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STANDARDS

Biomedical Laboratory Services

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BIOMEDICAL LABORATORY SERVICES

Accreditation Canada's Biomedical Laboratory Services Standards are for organizations providing laboratory services in a hospital or as an independent centre. These standards promote a collaborative approach to service delivery where the laboratory team works with the laboratory users to deliver safe and quality services to clients. These standards address all aspects of laboratory services, from responding to requests for services to communicating the results.

Accreditation Canada's Biomedical Laboratory Services Standards are based on the International Organization for Standardization (ISO) Standards 15189-12. These standards focus on activities related to planning and evaluating laboratory services provided within and outside the organization.

This set of standards contains the following sections:

- Planning, Designing, and Coordinating Laboratory Services
- Having the Right People
- Providing a Suitable Environment
- Complying with Good Laboratory Practice
- Operating and Maintaining Laboratory Equipment
- Using Supplies, Reagents, and Media
- Properly Preparing for the Analysis
- Conducting the Analysis Safely and Accurately
- Maintaining Efficient and Accessible Information Systems
- Monitoring the Safety and Quality of Laboratory Services

Legend

Dimensions

Population Focus: Work with my community to anticipate and meet our needs

Accessibility: Give me timely and equitable services

Safety: Keep me safe

Worklife: Take care of those who take care of me

Client-centred Services: Partner with me and my family in our care

Continuity: Coordinate my care across the continuum

Appropriateness: Do the right thing to achieve the best results

Efficiency: Make the best use of resources

Criterion Types

High Priority High priority criteria are criteria related to safety, ethics, risk management, and quality improvement. They are identified in the standards.

Required Organizational Practices Required Organizational Practices (ROPs) are essential practices that an organization must have in place to enhance client safety and minimize risk.

Tests for Compliance

Minor Minor tests for compliance support safety culture and quality improvement, yet require more time to be implemented.

Major Major tests for compliance have an immediate impact on safety.

Performance Measures Performance measures are evidence-based instruments and indicators that are used to measure and evaluate the degree to which an organization has achieved its goals, objectives, and program activities.

PLANNING, DESIGNING, AND COORDINATING LABORATORY SERVICES

1.0 The team plans and designs its laboratory services to meet the needs of current and future clients, and laboratory users.

Population Focus

1.1 The team collects information at least every two years about service volumes and wait times for accessing laboratory services.

Guidelines

Collecting this information helps the laboratory evaluate the demand for services, identify patterns in service needs, and determine the resources needed. The laboratory may collect this information by administering questionnaires to staff and reviewing internal databases related to service volumes and wait times.

ISO Reference: 15189-12, 4.14.4.

Population Focus

1.2 The team collects information at least every two years from laboratory users and clients about their needs for laboratory services.

Guidelines

The laboratory may collect this information by administering questionnaires or conducting interviews.

ISO Reference: 15189-12, 4.1.2.2, 4.14.3.

Population Focus

1.3 The team meets at least every two years to review information collected from clients and laboratory users to identify strengths and areas for improvement in service needs, and makes changes accordingly.

Guidelines

ISO Reference: 15189-12, 4.1.2.4.

2.0 **The team has agreements in place with laboratory users (organization).**

Appropriateness

2.1 The team establishes an agreement with each laboratory user (organization) that outlines their requirements and respective responsibilities.

Guidelines

ISO Reference: 15189-12, 4.4.1.

Appropriateness

2.2 The team verifies that it has the capacity to meet the requirements in the agreement.

Guidelines

Examples include having the right number of staff, and sufficient space and equipment.

ISO Reference: 15189-12, 4.4.1.

Appropriateness

2.3 The team reviews its agreements at least every two years to confirm requirements are being met and documents the reviews.

Guidelines

The team may need to review its agreements more often in certain situations, including following changes in service volumes, types of services provided, and if an amendment is made after the work has been done.

ISO Reference: 15189-12, 4.4.2.

Appropriateness

2.4 The team maintains records of all agreements, including any relevant changes made to meet applicable regulations.

Guidelines

ISO Reference: 15189-12, 4.4.2.

Client-centred Services

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2.5 The team informs laboratory users (organization) in a timely manner of changes to or significant deviations from the agreement that may have an impact on examination results.

Guidelines

This includes non-compliance with SOPs during the pre-examination, examination, and post-examination processes.

ISO Reference: 15189-12, 4.4.1.

3.0 The team is responsible for all services provided by referral laboratories and consultants.

Appropriateness

3.1 The team maintains a registry of the referral laboratories and external consultants that it uses.

Guidelines

The registry includes a list of all samples that have been referred to other laboratories.

ISO Reference: 15189-12, 4.5.1.

Appropriateness

3.2 The team regularly evaluates its arrangements with referral laboratories and external consultants to verify that the requirements are being met and documents the results.

Guidelines

When conducting the review, the team ensures that the requirements are properly defined and understood, the referral laboratory is able to meet the requirements, there are no conflicts of interest, examination procedures are appropriate, and responsibilities for interpreting the results are clearly defined. The laboratory also verifies that the referral laboratory is participating in an external quality control program.

ISO Reference: 15189-12, 4.5.1.

Accessibility

3.3 The team verifies that test results from referral laboratories are given to the laboratory user in a timely and accurate way.

Guidelines

If the laboratory prepares the final report, it includes all results from the referral laboratory using the referral laboratory's exact wording, if required by local or provincial laws. Additional comments added by the laboratory are clearly indicated.

The team prevents unnecessary delays in reporting results, with the understanding that what is timely depends on the test performed and the clinical context of the request.

ISO Reference: 15189-12, 4.5.2.

Appropriateness

3.4 The team provides a report that contains the name of the referral laboratory that conducted the examination, and retains a copy of the report in both the client file and in its permanent record.

4.0 The team works collaboratively with laboratory users to provide services.

Appropriateness

4.1 The team establishes working relationships within its team and with laboratory users.

Guidelines

Working relationships include efficient communication, understanding of roles and responsibilities, and coordination of tasks among team members, and with laboratory users within and outside the organization. For example, the team attends regular meetings such as clinical rounds to provide laboratory users with advice on individual cases.

ISO Reference: 15189-12, 4.1.2.6, 4.7.

Accessibility

4.2 The team works with laboratory users to identify and remove where possible barriers that prevent clients and laboratory users from accessing services.

Guidelines

Access may be compromised by barriers that are under the laboratory's control (e.g., hours of operation, physical or language barriers, human resources) or by barriers that are not (e.g., transportation, long wait times for services).

Client-centred Services

4.3 The team provides consultation on examination types and the use of laboratory services, including frequency of testing and the type of sample required.

Guidelines

ISO Reference: 15189-12, 4.7.

Efficiency

4.4 The team is available to assist laboratory users with how to interpret, evaluate, and use the test results.

Guidelines

ISO Reference: 15189-12, 4.7.

HAVING THE RIGHT PEOPLE

5.0 The organization has the appropriate mix and number of team members to provide safe and effective laboratory services.

Appropriateness

5.1 The organization defines clear lines of accountability for laboratory services delivered across the organization.

Guidelines

The organization defines who is responsible for ensuring that policies and procedures for laboratory services are consistently applied across the organization.

Appropriateness

5.2 The team defines each member's responsibilities and required qualifications in position profiles.

Guidelines

The laboratory's position profiles outline the responsibilities of each team member and may identify who is authorized to:

- Perform specific procedures
- Use equipment such as computers and the laboratory information system (LIS)
- Access data such as client results and billing information
- Make professional judgments or decisions.

The profiles also identify replacement team members, and to whom specific tasks will be delegated in a team member's absence.

ISO Reference: 15189-12, 5.1.3.

Appropriateness

5.3 The team recruits members based on the qualifications required in the position profiles.

Guidelines

The team members' qualifications are consistent with legislative requirements.

ISO Reference: 15189-12, 5.1.2.

Appropriateness

5.4 The team is made up of a sufficient number of qualified team members who are able to carry out the required volume of laboratory services, day-to-day operations, and any other responsibilities.

Guidelines

The number of team members required depends on the size and complexity of the organization and volume of laboratory services that are delivered.

Appropriateness

5.5 The team has a laboratory director who is responsible for overseeing clinical activities within and outside the laboratory.

Guidelines

Responsibilities may include providing advice and information about the choice of examinations, use of services, or interpretation of results; administering services effectively and efficiently; selecting and assessing the quality of services; and serving as an active member of the medical staff for facilities served.

Appropriateness

5.6 The team has an administrative leader who is responsible for the administration and management of services within and outside the laboratory.

Guidelines

The administrative leader's responsibilities may include:
• Allocating resources appropriately
• Defining, implementing, and monitoring standards and quality improvement activities
• Implementing the quality management system
• Assessing all work performed in the laboratory
• Overseeing research activities
• Liaising with accrediting and regulatory agencies, administrative officials, the health care community, and clients
• Ensuring an adequate number of team members
• Ensuring team members have access to training and professional development opportunities
• Ensuring the work environment is safe and positive
• Addressing complaints or concerns

ISO Reference: 15189-12, 4.1.1.4.

Appropriateness

5.7 The administrative leader or designate reviews team members' roles and responsibilities regularly and makes changes as needed.

Appropriateness

5.8 The administrative leader or designate regularly evaluates the mix and number of team members needed and makes changes as required.

6.0 The team is educated, trained, and evaluated on the organization's laboratory services.

Safety

6.1 The team receives a comprehensive orientation to the organization's laboratory's services.

Guidelines

The orientation program includes the laboratory's quality management system, standard operating procedures, ethics and confidentiality issues, information systems, and occupational health and safety issues.

ISO Reference: 15189-12, 5.1.4, 5.1.5.

Appropriateness

6.2 The team is trained on how to use the organization's laboratory equipment.

Guidelines

ISO Reference: 15189-12, 5.1.5, 5.3.1.3.

Client-centred Services

6.3 Education and training are provided to team members on how to work respectfully and effectively with clients and families with diverse cultural backgrounds, religious beliefs, and care needs.

Guidelines

Cultural education and training build the skills, knowledge, and attitudes that are required to safely and appropriately deliver interventions and services to culturally diverse populations. The training may cover topics such as disability, level of understanding, or mental health.

Cultural education and experience are part of the recruitment (including position advertisements) and selection processes.

Appropriateness

6.4 The team's competency is assessed following a new staff member's orientation and on a regular basis thereafter.

Guidelines

The competency assessment program applies to all team members. Competency assessment may include direct observation, monitoring the recording and reporting of results, reviewing records, assessing problem-solving skills through written tests or case studies, comparison exercises (e.g., revisiting previous samples, reviewing samples from other laboratories), or written exercises.

ISO Reference: 15189-12, 5.1.6.

Appropriateness

6.5 The team receives additional training when gaps in training or competency are identified, and reassesses competency following training.

Appropriateness

6.6 Each team member's performance is evaluated in an objective, interactive, and constructive way.

Guidelines

A performance evaluation is usually done before the probationary program is complete; annually thereafter or as defined by the organization; when new technology, equipment, and technical skills are introduced; and when the team member has been away from the workplace for an extended period of time.

ISO Reference: 15189-12, 5.1.7.

Worklife

6.7 The team has access to continuing education and professional development opportunities related to laboratory services.

Guidelines

ISO Reference: 15189-12, 5.1.8.

PROVIDING A SUITABLE ENVIRONMENT

7.0 **The laboratory is designed to provide safe, efficient, and confidential laboratory services.**

Safety

7.1 The organization limits access to the laboratory areas to authorized team members only.

Guidelines

For example, access to laboratory areas can be controlled by locking the doors, using key pad code entry, or issuing swipe cards with different levels of access.

ISO Reference: 15189-12, 5.2.2.

Appropriateness

7.2 The laboratory has sufficient space to carry out laboratory services.

Guidelines

The team determines the space needed to carry out the laboratory's services. This may include areas for:
- Storing clients' personal belongings
- Conducting the analysis
- Storing client records, data entry, and other administrative functions
- Storing equipment, supplies, and samples.

ISO Reference: 15189-12, 5.2.1.

Client-centred Services

7.3 The laboratory is accessible and safe for clients with limited mobility, visual, or hearing abilities.

Guidelines

A universally accessible environment may include washrooms accessible to clients with limited mobility, doorways sufficiently wide enough to allow access for clients in wheelchairs, and access to elevators.

Safety

7.4 Universal fall precautions, applicable to the setting, are identified and implemented to ensure a safe environment that prevents falls and reduces the risk of injuries from falling.

Guidelines

Organizations should identify and adopt precautions for all clients, regardless of risk of falling. The acronym S.A.F.E. (Safe environment; Assist with mobility; Fall-risk reduction; and Engage client and family) describes the key strategies for universal fall precautions. The following are examples of universal fall precautions: familiarize clients to new environments; if you have call buttons (e.g., in washrooms) ensure they are within reach; have sturdy handrails in bathrooms, rooms, and hallways; use appropriate lighting; provide chairs that are appropriate for clients with mobility issues; have mobility aids on hand as appropriate to your client population; keep floor surfaces clean and dry; clean up all spills promptly; keep hallways and care areas uncluttered. It is important to identify precautions that align with the clinical setting and needs of clients in that setting, including their right to live at risk.

Client-centred Services

7.5 The laboratory provides clients with access to washrooms.

Client-centred Services

7.6 The laboratory's sample collection areas are separate from reception and waiting areas.

Guidelines

ISO Reference: 15189-12, 5.2.5.

Appropriateness

7.7 The laboratory's space for record keeping and other administrative activities is separate from pre-analytical and analytical testing areas.

Appropriateness

7.8 The environmental conditions of the laboratory's storage space protect the integrity of its samples and supplies.

Guidelines

Protecting the integrity of samples and supplies includes preventing damage, deterioration, or loss; and prohibiting unauthorized access.

ISO Reference: 15189-12, 5.2.3.

Efficiency

7.9 The laboratory is equipped to communicate information within and outside the laboratory in an efficient manner.

Guidelines

The laboratory's communication systems to facilitate the efficient transfer of messages (i.e., access to computers, telephones, and fax machines) are appropriate to the size and complexity of its services.

ISO Reference: 15189-12, 5.2.2.

Client-centred Services

7.10 Access to spiritual space and care is provided to meet clients' needs.

Guidelines

Spiritual care is available to meet the needs of clients, as required. It includes access to a spiritual leader appropriate to the client's beliefs (e.g., a chaplain, imam, rabbi, or non-denominational counsellor). Clients and families have access to a designated space to observe spiritual practice.

The client's spiritual needs and preferences are seen as integral to the care and healing process, and are discussed when making care decisions that may involve an ethical or spiritual component.

8.0 The team follows best practices for infection prevention and control to maintain a clean physical environment.

Safety

8.1 The laboratory's work areas are clean and well-maintained.

Guidelines

Cleaning the work area is based on the organization's environmental services guidelines which address specific cleaning materials and equipment, disinfecting cleaning equipment, and properly storing and using disinfectants.

The laboratory properly uses and stores cleaning materials and disinfectants, including having appropriate documentation on how to use the disinfectants and cleaning equipment, how to dilute and apply the disinfectants, and the expiration date for the disinfectants.

ISO Reference: 15189-12, 5.2.6.

Safety

8.2 The layout of the laboratory prevents cross-contamination by separating incompatible activities.

Guidelines

The activities that need to be separated depend on the services provided by the laboratory. For example, laboratories performing moderate and/or high complexity testing involving the culture of microorganisms isolate activities requiring sterile techniques and perform these under aseptic conditions, as required.

ISO Reference: 15189-12, 5.2.6.


Safety

8.3 The layout of the laboratory makes it easy to clean and disinfect work areas, equipment, floors and walls.

Guidelines

Floors and walls are non-porous, non-slip, free of cracks and open joints, and able to resist cleaning agents and disinfectants (e.g., sealed with resistant coating).


Safety

8.4 The team receives training on hand-washing procedures and has access to hand-washing facilities that are adequately supplied.


Safety

8.5 The team ensures the safe collection, containment, and disposal of waste materials in line with applicable requirements.

Guidelines

The team collaborates with environmental services to ensure the safe collection, containment, and disposal of waste materials.

9.0 The team maintains appropriate environmental conditions in the laboratory.


Appropriateness

9.1 The team has the equipment needed to maintain appropriate environmental conditions in refrigerators and other critical equipment.

Guidelines

For example, refrigerators used for storing samples or reagents have an air-circulating fan or some other way to maintain proper temperatures.


Appropriateness

9.2 The team regularly monitors and records environmental conditions within the laboratory.

Guidelines

Environmental conditions include temperature and humidity levels. Requirements for temperature recording differ depending on the samples being used or stored.

ISO Reference: 15189-12, 5.2.6.


Safety

9.3 The team identifies and reports any environmental issues within the laboratory.

Guidelines

Maintaining proper environmental conditions (e.g., temperature, humidity, and ventilation) ensures client and staff safety, as well as optimum equipment function. The team collaborates with its engineering department to address any issues with the environmental conditions within the laboratory.


Safety

9.4 The team ensures critical equipment such as refrigerators is protected with an uninterruptible power supply.

Safety

9.5

The team maintains an alarm system for applicable equipment to alert team members to changes in environmental conditions or malfunctions and tests this alarm system regularly.

Guidelines

The alarm sounds in a location that is continuously monitored by the responsible staff member so that corrective action can be taken before temperatures or other conditions reach unacceptable levels.

Appropriateness

9.6

The team monitors and records that emergency backup equipment is available, functioning, and linked to the organization's safety system.

COMPLYING WITH GOOD LABORATORY PRACTICE

10.0 **The laboratory complies with applicable laws, regulations, standards of practice, and licensure requirements.**


Appropriateness

10.1 The laboratory has a license, certificate, or permit to carry out its services, as required by applicable laws and regulations.


Appropriateness

10.2 The team has access to applicable laws, regulations, and standards of practice.

Guidelines

Applicable laws, regulations, and standards of practice may differ provincially, regionally, or locally, depending on the specific services provided by the laboratory. Examples of regulating bodies include Health Canada and the Public Health Agency of Canada.


Appropriateness

10.3 The team has instructions on how to implement applicable laws, regulations, and standards of practice, and how to obtain more information or training about them.


Appropriateness

10.4 The team has a process to keep track of updates to applicable laws, regulations, and standards of practice.

Guidelines

For example, the team might be on an e-mail list or have electronic links to applicable laws, regulations, and standards of practice.

Appropriateness

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10.5 The team monitors its compliance with laws, regulations, and standards of practice, and makes improvements to its instructions or training activities as required.

11.0 The team develops, maintains, and evaluates Standard Operating Procedures (SOPs) for laboratory services.

Appropriateness

11.1 The team has a process to develop clear and concise SOPs that are in line with applicable regulations and standards of practice for laboratory services.

Appropriateness

11.2 The team has access to SOPs that are applicable to the activities it carries out.

Guidelines

The team's managers confirm that team members have access to and apply the relevant SOPs to their functions. The laboratory may have quick reference guides appended to the SOPs available at each workstation, provided that the complete documentation is available elsewhere in the laboratory.

ISO Reference: 15189-12, 4.2.2.2.

Appropriateness

11.3 The team updates its SOPs every two years or more often if required.

Guidelines

In addition to a review every two years, the team may review the SOPs following:

- Patient safety incidents
- Changes in methodology
- Changes in regulatory or legal requirements
- Updates from literature reviews
- Internal or external audits
- Other situations as defined in the laboratory's policies

ISO Reference: 15189-12, 4.3.

Appropriateness

11.4 The team has a process to review and approve revisions to the SOPs.

Guidelines

The process for reviewing and approving revisions to the SOPs and quick reference guides includes tracking changes and version numbers, and identifying team members who can review and approve changes to the SOPs.

ISO Reference: 15189-12, 4.3.

Appropriateness

11.5 The team provides information or training to team members before implementing a new or revised SOP, if required.

Guidelines

The team determines whether information or training is required depending on the extent of the revisions. The team's process for communicating changes to team members includes documenting team members' understanding of the changes. The team also keeps records of trainer's observations during practice and retraining sessions.

Appropriateness

11.6 The team regularly evaluates compliance with its SOPs and makes changes as needed.

Guidelines

The team makes changes to its SOPs, training activities, or monitoring processes as a result of the evaluation.

12.0 In accordance with the organization's policy, the team obtains the client's free and informed consent prior to the procedure.

Client-centred Services

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12.1 The team develops a transparent and respectful relationship with clients and laboratory users.

Appropriateness

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12.2 The team obtains the client's free and informed consent when appropriate, and collects only the personal information necessary to complete the procedure.

Guidelines

Informed consent requires that clients are provided with enough information about the procedure to make an informed decision, and have the opportunity to refuse the procedure. In most cases, consent is implied when the client voluntarily arrives at the laboratory to have the procedure. The laboratory may develop specific processes to share information and obtain consent from children or mentally challenged clients.

Complicated or invasive procedures require detailed explanations, including discussion of risks and benefits of the proposed procedure, written consent, and in some cases, counselling.

Additional information may be collected in the case of communicable diseases that have to be reported due to applicable regulations designed to protect the safety of staff and other clients.

ISO Reference: 15189-12, 5.4.2, 5.4.4.1..

Appropriateness

12.3 The team uses samples for the stated purpose only.

Guidelines

The laboratory does not use samples for purposes other than the stated one unless client consent has been obtained or residual samples are made anonymous or pooled with others.

Appropriateness

12.4 The team informs laboratory users if a critical result needs to be followed up with access to counselling.

Guidelines

The team defines critical results that need to be followed up with access to counselling (e.g., genetic or infectious disease examinations) based on a procedure established by the organization.

ISO Reference: 15189-12, 5.9.1.

Appropriateness

12.5

The team follows an SOP to address complaints from clients and laboratory users, and to respond to feedback about its services.

Guidelines

ISO Reference: 15189-12, 4.8.

Appropriateness

12.6

The team maintains a record of complaints, ensuing investigations, and corrective action(s) taken.

Guidelines

ISO Reference: 15189-12, 4.8.

Appropriateness

12.7

Team members adhere to their respective professional codes of ethics for laboratory practice, if applicable.

Guidelines

Codes of ethics may differ among professions and regional jurisdictions.

OPERATING AND MAINTAINING LABORATORY EQUIPMENT

13.0 The team selects and uses appropriate equipment for laboratory services.

Efficiency

13.1 The team has a process for selecting laboratory equipment that follows Health Canada regulations.

Guidelines

The process for selecting laboratory equipment takes into account the type of services provided; the knowledge and skills needed for use; occupational health and safety protocols; the latest research and evidence on advances in technology; and whether the benefits are worth the costs.

ISO Reference: 15189-12, 5.3.1.

Safety

13.2 The team selects equipment that can be easily cleaned and disinfected.

Guidelines

Laboratory equipment is made of materials that do not react with or absorb cleaning or disinfecting products.

Appropriateness

13.3 The team provides appropriate members with step-by-step equipment operating instructions as well as troubleshooting and equipment malfunction guidelines.

Guidelines

The operating instructions include manuals or directions provided by the manufacturer, and are easily accessible by team members. The team collaborates with its engineering department to provide this information.

ISO Reference: 15189-12, 5.3.1.3.

14.0 **The team regularly maintains, calibrates, and inspects its equipment.**


Appropriateness

14.1 The team follows manufacturer instructions and up-to-date SOPs to maintain, inspect, validate, and calibrate equipment.

Guidelines

ISO Reference: 15189-12, 5.3.1.4, 5.3.1.5.


Appropriateness

14.2 The team regularly cleans and disinfects equipment, and keeps the equipment protected when not in use.

Guidelines

The laboratory cleans and disinfects equipment prior to any service or repair, and provides the individual(s) servicing the equipment with a list of disinfection activities that were carried out. The team's procedure for handling, transporting, and storing equipment that is not in use prevents contamination and deterioration.

ISO Reference: 15189-12, 5.3.1.5.


Appropriateness

14.3 The team identifies, investigates, and corrects problems with equipment in a timely way.

Guidelines

ISO Reference: 15189-12, 5.3.1.6.


Safety

14.4 The team removes equipment that is damaged or in poor working condition from service and labels it as out of order along with a statement indicating the problem and the action to be taken.

Appropriateness

14.5

The team has a complete and up-to-date record of equipment inspections, calibrations, maintenance, and repairs.

Guidelines

The record may include:
• The name, location, and serial number or other unique identifier of the equipment
• The manufacturer and manufacturer's instructions, and up-to-date contact information
• Whether the equipment was obtained new, used, or reconditioned
• Pertinent dates (e.g., the date the laboratory began using the equipment, service dates)
• Calibration results and data collected on parameters measured
• Criteria for acceptable ranges
• General notes on performance, malfunctions or deviations, and actions taken
• Service reports for preventive maintenance or repair that specify the service contractor and any parts replaced.

The team establishes a regular maintenance schedule and maintains a record of when it plans to replace the equipment.

ISO Reference: 15189-12, 5.3.1.7.

Appropriateness

14.6

The team maintains accessible records for the lifespan of all equipment in accordance with applicable laws and regulations and manufacturer's instructions.

Guidelines

ISO Reference: 15189-12, 5.3.1.7.

USING SUPPLIES, REAGENTS, AND MEDIA

15.0 **The team's supplies, reagents, and media are appropriately purchased and safely labelled and used.**

Appropriateness

15.1 The team uses an inventory control system to maintain an adequate inventory of supplies, reagents, and media.

Guidelines

ISO Reference: 15189-12, 5.3.2.4.

Appropriateness

15.2 The team maintains a list of suppliers for all supplies, reagents, and media.

Guidelines

ISO Reference: 15189-12, 5.3.2.7.

Appropriateness

15.3 For purchased supplies, reagents, and media, the team validates the quality control testing done by the manufacturer.

Guidelines

The laboratory avoids using newly acquired supplies, reagents, or media until it verifies that they comply with standard specifications or requirements for the procedures concerned. This may entail examining quality control samples and confirming that results are acceptable, or checking the supplier's conformance with its quality management system.

ISO Reference: 15189-12, 5.3.2.3.

Appropriateness

15.4 The team uses a standardized format that complies with the Workplace Hazardous Materials Information System (WHMIS) to label supplies, reagents, and media.

Guidelines

Labels include name, title, strength or concentration, conditions for storage, expiry date, and special precautions as applicable.

Appropriateness

15.5 The team does not use inappropriate, deteriorated, and substandard supplies, reagents, and media.

Guidelines

Processes to prevent the use of inappropriate, deteriorated, and substandard supplies, reagents, and media include defining conditions for proper use and storage (e.g., temperature, pH, gas phase, safety, method of sterilization).

Appropriateness

15.6 The team follows a policy for using expired reagents only under exceptional circumstances that requires validating their continued suitability for use.

Appropriateness

15.7 The team uses supplies, reagents, and media only for their intended purpose.

Accessibility

15.8 The team has access to complete and up-to-date records of supplies, reagents, and media.

Guidelines

Each record includes manufacturer or supplier information, the batch or lot number, date of receipt or preparation, date placed in use, expiration date, technical identification, and chemicals used (e.g., catalogue number and certificates of analysis).

If reagents are prepared in-house, the record includes a list of chemicals and supplies used, parameter measures, and environmental conditions during preparation.

ISO Reference: 15189-12, 5.3.2.7.

Appropriateness

15.9 The team complies with applicable laws, regulations and standards of practice when retaining records of purchased supplies, reagents, and media.

16.0 The team follows SOPs to prepare supplies, reagents, or media safely and accurately.

Appropriateness

16.1 The team follows SOPs to prepare supplies, reagents, or media.

Safety

16.2 To avoid contaminations or toxicity, the team uses analytical grade materials to prepare supplies, reagents, or media as required by its SOPs.

 Safety	!	16.3	The team uses sterile techniques, as applicable, to prepare supplies, reagents, or media.
 Appropriateness		16.4	The team uses water of the highest purity to prepare supplies, reagents, or media as required by its SOPs.
 Appropriateness	!	16.5	The team follows instructions on how to implement the Material Safety Data Sheets (MSDS) and Workplace Hazardous Materials Information System (WHMIS) specifically for laboratory services.
 Appropriateness	!	16.6	The team assesses each lot of media that it produces on-site before it is used and records quality control results.
		17.0	**The team follows SOPs for reprocessing and sterilizing glassware and non-disposable plastic ware.**
 Safety	!	17.1	The team follows SOPs for reprocessing and sterilization that comply with applicable laws and regulations.

Appropriateness

17.2 The team uses non-toxic detergent and the highest purity water to wash and rinse glassware and non-disposable plastic ware when required by its SOPs.

Appropriateness

17.3 The team regularly monitors the water supply to ensure it meets manufacturer's instructions and tests it whenever problems are encountered.

Guidelines

The team collaborates with its engineering department to monitor the water supply.

PROPERLY PREPARING FOR THE ANALYSIS

18.0 The team manages and responds to requests for laboratory services.

Appropriateness

18.1 The team performs analyses at the written or electronic request of an authorized health care professional.

Appropriateness

18.2 The team follows an SOP to respond to verbal requests.

Guidelines

The SOP requires that verbal requests are verified using a read-back process and are followed by a request form within a timeframe set by the organization.

ISO Reference: 15189-12, 5.4.3.

Appropriateness

18.3 The team has standardized request forms to collect necessary information about the client, the sample(s), and the requested analyses.

Guidelines

The request form may vary depending on the type of examination. The request form may have space for:
• The client's unique identifier
• Name or other unique identifier of the health care professional authorized to request examinations
• Type of sample and anatomic site of origin
• Examinations requested
• Relevant clinical information about the client, including gender and date of birth
• Date and time the sample was collected
• Date and time when the laboratory received the sample

ISO Reference: 15189-12, 5.4.3.

Appropriateness

18.4 The request form complies with applicable requirements and standards of practice.

Accessibility

18.5 The team follows a policy for identifying and handling urgent requests.

Guidelines

The team uniquely identifies and labels urgent requests. The process for handling urgent requests includes methods for rapid processing, the special requirements for transporting the sample, and any specific or additional reporting requirements.

Appropriateness

18.6 The team monitors whether laboratory users are following established procedures for requesting laboratory services.

Guidelines

For example, the team may audit a sample of request forms.

19.0 **The team collects the appropriate sample(s) to perform the requested analysis.**


Appropriateness

19.1 The team follows SOPs for preparing the client, identifying the sample needed, collecting the sample, safely disposing of the materials used to collect the sample, and maintaining the client's confidentiality throughout the process.

Guidelines

The SOPs address any information the team must give to and gather from clients before collecting the sample and obtaining consent.

For each type of examination provided by the laboratory, the SOP may include:
- Type and amount of sample needed
- When it should be collected (if applicable)
- Any special handling or transport requirements (e.g., refrigeration)
- How to label the sample
- How to safely dispose of materials
- Instructions for storing used samples for future use
- Time limits and procedures for requesting and carrying out additional examinations
- Time limits and procedures for repeating any examinations or analyses

ISO Reference: 15189-12, 5.4.4.1, 5.4.4.2, 5.4.4.3.


Safety

19.2 REQUIRED ORGANIZATIONAL PRACTICE: Working in partnership with clients and families, at least two person-specific identifiers are used to confirm that clients receive the service or procedure intended for them.

Guidelines

Using person-specific identifiers to confirm that clients receive the service or procedure intended for them can avoid harmful incidents such as privacy breaches, allergic reactions, discharge of clients to the wrong families, medication errors, and wrong-person procedures.

The person-specific identifiers used depends on the population served and client preferences. Examples of person-specific identifiers include the client's full name, home address (when confirmed by the client or family), date of birth, personal identification number, or an accurate photograph. In settings where there is long-term or continuing care and the team member is familiar with the client, one person-specific identifier can be facial recognition. The client's room or bed number, or using a home address without confirming it with the client or family, is not person-specific and should not be used as an identifier.

Client identification is done in partnership with clients and families by explaining the reason for this important safety practice and asking them for the identifiers (e.g., “What is your name?”). When clients and families are not able to provide this information, other sources of identifiers can include wristbands, health records, or government-issued identification. Two identifiers may be taken from the same source.

Test(s) for Compliance

Major	19.2.1	At least two person-specific identifiers are used to confirm that clients receive the service or procedure intended for them, in partnership with clients and families.

Appropriateness

19.3 The team labels each sample with the relevant information.

Guidelines

Sample portions and samples retained for future examinations are also labelled with the relevant information.

ISO Reference: 15189-12, 5.4.4.3.

Appropriateness

19.4 The team ensures that all samples are traceable to the client.

Guidelines

The team avoids accepting or processing any sample that cannot be traced to a client. If the sample is urgent, irreplaceable, or of critical importance, the team processes the sample but avoids releasing the results until they are verified by the requesting individual or the team member responsible for collecting the sample. Verification is confirmed with the individual's signature or the name in the final report.

ISO Reference: 15189-12, 5.4.6.

20.0 The team transports samples in a safe and timely manner.

Safety

20.1 The team follows SOPs to transport samples to and from the laboratory in a safe and confidential manner that is in line with applicable laws and regulations.

Guidelines

The SOPs address the need for evidence that samples contain the specified preservatives (if applicable) and are transported within the appropriate time frame in a way that ensures they were not exposed to temperatures outside the acceptable range; and ensures the safety of the carrier, the community, and the receiving laboratory. The transportation requirements differ depending on the nature of the sample and examination(s) to be performed.

ISO Reference: 15189-12, 5.4.5.

Appropriateness

20.2 The laboratory follows an SOP for maintaining the integrity of samples handled after hours, if applicable.

Appropriateness

20.3 The team records all samples received, identifying the date and time they were received and the individual responsible for receiving them.

Guidelines

The laboratory records all the samples it receives in an accession book, worksheet, computer, or other information system.

ISO Reference: 15189-12, 5.4.6.

Appropriateness

20.4 The team accepts or rejects each sample according to established criteria.

Guidelines

The criteria for acceptance includes proper identification of the sample; acceptable volumes to perform certain tests (e.g., phlebotomy); and appropriate temperatures and storage conditions.

ISO Reference: 15189-12, 5.4.6.

Safety

20.5 The team follows an SOP for safely handling leaking samples and contaminated forms.

Safety

20.6 The team gives each sample it receives a unique identification number.

Appropriateness

20.7 The team appropriately stores samples based on the sample type and examination requirements.

Guidelines

When storing samples, the team preserves the integrity, stability, and containment of each sample, and prevents cross-contamination in case repeated or additional examinations and analyses need to be completed.

ISO Reference: 15189-12, 5.4.7, 5.7.2.

CONDUCTING THE ANALYSIS SAFELY AND ACCURATELY

21.0 The team processes samples in an appropriate and timely way.

Appropriateness

21.1 The team follows SOPs to decide on examinations that are needed and the procedures to be followed.

Guidelines

The SOPs include criteria for choosing and conducting the appropriate examination procedure including point-of-care testing.

For each examination, the SOP may include:
- Purpose, primary procedure, and procedural steps
- Performance specifications (e.g., precision)
- Detection limit
- Type of sample (e.g., plasma, serum, urine)
- Type of container and any required additives (e.g., preservatives)
- Necessary reagents and equipment, including requirements for calibration
- Quality control processes
- Interferences and cross-reactions
- Safety precautions.

The SOP also includes procedures for calculating results: measurement uncertainty, biological reference intervals, alert or critical values, and possible sources of variability and laboratory interpretation.

ISO Reference: 15189-12, 5.5.1, 5.5.2.

Appropriateness

21.2 The team only uses examination procedures that have been validated for their intended use.

Guidelines

ISO Reference: 15189-12, 5.5.1.

22.0 The team evaluates the quality of its examinations.

Appropriateness

22.1 The team has an internal quality control system to verify the accuracy of analyses and results.

Guidelines

Results are verified by tracing them to SI units or by referring to a natural constant or other reference. The laboratory may verify its results by one or more of the following:

- Participating in inter-laboratory comparisons
- Using valid reference materials
- Other calibration procedures
- Ratio or reciprocity-type measurements
- Consensus-based standards
- Documentation provided by the supplier or manufacturer.

ISO Reference: 15189-12, 5.6.2, 5.6.4.

Appropriateness

22.2 The team identifies possible uncertain results and determines their importance in how it might affect interpretation.

Guidelines

The possible sources of uncertainty include sample preparation or portion selection, calibrators, reference materials, equipment, environmental and sample conditions, and inter-individual variability.

ISO Reference: 15189-12, 5.5.1.3.

Appropriateness

22.3 The team identifies and quickly addresses all inaccuracies, problems, or deficiencies.

Safety

22.4 Once samples are no longer needed for examination, the team safely disposes of them in accordance with applicable regulations for waste management.

Guidelines

ISO Reference: 15189-12, 5.7.2.

Appropriateness

22.5 The team keeps records of quality control results, identified problems, and actions taken to fix the problems.

Appropriateness

22.6 The team participates in external quality control programs through proficiency testing and inter-laboratory comparisons.

Guidelines

The external quality control program is based on the laboratory's examination procedures and scope of analysis and is appropriate to the examination and interpretations provided by the laboratory.

23.0 The team reports results in an accurate, consistent, and timely manner.

Appropriateness

23.1 The team has a standardized report format that is communicated to all laboratory users.

Guidelines

The team's managers are responsible for the report format. They may seek input from laboratory users to develop it.

ISO Reference: 15189-12, 5.8.1.

Appropriateness

23.2 The report uses language, vocabulary, syntax, and nomenclature consistent with that used by international, national, or regional professional bodies.

Guidelines

Depending on the types of examinations performed, the laboratory uses language, vocabulary, syntax, and nomenclature consistent with that used by international, national, or regional professional bodies (e.g., the International Council for Standardization in Haematology [ICSH] and the Logical Observation Identifiers Names and Codes [LOINC]).

Appropriateness

23.3 The reports are legible and accurately reflect the results.

Guidelines

In addition to the results, the report may specify:
• The examining laboratory
• The client's and requester's unique identifiers
• Destination of the report
• The individual responsible for checking the report and authorizing the report's release, including their signature.

It may also include details on the examination itself, including:
• Measurements, if appropriate
• The date and time of sample collection, if relevant
• The date and time of receipt by the laboratory, and sample type
• Detailed results reported in SI units, if applicable
• Biological reference intervals
• Interpretation of results, both original and corrected, if applicable
• Other comments

ISO Reference: 15189-12, 5.5.3, 5.8.3.

Appropriateness

23.4 The report clearly states if the quality of the sample was unsuitable for the examination or may have compromised the end results.

Guidelines

ISO Reference: 15189-12, 5.8.2.

Safety

23.5 The team follows SOPs for handling results that fall within critical results.

Guidelines

The organization clearly defines critical results for each examination using an interdisciplinary approach.

The process includes immediately notifying the health care professional requesting the examination. The process also includes recording actions taken in response to critical results in the client file; the date, time, and name of team member; the name of the clinical person notified; and the examination results.

ISO Reference: 15189-12, 5.9.1.

Appropriateness

23.6 The team follows its reporting processes for both interim and final reports, as well as for results from referral laboratories and consultants.

Appropriateness

23.7 The team makes corrections to reports only in authorized circumstances.

Guidelines

Changes or modifications to the report show the time, date, and the name of the individual authorized to make the change, and content of the original report is still legible. If the change is made in an electronic system that cannot capture and retain changes, the team uses an audit log to track changes.

ISO Reference: 15189-12, 5.9.3.

Client-centred Services

23.8 The team has a policy for releasing examination results.

Guidelines

The policy includes to whom results may be released and procedures for reporting directly to clients and in emergency situations. The policy also includes procedures to ensure confidentiality when releasing results by telephone or electronically.

ISO Reference: 15189-12, 5.9.1.

Safety

23.9 The team follows an SOP for communicating results verbally.

Guidelines

The SOP requires that results are verified using a read-back process followed by a written report within a timeframe set by the organization.

ISO Reference: 15189-12, 5.9.1.

MAINTAINING EFFICIENT AND ACCESSIBLE INFORMATION SYSTEMS

24.0 **The Laboratory's Information System (LIS) allows team members to maintain, protect and access records and information.**

Appropriateness

24.1 The team has a policy and procedure manual for the LIS and its applications that is available to team members at all times, and that is regularly updated to make sure it is complete and accurate.

Guidelines

The policy and procedure manual includes a system overview and technical information as required, information on proper use of the LIS and its applications, and what to do in the case of a problem such as software failure.

Appropriateness

24.2 The team investigates errors related to the use of the LIS and implements and documents corrective action.

Appropriateness

24.3 The team reviews data entered into the LIS for accuracy and completeness.

Guidelines

For example, the team may implement spot checks, built-in consequence confirmation testing, override journals, or pending list verification.

Appropriateness

24.4 The team conducts and documents initial and regular testing of the LIS.

Guidelines

The team collaborates with its information management team to test the LIS and its components. The team makes changes to the LIS in compliance with established procedures, documents the changes, and re-validates as appropriate. If the team develops software or applications for the LIS, it documents the development procedures.

Appropriateness

24.5 The team carries out regular preventive maintenance on the LIS according to retail specifications and safety requirements.

Guidelines

Safety requirements may include verifying the LIS is appropriately protected from fire and that the laboratory has access to an uninterruptible power supply. The team carries out regular and preventive maintenance to avoid any service disruption. There are contingency plans for unscheduled shutdowns or problems, and the team documents these and any corrective actions it takes.

Appropriateness

24.6 The team develops controls to safeguard the LIS against loss, destruction or tampering of information, and unauthorized access to the system.

Guidelines

The LIS has effective back-ups to protect data from being altered or deleted. The data is checked following each backup. The team uses restricted access, passwords/encryption, and alarms to protect the LIS from unauthorized access. Where data is used for research, there are specific policies that govern confidentiality and access to it.

ISO Reference: 15189-12, 5.10.3.

Appropriateness

24.7 The team has a process for maintaining continuity of information in the event of system interruption.

Guidelines

ISO Reference: 15189-12, 5.10.3.

Appropriateness

24.8 The team's information system can provide a complete summary of all outcomes of a laboratory procedure and any abnormal or unusual events.

Guidelines

For example, the team is able to pull quality indicators from the overall results of analyses. The team may pull a history of positive results for certain analyses.

25.0 The team keeps accurate, up-to-date and secure records for each client and procedure.

Appropriateness

25.1 The team maintains a comprehensive record for each client and procedure that is in line with applicable regulations.

Guidelines

Each record may include:
- Name of the laboratory or site
- Date and a unique identifier
- Authorized signature(s)
- Page number and total number of pages
- Analyses and procedures performed
- Quality controls performed and corrective action taken
- Other clinical information.

It is clear how the record is to be used, and by whom. The team dates and signs changes to a client record and documents the reason for the change.

ISO Reference: 15189-12, 4.13.

Accessibility

25.2 The team can easily retrieve records as needed.

Guidelines

Records may be traced and retrieved in any accessible media.

ISO Reference: 15189-12, 4.13.

Appropriateness

25.3 The team disposes of and archives records based on the organization's policy.

Guidelines

ISO Reference: 15189-12, 4.13.

Continuity

25.4 The team coordinates its records system with those of other laboratories so samples can be traced throughout the laboratory's processing system.

Guidelines

To ensure recall if necessary, samples are traceable from collection to final processing (handling, storage, use, and disposal). This may require coordination with records systems of other laboratories to which the laboratory supplies or from which the laboratory receives samples.

Appropriateness

25.5 The team protects the security and confidentiality of records.

Guidelines

ISO Reference: 15189-12, 4.13.

MONITORING THE SAFETY AND QUALITY OF LABORATORY SERVICES

26.0 **The team develops, maintains, and monitors an effective laboratory safety program.**


Appropriateness

26.1 The team has a safety officer who develops, maintains, and monitors the laboratory safety program.

Guidelines

The safety program addresses occupational health and safety issues and other procedures that minimize risk and support a safe work environment.


Safety

26.2 The safety officer is authorized to stop any laboratory activities deemed unsafe.


Appropriateness

26.3 The safety program includes orientation and training programs, and monitoring and evaluation.

Guidelines

The safety program training includes topics related to occupational health and safety, such as how to:

- Prepare for and prevent fires
- Properly handle biological hazards to prevent infection
- Maintain chemical and radiation safety
- Properly identify and manage any other unsafe conditions.

Accessibility

26.4 The safety program includes a safety manual that is available to all team members at all times.

Guidelines

The safety manual includes occupational health and safety policies and procedures.

Appropriateness

26.5 The team regularly monitors and evaluates compliance with the safety program and makes revisions as needed.

Guidelines

Audits of the safety program may be in the form of inspections to verify that the team is following and complying with the safety program.

27.0 As part of the safety program, the team identifies, assesses, and minimizes risks for staff, clients, and visitors.

Appropriateness

27.1 The team uses risk group classifications to classify biological agents.

Guidelines

The team classifies biological agents based on the potential risk to the individual handling the agent, the potential risk to the community in the event of leakage or contamination, the possibility of transmission, and the availability of treatment.

The lowest classification is used for a biological agent with low individual and community risk (e.g., non-pathogenic agents). The highest classification is used for pathogens or infectious agents with high individual and community risk (e.g., agents with a high probability of transmission between individuals or those for which no treatment exists).


Safety

27.2 The team labels work area entrances and exits according to risks present within these areas.


Safety

27.3 The team wears protective clothing and Personal Protective Equipment (PPE) according to the organization's policy and applicable regulations.

Guidelines

The team identifies and provides the necessary PPE, such as gloves, gowns, or eye or face protection, based on its risk classification. Other personal clothing and equipment (e.g., footwear) complies with the laboratory's safety policies. When not being used, clean PPE is stored appropriately and away from working areas. The laboratory isolates and appropriately labels contaminated PPE and makes sure it is properly washed. Team members remove their PPE before leaving the laboratory working areas. If a team member's laboratory work takes them outside the laboratory, the individual wears appropriate and clean PPE when dealing with clients or completing laboratory tasks.


Safety

27.4 The team uses safety practices when handling, examining, or disposing of biological and chemical materials.

Guidelines

Safety practices apply whenever team members or visitors are at risk of being exposed to blood, body fluids, or other potentially infectious materials. Practices conform to relevant laws and regulations.


Safety

27.5 Patient safety incidents are reported according to the organization's policy and documented in the client and the organization record as applicable.

Guidelines

Reporting and recording is done in a timely way. Patient safety incidents include harmful incidents, no harm incidents, and near misses, as per the World Health Organization International Classification for Patient Safety.


Appropriateness

27.6 The team annually reviews its risk-reduction strategies as well as incidents that have occurred, and makes required changes to its policies or training activities.

28.0 Before their routine use, the team assesses new or amended methods, analytical procedures, or equipment.


Appropriateness

28.1 The team selects new methods based on available evidence such as scientific and literature reviews and best practice guidelines.

Guidelines

Periodically, government regulatory authorities or professional licensing bodies issue information that procedures, methodologies, or equipment previously considered experimental may now be considered clinically effective.


Appropriateness

28.2 The team conducts preliminary studies to validate new methods before their routine use.


Appropriateness

28.3 The team identifies appropriate measures to monitor the use of new methods.


Appropriateness

28.4 The team considers best practice guidelines when adopting new technologies.

Guidelines

Best and leading practice guidelines are evidence-based. These may be established by a committee or council, or by an individual who develops tools and makes recommendations to the laboratory administration.


Appropriateness

28.5 The team's processes include testing new methods with consenting clients, as appropriate.


Safety

28.6 The team has a process to receive, document, and follow up on medical alerts and safety notifications issued by Health Canada and provincial regulatory bodies.

29.0 The team collects and uses indicator data to guide its quality improvement initiatives.


Appropriateness

29.1 The team has a comprehensive quality management system.

Guidelines

The quality management system includes policies and procedures for achieving optimal results and ongoing quality improvement.

ISO Reference: 15189-12, 4.2, 4.12.

Appropriateness

29.2 The team defines the elements of the quality management system in a quality policy statement and makes it available in a quality manual.

Guidelines

The quality policy statement outlines the laboratory's services and the goals and objectives of the quality management system. It affirms the laboratory's commitment to good laboratory and professional practices, quality examinations, compliance with standards, and continual quality improvement. The policy outlines a process for establishing and reviewing quality objectives. The policy is regularly reviewed.

The quality manual outlines the quality policy and management system, roles and responsibilities of all team members, and all other policies and procedures related to the quality management system.

ISO Reference: 15189-12, 4.1.2.3, 4.2.2.2.

Appropriateness

29.3 The team assigns an individual to establish and oversee the quality management system.

Guidelines

Roles and responsibilities may include:
• Verifying that quality management system processes are established and implemented
• Reporting on the performance of the quality management system and areas for improvement
• Providing team members with orientation on the quality manual and its contents.

ISO Reference: 15189-12, 4.1.2.7.

Appropriateness

29.4 The team identifies measurable objectives for its quality improvement initiatives and specifies the timeframe in which they will be reached.

Guidelines

Quality improvement objectives define what the team is trying to achieve, and by when. Appropriate quality improvement objectives have targets that exceed current performance. Quality improvement objectives are typically short term and are aligned with longer-term strategic priorities or patient safety areas. The timeframe will vary based on the nature of the area for improvement.

The SMART acronym is a useful tool for setting meaningful objectives, in that they should be Specific, Measurable, Achievable, Realistic, and Time-bound. The United States Centers for Disease Control and Prevention offers a guide to writing SMART objectives.

ISO Reference: 15189-12, 4.14.7.

Appropriateness

29.5 The team identifies the indicator(s) that will be used to monitor progress for each quality improvement objective.

Guidelines

The team uses indicators to monitor whether the activities resulted in change and if the change is an improvement. Primarily, indicators are selected based on their relevance and ability to accurately monitor progress. When there are multiple potential indicators, the team uses criteria to select indicators, such as scientific validity and feasibility. If the team has difficulty selecting indicators, it may mean the quality improvement objective needs further clarification.

Appropriateness

29.6 The team regularly monitors the use of its services and uses the results to learn about the appropriate use of laboratory services.

Guidelines

The laboratory may compare its results to external standards or to peer organizations.

Appropriateness

29.7 The team sets targets and tracks wait times and average response times for elective, urgent, and emergent requests for laboratory services.

Guidelines

Response times will vary depending on the urgency of the request.

Turnaround times are developed in consultation with the users of laboratory services and reflect clinical requirements (e.g., emergent and urgent results). The team monitors the turnaround times and notifies the requester if there is a critical delay that could impact service.

The team's managers and the person who requests the examination are jointly responsible for ensuring the examination results are passed to the appropriate individuals within the agreed-upon turnaround time.

ISO Reference: 15189-12, 4.14.7.

Appropriateness

29.8 The team designs and tests quality improvement activities to meet its objectives.

Guidelines

Quality improvement activities are the actions used to initiate improvements, and are part of the larger quality improvement plan. Activities are first designed and tested on a small scale to determine their effect prior to implementing them more broadly.

The Getting Started Kit for Improvement Frameworks is a resource created by the Canadian Patient Safety Institute and is based on the Model for Improvement. The Institute for Healthcare Improvement offers a framework to guide quality improvement activities using Plan, Do, Study, Act cycles.

Appropriateness

29.9 The team collects new or uses existing data to establish a baseline for each indicator.

Guidelines

Establishing a baseline reference point makes it possible to monitor progress towards meeting quality improvement objectives by comparing pre- and post-activity data and noting changes. Establishing a baseline may require one or many data points, and occurs over a defined period of time. Once the baseline is established, the team may need to reevaluate their quality improvement objectives to ensure they remain feasible and relevant.

Appropriateness

29.10 The team follows a process to regularly collect indicator data to track its progress.

Guidelines

The team determines how the data will be collected and how often it will be collected. Regularly collecting data allows the team to track its progress over time and understand the normal variation of values.

Appropriateness

29.11

The team regularly analyzes and evaluates its indicator data to determine the effectiveness of its quality improvement activities.

Guidelines

The team compares the intended and actual effects of its quality improvement activities, and, if the objective has not been achieved, adjusts its actions accordingly to meet the objective.

Analyzing data identifies trends and may reveal service areas that may need to be considered for quality improvement initiatives. Indicator data collected over time can be displayed in a run chart or control chart, both of which are valid means of data analysis. Safer Healthcare Now! offers Patient Safety Metrics, a web-based tool where organizations can submit data on various interventions, analyze results over time, and generate reports.

If it is not within the team's capacity to analyze the data, it seeks qualified internal or external assistance.

ISO Reference: 15189-07, 4.14.7, 4.15.2.

Appropriateness

29.12

As part of the quality management system, the team evaluates its services using formal internal audits, evaluations, and improvement processes.

Guidelines

The internal audits focus on critical service areas. They evaluate whether examinations meet laboratory user requirements, comply with the quality management system, and support continuous quality improvement. Objective individuals who are qualified to assess managerial and technical performance plan, organize, and conduct the audits using audit procedures provided by the laboratory. These procedures include the types, frequency, and methods of audit(s) to be conducted, and the required documentation resulting from the audits. Opportunities for improvement and corrective action taken are documented. The laboratory's leaders review the audit results and use them to guide decision-making. The audits take place at planned intervals and any time a potential for non-compliance is identified.

ISO Reference: 15189-12, 4.14.1, 4.14.5.

Appropriateness

29.13 The team identifies potential sources of nonconformities and their root causes, and implements and monitors preventive and corrective action plans.

Guidelines

For each nonconformity, particularly those likely to recur or in cases where the laboratory was in compliance with its policies and procedures, the laboratory investigates the incident to determine the root cause, evaluates the need for corrective action to prevent recurrence, and, if required, determines and implements the required corrective action. Corrective action is appropriate to the size, severity, and risk of the problem. The laboratory reviews the effectiveness of the corrective action.

The laboratory also proactively identifies potential nonconformities through analysis of data, such as trend- and risk-analyses, and any results from external quality control programs. Evaluating the need for preventive action may prevent a recurrence. Preventive actions are implemented immediately and evaluated for effectiveness.

ISO Reference: 15189-12, 4.9, 4.10, 4.11.

Appropriateness

29.14 The team follows up on reports or recommendations from recognized agencies.

Guidelines

Recognized agencies include l'ordre professionnel des technologistes médicaux du Québec (OPTMQ), the Ontario Laboratory Accreditation (OLA), and Cancer Care Ontario.

ISO Reference: 15189-12, 4.14.8.

Appropriateness

29.15 The team implements effective quality improvement activities broadly.

Guidelines

The team broadly implements the quality improvement activities that were shown to be effective in the testing phase. The way in which the team implements activities broadly will vary based on the scope and scale of the team's services and considers the timeframe, e.g., an effective activity is implemented in more than one area of care and for a longer period of time.

Population Focus

29.16 The team shares information about its quality improvement activities, results, and learnings with clients, families, staff, service providers, organization leaders, and other organizations, as appropriate.

Guidelines

The team tailors the information to the audience and considers the messaging and language level that is appropriate for each audience.

Sharing the results of evaluations and improvements helps staff, service providers, and stakeholders become familiar with the philosophy and benefits of quality improvement and engages the organization's leaders in the process. It also helps the organization to spread successful quality improvement activities within and outside the organization and demonstrate its commitment to ongoing quality improvement. Among other benefits, sharing indicator data externally allows for comparison with organizations offering similar services.

Appropriateness

29.17 The team regularly reviews and evaluates its quality improvement initiatives for feasibility, relevance and usefulness.

Guidelines

The team regularly reviews and evaluates its quality improvement initiatives, including its activities, objectives, and indicators. The team uses the information to plan its future quality improvement initiatives including how and when to sustain or spread existing initiatives within the organization. The team considers outcomes of the quality improvement initiatives as they align with the organization's overall quality improvement plan, goals and objectives, mission and values, and strategic plan. The team evaluates whether objectives were met within their timeframes and whether the timeframes remains relevant.

Based on the review of the initiatives, objectives and indicators may be added, amended, or removed as appropriate. The rationale for amending or removing them is documented.

Accreditation Canada would appreciate your feedback on these standards

Your Name: _____

Organization Name: _____

Email address or telephone number: _____

(A Product Development Specialist may contact you about your feedback.)

Feedback: Please indicate the name of the standard, as well as the criterion number in your comments. Please be as specific as possible in your comments.

For example: I would like to provide comments on the Long-Term Care Services standards, criterion 3.12. Clients should be included in this process. I suggest you change the wording to "The team engages staff, service providers, and clients in the process to plan services."

You may also submit your feedback online HERE

[YOUR COMMENTS HERE]

Thank you for your input! Please send this page to:
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