Alberta Health

# Standards for Cleaning, Disinfection and Sterilization of Reusable Medical Devices for Health Care Facilities and Settings



June 2012

Alberta Government

# Reader Information

The *Standards for Cleaning, Disinfection and Sterilization of Reusable Medical Devices for Health Care Facilities and Settings* have been developed with input from experts including an infectious disease physician, infection prevention and control professionals, medical device reprocessing technicians, an occupational health professional and public health professionals. Alberta Health acknowledges the Ontario Provincial Infectious Diseases Advisory Committee for permission to use its best practices document, approved by the Ontario Ministry of Health and Long-Term Care, to inform the development of these Standards. Information from various sources has been considered including the Canadian Standards Association, Accreditation Canada and Health Canada.

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## Definitions

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| **Automated Endoscope Reprocessor (AER)** | Machine designed to assist with the Cleaning and Disinfection of endoscopes.[1] |
| **Biological Indicator (BI)** | A test system containing viable bacterial spores providing a defined resistance to a specified Sterilization process.[2] |
| **Canadian Standards Association (CSA)** | A not-for-profit, non-statutory, voluntary membership association engaged in standards development and certification activities. CSA Standards reflect a national consensus of producers and users including Manufacturers, consumers, retailers, unions, professional organizations and government agencies.[3] |
| **Chemical Indicator (CI)** | A system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to the process.[2] |
| **Cleaning** | Removal of contamination from an item to the extent necessary for its further Reprocessing and its intended subsequent use.[2] |
| **Client** | A person, including a patient or a resident, receiving health care services.[4] |
| **Competent** | In relation to a person, means adequately qualified, suitably trained and with sufficient experience to safely perform work without supervision or with only a minimal degree of supervision.[5] |
| **Critical Medical Device** | A Medical Device that enters sterile tissues, including the vascular system.[6] |
| **Decontamination/ Decontaminate/Decontaminated** | The process of Cleaning, followed by the inactivation of pathogenic microorganisms, in order to render an object safe for handling.[6] |
| **Disinfectant** | A chemical agent that kills most disease-producing microorganisms, but not necessarily resistant bacterial spores.[6] |
| **Disinfection/Disinfect/** | Reduction of the number of viable microorganisms on |

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| **Disinfected** | a product to a level previously specified as appropriate for its intended further handling or use.[7] |
| **Drug Identification Number (DIN)** | An identifying number provided by Health Canada for a drug product prior to marketing and which is required by Canada's *Food and Drug Act* and Food and Drug Regulations and which illustrates that the drug product is effective and safe for its intended use.[8] |
| **Flexible Endoscope** | Fiberoptic or video visualization Medical Device used in the examination of hollow viscera.[9] |
| **Endoscope Accessory Instruments** | Medical Devices designed for insertion into a Flexible Endoscope and are used during endoscopy.[9] |
| **End User** | Health care providers, including physicians, nurses, and specialty professionals, who utilize Reprocessed Medical Devices to provide health care services to Clients. |
| **Flash Sterilization** | A special steam Sterilization process designed and used for the emergency Sterilization of Medical Devices when routine Sterilization can not be done. [10] |
| **Foot Care** | Health care services performed on a Client's feet, which may include clipping, cutting, filing of nails and callous removal.[11] |
| **Hand Hygiene** | Refers to the process of removing or reducing the number of microorganisms on hand surfaces with soap and water or through the use of alcohol based hand rubs with an alcohol concentration of 60 to 90%.[4] |
| **Health Care Facility or Setting** | A facility or setting in which a Client receives health care services including, but not limited to, the following:<br>• hospitals;<br>• surgical facilities;<br>• ambulatory care clinics;<br>• pre-hospital settings;<br>• public health clinics;<br>• nursing homes;<br>• designated assisted living facilities; |

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| | • extended and long term care facilities;<br>• hospice; and<br>• in the case of health care services provided through home care, private dwellings. |
| **High Efficiency Particulate Air (HEPA) Filter** | An air filter with an efficiency of 99.97% in the removal of airborne particles 0.3µm or larger in diameter.[3] |
| **High Level Disinfection** | 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.[6] |
| **Implantable Medical Device** | A Medical Device that is placed into the human body to remain there for a period of 30 days or more.[12] |
| **Infection Prevention and Control (IPC)** | A discipline that applies epidemiologic principles and evidence-based strategies to prevent infections and improve quality and safety for both Clients and Personnel across the spectrum of care. |
| **IPC Executive** | The individual appointed as the IPC Executive in accordance with the *Standards for IPC – Accountability and Reporting* and includes an individual designated in writing by the IPC Executive to carry out some or all of the duties and responsibilities of the IPC Executive under the *Standards for IPC – Accountability and Reporting.* |
| **Infection Prevention and Control Professional (ICP)** | Personnel specially trained and responsible for surveillance of infections, education and consultation of other Personnel, Clients and the general public, to manage IPC issues.[13] |
| **Loaned Equipment** | Medical Devices used in more than one Health Care Facility or Setting, including borrowed, shared or consigned Medical Devices which are used on Clients.[1] |
| **Low Level Disinfection** | A process capable of killing most vegetative bacteria, some viruses and some fungi.[6] |
| **Manufacturer** | A person, (including a partnership, firm or association) who sells a Medical Device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person and with respect to the Medical Device, is responsible for the |

following:

- designing;
- manufacturing;
- assembling;
- processing
- labeling;
- Packaging;
- refurbishing;
- modifying; or
- assigning the Medical Device an intended purpose,

whether those tasks are performed by that person or on their behalf.[14]

**Manufacturer's Instructions**

The Validated, written directions provided by the Manufacturer or distributor of a Medical Device or product that contain the necessary information for the safe and effective use of the Medical Device or product.[6]

**Material Safety Data Sheet (MSDS)**

Descriptive document with information about a controlled product, material or substance that provides instructions for safe use and potential hazards. The MSDS includes information about physical data, toxicity, health effects, reactivity, storage, disposal, PPE needed and first aid required in the event of exposure.

**Mechanical Monitoring**

Measurement of physical parameters such as time, temperature and pressure.[1]

**Medical Device**

Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the Manufacturer to be used for a human being for any of the following purposes:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;

- diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury or handicap;

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| | • investigation, replacement or modification of the anatomy, or of a physiologic process; or control of conception,<br><br>and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that can be assisted in its function by such means.[14] |
| **Medical Device Reprocessing (MDR) Area** | An area or facility that is dedicated to Reprocessing Medical Devices. |
| **Negative Pressure** | Air pressure differential between two adjacent airspaces such that air flow is directed into the room relative to the corridor and room air is prevented from flowing out of the room and into adjacent areas.[15] |
| **Non-Critical Medical Device** | A Medical Device which either touches only intact skin but not mucous membranes or does not directly touch the Client. |
| **Occupational Health and Safety (OHS)** | A cross-disciplinary field that is concerned with protecting the health and safety of people at work, preventing worker injury and illness, and considers both the worker and the work environment. |
| **One-Way Workflow** | The practice of ensuring that Reprocessing work flows in one direction from the dirtiest to the cleanest.[6] |
| **Organization** | An owner, operator or other person responsible for the management of a Health Care Facility or Setting, including the owner, operator or other person responsible for the management of health care services to a Client in the Client's own home, but excluding the owner of a private dwelling in the case of health care services provided through home care. |
| **Packaging** | A step in the Sterilization process in which a Medical Device is enclosed in material or a container designed to allow the penetration and removal of the sterilant during Sterilization and protect the Medical Device from contamination and other damage following Sterilization and during storage.[2] |
| **Personal Protective Equipment (PPE)** | Equipment or clothing worn by a person for protection from health or safety hazards associated with conditions at a work site.[5] |



 

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| **Personnel** | Persons (e.g., employees, students, contractors, attending clinicians, public-safety workers, or volunteers) whose activities involve direct contact with Clients or with blood or other body fluids from Clients.[16] |
| **Point of Use** | A specific point in time and place at which a Medical Device is used on a Client. |
| **Policy** | The general written principles that set the direction for these Standards and by which the Organizations responsible for IPC are guided in the delivery and management of IPC programs. |
| **Positive Pressure** | Air pressure differential between two adjacent air spaces such that air flow is directed from the room relative to the corridor ventilation that air from corridors and adjacent areas is prevented from entering the room.[15] |
| **Procedure** | A specific mode or method of performing a task in a sequential manner and used for implementing Policies.[17] |
| **Reprocessing/Reprocess/ Reprocessed** | The steps performed to prepare a used Medical Device for reuse.[6] |
| **Reusable** | Any product or Medical Device intended by the Manufacturer for multiple uses.[17] |
| **Routine and Preventive Maintenance** | Regularly scheduled upkeep of equipment to ensure safe functioning and to identify and prevent potential problems.[18] |
| **Semi-Critical Medical Device** | A Medical Device that comes into contact with mucous membranes or non-intact skin, but ordinarily does not penetrate them.[6] |
| **Sharps** | Objects capable of causing punctures or cuts.[1] |
| **Sterilization/Sterilize/Sterilized** | The Validated process used to render a product free from viable microorganisms.[6] |
| **Thermal Disinfection** | A process of hot water Disinfection which is accomplished through the use of automated pasteurizers or washer disinfectors with a Validated Thermal Disinfection cycle. The exposure time and |

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| | temperature will vary with the level of Thermal Disinfection required.[19] |
| **Validation/Validated** | A documented Procedure for obtaining, recording, and interpreting the results required to establish that a process for Cleaning, Disinfection or Sterilization of a Medical Device will consistently yield safe products complying with the CSA Standard Z17664. |
| **Workplace Hazardous Materials Information System (WHMIS)** | A Canadian system designed to protect workers by providing them and their employers with vital information about hazardous materials. |





 

# Introduction

The goals of these Standards are to:

- minimize the risk of exposure or injury and prevent transmission of microorganisms to Clients, Personnel, the public and the environment;
- contain contaminated materials to protect Clients, Personnel, the public and the environment;
- minimize damage to Medical Devices from foreign material or inappropriate handling; and
- minimize the time from the Point of Use to Reprocessing of the Medical Device.

These Standards set minimum requirements for Cleaning, Disinfection and Sterilization of Reusable Medical Devices for Health Care Facilities or Settings. Higher standards may be required based on specific circumstances (adherence to higher standards is permitted). Standards and guidelines established by Health Canada and the CSA may also be applicable.

These Standards are based on current information and will evolve as evidence and technology change. It is the responsibility of the Organizations to ensure current IPC practices are in place.



 

# 1. Spaulding Classification of Medical Devices

1.1. The Spaulding Classification system divides Medical Devices into the following three categories based on the potential risk of infection involved in their use: Critical Medical Devices, Semi-Critical Medical Devices, and Non-Critical Medical Devices.

1.2. The Spaulding Classification system also establishes the following three levels of germicidal activity: Sterilization, High Level Disinfection, and Low Level Disinfection.

1.3. If there is a discrepancy between the Reprocessing level recommended by the Manufacturer and the intended use of the Medical Device pursuant to the Spaulding Classification, the higher level of Reprocessing must be used.[8, 1]

| **Classification** | **Level of Reprocessing** | **Examples of Medical Devices (non-exhaustive)** |
|---|---|---|
| Critical | Cleaning followed by Sterilization | • surgical instruments<br>• biopsy forceps arthroscopes<br>• laparoscopes<br>• cystoscopes<br>• dental hand pieces<br>• Foot Care instruments |
| Semi-Critical | As a minimum, Cleaning followed by High Level Disinfection<br><br>Sterilization is required for heat tolerant Semi-Critical Medical Devices | • Flexible Endoscopes used on mucous membranes<br>• laryngoscopes<br>• respiratory and anaesthesia therapy equipment<br>• tonometers<br>• ear syringe nozzles<br>• vaginal specula<br>• diagnostic imaging probes (for example, vaginal probes, transesophageal echocardiogram probes)<br>• pessary and diaphragm fitting rings |
| Non-Critical | Low Level Disinfection | • stethoscopes<br>• blood pressure cuffs<br>• Client lifting/transfer devices |

# 2. Environmental and Structural Requirements

2.1. The MDR Area shall be physically separate from Client care areas.

2.2. There shall be a centralized MDR Area for collecting and Reprocessing Reusable Medical Devices.

2.3. Reprocessing Medical Devices outside of a centralized MDR Area shall be approved by the person designated by the IPC Executive as responsible for safe Reprocessing practices.

2.4. All MDR Areas shall:

2.4.1. have space for the Cleaning process and storage of necessary equipment and supplies;

2.4.2. have physically separate Decontamination areas from areas where clean, Disinfected or sterile Medical Devices are handled or stored;

2.4.3. have easy access to Hand Hygiene facilities;

2.4.4. have surfaces that can be easily cleaned;

2.4.5. have restricted access during Reprocessing from other areas in the Health Care Facility or Setting;

2.4.6. be designed to permit One-Way Workflow;

2.4.7. have air changes, temperature and humidity appropriate to the process and product being used as set out by the Manufacturer's Instructions and CSA Standards;

2.4.8. have lighting that facilitates Reprocessing;

2.4.9. have Negative Pressure air flow in Decontamination areas and Positive Pressure air flow in clean areas;[20] and

2.4.10. use a water supply which is tested for and free of contaminants.[21]

2.5. The Organization shall have written Reprocessing contingency plans for loss of potable water, boil water advisories and other situations where the water supply becomes compromised.



 

# 3. Assessing, Selecting and Purchasing Medical Devices and Products for Reprocessing

3.1. The Manufacturer's Instructions for Reprocessing a Medical Device shall be acquired prior to purchase and use of the Medical Device in accordance with CSA Standard Z17664.

3.2. All Medical Devices shall meet established quality Reprocessing parameters[1] and the Manufacturer must supply:

3.2.1. information about the design of the Medical Device;

3.2.2. manuals/directions for use;

3.2.3. Personnel training materials on the use and Reprocessing of the Medical Device; and

3.2.4. inspection, maintenance and testing methods required for any stage of Reprocessing.

3.3. All Reusable Medical Devices purchased shall have specific Manufacturer's Instructions for Reprocessing.

3.3.1. The processes and products used for Reprocessing shall be determined by the intended use of the Medical Device in accordance with the Spaulding Classification.

3.3.2. The processes and products used for Reprocessing shall be compatible with each other and the Medical Device.

3.3.3. If disassembly or reassembly is required, the Organization shall ensure that the Manufacturer's Instructions are detailed and include diagrams.

3.3.4. Personnel training shall be provided on disassembly, reassembly and Reprocessing before the Medical Device is placed into circulation.

3.4. All products and equipment used in Reprocessing shall be approved by Personnel who have successfully completed a recognized Reprocessing certification program, a workplace health and safety personnel and an ICP.

3.5. Purchasing decisions for reusable surgical textiles (i.e. gowns, drapes and wrappers) shall involve representatives from the departments in the Organization that will use, Reprocess or be affected by these products.[22]



 

3.6. All Medical Devices and products used in Reprocessing shall meet OHS requirements as set out in Alberta's *Occupational Health and Safety Act*, the OHS Regulation and the OHS Code.

3.7. ICPs, Reprocessing Personnel, biomedical engineers and workplace health and safety personnel shall be included to assist End Users and purchasing personnel with the review, evaluation and recommendations regarding the suitability of the Medical Device for purchase. The criteria that shall be met includes:

3.7.1. ability to safely undergo Reprocessing;

3.7.2. presence of appropriate equipment and space for Reprocessing;

3.7.3. the Manufacturer's Instructions; and

3.7.4. the Health Canada Medical Devices Regulations and licensing requirements and CSA Standards.

3.8. ICPs, Reprocessing Personnel, biomedical engineers, workplace health and safety personnel, and facilities maintenance personnel shall also be included to assist End Users and purchasing personnel with the review, evaluation and recommendations regarding the suitability of sterilizers, AERs, and Thermal Disinfection equipment prior to purchase.

3.9. Newly purchased, repaired or refurbished non-sterile Critical Medical Devices and Semi-Critical Medical Devices shall be inspected and processed according to the Manufacturer's Instructions prior to use.

3.10. Medical Devices that come into contact with neurological and eye tissue from Clients at high risk or known to have Creutzfeldt - Jakob disease shall be handled in accordance with the Health Canada/Public Health Agency of Canada infection control guideline, *Classic Creutzfeldt - Jakob Disease in Canada*[23] and Quick reference guide.[24]



 

# 4. Transportation and Handling of Contaminated Medical Devices

4.1. Disposable Sharps shall be removed and disposed of in an appropriate puncture-resistant Sharps container at Point of Use.

4.2. If Reprocessing is delayed following use, the Medical Devices shall be kept moist using a towel moistened with water (not saline) or a product intended for this purpose (e.g. foam, spray or gel product).

4.3. Contaminated Medical Devices shall be handled in a manner which reduces the risk of exposure or injury to self, other Personnel and Clients, and contamination of environmental surfaces.

4.3.1. Contaminated Medical Devices shall be secured in a closed, leak-proof container at Point of Use and be taken directly to the area designated for handling such Contaminated Medical Devices.

4.4. A Procedure shall be in place to identify Contaminated Medical Devices which have not undergone Reprocessing.

# 5. Disassembling and Cleaning Reusable Medical Devices

5.1. Reusable Medical Devices shall undergo Cleaning in accordance with the Manufacturer's Instructions before undergoing Disinfection or Sterilization.

5.2. Cleaning shall include sorting, disassembly (if required), soaking, physical removal of organic material, rinsing, drying, physical inspection and wrapping (if required).

5.2.1. Immediately after use, the Medical Device shall be cleaned of gross soil, if present, prior to containment and transport.[6]

5.2.2. Following Cleaning, Medical Devices shall be thoroughly rinsed to remove residual detergent and soil.

5.2.3. Following rinsing, Medical Devices shall be dried in accordance with Manufacturer's Instructions.

5.3. In contrast to Critical Medical Devices and Semi-Critical Medical Devices, most Reusable, Non-Critical Medical Devices may be Decontaminated where they are used and do not need to be transported to a centralized MDR Area.

5.4. Low Level Disinfectants may be used for Cleaning and Disinfecting Non-Critical Medical Devices.

5.5. Cleaning accessories shall:

5.5.1. be intended for use on Medical Devices;

5.5.2. be used in accordance with the Manufacturer's Instructions;

5.5.3. where Reusable, be inspected for damage and Reprocessed in accordance with the Manufacturer's Instructions;

5.5.4. stored in a clean, dry location; and

5.5.5. where single-use, be discarded following use.

5.6. Medical Devices which are difficult to clean (for example, reamers and laparoscopic instrumentation) shall be identified and documented Procedures put in place to ensure they undergo Cleaning in accordance with the Manufacturer's Instructions.[6]



 

5.7. With respect to manual Cleaning:

5.7.1. the Manufacturer's Instructions for the Medical Device shall be followed, including specifications for detergent type, water temperature, and Cleaning methods;[6]

5.7.2. safe protocols must be used, including the use of PPE, as manual Cleaning involves a higher risk of Personnel injury;

5.7.3. manual Cleaning processes should prevent environmental contamination;[6]

5.7.4. unless otherwise recommended by the Manufacturer's Instructions, Medical Devices with lumens shall be cleaned with a brush and flushed;[6] and

5.7.5. unless otherwise recommended by the Manufacturer's Instructions, a Medical Device shall be pre-cleaned before being placed into ultrasonic Cleaning equipment.

5.8. With respect to mechanical (automated) Cleaning:

5.8.1. Reusable Medical Devices should be mechanically cleaned whenever possible, and in accordance with the Manufacturer's Instructions;[6]

5.8.2. all mechanical Cleaning equipment shall be installed, maintained, loaded, and used in accordance with the Manufacturer's Instructions;

5.8.3. loading procedures shall be consistent with the Manufacturer's Instructions;

5.8.4. all Mechanical Cleaning equipment shall be monitored according to the Manufacturer's Instructions; and

5.8.5. the Manufacturer's Instructions shall be followed to ensure Medical Devices are compatible with the mechanical washer's process conditions (for example, moisture, temperatures, chemicals, water quality, and pressure).[6]





 

# 6. Disinfection of Reusable Medical Devices

6.1. Low Level Disinfection of Non-Critical Medical Devices shall occur between Clients and after the Client has been discharged.

6.2. As a minimum, heat sensitive Semi-Critical Medical Devices shall be Disinfected using High Level Disinfection in accordance with the Manufacturer's Instructions.

6.3. Client-specific:

6.3.1. Non-Critical Medical Devices;

6.3.2. Semi-Critical Medical Devices; and

6.3.3. Medical Devices used for Foot Care,

reused only by that Client in their own private dwelling must undergo Cleaning in accordance with the Manufacturer's Instructions.

6.4. All Disinfectants used for the Disinfection of Medical Devices shall have a DIN from Health Canada[8] and a MSDS.

6.5. High Level Disinfectants shall be monitored according to the Manufacturer's Instructions and the results shall be recorded. If a Reusable chemical product is used, the concentration of the active ingredient(s) shall be verified at least daily and a log of concentration test results shall be maintained.

6.6. With respect to the Reprocessing of respiratory/anesthesia Medical Devices:

6.6.1. Medical Devices intended to undergo Disinfection shall undergo Cleaning prior to terminal Thermal Disinfection;

6.6.2. the Manufacturer's Instructions for installation, operation and maintenance of Thermal Disinfection equipment shall be followed;

6.6.3. a Routine and Preventive Maintenance program for terminal Thermal Disinfection equipment shall be implemented and documented, including maintaining records of any maintenance or repairs;

6.6.4. Medical Devices which have undergone terminal Thermal Disinfection shall be handled and transported in a manner that prevents re-contamination;



 

6.6.5. following the terminal Thermal Disinfection cycle, Medical Devices shall be thoroughly dried in a drying cabinet that is equipped with a HEPA filter and that is used exclusively for the drying of Medical Devices which have undergone terminal Thermal Disinfection; and

6.6.6. a log of contents, temperature and time for each load shall be maintained for pasteurizing equipment.

# 7. Sterilization of Reusable Medical Devices

7.1. Critical Medical Devices shall undergo Sterilization prior to reuse in accordance with the Manufacturer's Instructions.[8]

7.1.1. Steam Sterilization shall be used for Semi-Critical Medical Devices or Critical Medical Devices that are compatible with heat and moisture.

7.1.2. All Medical Devices used for Foot Care shall undergo Sterilization prior to reuse on another Client.

7.1.3. Flash Sterilization shall only be used in emergency situations and shall never be used for Implantable Medical Devices.

7.2. The Manufacturer's Instructions for installation, loading, operation, Routine and Preventive Maintenance and quality assurance monitoring of Sterilization equipment shall be followed.

7.3. For all sterilizers, the following monitoring shall be completed and documented[1] to ensure that Sterilization has been achieved:

7.3.1. all monitoring as required by the Manufacturer's Instructions;

7.3.2. monitoring of the operation of the sterilizer for each cycle, including documentation of any malfunction or actions taken to ensure that the Medical Device is either released if all parameters have been met or is returned for Reprocessing if all parameters are not met.

7.3.3. Mechanical Monitoring of Sterilization parameters;

7.3.4. chemical monitoring whereby each package or set must have internal and external CIs; and

7.3.5. biological monitoring whereby a BI shall be:

- included each day a sterilizer is used and for each cycle that the sterilizer will perform; and
- used with each load containing Implantable Medical Devices. The load shall be quarantined until the result of the BI is known to be negative.

7.4. Following each Sterilization cycle, the load shall be protected, managed, transferred and stored in a manner that does not compromise sterility.

7.5. Sterilizers shall be subjected to testing and monitoring on installation and following disruptions to their normal activity in accordance with:



 

7.5.1. CSA Standard Z314.2 where an ethylene oxide sterilizer is used;

7.5.2. CSA Standard Z314.3 where a steam sterilizer is used; or

7.5.3. the Manufacturer's Instructions for all other sterilizers.

7.6. The following processes or equipment shall not be used for Sterilization:

7.6.1. boiling;

7.6.2. ultraviolet light;

7.6.3. glass bead Sterilization;

7.6.4. microwave ovens;[1]

7.6.5. conventional ovens; or

7.6.6. dishwashers.

# 8. Reprocessing of Flexible Endoscopes

8.1. With respect to the Reprocessing of Flexible Endoscopes:

8.1.1. the Organization shall ensure that all Personnel responsible for Reprocessing Flexible Endoscopes are Competent in Flexible Endoscope Reprocessing.

8.1.2. Reprocessing of Flexible Endoscopes shall be in accordance with the Manufacturer's Instructions;

8.1.3. Cleaning of Flexible Endoscopes shall commence immediately at the Point of Use following completion of the clinical procedure;

8.1.4. manual Cleaning shall precede High Level Disinfection or Sterilization of the Flexible Endoscope;

8.1.5. following Cleaning and Disinfection and before storage, the lumens of the Flexible Endoscope shall be flushed with medical or filtered air, followed by 70% isopropyl alcohol, and followed by a second purging of the channels with filtered air to facilitate drying;

8.1.6. critical Reusable Endoscope Accessory Instruments shall undergo Cleaning and Sterilization after each use; and

8.1.7. unless a clinical procedure requires the use of a sterile water bottle, a water bottle and its connecting tube used for Cleaning an endoscope lens and irrigation, if designated Reusable in the Manufacturer's Instructions, shall undergo daily Sterilization when used. If such Sterilization is not reasonably possible, High Level Disinfection is acceptable.

8.2. With respect to the storage of endoscopes:

8.2.1. channeled semi-critical endoscopes shall be stored without valves and caps attached, hanging vertically in an enclosed, secure and well-ventilated endoscope storage cabinet;

8.2.2. Cleaning and Disinfection of endoscope storage cabinets shall occur weekly and shall be documented in a log book; and

8.2.3. if endoscopes reach their maximum allowable storage time of seven days, the endoscopes shall be completely Reprocessed before Client use.



 

8.3. With respect to automated equipment used in reprocessing endoscopes generally:

8.3.1. AERs shall be compatible with endoscope and endoscope components;

8.3.2. a Routine and Preventive Maintenance program as required by the Manufacturer's Instructions for AERs shall be implemented and documented; and

8.3.3. automated lumen cleaners shall be used and maintained in accordance with the Manufacturer's Instructions.

8.4. The Organization shall:[6]

8.4.1. have a Procedure in place to clearly distinguish a Reprocessed endoscope from a contaminated endoscope;

8.4.2. maintain a permanent record of endoscope use and Reprocessing; and

8.4.3. maintain a system to track endoscopes and Clients that includes recording in the Client record the serial number of the endoscope used.

# 9. Storage and Use of Reprocessed Medical Devices

9.1. Critical Medical Devices shall be maintained as sterile until Point of Use.

9.2. Reprocessed Medical Devices shall be handled, transported and stored in a manner that maintains cleanliness and dryness and that prevents contamination or damage.

9.3. At Point of Use and upon opening the Packaging of a Reprocessed Medical Device, the End User shall:

9.3.1. inspect the Packaging for integrity, including reviewing the results of the internal and external CIs; and

9.3.2. inspect the Reprocessed Medical Device to ensure no obvious contamination or damage exists.

## 10. Education and Training

10.1. Personnel employed to work in MDR Areas, endoscopy departments or any department performing Sterilization of Reusable Medical Devices shall be certified in one of the following recognized certification programs:

10.1.1. CSA Certification for Certified Medical Device Reprocessing Technicians; or

10.1.2. International Association of Healthcare Central Service Material Management Certification for Certified Registered Central Service Technicians.

10.2. If Personnel have not yet been certified in accordance with Section 10.1, the Organization shall have in place a written plan for each such Personnel to become certified by April 1, 2015.

10.3. If an Organization does not employ any Personnel who are certified in accordance with Section 10.1, that Organization may enter into a written arrangement for Reprocessing with another Organization employing Personnel certified in accordance with Section 10.1.

10.4 Where there are any Personnel performing Reprocessing tasks who are not employed to work in MDR Areas, endoscopy departments or any department performing Sterilization of Reusable Medical Devices pursuant to Section 10.1, the Organization shall ensure that such Personnel are Competent and Reprocessing is supervised.



## 11. Occupational Health and Safety Requirements

11.1. The Organization shall comply with Alberta's *Occupational Health and Safety Act*, the OHS Regulation, and the OHS Code.

11.2. The Organization shall ensure that a written hazard assessment is completed, Personnel are informed of the hazard and appropriate controls are implemented based on the hazard assessment, including ensuring that:

11.2.1. Sharps systems are adequate to protect Personnel from injury;[23]

11.2.2. air handling systems are adequate to protect Personnel from toxic vapours, including those generated by, or emitted from, Cleaning or Disinfection agents;

11.2.3. chemicals are stored in accordance with the Manufacturer's Instructions and MSDS requirements;

11.2.4. MSDS documentation is available as required by the WHMIS;

11.2.5. Personnel have available, wear and maintain appropriate PPE as per hazard assessment and the MSDS;[25]

11.2.6. Personnel who perform Reprocessing are assessed regarding their immunity to Hepatitis B and offered Hepatitis B immunization, if required;

11.2.7. first aid plans, equipment and services are in place in accordance with Alberta's OHS Code;[26] and

11.2.8. Policies are in place for response to Personnel exposure to any hazard including, but not limited to, the following:

- chemical leaks or spills;
- blood and body fluids (including post-exposure management); or
- heat sources which may cause thermal injury.

11.3. The MDR Area shall be limited to Reprocessing only and all other activities in the MDR Area are prohibited.



 

# 12. Policies and Procedures

12.1. The Organization shall have Personnel with accountability to develop, approve, monitor and maintain Medical Device Reprocessing Policies.

12.2. The Organization shall have Medical Device Reprocessing Policies to ensure that Reprocessing Procedures:

12.2.1. follow Manufacturer's Instructions;

12.2.2. follow IPC principles as set out by Health Canada, CSA Standards and Alberta Health Standards;

12.2.3. follow Alberta's *Occupational Health and Safety Act,* the OHS Regulation, and the OHS Code; and

12.2.4. address the transporting, receiving, handling and processing of trialed or Loaned Equipment.

12.3. The Organization shall periodically review and update all Policies to ensure that they are current.



 

## References

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3. Canadian Standards Association, *CSA Z317.13: Infection Control during Construction or Renovation of Health Care Facilities.*

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5. Government of Alberta, *Occupational and Health and Safety Code* (2009).

6. Canadian Standards Association, *CSA Z314.8: Decontamination of Reusable Medical Devices.*

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20. Canadian Standards Association, *CSA Z317.2: Special Requirements for Heating, Ventilation and Air Conditioning (HVAC) Systems in Health Care Facilities.*

21. Canadian Standards Association, *CSA Z314.8: Decontamination of Reusable Medical Devices, Update No. 2* (January 2010).

22. Canadian Standards Association, *CSA Z314.10: Selection and use of Gowns, Drapes and Wrappers in Health Care Facilities.*

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25. See Government of Alberta, *Occupational and Health and Safety Code,* Part 18 (2009).

26. See Government of Alberta, *Occupational and Health and Safety Code,* Part 11 (2009).