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STANDARDS

Reprocessing of Reusable Medical Devices

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REPROCESSING OF REUSABLE MEDICAL DEVICES

Accreditation Canada's sector- and service-based standards help organizations assess quality at the point of service delivery and embed a culture of quality, safety, and client- and family-centred care into all aspects of service delivery. The standards are based on five key elements of service excellence: clinical leadership, people, process, information, and performance.

Accreditation is one of the most effective ways for organizations to regularly and consistently examine and improve the quality of their services. The standards provide a tool for organizations to embed accreditation and quality improvement activities into their daily operations with the primary focus being on including the client and family as true partners in service delivery.

Client- and family-centred care is an approach that guides all aspects of planning, delivering and evaluating services. The focus is always on creating and nurturing mutually beneficial partnerships among the organization's staff and the clients and families they serve. Providing client- and family-centred care means working collaboratively with clients and their families to provide care that is respectful, compassionate, culturally safe, and competent, while being responsive to their needs, values, cultural backgrounds and beliefs, and preferences (adapted from the Institute for Patient- and Family-Centered Care (IPFCC) 2008 and Saskatchewan Ministry of Health 2011).

Accreditation Canada has adopted the four values that are fundamental to this approach, as outlined by the IPFCC, and integrated into the service excellence standards. The values are:

- 1. Dignity and respect:** Listening to and honouring client and family perspectives and choices. Client and family knowledge, values, beliefs, and cultural backgrounds are incorporated into the planning and delivery of care.
- 2. Information sharing:** Communicating and sharing complete and unbiased information with clients and families in ways that are affirming and useful. Clients and families receive timely, complete, and accurate information in order to effectively participate in care and decision-making.
- 3. Partnership and participation:** Encouraging and supporting clients and families to participate in care and decision making to the extent that they wish.
- 4. Collaboration:** Collaborating with clients and families in policy and program development, implementation and evaluation, facility design, professional education, and delivery of care.

Accreditation Canada's *Reprocessing of Reusable Medical Device Standards* have been developed in collaboration with CSA. The standards provide a quality improvement framework for the medical device reprocessing (MDR) department that covers cleaning, disinfection, and sterilization services.

This set of standards describes the requirements for reprocessing, and distribution/transportation of reusable medical devices-critical, semi-critical, and non-critical items, including (but not limited to) respiratory/anaesthesia devices, ultrasound transducer probes, and endoscopes.

Preferably, medical device reprocessing (MDR) is done through a centralized system that provides reprocessing services to multiple areas within the organization. From a safety and cost-effectiveness perspective, centralizing reprocessing services is preferred to replicating them in several areas of the organization. If reprocessing services are decentralized, they are held to the same standards as the MDR department.

Accreditation Canada also covers reprocessing content in the *Infection Prevention and Control (IPC) Standards* for organizations that do not have an MDR department and therefore will not be evaluated against the MDR standards. To avoid duplication in requirements, the reprocessing section in the IPC standards is removed for organizations that are using the MDR standards.

This set of standards contains the following sections:

- **Investing in Quality Services**
- **Building a Prepared and Competent Team**
- **Complying with Policies, Standard Operating Procedures and Manufacturers' Instructions**
- **Performing Reprocessing (Cleaning, Disinfection and Sterilization) and Packaging Services**
- **Monitoring Quality and Achieving Positive Outcomes**

All Accreditation Canada standards are developed through a rigorous process that includes a comprehensive literature review, consultation with a standards working group or advisory committee comprised of experts in the field, and evaluation by client organizations and other stakeholders.

If you would like to provide feedback on the standards, please complete the feedback form in this document.

Glossary

Care delivery model: A conceptual model that broadly outlines the way services are delivered. It is based on a thorough assessment of client needs, involving a collaborative approach and stakeholder input, which considers the best use of resources and services that are culturally appropriate. The benefits of using a care delivery model include improving access to services, providing safe, quality care, promoting a client-centred continuum of care, providing access to a balanced range of services, supporting a highly skilled and dedicated workforce, and reducing inequities in health status.

Care plan: May also be known as the service plan, plan of care, or treatment plan. It is developed in collaboration with the client and family and provides details on the client history as well as the plan for services including

treatments, interventions, client goals, and anticipated outcomes. The care plan provides a complete picture of the client and their care and includes the clinical care path and information that is important to providing client-centred care (e.g., client wishes, ability/desire to partner in their care, the client's family or support network). The care plan is accessible to the team and used when providing care.

Client: The recipient of care. May also be called a patient, consumer, individual, or resident. Depending on the context, client may also include the client's family and/or support network when desired by the client. Where the organization does not provide services directly to individuals, the client refers to the community or population that is served by the organization.

Client representative or client advisor: Client representatives work with the organization and often individual care teams. They may be involved in planning and service design, recruitment and orientation, working with clients directly, and gathering feedback from clients and team members. Integrating the client perspective into the system enables the organization to adopt a client- and family- centred approach.

Co-design: A process that involves the team and the client and family working in collaboration to plan and design services or improve the experience with services. Co-design recognizes that the experience of and input from the client and family is as important as the expertise of the team in understanding and improving a system or process.

Electronic Health Record (EHR): An aggregate, computerized record of a client's health information that is created and gathered cumulatively from all of the client's health care providers. Information from multiple Electronic Medical Records is consolidated into the EHR.

Electronic Medical Record (EMR): A computerized record of a client's health information that is created and managed by care providers in a single organization.

Family: Person or persons who are related in any way (biologically, legally, or emotionally), including immediate relatives and other individuals in the client's support network. Family includes a client's extended family, partners, friends, advocates, guardians, and other individuals. The client defines the makeup of their family, and has the right to include or not include family members in their care, and redefine the makeup of their family over time.

Indicator: A single, standardized measure, expressed in quantitative terms, that captures a key dimension of individual or population health, or health service performance. An indicator may measure available resources, an aspect of a process, or a health or service outcome. Indicators need to have a definition, inclusion and exclusion criteria, and a time period. Indicators are typically expressed as a proportion, which has a numerator and denominator (e.g., percentage of injuries from falls, compliance with standard procedures, staff satisfaction). Counts, which do not have a denominator, may also be used (e.g., number of complaints, number of clients harmed as a result of a preventable error, number of policies revised). Tracking indicator data over time identifies successful practices or areas requiring improvement; indicator data is used to inform the development of quality improvement activities. Types of indicators include structure measures, process measures, outcome measures, and balancing measures.

Interoperable: The ability of two or more systems to exchange information and use the information that has been

exchanged.

In partnership with the client and family: The team collaborates directly with each individual client and their family to deliver care services. Clients and families are as involved as they wish to be in care delivery.

Medical devices and equipment: An article, instrument, apparatus or machine used for preventing, diagnosing, treating, or alleviating illness or disease; supporting or sustaining life; or disinfecting other medical devices. Examples include blood pressure cuffs, glucose meters, breathalyzers, thermometers, defibrillators, scales, foot care instruments, client lifts, wheelchairs, syringes, and single-use items such as blood glucose test strips.

Medical equipment: A subset of medical devices, considered to be any medical device that requires calibration, maintenance, repair, and user training.

Partner: An organization or person who works with another team or organization to address a specific issue by sharing information and/or resources. Partnership can occur at the organization level, team level, or through individual projects or programs.

Patient safety incident: An event or circumstance that could have resulted, or did result, in unnecessary harm to a client. Types of patient safety incidents are:

- *Harmful incident:* A patient safety incident that resulted in harm to the client. Replaces adverse event and sentinel event.
- *No harm incident:* A patient safety incident that reached a client but no discernible harm resulted.
- *Near miss:* A patient safety incident that did not reach the client.

Policy: An organization's position on an issue, plan, or course of action.

Population: Also known as community. A specific group of people, often living in a defined geographical area who may share common characteristics such as culture, values, and norms. A population may have some awareness of their identity as a group, and share common needs and a commitment to meeting them.

Procedure: A written series of steps for completing a task, often connected to a policy.

Process: A series of steps for completing a task, which are not necessarily documented.

Scope of practice: The procedures, actions, and processes that are permitted for a specific health care provider. In some professions and regions, scope of practice is defined by laws and/or regulations. In these cases, licensing bodies use the scope of practice to determine the education, experience, and competencies that are required for health care providers to receive a license to practice.

Self-efficacy: A person's estimate or judgment of his or her ability to cope with a given situation, or to succeed in completing tasks by attaining specific or general goals. An example of achieving a specific goal includes quitting smoking, whereas achieving a general goal includes continuing to remain at a prescribed weight level.

Team: The group of the care professionals who work together to meet the complex and varied needs of clients, families and the community. Teams are collaborative, with different types of health care professionals working together in service provision. The specific composition of a team depends on the type of service provided.

Team leader: Person(s) responsible for the operational management of a team. Duties include identifying needs, staffing, and reporting to senior management. Team leaders may be formally appointed or take a role naturally within the team.

Timely/regularly: Carried out in consistent time intervals. The organization defines appropriate time intervals for various activities based on best available knowledge and adheres to those schedules.

Transition in care: A set of actions designed to ensure the safe and effective coordination and continuity of care as clients experience a change in health status, care needs, health-care providers or location (within, between, or across settings (as defined by the Registered Nurses' Association of Ontario).

With input from clients and families: Input from clients and families is sought collectively through advisory committees or groups, formal surveys or focus groups, or informal day-to-day feedback. Input can be obtained in a number of ways and at various times and is utilized across the organization.

Service-specific Glossary

Cleaning: The removal of foreign and organic material (blood, secretions) prior to further processing. Cleaning is a necessary step in the decontamination process. Cleaning is essential prior to disinfection or sterilization as the effectiveness of disinfection or sterilization processes can be impacted by residual debris or soil on instruments. In addition, cleaning (manual, automated) removes visible debris and visible soiling to render the item safe for further handling by persons involved in reprocessing when these persons use appropriate barriers (e.g., gloves, gowns, and face protection).

Decontamination: The process of cleaning by physical or chemical means to remove or inactivate pathogenic micro-organisms in order to render an object safe for handling.

Disinfection: The process of inactivating disease-producing microorganisms by chemical or thermal means. Levels of chemical disinfection include the following:

- **High-level disinfection (HLD)** - A process capable of killing vegetative bacteria, mycobacteria including *Mycobacterium tuberculosis*, fungi, and lipid and nonlipid viruses, as well as some, but not necessarily high numbers of, bacterial spores. HLD is considered to be the minimum level of reprocessing required for semi-critical medical devices. High-level disinfection can be performed by chemicals at concentrations that are sporicidal when the contact time is prolonged; however, these chemicals are usually used as disinfectants for much shorter contact periods. High-level disinfectants are therefore potent disinfectant chemicals, and appropriate precautions should be taken.
- **Intermediate-level disinfection (ILD)** - A process capable of killing vegetative bacteria, mycobacteria including *Mycobacterium tuberculosis*, fungi, and lipid and nonlipid viruses. ILD does not necessarily kill bacterial spores.

Chemicals considered to have an intermediate level of activity will have approved label claims against both mycobacteria and nonlipid viruses such as poliovirus, enterovirus, hepatitis A, etc. In Canada, disinfectants with an approved label claim against poliovirus are considered to be general virucides. Currently, in the U.S., disinfectant labels are required to carry separate claims against each virus for which activity is claimed. Products with label claims against enveloped viruses such as influenza virus, herpes virus, or HIV are considered to be low-level disinfectants.

- **Low-level disinfection (LLD)** - A process capable of killing most vegetative bacteria and some fungi, as well as enveloped (lipid) viruses (e.g., influenza, hepatitis B and C, and HIV). LLDs do not kill mycobacteria, non-enveloped viruses, or bacterial spores. Labels of low-level disinfectants cannot carry any claims in addition to those for vegetative bacteria; however, some products will carry claims for one or more viruses or fungi. Low Level disinfection can be used for processing non-critical items and some environmental surfaces.

Endoscope - Critical: Endoscopes used in the examination of critical spaces, such as joints and sterile cavities. These endoscopes may be flexible or rigid. Examples of critical endoscopes are arthroscopes, cystoscopes and laparoscopes.

Endoscope - Semicritical: Fibreoptic or video endoscopes used in the examination of the hollow viscera. These endoscopes generally invade only semicritical spaces, although some of their components might enter tissues or other critical spaces. Examples of semicritical endoscopes are laryngoscopes, nasopharyngeal endoscopes, transesophageal probes, colonoscopes, gastroscopes. Duodenoscopes, sigmoidoscopes and enteroscopes.

Immediate Use Steam Sterilization (IUSS)/ Flash Sterilization: A steam sterilization process designed and used for the emergency sterilization of surgical devices when routine sterilization cannot be used.

Installation Qualification (IQ): The process of obtaining and documenting evidence that the equipment has been provided and installed in accordance with its specification.

Medical Device Reprocessing Department (MDRD): A segregated, functional area (not necessarily centralized) where reprocessing of reusable medical devices takes place away from patients.

Operational Qualification (OQ): The process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

Performance Qualification (PQ): The process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

Pre-cleaning: The removal of foreign and organic material (blood, secretions) performed at the point of use, immediately following the clinical procedure.

Reprocessing: The process of rendering a potentially contaminated medical device safe and effective for use on a patient. This includes cleaning, disinfecting, packaging, and sterilizing the medical device as required, and can also include sharpening, repairing, relubricating, and recalibrating. Reprocessing also covers the activities related to

correct handling after sterilization including storage, transport, and distribution; documentation; and quality control.

Reprocessing Equipment: Equipment that has been designed to reprocess medical devices (for example, washer-disinfectors, sterilizers, and ultrasonics).

Reusable device: A device that has been designed by the manufacturer through the selection of materials and/or components to be reused after appropriate reprocessing is performed.

Risk class: The classification assigned to a device involved in patient care based on the risk of infection involved with the use of the device. The classes are as follows:

- **Critical devices** - Devices that enter sterile tissues, including the vascular system (for example biopsy forceps, foot care equipment, dental hand pieces, etc.). Reprocessing critical devices involves meticulous cleaning followed by sterilization.

Note: Critical devices present a high risk of infection if the item is contaminated with any class of microorganism, including bacterial spores.

- **Semi-critical devices** - Devices that come in contact with mucous membranes or non-intact skin, but ordinarily do not penetrate them (for example, respiratory therapy equipment, transrectal probes, specula). Reprocessing semi-critical items involves meticulous cleaning followed by high-level disinfection or sterilization.

- **Non-critical devices** - Devices and patient care equipment that touch intact skin but not mucous membranes (for example, blood pressure cuffs or stethoscopes). Reprocessing of non-critical items involves thorough cleaning and/or low-level or intermediate disinfection.

Single-use/disposable device: A device designated by the manufacturer for single use only.

Spauldings Classification: Classification system used to select the reprocessing level and products required for medical equipment/devices. The classification system divides medical equipment/devices into three categories, based on the potential risk of infection involved in their use. Medical equipment/devices are assigned varied levels of processing/reprocessing depending on whether they are classified as critical equipment/device, semicritical equipment/device or noncritical equipment/device.

Stakeholder: A person with an interest in or concern for the organization and its services. Stakeholders may be internal (e.g., staff) or external (e.g., physician office or clinic).

Standard Operating Procedure (SOP): Written instructions explaining the key steps of a procedure or a process in a clear and concise manner. Using SOPs helps minimize risk and promote consistency in daily activities. SOPs should show the title and purpose, a unique identification number, the date it was implemented or revised, the signature of the authorizing person(s) and the date of authorization, the steps to be followed in the procedure, and who is responsible for approving the SOP. The standards require teams to establish, follow, and evaluate their SOPs on a regular basis.

Sterilization: A validated process used to render a device free from viable micro-organisms.

In a sterilization process, the nature of microbial death is described by a mathematical function. Therefore, the presence of micro-organisms on any individual device can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

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.

INVESTING IN QUALITY SERVICES

1.0 **Services are designed collaboratively to meet the needs of patients and team members.**



Appropriateness



- 1.1 Information about service volumes is collected at least annually from all areas in the organization that require reprocessing services, and is shared with the MDR department.

Guidelines

Examples include operating room, ambulatory care areas, obstetrics services or delivery areas, diagnostic imaging, areas using endoscopes, including any area that reprocesses medical devices (cleaning, disinfecting and sterilizing).



Appropriateness



- 1.2 Information collected about services offered and their volumes is used to determine the range of reprocessing services and how they are delivered.

Guidelines

The MDR department must be involved in program development and delivery to ensure adequate equipment and staffing. The range of reprocessing services covers the needs of the organization. Service volumes are analyzed to determine which reprocessing services will be delivered within a centralized MDR department (preferred), a decentralized area, at the point of use, and whether services will be shared between organizations, between locations within the same organization, or contracted to external providers.



Appropriateness



- 1.3 If services for reprocessing of reusable medical devices are contracted to external providers, a written agreement is maintained with each provider that outlines requirements and respective roles and responsibilities.

Guidelines

The agreement requires that contracted service providers adhere to accepted standards of practice (e.g., CSA standards) and that the quality of reprocessing services are monitored. Examples include daily monitoring of printouts or electronic records, maintaining records of each sterilization cycle, and having a process to report issues with reprocessed devices (e.g., defective wraps or medical devices and equipment that arrive soiled). For more information, see CSA Standards Z314.0.



Appropriateness



1.4

Written agreements with external providers are regularly evaluated to verify that the requirements are being met.

Guidelines

The evaluation includes verifying that the external provider continues to meet the requirements, including adherence to accepted standards of practice. The organization must be able to demonstrate that the external provider (third-party organization) is meeting the MDR department quality requirements. For more information, see CSA Standards Z314.0.

2.0

Sufficient resources are available to provide safe and high-quality services.



Appropriateness

2.1

Resource requirements and gaps are identified and communicated to the organization's leaders.

Guidelines

The resources needed to provide safe, effective, and high quality services are determined by team members and the organization. Resources may be human, financial, structural, informational, or technological.

Identifying resource requirements is a collaborative process between the team and the organization's leaders. It includes criteria to determine where resources are required, potential risks to the team and clients, gaps in services, service bottlenecks, or barriers to service delivery or access.

The team and the organization's leaders work together to determine how to effectively use available resources or where additional resources are required.



Appropriateness

2.2

Technology and information systems requirements and gaps are identified and communicated to the organization's leaders.

Guidelines

Technology includes electronic medical/health records (EMR/EHR), decision tools, client tracking systems, wait list management systems, client self-assessment tools, or access to service-specific registries and/or databases. Depending on the organization, the need for systems could be complex (e.g. advanced software to increase interoperability) or support basic operation (e.g. newer computer systems).

As much as possible, innovative information technology is used to support the work of the service area.



Efficiency

2.3

An appropriate mix of skill level and experience within the team is determined to support quality service delivery.

Guidelines

Ensuring an appropriate and optimal mix of skill level, competency, and experience supports safe and effective, service delivery and creates learning opportunities for team members.

Optimal ratios of skills and experience are determined based on service volumes, and types of medical devices and equipment reprocessed in the organization.



Appropriateness



2.4

A designated individual is accountable for quality oversight and for coordinating all reprocessing services across the organization, including those performed outside the MDR department.

Guidelines

The designated team member has the knowledge, formal MDR training and competence to understand key issues in reprocessing. Accountability for reprocessing is clearly written, e.g., reflected on an organization chart. The designated person reports directly to the organization's senior management or the executive office.

In organizations with multiple sites or locations, the designated individual is accountable for all reprocessing and sterilization activities across all sites and locations.



Appropriateness

2.5

The effectiveness of resources, space, and staffing is evaluated with input from the team, and stakeholders.

Guidelines

Evaluating resources, space, and staffing helps determine the extent to which effective services are being provided and identifies opportunities for improvements. Input from the team, and stakeholders is gathered through surveys, focus groups, advisory committees, and informal feedback.



Efficiency

3.0 The MDR department, centralized or de-centralized, is organized to facilitate one-way workflow to prevent cross-contamination.

3.1 The layout of the MDR department is designed based on service volumes, range of reprocessing services, and one way flow of medical devices.

Guidelines

For more information, see CSA Standards Z314.0.



Safety



3.2 The MDR department is designed to prevent cross-contamination of medical devices, isolate incompatible activities, and clearly separate work areas.

Guidelines

To prevent cross-contamination, medical device reprocessing flows in one direction only; from dirtiest (most contaminated), to clean, to sterile. Items at an individual work station cannot be at different stages of the reprocessing process.



Safety



3.3 Access to the MDR department is controlled by restricting access to authorized team members only and being identified with clear signage.

Guidelines

For example, access to the MDR department can be controlled by locking the doors, using key pad code entry, or issuing swipe cards with different levels of access. Specific criteria are applied if other team members need to access the MDR department (e.g., appropriate personal protective equipment, hand hygiene).



Safety



3.4 The MDR department has an area for decontamination that is physically separate from other reprocessing areas and the rest of the facility.

Guidelines

The risk of microbial and particulate contamination is increased in the decontamination area. For more information, see CSA Standards Z314.0, and Z314. 8.



Appropriateness



3.5

Appropriate environmental conditions are maintained within the MDR department and storage areas.

Guidelines

Environmental conditions include water quality, ventilation, temperature, humidity, and lighting.

Ventilation in the MDR department is designed to prevent the infiltration of lint into the air stream and provide directional airflow from clean areas. Preparation and reprocessing areas are kept under positive pressure in relation to contaminated areas. Portable fans, dehumidifiers, humidifiers, and heaters are prohibited.

To monitor temperature and relative humidity levels, the MDR department and storage areas are equipped with an alert system that is activated when levels are outside the acceptable ranges. For more information, see CSA Standards Z317.2, Z317.5, Z314.0 and Z314. 8 and Z314.3.



Appropriateness



3.6

The MDR department has floors, walls, ceilings, fixtures, pipes, and work surfaces that are easy to clean, non-absorbent, and will not shed particles or fibres.

Guidelines

Materials are flat or flush, and non-porous. Fixtures and pipes above work areas are recessed and concealed.



Safety



3.7

The MDR department is clean and well-maintained.

Guidelines

Cleaning the work area is based on the organization's environmental services policies and procedures which address specific cleaning materials and equipment, disinfecting cleaning equipment, and properly storing and using disinfectants. The cleaning frequencies are clearly defined and documented. For more information, see CSA Standards Z314.0 and Z314.15.

4.0

Reprocessing equipment is installed and maintained according to manufacturers' specifications and installation qualifications.



Efficiency

4.1

Reprocessing equipment is purchased based on service volumes, input from team members, and considerations for maintenance, cleaning, and infection prevention and control.

Guidelines

There is a process to approve the purchase of new reprocessing equipment that involves team members from reprocessing services (e.g., MDR department, ambulatory care, and operating room); infection prevention and control; occupational health and safety; and biomedical engineering, as appropriate. For more information, see CSA Standards Z314.0.



Efficiency

4.2

Medical devices are purchased based on user requirements, service volumes, input from team members, and considerations for maintenance, cleaning, and infection prevention and control.

Guidelines

There is a process to approve the purchase of new reusable medical devices that involves team members from reprocessing services (e.g., MDR department, ambulatory care, and operating room); infection prevention and control; occupational health and safety; and biomedical engineering, as appropriate. For more information, see CSA Standards Z314.0.



Safety



4.3

Reprocessing equipment is installed based on manufacturers' specifications.

Guidelines

The manufacturer is involved directly for clarification or additional information as needed. For more information, see CSA Standards Z314.0.



Safety



4.4

Before releasing reprocessing equipment for use, appropriate installation qualification (IQ), operation qualification (OQ), and performance qualification (PQ) testing is completed and documented.

Guidelines

Installation testing is completed following the installation of new/replacement reprocessing equipment; upon completion of major maintenance and repairs; following construction, relocation, or environmental changes; after major changes to packaging, wraps, or load configurations; and after unexplained failures. For more information, see CSA Standards Z314.3.



Appropriateness



4.5

A preventive maintenance program is implemented for reprocessing equipment.

Guidelines

The program includes regular inspection and maintenance. It also includes cleaning, lubricating, checking for leaks, changing filters, and verifying settings and calibration.

The program may be implemented by in-house personnel or contracted to an external provider. For more information, see CSA Standards Z314.0.



Appropriateness



4.6

Preventive maintenance is documented for reprocessing equipment.

Guidelines

The preventive maintenance record includes the date on which an inspection or maintenance procedure was initiated and completed; the name of the person who carried out the inspection or maintenance procedure; components that were inspected and replaced, and the extent of any maintenance procedures; when biological tests were successfully performed and the signature of the person qualified to release the sterilizer for service following major repairs or replacement; the signature of the person qualified to confirm that the specified inspection or maintenance procedures have been completed by competent individuals; and, the model, serial number, and location of the equipment. For more information, see CSA Standards Z314.0.



Safety



4.7

Routine testing of reprocessing equipment is performed and documented as per manufacturers' instructions.

Guidelines

Reprocessing equipment requires testing to ensure its safe operation. Process challenge indicators are used to test reprocessing equipment.

Examples of tests: For washer-disinfectors-testing of cleaning efficacy and thermal disinfection; Ultrasonic- the foil test. Sterilizers-biological indicators and chemical indicators. For more information, see CSA Standards Z314.23, Z314.3, and Z314.8.

BUILDING A PREPARED AND COMPETENT TEAM



Worklife

5.0 Team members are qualified and have relevant competencies.

- 5.1 Position profiles with defined roles, responsibilities, and scope of employment or practice exist for all positions.

Guidelines

Position profiles include a position summary, qualifications and minimum requirements, the nature and scope of the work, and reporting relationships. They are developed for all team members including those who are not directly employed by the organization (e.g., contracted team members and stakeholders).

Role clarity is essential in promoting team safety as well as a positive work environment. Understanding roles and responsibilities and being able to work to one's full scope of practice helps create meaning and purpose for team members.



Appropriateness



- 5.2 Qualifications, training, and education are defined for all team members with input from stakeholders.

Guidelines

Qualifications are defined for all team members, including unregulated staff.

Qualifications, training, and education varies by role. They may be defined by a professional regulating body, may be formal or informal, and may include lived experience or work experience. For more information, see CSA Standards Z314.0.



Appropriateness



- 5.3 Qualifications, requirements, and competencies are verified, documented, and up-to-date.

Guidelines

Requirements vary for different roles in the organization, including for regulated or unregulated team members.

Designations, qualifications, competency assessments, and training are monitored and maintained to ensure safe and effective delivery of services. Professional requirements are kept up-to-date in accordance with provincial and organizational policies.

Services are delivered within accepted scopes of practice. Team members have the appropriate training and capacities to use equipment, devices, and supplies safely.



Worklife



5.4

The team involved in reprocessing medical devices is prepared for the functions it performs through education and training in a formal medical device reprocessing training program recognized by the health care setting.

Guidelines

Training and continuing education for all personnel involved in the reprocessing of devices is provided and documented including information and instruction on all policies and procedures relating to reprocessing of medical devices, occupational health and safety, and infection prevention and control. The health care setting's reprocessing policies specify the requirements for and frequency of education, training, and competency assessment for each employee involved with the transportation, cleaning, and reprocessing of reusable devices. For more information, see CSA Standards Z314.0.



Appropriateness

5.5

A comprehensive orientation is provided to new team members.

Guidelines

The orientation program covers, at minimum, the organization's mission, vision, and values; the team's mandate, goals, and objectives; the philosophy of client-centred care and how to apply its principles to practice; roles, responsibilities, and performance expectations; policies and procedures, including confidentiality; worklife balance initiatives; and the organization's approach to integrated quality management (e.g., quality improvement, risk management, utilization management, efficient use of resources).

Orientation processes and activities are documented. For more information, see CSA Standards Z314.0.



Safety



5.6

The orientation program addresses safe work practices, including patient safety, occupational health and safety, and infection prevention and control.

Guidelines

Initial orientation addresses occupational health and safety, infection prevention and control, the facility's policies and procedures, personal protective equipment (PPE), and principles of containment and confinement. It also covers basic microbiology, such as basics of microbial growth related to medical devices and the transmission risk of micro-organisms.

The orientation covers the Workplace Hazardous Materials Information System (WHMIS), including the product identifiers of hazardous substances in the workplace; the information on labels and materials data sheets; procedures for safe storage, use, handling, and disposal of hazardous materials; the locations of pipes, valves, controls, and safety devices; and procedures for emergencies. For more information, see CSA Standards Z314.0.



Safety



5.7

Initial and ongoing education and training are provided on the safe use of equipment, devices, and supplies used in service delivery.

Guidelines

Information about the safe use of equipment, devices and supplies used in service delivery is provided to all team members.

Team members are trained on how to use existing and new equipment, devices, and supplies. Retraining may be requested or required if a team member does not feel prepared to use the equipment, device, or supplies, or has not used the equipment or device for a long time. Training includes handling, storage, operation, and cleaning; preventive maintenance; and what to do in case of breakdown.



Appropriateness

5.8

Initial and ongoing education and training are provided on information systems and other technology used in service delivery.

Guidelines

Education and training may cover topics such as knowledge of computer applications, word processing, software, time management tools, communication tools, research applications, cell phone use, and protecting the privacy of client information.



Safety



5.9

Education and training are provided and documented on how to reprocess medical devices and operate reprocessing equipment when team members are first employed, when there is a change in the reprocessing process, and on an ongoing basis.

Guidelines

For more information, see CSA Standards Z314.0.



Safety



5.10

Education and training are provided and documented when new medical devices and reprocessing equipment are purchased.

Guidelines

For more information, see CSA Standards Z314.0.



Worklife



5.11

Team member performance is regularly evaluated and documented in an objective, interactive, and constructive way.

Guidelines

An established process to evaluate each team member's performance is followed. Stakeholder and/or peer input is part of the evaluation process.



Worklife



5.12

Team members are supported by team leaders to follow up on issues and opportunities for growth identified through performance evaluations.

Guidelines

Issues may be identified by the team member or the team leaders and are used to develop an action plan or professional development plan.



Worklife

5.13

Ongoing professional development, education, and training opportunities are available to each team member.

Guidelines

Team leaders encourage team members to participate in opportunities for professional or skills development on a regular basis. Additional training or education may be given based on the team member's performance evaluation or as identified through professional development plans.

6.0

Well-being and worklife balance is promoted within the team.



Worklife

- 6.1 The workload of each team member is assigned and reviewed in a way that ensures client and team safety and well-being.

Guidelines

Appropriate criteria are used for determining workload depending on the environment and the unique demands of different services areas, including hours of work, caseload, role complexity, complexity of client care, physical or emotional demands, repetitive nature of tasks, and level of responsibility. The preferences and availability of each team member are also considered.

In some cases teams may designate a maximum workload for team members. The process of assigning and reviewing workload includes monitoring and tracking hours and clients and when additional measures are needed (e.g., staffing transfers or team re-design).

An environment where team members are comfortable discussing demands and stress levels in the workplace is promoted by the organization and leaders. Measures are taken to alleviate these pressures as much as possible. These can include scheduling strategies, workload sharing, and scheduled time for documentation.



Worklife

- 6.2 Work and job design, roles and responsibilities, and assignments are determined with input from team members, and stakeholders where appropriate.

Guidelines

Job design refers to how a group of tasks, or an entire job, is organized. Job design addresses all factors that affect the work, including job rotation, work breaks, and working hours. Stakeholder input and feedback is considered in job design.



Worklife

- 6.3 Team members are recognized for their contributions.

Guidelines

Recognition activities may be individual, such as awards for years of service or special achievements, or they may involve team recognition or activities. Recognition can be formal or informal and may be verbal, written, or focus on promoting an atmosphere where team members feel appreciated for their contributions.



Worklife

6.4

There is a policy that guides team members to bring forward complaints, concerns, and grievances.



Safety



6.5

Education and training on occupational health and safety regulations and organizational policies on workplace safety are provided to team members.



Safety



6.6

Education and training are provided on how to identify, reduce, and manage risks to client and team safety.

Guidelines

Training may include physical hazards; challenges with equipment; handling spills, waste, or infectious materials; and challenges with handling or storing materials. Common risks to the team may include lack of training on safety issues, improper body mechanics, improper use of equipment, or working alone.



Safety



6.7

Education and training are provided to team members on how to prevent and manage workplace violence, including abuse, aggression, threats, and assaults.

Guidelines

Acts of violence include abuse, aggression, threats, and assaults. They may be committed by clients, their families, teams, or anyone else in the workplace.

Where possible, team members use de-escalation techniques as a preventive measure. De-escalation techniques are minimally intrusive and the least restrictive way to manage violence. Some training programs on how to safely work with clients who are at risk of or who exhibit aggressive or responsive behaviors include:

- CPI Training (Crisis Prevention and Intervention)
- GPA (Gentle Persuasive Approach)
- U-First!

Training and education include the use of a standardized risk assessment tool such as the Hamilton Anatomy of Risk Management (HARM) tool. Training may address:

- Identifying triggers
- Assessing and communicating a client's potential for violence and recognizing signs of agitation and aggression
- Reducing harassment
- Responding to and managing violence (e.g., non-violent crisis intervention, emergency code response guidelines, conflict resolution and mediation, and self-defense)
- The trauma-informed approach
- Communication techniques

Training may also specify the team's alternate procedure for when de-escalation techniques are unsuccessful.



Safety



6.8

The organization's policy on reporting workplace violence is followed by team members.

Guidelines

Perceived, potential, or actual incidents of physical or verbal violence are reported to the appropriate authorities in accordance with applicable legislation.

COMPLYING WITH POLICIES, STANDARD OPERATING PROCEDURES, AND MANUFACTURERS' INSTRUCTIONS

7.0 **Policies and Standard Operating Procedures (SOPs) are developed, maintained, and evaluated for medical device reprocessing services.**



Appropriateness



7.1 Clear and concise policies are developed and maintained for reprocessing services.

Guidelines

The policies are based on accepted standards such as CSA Standards. The policies include team member responsibilities; qualifications, including training, education, and competency assessment; infection prevention and control; occupational health and safety; and the requirements of subcontractors inside and outside the organization. They also address ongoing quality improvement, including controls to ensure medical devices and equipment are functional and sterile before being released from the sterilization area; recall procedures; the evaluation and purchase of medical devices and equipment; and back-up and contingency planning regarding inventory and temporary shortages.



Safety



7.2 The reprocessing of critical and semi-critical single-use devices (SUD) is not permitted on-site in line with the organization's policy and the provincial/territorial regulations.



Safety



7.3 The organization has policies and procedures for loaned, shared, consigned, and leased medical devices.

Guidelines

If the organization uses or provides loaned, shared, consigned, or leased medical devices, policies and procedures must be developed to address the receiving and transport of these devices to and from the organization, and to handle items that are delivered unexpectedly, contaminated, unsterilized, or incomplete. For more information, see CSA Standards Z314.22.



Safety



7.4

Immediate-use steam sterilization (IUSS) is limited to emergencies only, and never for complete sets or implantable devices in line with the organization's policy and the provincial/territorial regulations.

Guidelines

Areas where immediate-use steam sterilization is likely to be used in emergency situations include the operating room and obstetric services when there is an urgent need and no other options are available. There are policies and procedures for the use and documentation of this method. For more information, see CSA Standards Z314.3.



Appropriateness

7.5

Clear and concise Standard Operating Procedures (SOPs) are developed and maintained for reprocessing services.

Guidelines

The SOPs address all stages of the reprocessing process including the management and reporting of patient safety incidents; the reprocessing of medical devices according to risk class and manufacturers' instructions; reprocessing equipment; special precautions for the reprocessing of medical devices that are difficult to clean, disinfect, or sterilize; packaging; the reassembly and functional testing of complex devices; on or offsite transportation of medical devices; quarantine of reprocessed medical devices; recall procedures; and procedures for various emergencies including sterilizer shutdowns, utility failures or shutdowns, an emergency plan to transfer services offsite, or a large-scale inventory loss or recall. For more information, see CSA Standards Z314.0.



Appropriateness

7.6 Current manufacturers' instructions are upheld for all medical devices and equipment.

Guidelines

This also applies to medical devices and equipment that are introduced from outside the organization. For more information, see CSA Standards Z314.0.



Accessibility

7.7 Policies, SOPs, and manufacturers' instructions are accessible to all team members.

Guidelines

The instructions may be in written form (e.g., binders, manuals, and monographs) and/or in electronic format. Team members know where and how to access the instructions. For more information, see CSA Standards Z314.0.



Worklife

7.8 Information or training is provided to team members before implementing a new or revised policy, SOP, or manufacturer's instructions.

Guidelines

The amount and detail of information or training that is provided depends on the extent and nature of the revisions. Processes for communicating updates to team members are in place.



Appropriateness



7.9 Policies and SOPs are regularly updated, and signed off according to organizational requirements, as appropriate.

Guidelines

Policies and SOPs may be reviewed or revised following patient safety incidents, changes in regulatory or legal requirements, changes to standards, and audits.

Policies and SOPs are reviewed and revised using a document control procedure to track changes. For more information, see CSA Standards Z314.0.



Appropriateness

7.10 Compliance with policies, SOPs and manufacturers' instructions are regularly evaluated and changes made as needed.

Guidelines

Changes are made to policies, SOPs, training activities, or monitoring processes as a result of the evaluation.

8.0 Occupational Health and Safety (OHS) and infection prevention and control (IPC) requirements are followed to ensure the safety of team members in the reprocessing area.



Accessibility



8.1 The reprocessing area is equipped with hand hygiene facilities at entrances to and exits from the reprocessing areas, including personnel support areas.

Guidelines

Hand hygiene facilities include designated hand washing sinks and alcohol-based hand rub stations. If soiled, hands should be washed with soap and water. For more information, see CSA Standards Z314.0 and PHAC Hand Hygiene Practices in Healthcare Settings.



Safety

8.2 The reprocessing area's designated hand-washing sinks are equipped with faucets supplied with foot-, wrist-, or knee-operated handles, electric eye controls, automated soap dispenser and single-use towels.

Guidelines

Foot-, wrist-, and knee-operated faucets or electric eye controls help prevent the recontamination of hands. If such faucets are not available, access is provided to single-use towels for turning off faucets.



Safety



8.3

Training is provided on proper hand hygiene techniques.

Guidelines

Training on hand hygiene is multimodal and addresses the importance of hand hygiene in preventing the spread of infections, and factors that have been found to influence hand hygiene behaviour. Training includes recommendations on when to clean one's hands, as well as proper technique for hand-washing and use of alcohol based hand rub.



Accessibility



8.4

Access is provided to hand hygiene supplies, including properly functioning soap and towel dispensers and alcohol-based hand rub stations in the working environment.



Safety



8.5

Hand hygiene is performed before beginning and after completing work activities, as well as at other key points, to prevent infection.

Guidelines

Hand hygiene (either by using alcohol-based hand rubs or washing with soap and water) is an important practice in MDR areas. Hand hygiene using water is required at all entrances and exits to decontamination areas. Hands are to be washed with soap and water to remove visible soil/organic material or immediately after using the toilet facilities. Hand hygiene, preferably using alcohol-based hand rubs, is recommended after handling items contaminated, or likely contaminated, with blood, bodily fluids, excretions, or secretions; before putting gloves on and after removing gloves; before leaving the decontamination area; and at any other time specified by the organization's policies. For more information, see CSA Standards Z314.8.



Safety



8.6

Eating and drinking, storing food, applying cosmetics, and handling contact lenses are all prohibited in the reprocessing area.

Guidelines

For more information, see CSA Standards Z314.0.



Safety



8.7

The MDR department dress code addresses clothing, hair covering, dedicated footwear, jewellery, artificial fingernails, and PPE.

Guidelines

Among other requirements, the dress code specifies when attire is to be changed, for example, at the end of each shift, and immediately if it becomes wet, grossly soiled, or contaminated with blood or other potentially infectious matter. For more information, see CSA Standards Z314.0.



Safety



8.8

Appropriate and properly maintained PPE is worn in the decontamination area.

Guidelines

The appropriate PPE includes gloves that are suitable to the task; a fluid-resistant cover garment with sleeves (e.g., backless gown, jumpsuit, or surgical gown); and a full face shield or a fluid-impervious face mask to fully protect eyes, nose, and mouth. The importance of proper donning and doffing PPE is emphasized. For more information, see CSA Standards Z314.0.



Worklife



8.9

Workplace assessments of the MDR department are regularly conducted for ergonomics and occupational health and safety.

Guidelines

Ergonomic and occupational health and safety assessments include height adjustment for sinks, configuration of work stations, and anti-fatigue mats.

PERFORMING REPROCESSING (CLEANING, DISINFECTION AND STERILIZATION) AND PACKAGING SERVICES

9.0 **Medical devices are reprocessed according to the Spaulding classification and manufacturers' instructions.**



Safety



9.1 Safe work practices and infection prevention and control precautions are followed when handling contaminated medical devices and equipment.

Guidelines

All medical devices received in the decontamination area are considered contaminated with infectious material. For more information, see CSA Standards Z314.8.



Safety



9.2 Point of use cleaning of a device or equipment is performed as part of the decontamination process and occurs immediately after use and prior to decontamination in an MDRD and following manufacturers' instructions.

Guidelines

Pre-cleaning at point of use is required when soil or dried organic matter is present on a device. This may include removing soil and flushing lumens as required. Prior to decontamination in the MDRD, devices should be kept moist using an approved product to prevent organic matter from drying, as dried soil is difficult to remove with normal decontamination measures.

Inorganic and organic matter (e.g., blood, protein) retained on devices can inhibit the cleaning, disinfection, sterilization process by providing a medium for the growth of micro-organisms, rendering chemical germicides inactive, or by physically protecting micro-organisms from the sterilization process. For more information, see CSA Standards Z314.8.



Safety

9.3 Contaminated medical devices are sorted before reprocessing.

Guidelines

Sorting ensures that medical devices that belong to a set are kept together. Medical devices requiring similar decontamination procedures or the same cleaning agents are also kept together. For more information, see CSA Standards Z314.8.



Safety

- 9.4 Devices that contain multiple components are disassembled according to the manufacturers' instructions.

Guidelines

Disassembly exposes soil to the cleaning process. For more information, see CSA Standards Z314.8.



Appropriateness

- 9.5 The medical device and reprocessing equipment manufacturers' instructions, as well as accepted standards of practice, are followed to perform manual or automated methods of cleaning.

Guidelines

Cleaning may be done manually or using automated methods. The automated method is preferable because it standardizes the process and controls exposure to aerosols. For more information, see CSA Standards Z314.8.



Appropriateness

- 9.6 Detergents, lubricants, disinfectants, and sterilants are verified to ensure compatibility with the devices being reprocessed, the lubricants used, the equipment used for cleaning or sterilization, and the reprocessing (cleaning, disinfection, or sterilization) processes used.

Guidelines

The disinfectant to be used is documented. All disinfectants have a Drug Identification Number (DIN) from Health Canada. Others in the organization may need to be consulted (e.g., infection prevention and control or occupational health and safety) when selecting appropriate cleaning or disinfecting agents. For more information, see CSA Standards Z314.8.



Safety



9.7

For each cleaner and disinfectant, manufacturers' instructions for use are followed including ventilation requirements, contact time, shelf life, storage, appropriate dilution, testing for appropriate concentration and effectiveness, and required PPE.

Guidelines

For more information, see CSA Standards Z314.8.



Safety

9.8

Chemical residue and loosened soil is rinsed from the medical device prior to disinfection.

Guidelines

Rinsing may be included in the automated cleaning process; if not, the device must be rinsed manually. Tap water may be used. For more information, see CSA Standards Z314.8.



Safety



9.9

Following decontamination, and prior to additional reprocessing, each device is inspected for cleanliness, functionality, and defects such as breaks, chips, or cracks.

Guidelines

A magnifying device is available to inspect medical devices as required following cleaning. For more information, see CSA Standards Z314.8.



Safety



9.10

Following decontamination, and prior to additional reprocessing, devices with problems undergo additional cleaning, lubrication or maintenance as required.

Guidelines

For more information, see CSA Standards Z314.8.



Appropriateness



9.11

Each device or set of devices are prepared for sterilization according to manufacturers' instructions.

Guidelines

For more information, see CSA Standards Z314.8.



Appropriateness



9.12

Each device or set of devices are packaged for sterilization using a validated packaging material and process.

Guidelines

Packaging is a critical component of the sterilization process. Improper packaging materials and processes can inhibit sterilization and lead to failure to maintain sterility.

The packaging material or system allows appropriate and thorough sterilization, maintains sterility until the package is opened for use, and permits the removal of the device without contamination. For more information, see CSA Standards Z314.10.1, Z314.10.2 and Z314.14.

Steps in the packaging process depend on the type of packaging being used. Steps include inspection; set assembly, where appropriate, with disassembly of multipart devices as per manufacturers' instructions; wrapping; and labeling. For more information see CSA Standards Z314.23 and Z314.3.



Appropriateness



9.13

The package or container has an externally visible chemical indicator to differentiate between reprocessed and unprocessed packages.



Appropriateness



9.14

An internal chemical indicator is placed in each package or container, according to the organization's quality control processes, to verify that sterilizer penetration has occurred.

Guidelines

Chemical indicators signal when certain parameters are met in their particular location. Care should be taken to place all indicators in locations that are representative of the load or, better still, in the most difficult to sterilize locations. For more information, see CSA Standards Z15882.



Safety

9.15

A Process Challenging Device (PCD) equipped with a biological indicator and internal chemical indicator is included in every sterilization load containing implantable devices.

Guidelines

Implantable devices are quarantined until the results of the biological indicator test are available. For more information, see CSA Standards Z314.3.



Safety



9.16

For organizations providing neurosurgical services, there are SOPs in place to prevent the transmission of Creutzfeldt-Jakob Disease (CJD).

Guidelines

SOPs include completing a pre-operative assessment for high-risk surgical procedures; completing a pre-operative assessment for high-risk patients; and having either 1) a dedicated set of neurosurgical, neuroendoscopic, ortho-spine devices and intubation equipment to be used when the diagnosis of CJD has been made or is suspected pre-operatively, or 2) re-usable equipment that is quarantined immediately post-surgery and prior to reprocessing until the post-operative diagnosis of CJD is either validated or ruled out. For more information, refer to PHAC's guidelines for Classic Creutzfeldt-Jakob Disease in Canada.



Safety



9.17

If prion contamination is suspected (e.g., Creutzfeldt-Jakob disease), accepted guidelines from the Public Health Agency of Canada are followed to appropriately manage the surgical equipment.

Guidelines

When prion contamination is suspected pre-operatively, a risk assessment for high-risk surgical procedures is performed prior to the surgical intervention.

10.0

Sterilization is completed safely and accurately.



Safety



10.1

The most complex or challenging packs or containers within each product family class are used to verify that all devices can be sterilized.

Guidelines

Performance qualification refers to the program of tests performed by the facility, in consultation with the sterilizer manufacturer, to demonstrate that the medical devices and instrument sets typically reprocessed can be sterilized by the facility's personnel and equipment. This includes testing of products such as trays, packages or instrument sets and loads that have been developed by the health care facility (in consultation with the sterilizer manufacturer). The sterilizer manufacturer's instructions are followed to ensure that load parameters are not exceeded. For more information, see CSA Standards Z314.23 and Z314.3.



Appropriateness



10.2

SOPs and manufacturers' instructions are followed for devices and equipment when loading the sterilizer.

Guidelines

For more information, see CSA Standards Z314.23 and Z314.3.



Appropriateness



10.3

The configuration of the load is verified visually before beginning the sterilization.

Guidelines

The configuration of acceptable loads is identified in the sterilizer's operating manual and in the organization's SOPs. This includes specific load types that have been verified as producing consistent and effective results. Depending on the type of load, visual verification may include ensuring the load does not come into contact with the interior surfaces of the sterilizer chamber; that packages are not stacked (unless validated by package manufacturer); that peel pouches are placed on edge, plastic to paper; and that there is sufficient space between packages to allow unimpeded sterilants circulation. For more information, see CSA Standards Z314.23.



Safety



10.4

Manufacturers' instructions are followed while operating the sterilizer.

Guidelines

Manufacturers' instructions are followed for both the sterilizer and the devices being sterilized. Recommended sterilization cycle parameters (e.g., for steam--exposure time and temperature) are selected. For more information, see CSA Standards Z314.23 and Z314.3.



Appropriateness



10.5

Following the sterilization cycle and before unloading, the team member verifies that the required parameters have been met.

Guidelines

This verification includes checking the cycle record (e.g., recording chart or printout) and signing in the designated place. Records are audited on a regular basis to ensure compliance. For more information, see CSA Standards Z314.3 and Z314.23.



Appropriateness



10.6

During unloading, all packs are inspected.

Guidelines

Inspection criteria includes verifying package integrity and that seals are intact, appropriate change to external chemical indicators, and complete dryness. For more information, see CSA Standards Z314.3 and Z314.23.



Appropriateness



10.7

Reprocessing is repeated for any items with a damaged pack or seal, or that are compressed, torn, wet, or have been dropped on the floor.

Guidelines

For more information, see CSA Standards Z314.3 and Z314.23.



Safety



10.8

Sterilized packages are clearly identifiable and distinguished from non-sterilized items.

Guidelines

This helps prevent the release and use of unsterile medical devices. For more information, see CSA Standards Z314.23 and Z314.3.

11.0

Specific requirements are followed to reprocess flexible endoscopic devices. (Note: The following criteria are additional requirements that apply specifically to reprocessing flexible endoscopes).



Safety



11.1

Training is provided and documented for reprocessing flexible endoscopic devices.

Guidelines

Verifying the qualifications and competencies of team members involved in the reprocessing of flexible endoscopic devices is important in preventing the mishandling or improper reprocessing of these devices. Examples of flexible endoscopic devices include gastroscopes, duodenoscopes, colonoscopes, sigmoidoscopes, flexible cystoscopes, bronchoscopes, laryngoscopes, enteroscopes, and nasopharyngeal endoscopes.



Safety



11.2

All flexible endoscopic reprocessing areas are physically separate from patient care areas.

Guidelines

For more information, see CSA Standards Z314.0 and Z314.8.



Safety

11.3

All flexible endoscopic reprocessing areas are equipped with separate clean and contaminated/dirty work areas as well as storage, dedicated plumbing and drains, and proper air ventilation.

Guidelines

The reprocessing areas for flexible endoscopes have adequate space for reprocessing activities, with sinks and counters large enough for intended uses. One-way workflow patterns are supported through separate clean and soiled areas. Work surfaces are cleanable and task lighting is adequate. Utilities such as electrical, instrument-grade filtered air (for drying purposes), suction and water are provided. There is adequate space for the storage of supplies. The air quality follows local requirements, set out by provincial and other jurisdictional occupational health and safety legislation and regulations. For more information, see CSA Standards Z314.8.



Appropriateness



11.4

Manufacturers' instructions are followed to pre-clean flexible endoscopic devices immediately at point of use.

Guidelines

If cleaning is not done immediately following a procedure, soil residue on the flexible endoscope can harden, becoming very difficult to remove. For more information, see CSA Standards Z314.8.



Safety



11.5

Before cleaning, the flexible endoscope is checked for internal and external damage, and if repairs are required, the flexible endoscope is prepared and packaged for shipping in accordance with manufacturers' instructions.

Guidelines

The integrity of the flexible endoscope is verified through leak testing. Damaged flexible endoscopes are identified, removed from service, and shipped for repair following the manufacturers' packaging, labeling, and shipping instructions. Shipping is done in compliance with federal, provincial, or territorial regulations for the transportation of dangerous goods. For more information, see CSA Standards Z314.8.



Appropriateness



11.6

Before beginning high level disinfection, each flexible endoscopic accessory is cleaned, rinsed, and dried according to the manufacturers' instructions for use.

Guidelines

For more information, see CSA Standards Z314.8.



Appropriateness



11.7

Before beginning high level disinfection, immersible flexible endoscopic components are soaked and manually cleaned and brushed using water and an approved cleaning agent.

Guidelines

An approved cleaning agent is an enzymatic detergent solution prepared and used according to the manufacturers' instructions for use and that is compatible with the device.

While fully immersed, channels and lumens are flushed and brushed to remove debris; brushes are appropriately sized, inspected before and after use, and either discarded or cleaned, disinfected, and dried after use.



Safety



11.8

Flexible endoscopic devices are appropriately stored following manufacturers' instructions in a manner that minimizes contamination and damage.

Guidelines

The organization does not store flexible endoscopes coiled or in their cases. Flexible endoscopic devices are not stored with channel valves or water resistant cap in place. Flexible endoscopes are stored in a dedicated, closed, ventilated cabinet that is equipped with HEPA filtration. The storage cabinet is outside of the decontamination area and procedure room. For more information, see CSA Standards Z314.8.



Appropriateness



11.9

A permanent record is maintained of the reprocessing history of each flexible endoscopic device.

Guidelines

Identifying the patient, the flexible endoscopic device, and the medical equipment used helps facilitate outbreak investigations, device tracking, and quality control. For more information, see CSA Standards Z314.8.



Appropriateness



11.10

The record of flexible endoscopic device reprocessing includes the identification number and the type of flexible endoscope, the identification number of the automated endoscope reprocessor (if applicable), the date and time of reprocessing, the name or unique identifier of the patient, the completion of the individual inspection and leak test, and the name of the person reprocessing the flexible endoscope.

Guidelines

Identifying the patient, the flexible endoscopic device, and the medical equipment used helps facilitate outbreak investigations, device tracking, and quality control. For more information, see CSA Standards Z314.8.



Appropriateness



11.11

Preventive and scheduled maintenance, including repairs, is completed and documented for each automated endoscope reprocessor.

Guidelines

Documentation about the maintenance and repair of medical equipment assists with device tracking and recall.



Appropriateness



12.0

Medical devices are stored in a way that prevents contamination.

12.1

The MDR department has an appropriate storage area for sterilized medical devices and equipment.

Guidelines

The appropriate area is large enough to prevent crushing or damage to packages. In addition, it is protected from moisture contamination, dust from adjacent areas and ventilation systems, and vermin.

The use of closed shelves may help with storage of devices and equipment, in particular those that are infrequently used. If open shelves are used, top and bottom shelves should be impervious and/or plastic shelf liners should be used. Devices are also stored away from the floor, ceiling, window sills, sinks, and outside walls. For more information, see CSA Standards Z314.15 and Z314.0.



Accessibility



12.2

Access to the sterile storage area is limited to authorized team members.

Guidelines

The sterile storage area must be kept clean and protected. Limiting admittance to authorized team members lessens the risk of contamination. For more information, see CSA Standards Z314.15.



Appropriateness

12.3

When cleaning the sterile storage area, the amount of air turbulence and excess moisture is minimized.

Guidelines

Damp, rather than dry, dusting or sweeping is performed whenever possible. Dry cleaning is done carefully with a chemically treated dry mop or a vacuum cleaner equipped with a hepa exhaust filter, rather than a broom. For more information, see CSA Standards Z314.0.



Safety



12.4

The integrity of each sterile package is maintained during storage.

Guidelines

Items that have been properly decontaminated, wrapped, sterilized, stored, and handled will remain sterile indefinitely, unless the integrity of the package is compromised. The integrity of the package is based on the type of wrapper used; the method of sealing the package; the type of shelving used, including open or closed; the method and frequency of handling; the method, frequency, and conditions of transportation and distribution; the environmental conditions of the storage area, e.g., temperature, humidity, ventilation, cleanliness; and control and monitoring of access to storage areas. For more information, see CSA Standards Z314.0.



Appropriateness



12.5

SOPs are followed for handling, distributing, and transporting sterile medical devices and equipment.

Guidelines

This includes maintaining sterility during distribution and transportation between locations. Contaminated medical devices and equipment are not transported through clean areas, and sterile and soiled medical devices and equipment are not transported together. For more information, see CSA Standards Z314.0 and Z314.15.



Appropriateness

12.6

Sterile medical devices are distributed and transported using clean, enclosed, or covered carts and bins, or plastic bags.

Guidelines

Carts are kept clean. Reusable covers for protection of devices, carts, or containers during transport are cleaned regularly in accordance with an established schedule. For more information, see CSA Standards Z314.0 and Z314.15.

MONITORING QUALITY AND ACHIEVING POSITIVE OUTCOMES

13.0 **Up-to-date and accessible documentation and records are maintained for sterilization services.**



Appropriateness



13.1 A complete record is maintained of each sterilization cycle, including the load control label and load process record.

Guidelines

For more information, see CSA Standards Z314.23 and Z314.3.



Appropriateness



13.2 The record includes details of the sterilization cycle, including type of cycle; date and time; exposure time; temperature; pressure; sterility test results; and the kind, quantity, and origin of the devices sterilized.



Appropriateness



13.3 Sterilization records are retained and stored according to the organization's policies, and any applicable laws and regulations.

Guidelines

The organization's policies for retaining and storing records are developed in consultation with legal advisors and individuals responsible for risk management.

14.0 **Sterilized loads are tracked to facilitate recalls.**



Safety



14.1 There is a system that allows for the recall of medical devices associated with a sterilization cycle.

Guidelines

The record includes information that may be required for a recall action. For more information, see CSA Standards Z314.23 and Z314.3.



Appropriateness

- 14.2 SOPs are applied for inventory control of sterilized devices.

Guidelines

This includes documentation of the sterilization load indicator for tracking purposes; documentation of the sterilization date for rotation purposes, e.g., first-in/first-out; adequate spacing of packages; and easy visibility and retrieval of packages.



Safety



- 14.3 All sterilized items in storage, or transported to patient service areas or other organizations, can be tracked.

Guidelines

Tracking ensures that the necessary items can be identified in the case of a recall. For more information, see CSA Standards Z314.0.



Safety



- 14.4 SOPs are used by staff to identify when there may be a problem with sterilization and when a recall is needed.

Guidelines

For more information, see CSA Standards Z314.0.



Safety



- 14.5 SOPs are applied to recall sterilized items that may have been compromised.

Guidelines

The SOP for recall is in writing and identifies the circumstances for issuing the recall order, the team member authorized to issue a recall order, the SOP to be followed when recall is necessary, and the team member responsible for reporting on the execution of a recall order.



Appropriateness



14.6

A complete and written report is issued of all recalls.

Guidelines

A complete recall report identifies the circumstances that prompted the recall order; specifies the corrective action taken to prevent recurrence; and states the percentage of devices actually located in the recall, i.e., in terms of the total number of items intended to be recalled.



Safety



14.7

For each recall, a complete and written notification is issued to all affected areas of the organization that use reprocessed medical devices and equipment identifying the items to be recalled and the actions needed to recall the items.

Guidelines

As appropriate, notice of a recall should be circulated to departments/individuals such as operating room, user department, purchasing, biomedical, infection prevention and control, risk management, medical devices reprocessing, and health care professionals using the product. For more information, see CSA Standards Z314.0 and Z314.23.



Appropriateness

14.8

A policy is followed to retain recall orders and reports.



15.0 Indicator data is collected and used to guide quality improvement activities.

15.1 There is a quality improvement program for reprocessing services that integrates the principles of quality control, risk management, and ongoing improvements.

Guidelines

The quality improvement program addresses quality control for reprocessing activities, education and training, and requirements for written policies. For more information, see CSA Standards Z314.0.



15.2 Information and feedback is collected about the quality of services to guide quality improvement initiatives with input from stakeholders and team members.

Guidelines

Information and feedback is collected in a consistent manner from key stakeholders about the quality of services. Feedback can take the form of stakeholder satisfaction or experience data, complaints, indicators, outcomes, scorecards, incident analysis information, and financial reports. It may be gathered by a variety of methods, including surveys, focus groups, interviews, meetings, or records of complaints. For more information, see CSA Standards Z314.0.



15.3 The information and feedback gathered is used to identify opportunities for quality improvement initiatives and set priorities with input from stakeholders.

Guidelines

Feedback and other forms of information, observation, and experience are used to identify and prioritize areas for quality improvement initiatives. This is done using a standardized process based on criteria such as expressed needs of stakeholders, risk, volume, or cost. For more information, see CSA Standards Z314.0.



Appropriateness



15.4

Measurable objectives with specific timeframes for completion are identified for quality improvement initiatives with input from stakeholders.

Guidelines

Quality improvement objectives define what the team is trying to achieve and by when. Appropriate quality improvement objectives are typically short term, have targets that exceed current performance, and are usually aligned with longer-term strategic priorities or patient safety areas. The timeframe will vary based on the nature of the objective. The SMART acronym is a useful tool for setting meaningful objectives. The objectives 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. For more information, see CSA Standards Z314.0.



Appropriateness

15.5

Indicator(s) that monitor progress for each quality improvement objective are identified, with input from stakeholders.

Guidelines

Indicators are used to monitor whether the activities resulted in change and if the change is an improvement. Primarily, indicators are selected based on their relevance and whether they can accurately monitor progress. When there are multiple potential indicators, criteria such as scientific validity and feasibility are used to select them.

If there are difficulties selecting indicators, it may mean the quality improvement objective needs clarification. For more information, see CSA Standards Z314.0.



Appropriateness



15.6

Quality improvement activities are designed and tested to meet objectives.

Guidelines

Quality improvement activities are the actions that are undertaken 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. For more information, see CSA Standards Z314.0.



Appropriateness

15.7

New or existing indicator data are used 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 re-evaluate its quality improvement objectives to ensure they remain feasible and relevant. For more information, see CSA Standards Z314.0.



Appropriateness

15.8

There is a process to regularly collect indicator data and track progress.

Guidelines

How indicator data will be collected and how often is determined. Regularly collecting data allows the team to track its progress and understand the normal variation of values. For more information, see CSA Standards Z314.0.



Appropriateness



15.9

Indicator data is regularly analyzed to determine the effectiveness of the 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 helps identify trends and may reveal areas that could be considered for future quality improvement initiatives. Indicator data 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, and generate reports.

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

For more information, see CSA Standards Z314.0.



Appropriateness



15.10

Quality improvement activities that were shown to be effective in the testing phase are implemented broadly throughout the organization.

Guidelines

The way in which activities are implemented broadly will vary based on the scope and scale of the team's services and the timeframe (e.g., an effective activity is implemented in more than one area of care and for a longer period of time). For more information, see CSA Standards Z314.0.



Population
Focus

- 15.11 Information about quality improvement activities, results, and learnings is shared with stakeholders, teams, organization leaders, and other organizations, as appropriate.

Guidelines

Information is tailored to the audience and considers the messaging and language that is appropriate for each audience.

Sharing the results of evaluations and improvements helps familiarize stakeholders with the philosophy and benefits of quality improvement and engage them in the process. It is also a way for organization to spread successful quality improvement activities and demonstrate its commitment to ongoing quality improvement.

Among other benefits, sharing indicator data externally allows for comparisons with organizations offering similar services.

For more information, see CSA Standards Z314.0.



Appropriateness

- 15.12 Quality improvement initiatives are regularly evaluated for feasibility, relevance, and usefulness, with input from stakeholders.

Guidelines

The evaluation of quality improvement initiatives includes activities, objectives, and indicators. Results are used to plan future quality improvement initiatives including how and when to sustain or spread existing initiatives.

Outcomes of the quality improvement initiatives are considered with respect to how 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 the timeframes and whether the timeframes are still 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.

For more information, see CSA Standards Z314.0.

Resources

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Service-Specific Resources

Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities
<http://www.health.gov.bc.ca/library/publications/year/2011/Best-practice-guidelines-cleaning.pdf>

Centre d'expertise en retraitement des dispositifs médicaux de l'Institut national de santé publique du Québec, Processus d'audit en lien avec le retraitement des dispositifs médicaux critiques
<http://www.inspq.qc.ca>

CSA Standards Z314.0-13 Medical device reprocessing - General requirements
<http://shop.csa.ca/>

CSA Standards Z314.3-14 Effective sterilization in health care settings by steam process.
<http://shop.csa.ca>

CSA Standards Z314.8-14 Decontamination of reusable medical devices

<http://shop.csa.ca/>

CSA Standards Z314.10.1-15 Selection and use of gowns and drapes intended for use in health care settings.

<http://shop.csa.ca/>

CSA Standards Z314.10.2-15 Laundering, maintenance, and preparation of reusable gowns, drapes, and wrappers in health care settings and laundries.

<http://shop.csa.ca/>

CSA Standards Z314.14-10 Selection and use of rigid sterilization containers

<http://shop.csa.ca/>

CSA Standards Z314.15-15 Storage, transportation, and distribution of single-use and reusable medical devices.

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CSA Standards Z314.23-12 Chemical sterilization of reusable medical devices in health care facilities

<http://shop.csa.ca/>

CSA Standards Z317.2-10 Special requirements for heating, ventilation, and air-conditioning (HVAC) systems in health care facilities

<http://shop.csa.ca/>

CSA Standards Z317.5-98 Illumination Systems in Health Care Facilities

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Provincial Infectious Diseases Advisory Committee.(2013) Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings
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<http://www.phac-aspc.gc.ca>

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<http://www.phac-aspc.gc.ca>

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Standards for Clearing, Disinfection and Sterilization of Reusable Medical Devices for Health Care Facilities and Settings - Alberta Government
<http://www.health.alberta.ca/documents/IPC-Medical-Device-Cleaning-2012.pdf>

Accreditation Canada would appreciate your feedback on these standards

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(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](#)

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