis report (paper or electronic) as well as the specific means by which the report will be communicated.¹

In addition, it shall ensure that the analysis report is transmitted to the client by appropriate means and within a time period respecting established directives.¹¹

Several laws and regulations govern the mode of transmission of analysis reports, access to information, and confidentiality of information,^{5,10,34,35} among others, the *Act to establish a legal framework for information technology*³⁹ and the *Personal Information Protection and Electronic Documents Act*.³³

A procedure for disclosing results, including mode of transmission, shall be established by the laboratory in compliance with the *Act respecting health services and social services*.⁵

Depending on the procedures used in disclosing results, the medical technologist shall guarantee protection of confidentiality of information by an appropriate means of transmission.^{39,109}

The medical technologist shall respect the *Code of Ethics* as well as the laws and regulations governing his or her profession.

12.8.1 Disclosure by telephone

The laboratory shall have a policy and a procedure for transmission of results by telephone. Telephone transmission shall be followed by sending the analysis report in compliance with established conditions.

12.8.2 Use of fax machines

The laboratory shall protect the confidentiality of all personal information that it collects, holds, uses or communicates, pursuant to the laws and regulations in force.¹⁰⁹

According to the Commission d'accès à l'information du Québec:¹⁰⁹

- The fax machine shall be installed in a monitored area with no public access, and it shall be used only by authorized persons.¹⁰⁹
- At all times, when transmitting personal information, the user shall:¹⁰⁹
 - complete a transmission form indicating the telephone number of the sender as well as the name, address, and telephone number of the recipient, along with the confidential nature of the information;
 - inform the recipient of the time of the transmission and make sure that he or she is present at the time of receipt;
 - check the fax machine window to make sure that the number dialled is that of the recipient;
 - check the fax transmission report at the end of the transmission;
 - obtain a confirmation of receipt from the recipient who is authorized to receive the transmission.

Note: It is recommended that the fax transmission report be retained as the record of transmissions.

12.8.3 Electronic transmission of analysis reports

Some information systems permit delivery of reports by computer transmission as well as remote access to laboratory results. Measures shall be taken to ensure the protection of confidential information.¹¹⁰ Some examples:^{40,42}

- use an up-to-date antivirus software;
- use an encryption software;
- change the password regularly;
- ensure that the password is known only by personnel with authorized access to confidential information.

12.9 Test results for reportable intoxications, infections and diseases

According to section 82 of the *Public Health Act*,¹¹¹ a written report shall be made by “any chief executive officer of a private or public laboratory or of a biomedical department, where a laboratory analysis conducted in the laboratory or department under his or her authority shows the presence of any reportable intoxications, infections, or diseases,”¹¹¹ as established by the Ministère de la Santé et des Services sociaux du Québec.

This written report shall be submitted to the appropriate regional public health director and, in certain cases provided for in the regulation, to the national public health director, or to both.¹¹¹

Available only in French at the following Web site is an information document for laboratories, containing the list of reportable intoxications, infections and diseases, transmission deadlines, as well as information required by the Direction de la santé publique:

<http://publications.msss.gouv.qc.ca/acrobat/f/documentation/preventioncontrole/03-268-02.pdf>.

12.10 Correction of errors in reports

A policy and a procedure for correcting errors in reports shall be established by the laboratory and followed by the medical technologist whenever an error in a transmitted result is found.

This procedure shall make provision for all steps necessary for the final correction in the patient’s file and shall respect the following points:

- The prescriber is advised of the correction.¹
- A report that has been signed and placed in the patient’s file cannot, under any circumstances, be withdrawn from the file.¹¹²
- When a new report is written, an initialled and dated note mentioning the correction shall be entered in the first report.¹¹²
- Errors shall not in any way be erased or hidden. Whenever a correction must be made to a report already transmitted (paper format), the error should be lightly crossed out yet remain legible, and the new information should be added, dated, and initialed.^{1,112} Whenever a correction is made to an already transmitted electronic report, a corrected report with special mention to that effect shall be transmitted.

12.11 Retention of reports

The laboratory shall establish a retention schedule for its documentation. (See 3.6.4 and Appendices 9 and 10.)

According to ISO 15189, the laboratory shall have a policy that defines the length of time various records pertaining to the quality management system and examination results are to be retained. Retention time shall be defined by the nature of the examination or specifically for each record.

The laboratory shall keep documents according to a retention schedule and established policies.²⁴

12.12 Retention and storage of samples after analysis

Samples shall be stored in a way that maintains their integrity in case of additional analysis later or for future consultation.¹ Procedures shall be established specifying the duration and conservation temperature required, among others.

Appendix 10 as well as the OPTMQ document *Transport et conservation des échantillons dans le domaine de la biologie médicale*⁵³ can be consulted for recommendations regarding specific storage periods.

12.13 Sample disposal

Once an analysis ends or the storage period has expired (in accordance with the established procedure), the samples shall be disposed of in compliance with the regulation in force, the *Regulation respecting biomedical waste*.²⁹

Sharps or breakable objects having been in contact with blood or with a biological fluid or tissue, blood containers, or materials that have been impregnated with blood are included in biological waste that shall be disposed of in approved containers that are rigid and airtight and that can be sealed and identified as biomedical waste.²⁹

12.14 Destruction of documents containing personal information

The *Act respecting access to documents held by public bodies and the protection of personal information*¹¹³ and the *Act respecting the protection of personal information in the private sector*¹¹⁰ require every public or private enterprise that collects, holds, uses or communicates personal information to implement security measures to protect data confidentiality.

The Commission d'accès à l'information recommends that:¹¹⁴

- Each employee shall take responsibility for protecting personal information he or she deals with. When disposing of documents, diskettes, cartouches, or tapes, the employee shall ensure that their confidential content cannot be reconstituted.
- A policy on destroying documents containing personal information shall be established, and a coordinator should be designated for implementing, monitoring, and applying it.
- Shredding is considered to be the method of choice for destroying confidential documents.

13.0 Point-of-care testing (POCT)

Advances in technology have made it possible to design compact and easy-to-use *in vitro* diagnostic medical devices that make it possible to do some near-patient testing.¹¹⁵

These tests shall meet the standards for quality and efficiency similar to those of tests performed in laboratories. They shall meet a medical need and provide a demonstrable added value in the quality of patient care.¹¹⁶

ISO has published a standard that deals with this topic: ISO 22870 *Point-of-care testing (POCT)—Requirements for quality and competence*.¹¹⁵

The information that follows sums up the main points to be considered. Please consult the document cited above for further information.

13.1 Responsibilities

The head of the biomedical department shall establish a multidisciplinary committee on POCT. This committee has the following mandate:¹¹⁶

- to determine the analyses that could be performed at point of care;
- to define the context and use of POCT and to determine the services that could make use of this type of testing;
- to ensure the proper use of POCT;
- to periodically reassess the practices associated with POCT testing in the institution;

Healthcare institutions without a laboratory shall establish a relationship with a centre that has a biomedical laboratory so as to obtain professional and technical support.¹¹⁶ The multidisciplinary committee, in agreement with the head of the biomedical department, shall designate a person with the required training and experience to be responsible for POCT quality.^{115,116}

The POCT quality coordinator shall continually assume responsibility for logistical support, monitoring of the quality assurance program, and implementation of POCT guidelines.¹¹⁶

13.2 POCT supplies

Choosing POCT devices shall take into consideration their precision, accuracy, detection limits, use limits, interferences, and robustness. Practicality should also be considered.

An inventory of all POCT equipment shall be maintained, including serial number, name of manufacturer, location, date purchased, service history, including dates out-of-service.¹¹⁵

13.3 Training

A program of theoretical and practical training appropriate for all personnel involved in POCT shall be developed and kept up to date. Only those personnel who have completed their training can perform POCT. Records shall be kept of training or certification as well as of retraining and recertification.¹¹⁵

The training program shall include the following, among others:¹¹⁵

- sample collection
- proper use of devices;
- theory of measurement systems;
- reagent storage;
- quality control and quality assurance (including frequency of internal quality control);
- technical limitations of the device;
- response to results that fall outside of predefined limits;
- infection control practices;
- documentation of results.

13.4 Maintenance

There shall be procedures for the maintenance and use of POCT equipment. Maintenance activities shall be controlled and documented.

The POCT quality coordinator shall ensure that a POCT device not in compliance with requirements is identified and withdrawn from service so as to prevent its accidental use.¹¹⁵

13.5 Records

A procedure shall be established to define the controls necessary for identification, storage, protection, retrieval, retention schedule, and disposal of records.

POCT results shall be permanently entered in the patient's medical file in such a way as to prevent any confusion with results produced by the laboratory. Date and time of the analysis as well as the name of the person who performed the analysis shall be recorded.^{1,115}

13.6 Quality control

POCT shall be subjected to internal and external quality control assessments. If such programs are not available, an internal quality assurance program shall be implemented, using a replica of the assay in the laboratory.¹¹⁵

The relationship between values obtained in the laboratory and those obtained by POCT devices shall be established and published or be available upon request.¹¹⁵

13.7 Corrective and preventive action

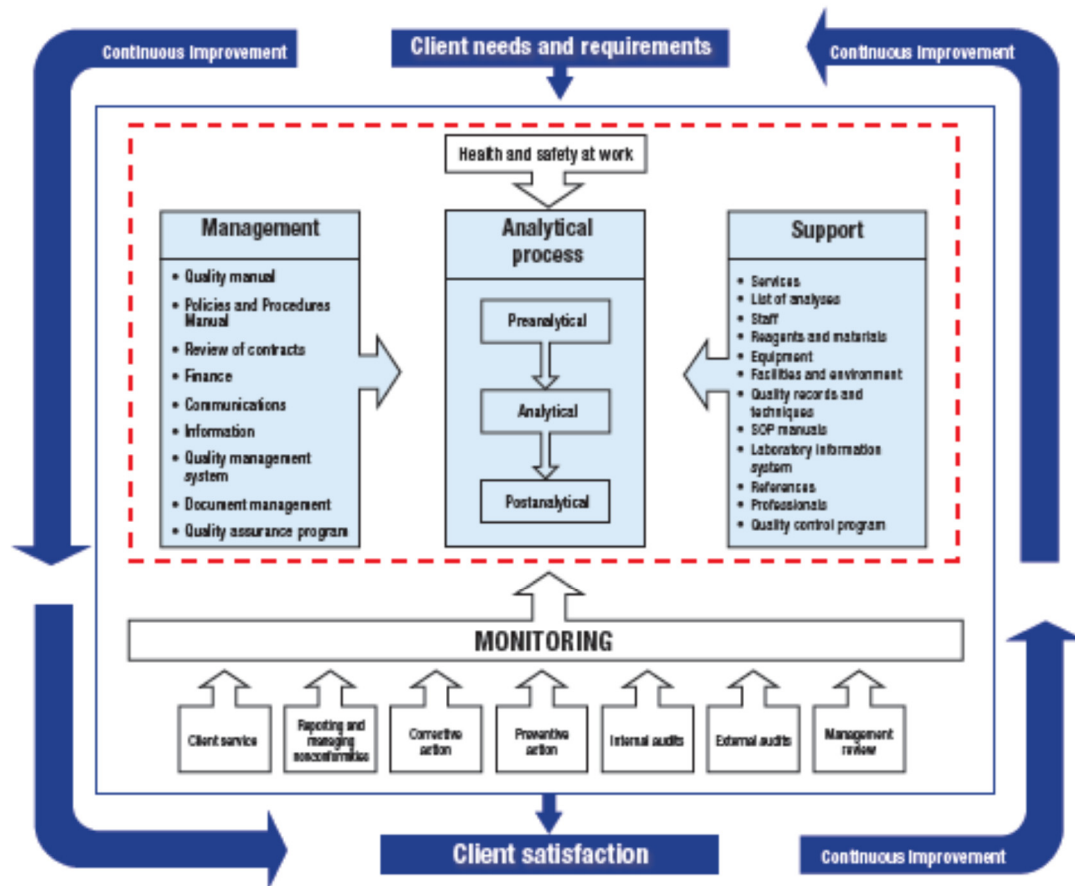
Corrective action shall be adapted to the effects of the nonconformities identified. Preventive action shall be adapted to the effects of potential problems.¹¹⁵ (See point 3.3.3.)

APPENDICES

Note: The appendices are not part of this guide but are added here as complementary information.

Appendix 1

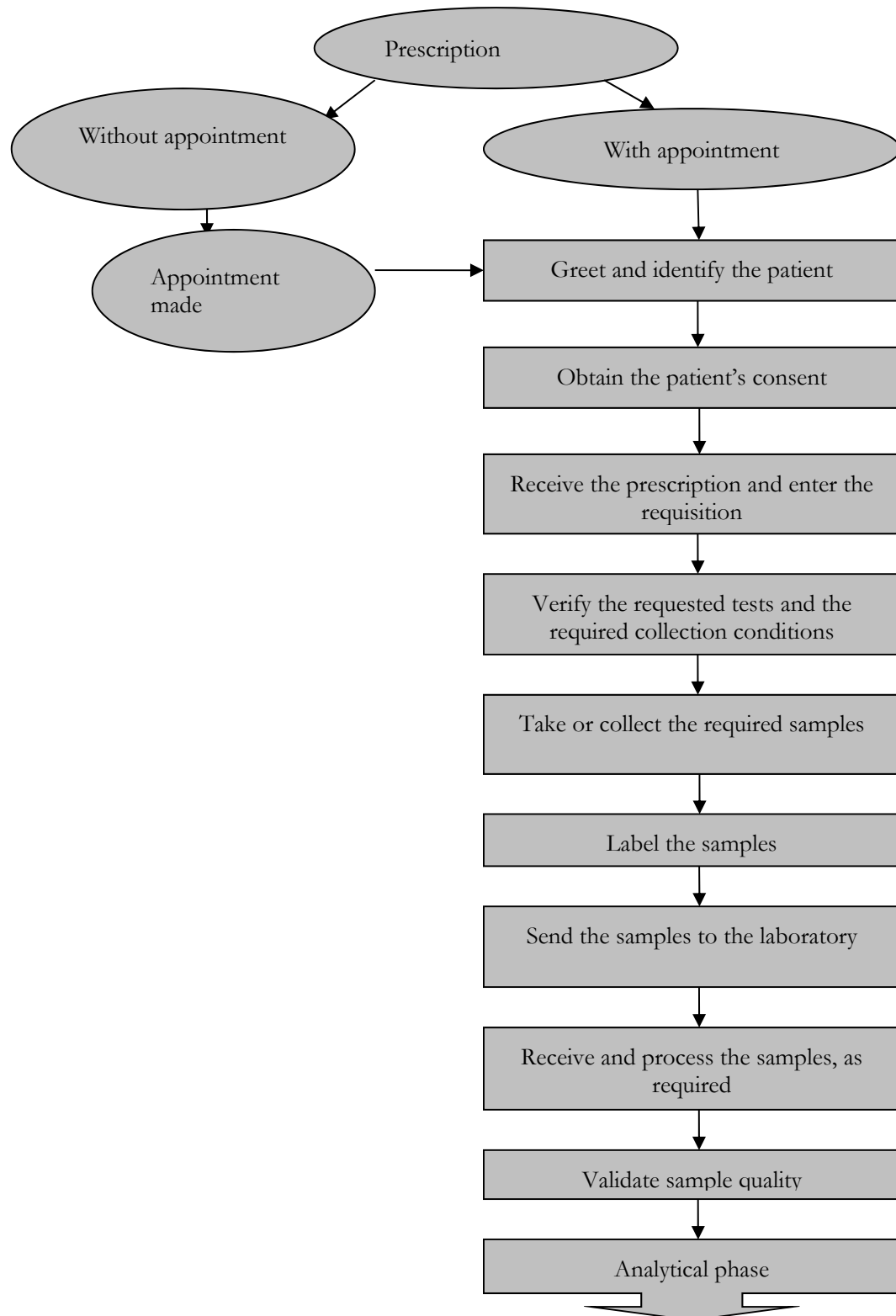
EXAMPLE OF A QUALITY MANAGEMENT SYSTEM



This flowchart was developed by France Pouliot, TM, a consultant specialized in laboratory quality control, Direction des services hospitaliers, CHUM Saint-Luc. Reproduced with permission of the Direction des services hospitaliers du Centre hospitalier de l'Université de Montréal.

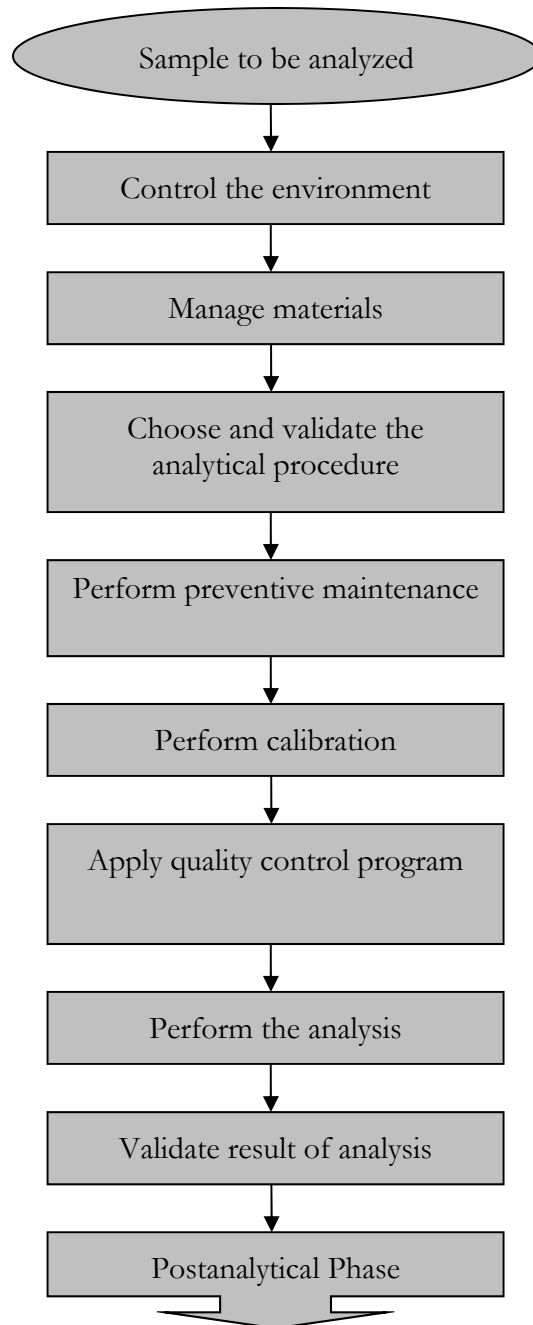
Appendix 2

Example of a Preanalytical Process Flowchart



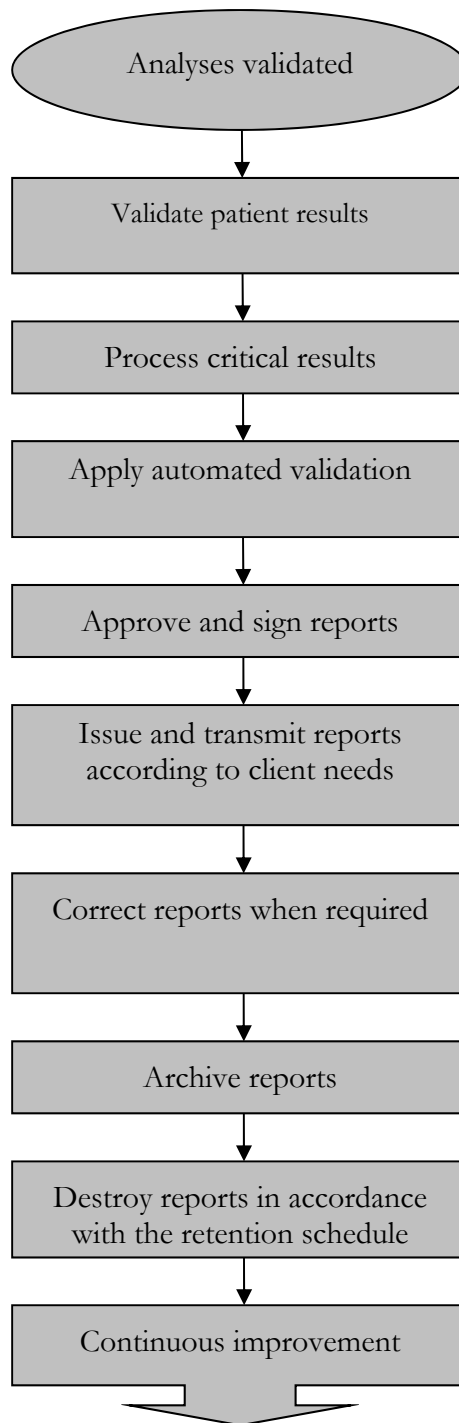
Appendix 3

Example of an Analytical Process Flowchart



Appendix 4

Example of a Postanalytical Process Flowchart



Appendix 5

Example of a Form for Recording an Incident, Accident, or Nonconformity

Hospital XYZ	RECORD NUMBER	QC-ENR-001		VERSION :	1
EFFECTIVE DATE:			APPROVED BY:		
Incident, accident, or nonconformity record					N°
Section 1					
Date of the occurrence:		Location:		Time:	
Date discovered:		Location:		Reported by:	
Describe the incident, accident, or nonconformity					
Completed by:					
Describe the immediate corrective action or actions					
Completed by:					
Responsible department or service:					
☐ Data entry ☐ Collection ☐ Client complaint ☐ Personnel complaint		☐ Purchase, supplier ☐ Computer ☐ Other centres		☐ Quality control ☐ Equipment, material ☐ Analysis report ☐ Administration ☐ Accommodation, environment ☐ Transport ☐ Other	
Section 2 Supervisor review of the incident, accident, or nonconformity					
Reviewed by:		Date:			
Follow-up necessary: ☐ Yes ☐ No If yes, forward to:					
Section 3					
Outcomes of the incident, accident, or nonconformity					
☐ Documentation corrected ☐ Collection—repeated		☐ Equipment repaired ☐ Report corrected		☐ Other (specify)	
Causes of the incident, accident, or nonconformity					
☐ Procedure deficient ☐ Collection—inadequate		☐ Training ☐ Reagent		☐ Inadequate accommodation ☐ Accident ☐ Other (specify)	
Corrective action: ☐ Yes ☐ No					
If yes, describe action(s) taken and refer to related documentation					
Reviewed by:			Date:		
Preventive action: ☐ Yes ☐ No					
If yes, describe action(s) taken and refer to related documentation					
Reviewed by:			Date :		

Adapted from CLINICAL AND LABORATORY STANDARDS INSTITUTE: QMS01, *Quality Management System: Model for Laboratory Services; Approved Guideline*.¹¹⁷

Appendix 6

Example of a Form for Corrective and Preventive Action

Institution name:	Document: ENR-QAC-002	Version: 1	Number:
TITLE	Managing Corrective and Preventive Action		

1. Description
☐ Corrective Action ☐ Preventive Action NC number, if applicable: _____
Description of the problem:
Probable causes:
Person in charge / Date:
2. Suggested actions
1 st action:
Person in charge / Date:
Effective Yes ☐ No ☐ Go on to next action ☐ Person in charge / Date: _____
2 nd action:
Person in charge / Date :
Effective: Yes ☐ No ☐ Go on to next action ☐ Person in charge: _____
3. Closing the file
Long-term effectiveness: Yes ☐ No ☐ Person in charge / Date: _____
Comments:
Closed by: _____ Date: _____

This form was developed by Séverine Labrude, MSc, DEA, QualiSciences Inc. Reproduced with her permission.

Appendix 7

Quality Manual—Example of Content

Introduction
Section 1. Mission and ethics
Section 2 Activity area
2.1 Laboratory Description
2.2. Legal Name
2.3 Resources
2.4 Main activities
Section 3 Quality policy
3.1 Quality goals and objectives
Section 4 Quality management requirements
4.1 Staff competence and training
4.2 Quality assurance
4.3 Research and development, if applicable
4.4 Document control
4.5. Records, storage, and archiving
4.6 Laboratory physical environment
4.7 Environmental aspects
4.8 Safety
4.9 List of analytical procedures and methods
4.10 Prescription procedures, sample collection, and laboratory sample processing
4.11 Management of instruments, reagents and consumables
4.12 Verification of analytical procedures
4.13 Quality management, including interlaboratory comparisons
4.14 Validation of results
4.15 Test reports
4.16 Corrective action and complaint resolution
4.17 Communication and other relationships with patients, health professionals, and suppliers
4.18 Audits
Section 5 Laboratory information system

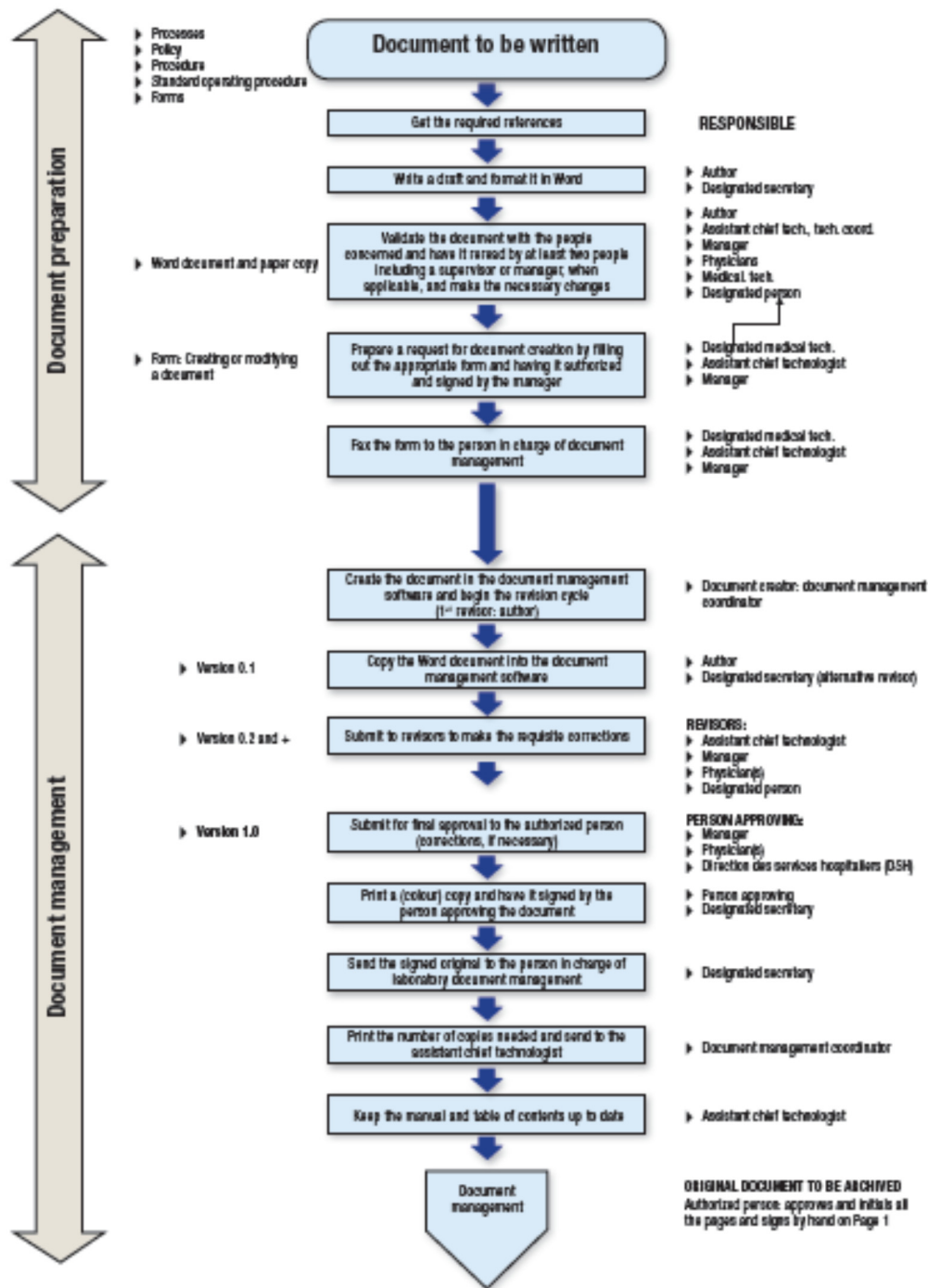
Adapted from ISO 15189. *Medical laboratories—Requirements for quality and competence*.¹

An example of a quality manual is available in a tool kit related to the Z316.7 Standard from CSA Group at the following address: <http://shop.csa.ca/en/canada/medical-laboratory-systems/z3167-12/invt/27034862012>.

Appendix 8

Example of a Document Management Process

DOCUMENT Creation, Revision, and Approval



This sample process was written by France Pouliot, TM, consultant specializing in laboratory quality, Direction des services hospitaliers, CHUM St. Luc. Reproduced with the permission of the Direction des services hospitaliers du Centre hospitalier de l'Université de Montréal.

Appendix 9

Retention Schedule

Pursuant to section 7 of the *Archives Act*²⁴, health and social services institutions are required to establish a retention schedule and to keep it up to date.⁷⁹ The ISO standard 15189 states the same requirement, specifying that the retention period shall be defined in terms of the nature of the analysis, the report made, or in some cases, legal requirements.¹

Below is a non-exhaustive list of records subject to a retention schedule.¹

Type of record or document
1. Request forms or prescriptions. 2. Patient analysis results and reports. 3. Instrument printouts. 4. Analytical procedures. 5. Laboratory workbooks or worksheets. 6. Accession records. 7. Calibration functions and conversion factors. 8. Quality control records. 9. Complaints and actions taken. 10. Records of internal and external audits. 11. Records of management reviews. 12. External quality assessment records and interlaboratory comparisons. 13. Quality improvement records. 14. Instrument identification and maintenance records, including all internal and external calibration records. 15. Lot documentation, certificate of supplies, package inserts. 16. All records of incidents, accidents, or nonconformities and actions taken. 17. Staff training and competency records.

Appendix 10

Summary of Minimal Retention Periods

According to the Recommendations of Various Organizations

Note: Retention periods given in the OPTMQ, LPSP, and Z902 columns are prescribed by current regulations. The other references are for information purposes **only**.

Note: Refer to the documents cited, notably to CAN/CSA Standard Z902 *Blood and blood components*, given that not all requirements for donors and recipients have been listed here.

ORGANIZATION	OPTMQ ^{I*} C-26, .175	LPSP ^{II} P-35, r.1	Z902 ^{III}	OAML ^{IV}	OLA ^V	CLIA ^{VI}	CAP ^{VII}	BAnQ ^{VIII}	CSC ^{IX}
SPECIMEN TYPES									
Cytology, negative or unsatisfactory slides					5 years	5 years	5 years		5 years
Cytology, positive or suspicious slides					20 years	5 years	5 years		20 years
Bone marrow slides		10 years					10 years	10 years	
Paraffin blocks		10 years			20 years	2 years	10 years	10 years	
Pathology slides		10 years			10 years	10 years	10 years	10 years	

ORGANIZATION	OPTMQ ^{I*} C-26, .175	LPSP ^{II} P-35, r.1	Z902 ^{III}	OAML ^{IV}	OLA ^V	CLIA ^{VI}	CAP ^{VII}	BAnQ ^{VIII}	CSC ^{IX}
DOCUMENTS									
Prescriptions and test reports	5 years	2 years (10 years for pathology)		7 years		2 years	2 years	2 years (10 years for pathology)	
Cytology reports, normal diagnosis	5 years				5 years		10 years		Indefinitely
Cytology reports, abnormal diagnosis	5 years				20 years		10 years		Indefinitely
Pathology reports	5 years	10 years			20 years	10 years	10 years	10 years	
Analysis results not related to transfusions	5 years	2 years		7 years		2 years	2 years	2 years	
Bone marrow results	5 years	10 years					10 years		
Staff records containing signature, initials, and ID			10 years after an employee's departure	10 years			10 years (Blood bank)		
Blood donation records (donor and recipient) as well as worksheets, results of serological testing, and transfusion labels			50 years					5 years	

- According to the *Regulation respecting the keeping of records by medical technologists*,⁶⁵ a medical technologist who is practicing in the public sector and who is authorized to enter client data in the institution records or to have such data entered in these records, is not required to be in conformance with the five-year retention period. However, he or she shall respect the retention periods provided for by the institution's retention schedule.

ORGANIZATION	OPTMQ ^{I*} C-26, .175	LPSP ^{II} P-35, r.1	Z902 ^{III}	OAML ^{IV}	OLA ^V	CLIA ^{VI}	CAP ^{VII}	BAnQ ^{VIII}	CSC ^{IX}
DOCUMENTS AND QUALITY ASSURANCE RECORDS									
Obsolete or archived procedures			10 years			Archive date + 2 years			
Printed lists (worksheets, lists, etc.)						2 years	2 years		
Quality control and quality assurance records			5 years		2 years 5 years (Blood bank)	2 years	2 years 5 years (Blood bank)		
Equipment maintenance records				As long as used + 2 years			2 years	As long as used + 3 years	
Employee training records			10 years after the employee's departure						

^I OPTMQ: *Regulation respecting the keeping of records by medical technologists* (RLRQ, c. C-26, r.254).⁶⁵

^{II} LPSP: *Règlement d'application de la Loi sur les laboratoires médicaux, la conservation des organes et des tissus, et la disposition des cadavres*. RLRQ, c. L-0.2, r.1, art. 138.²⁶

Note: This regulation does not apply to public sector biomedical laboratories.

^{III} Z902: CAN/CSA Z902 *Blood and blood components*, Canadian Standards Association, 2015.³

^{IV} OAML: Ontario Association of Medical Laboratories, *Guidelines for the Retention of Laboratory Records & Materials*, CPL020-001, revised June 2006.¹¹⁸

^V OLA: Ontario Laboratory Accreditation, *Quality Management Program—Laboratory Services*, version 3.¹¹⁹

^{VI} CLIA: Clinical Laboratory Improvement Amendments, 1988. Subpart J-Facility *Administration for Nonwaived Testing*, Section 493.1105: Retention requirements.¹²⁰

^{VII} CAP: College of American Pathologists, *Retention of laboratory records and materials*, revised March 2010.¹²¹

^{VIII} AQESSS: Bibliothèque et Archives nationales du Québec, *Recueil de règles de conservation des documents des établissements de santé et de services sociaux du Québec*, Édition 2017.⁷⁹

^{IX} CSC: Canadian Society of Cytology, *Guidelines for Practice and Quality Assurance in Cytopathology*. 3rd revision, 2005.⁶⁷

Appendix 11

Illumination Adjustment

Numerous adjustments are necessary for obtaining an optimal image for microscopic analysis.

To obtain an optimal image, the following adjustments must be carried out:

- The light path must be centered to ensure a straight optimal axis.
- The beam of light must be centered in the field.
- The field aperture must be opened slightly larger than the field.
- The condenser must be adjusted to the correct position.
- The iris diaphragm must be adjusted to correspond to 75% of the numerical aperture of the objective.



Once these adjustments are complete, the intensity of the light source is decreased or increased uniquely with the lamp rheostat.

Classic Illumination Adjustments

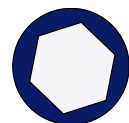
These instructions apply to microscopes without a field diaphragm whose light source is a simple lamp filament.

1. Remove the filter filament from the light path.
2. Place a slide with a sample on the stage of the microscope and bring into focus.
3. Open the iris diaphragm and adjust the intensity of the light using the rheostat.
4. Lower or raise the condenser to bring the lamp filament into focus.
5. Center the light in the field using the centering screws of the condenser.
6. Open the iris diaphragm to 75 % of the objective numerical aperture (see adjustment below).
7. Place the diffuser filter back in position.



Iris Diaphragm Adjustment

The amount of light passing through the condenser lens is optimal when the iris diaphragm corresponds to 70 to 80 % of the numerical aperture indicated on the objective. To perform this adjustment, remove an ocular and look into the tube to verify the field diameter that is illuminated.



When carrying out wet mount observations, this adjustment often has to be performed with each objective change to optimise the image contrast, while remembering that the closing of the iris diaphragm increases contrast, but decreases resolution.

Appendix 11

Illumination adjustment (continued)

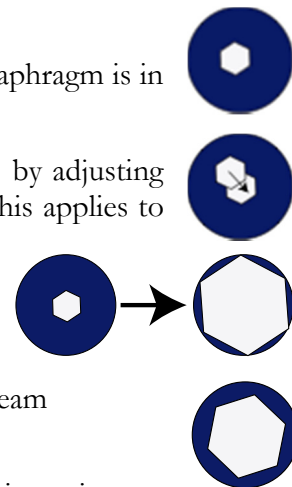
Köhler Illumination

Adjusting for Köhler illumination ensures a total and uniform illumination of the microscope's field of view and gives a clear and precise specimen image definition.

The zone illuminated by the field diaphragm must correspond to the field observed. If the illuminated zone is larger than the observed field, the contrast will be diminished.

Steps of the adjustment:

1. Turn on the light and adjust the light intensity with the rheostat.
2. Switch to the 10x objective, place a slide with a sample on the stage and focus using the focus control knobs. If the condenser has a retractable front lens, swing it out when using objectives 10x and lower and swing it in when using objectives higher than 10x.
3. Completely open the iris diaphragm.
4. Raise the condenser to its highest position.
5. Close the field diaphragm.
6. Lower the height of the condenser until the image of the field diaphragm is in sharp focus.
7. Align the condenser to ensure a straight optical axis (light path) by adjusting the centering screws until the image is centered in the field (if this applies to the microscope model).
8. Enlarge the field diaphragm until the light beam illuminates the entire observation area without overflow.
9. Remove one eyepiece, adjust the iris diaphragm until the light beam illuminates approximately 75% of the field. Replace the eyepiece.
10. The Köhler illumination is complete. After this, to adjust light intensity, use only the rheostat.



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COMMENTS

Given technological change, this guide is subject to periodical revision.
Please send us any suggestions you may have for improving its content.

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