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

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Contents	Page
1. Definitions	1
2. Introduction.....	10
3. Environmental and Structural Requirements	11
4. Purchasing and Assessing Medical Devices and Products for Disinfection or Sterilization Processes	12
5. Selection of Products and Processes for Reprocessing.....	14
6. Disassembling and Cleaning Reusable Medical Devices.....	15
7. Disinfection of Reusable Medical Devices.....	16
8. Reprocessing Endoscopes	17
9. Sterilization of Reusable Medical Devices.....	19
10. Storage and Use of Reprocessed Medical Devices	21
11. Transportation and Handling of Contaminated Medical Devices.....	22
12. Education and Training	23
13. Occupational Health and Safety Requirements.....	24
14. Written Policies and Procedures.....	26
15. References	27

1. Definitions

Accountability	The state of being accountable, liable or answerable. ¹
Assurance	A positive declaration intended to give confidence; promise or pledge; guaranty; surety; full confidence; freedom from doubt; or certainty. ¹
Audit	To make an audit of, examine (accounts, records etc.) for purposes of verification or to make an audit of (a building or other facility) to evaluate or improve its safety, efficiency or the like. ¹
Automated endoscope reprocessor (AER)	Machines designed to assist with the cleaning and disinfection of endoscopes. ²
Biological monitor	A sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to have a high resistance to the mode of sterilization being monitored. ³
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 and professional organizations, and government agencies. ⁴
Centralized reprocessing area	A centralized area within a health care setting for cleaning, disinfection or sterilization of medical devices. In community settings and offices, any segregated area where reprocessing of devices takes place away from clients and clean areas (e.g. Central Processing Department (CPD), Central Processing Service (CPS), Central Surgical Supply (CSS), Surgical Processing Department (SPD)). ²
Certification	Certification provides internationally recognized competency based on measurable standards.
Chemical indicator	A sterilization monitoring assistive device used to monitor certain parameters of a sterilization process by means of a characteristic color change (e.g. chemically treated paper, pellet sealed in a glass tube, pressure-sensitive tape). ³

Cleaning	The removal of soil. Note: soil includes, but is not limited to, the bioburden plus the client-derived cells, secretions or excretions. ³ Bioburden is contamination of the environment, supplies, and/or equipment with microorganisms. ³
Cleaning process	Steps in the cleaning process include: disassembly, sorting and soaking, physical removal of organic material, rinsing, drying, inspection, and wrapping prior to disinfection and sterilization. ²
Client	Any person receiving health care within any health care setting. ² For readability, this document uses the term “client” to represent client/patient/resident.
Contaminated	State of having been actually or potentially in contact with microorganisms. As used in health care, the term generally refers to the presence of microorganisms that could be capable of producing disease or infection. ³
Critical medical device	A medical device that enters sterile tissues, including the vascular system. Critical medical devices present a high risk of infection if the device is contaminated with any microorganisms, including bacterial spores. ³ Examples of critical medical devices include but are not limited to needles, syringes, scalpels and invasive/surgical instruments, all implantable devices, biopsy forceps and all instruments used for foot care.
Decontamination	The process of cleaning, followed by the inactivation of pathogenic microorganisms, in order to render an object safe for handling. ²
Device	See Medical Device
Directions for use	In respect to a medical device, means full information from manufacturer as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contraindications and possible adverse effects. ⁵
Disassembly	To take apart; separate into constituent parts. ⁶

Disinfectant	A chemical agent used on inanimate objects to destroy virtually all recognized pathogenic microorganisms, but not all microbial forms (e.g. bacterial spores). ⁷
Disinfection	A process that destroys some forms of microorganisms excluding bacterial spores; a process that kills most forms of microorganisms on inanimate surfaces. ³
Drug identification number (DIN)	A drug identification number (DIN) provided by Health Canada prior to marketing, is required by the <i>Food and Drugs Act and Regulations</i> . A DIN ensures that labeling and supporting data have been provided and that it has been established by the Therapeutic Products Directorate that the product is effective and safe for its intended use. ⁸
Emergency	An unexpected situation in which there is a pressing threat to a client’s life or health. ³
Endoscope	An instrument that allows the examination and treatment of the interior of the body canals and hollow organs. ³
Endoscope accessories	All devices used in conjunction with an endoscope to perform diagnosis and therapy, excluding peripheral equipment, e.g. biopsy forceps. ⁹
Endoscope – critical	Endoscopes used in the examination of critical spaces, such as joints and sterile cavities. Many of these endoscopes are rigid with no lumen. Examples of critical endoscopes are arthroscopes, laparoscopes and cystoscopes. ²
Endoscope – semi-critical	Endoscopes used in the examination of the hollow viscera. These endoscopes generally invade only semi-critical spaces, although some of their components might enter tissues or other critical spaces. Examples of semi-critical endoscopes are laryngoscopes, nasopharyngeal endoscopes, transesophageal probes, colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes and enteroscopes. ²
Endoscope – single use accessories	Also called “disposable”, these are provided in a sterile state ready for use. ⁹
End user	Health care providers, including physicians, nurses, and specialty professionals, who utilize the reprocessed materials to provide a health care service to clients.

Flash sterilization	A special steam sterilization cycle designed for the unplanned sterilization of unwrapped surgical goods. Note: Cycles currently employed for emergency sterilization are gravity displacement, dynamic air removal, and a cycle that may be available on some steam sterilizers that is designed to permit the use of a single wrapper on the instrument tray. ³
Foot care	Care performed by health care personnel on client's feet, which may include clipping, cutting, filing of nails and callous removal. ¹⁰
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 waterless antiseptic hand rubs. ¹¹
Health care facility or setting	A facility or setting in which clients receive health care services including but not restricted to public hospitals and surgical facilities, nursing homes, extended care facilities, long term care facilities, clinics, medical and dental offices, and health units in industry. ³
High efficiency particulate air (HEPA) filter	An air filter with an efficiency of 99.7 per cent in the removal of airborne particles 0.3 μ or larger in diameter. ⁴
High level disinfection (HLD)	The level of disinfection required when processing semi-critical medical devices. High level disinfection processes destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores. ²
Huck towel	An all cotton surgical towel with a honey-comb-effect weave; both warp and fill yarns are tightly twisted. ¹²
Implantable device	Device that is placed into a surgically or naturally formed cavity of the human body to remain there for a period of 30 days or more. ¹²
Inspect	To look carefully at or over; view closely and critically. ⁶
Infection prevention and control (IPC)	Evidence-based practices and procedures that, when applied consistently in health care facilities and settings, can prevent or reduce the risk of transmission of microorganisms to health care personnel, clients and visitors. ²

IPC executive	The member of the organization who reports to the Chief Executive Officer and who is responsible for the oversight of IPC standards and IPC activities.
Infection prevention and control practitioners (ICP)	Personnel specially trained and responsible for surveillance of infections, education and consultation of staff, clients and the general public, to manage infection prevention and control issues. ¹³
Leak test	A test, performed on endoscopes according to manufacturer's instructions, prior to immersion and between client use to detect damage to the interior or exterior of the endoscope. ¹⁴
Loaned equipment	Medical devices used in more than one facility, including borrowed, shared or consigned devices which are used on clients. ²
Low level disinfection (LLD)	A process using low level disinfectants to kill most vegetative bacteria and some fungi as well as enveloped (lipid) viruses (e.g. Hepatitis B, C, Hantavirus, and HIV). Low level disinfectants do not kill mycobacteria, or bacterial spores. Low level disinfectants are used to clean and disinfect non-critical medical devices and environmental surfaces. ⁷
Manufacturer	Any person, partnership or incorporated association that manufactures and, under its own name or under a trade mark, design, trade name or other name or mark owned or controlled by it, sells medical devices. ²
Material Safety Data Sheet (MSDS)	Provides detailed hazard and precautionary information for hazardous materials. ¹⁵
Mechanical monitoring	Measurement of parameters such as time, temperature and pressure graphs used to ensure that effective sterilization is achieved. ²
Medical device	Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination intended by a manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment, surgery, or alleviation of disease, injury or handicap; investigation, replacement or modification of the anatomy, or of a

***Medical
device...continued***

physiologic process; or control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological means, but which may be assisted in its function by such means.²

For readability, this document uses the term “medical device” to represent equipment, device or instrument.

**Medical Device
Classification System**

Under the *Health Canada Medical Devices Regulations*, a risk-based classification system has been implemented to categorize medical devices as to their potential risk. The system is based on four classes (Class I, II, III and IV) representing increasing degrees of risk. Assignment of products to each risk class is based on factors such as degree of invasiveness, duration of contact with client, energy transmission hazard and consequences of device malfunction or failure.

Class I Lowest Risk, e.g., surgical instruments, culture media

Class II Low Risk – e.g., contact lenses, epidural catheters, pregnancy test kits, surgical gloves, ultrasound scanner

Class III Moderate Risk – e.g. orthopedic implants, glucose monitors, dental implants, haemodialysis systems

Class IV High Risk – e.g. HIV test kits, pacemakers, angiographic catheters.⁵

Monitor

To observe, record or detect (an operation or condition) with instruments that have no effect upon the operation or condition;

To oversee, supervise or regulate;

To watch closely for purposes of control, surveillance.¹

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.¹⁶

**Non-critical medical
device**

Medical device that touches only intact skin (but not mucous membranes) or does not directly touch the client.² Intact skin acts an effective barrier against most microorganisms; therefore, the sterility of items coming in contact with skin is “non-critical”.⁷

Occupational Health and Safety	An area of specialization in health care which concerns the factors such as working conditions and exposure to hazardous materials in an occupation that influences the health of workers in that occupation, and which is concerned generally with the prevention of disease and injury and the maintenance of fitness. ¹⁷
Organization	The owner, operator and other person responsible for the management of a health care facility or setting.
Pasteurization	A high level disinfection process using hot water at a temperature of 75°C, for a contact time of at least 30 minutes. ²
Personal protective equipment (PPE)	Specialized equipment or clothing used by health care workers to protect themselves from direct exposure to clients' blood, tissue or body fluids. Personal protective equipment may include gloves, gowns, fluid-resistant aprons, head and foot coverings, face shields or masks, eye protection, and ventilation devices (e.g. mouthpieces, respirator bags, pocket masks). ³
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 in health care, laboratory or public safety setting. ⁷
Point of use	Refers to the point in time and place at which medical devices are used on the client.
Policy	The general principles that set the direction for the IPC Cleaning, Disinfection and Sterilization 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 is air from corridors and adjacent areas is prevented from entering the room. ¹⁶
Procedure	A specific mode or method of performing a task in a sequential manner. Procedures are tools to implement policies. ³

Reprocessing	All steps necessary to make a contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labeling, disinfection and sterilization. ¹⁸
Reprocessing area	See Centralized Reprocessing Area
Reusable	Any product or piece of equipment intended by the manufacturer for multiple uses. The manufacturer is to provide instructions for reprocessing, care and maintenance as appropriate to each medical device. ³
Semi-critical medical device	A medical device that comes in contact with mucous membranes or non-intact skin, but does not penetrate them, including but not limited to respiratory therapy equipment, trans-rectal probes, vaginal and rectal specula, gastro endoscopes. ²
Sharps	Objects capable of causing punctures or cuts such as needles, syringes, blades, or glass. ²
Single client-use medical device	A medical device that may be used and reused on a single client, but may not be reused on other clients. ²
Single-use/disposable medical device	A medical device, also referred to as “SUMeD”, designated by the manufacturer for single-use only. ⁷
Spaulding Classification	A strategy for reprocessing contaminated medical devices. The system classifies medical devices as critical, semi-critical, or non-critical based upon the risk from contamination on a device to client safety. The system also establishes three levels of germicidal activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semi-critical and non-critical). ⁸
Sterilization	The sterilization process results in the destruction of all forms of microbial life including bacteria, viruses, spores and fungi. ²
Validated	Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications. ¹²

**Workplace Hazardous
Materials Information
System (WHMIS)**

A Canadian program designed to protect workers by providing them and their employers with vital information about hazardous materials. Key features of WHMIS include: criteria to identify controlled products and to provide information about them in their workplace; a cautionary labeling system for containers of controlled products; requirements for the disclosure of information by the use of material safety data sheets; worker education programs; and a mechanism to protect trade secrets. WHMIS is implemented by a series of federal, provincial and territorial acts and regulations.¹⁹

Worker

A person engaged in an occupation.²⁰

2. Introduction

The goals of these standards are to:

- Minimize the risk of exposure or injury and prevent transmission of microorganisms to personnel and clients, 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 the medical device cleaning and decontamination.

These standards set minimum requirements for cleaning, disinfection and sterilization of reusable medical devices for all health care facilities and settings. Higher standards may be required based on specific circumstances. Standards and guidelines established by Health Canada and the Canadian Standards Association (CSA) may also be applicable.

These standards are based on current information and will evolve as evidence and technology changes. It is the responsibility of organizations to ensure current infection prevention and control (IPC) practices are in place.

3. Environmental and Structural Requirements

- 3.1. There shall be a centralized reprocessing area for collecting, cleaning and decontaminating contaminated medical devices.
- 3.2. Reprocessing medical devices outside of a centralized reprocessing area shall be approved by the person designated by the IPC executive for safe reprocessing practices and shall conform to the requirements for reprocessing space.
- 3.3. The reprocessing space shall:
 - 3.3.1. have space for the cleaning process and storage of necessary equipment and supplies;
 - 3.3.2. have physically separate decontamination areas from areas where clean, disinfected or sterile medical devices are handled or stored;
 - 3.3.3. have easy access to hand hygiene facilities;
 - 3.3.4. have surfaces that can be easily cleaned;
 - 3.3.5. have restricted access from other areas in the setting and ensure one-way movement by staff;
 - 3.3.6. have air changes, temperature and humidity appropriate to the process and product being used as set out by manufacturers' instructions and CSA Standards;
 - 3.3.7. have negative pressure airflow in decontamination areas, and positive pressure airflow in clean areas;²¹ and
 - 3.3.8. use a water supply which is tested for and free of contaminants.²²
- 3.4. 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.

4. Purchasing and Assessing Medical Devices and Products for Disinfection or Sterilization Processes

- 4.1. Manufacturer's reprocessing information for all medical devices shall be acquired prior to purchase and use of the device.
- 4.2. Reusable medical devices that cannot be reprocessed according to the manufacturer's instructions and Alberta Health and Wellness standards shall not be purchased.
- 4.3. All medical devices or chemical products used in reprocessing shall meet Occupational Health and Safety (OHS) requirements.
- 4.4. All medical devices shall meet established quality reprocessing parameters.²
 - 4.4.1. The manufacturer must supply:
 - information about the design of the medical device;
 - manuals/directions for use;
 - medical device-specific recommendations for cleaning and reprocessing of device;
 - personnel training materials on the use, cleaning and the correct reprocessing of medical devices; and
 - recommendations for auditing the recommended process.
 - 4.4.2. Infection prevention and control practitioners (ICP), reprocessing personnel, and biomedical engineers shall be included to assist end users and purchasing personnel with review, evaluation and recommendations regarding the suitability of the medical device for purchase. The criteria that shall be met include:
 - ability to be cleaned and safely reprocessed;
 - appropriate equipment to reprocess;
 - manufacturer's directions;
 - CSA Standards regarding the medical device;
 - Health Canada/Public Health Agency of Canada Guidelines regarding the medical device; and

- a valid medical device license issued by the Therapeutic Products Directorate of Health Canada <http://www.mdall.ca/> or provided by the manufacturer must be available for all medical devices that are Class II and higher.
- 4.5. Newly purchased non-sterile critical and semi-critical medical devices shall be inspected and processed according to manufacturer's written instructions prior to use.
- 4.6. Surgical instruments that are used on high risk neurological and eye tissue from clients at high risk for Creutzfeldt - Jakob Disease (CJD) shall be decontaminated in accordance with the Health Canada/Public Health Agency of Canada infection control guideline, *Classic Creutzfeldt - Jakob Disease in Canada*.²³

5. Selection of Products and Processes for Reprocessing

- 5.1. All materials used in any reprocessing stage shall be approved by an individual who has completed a recognized qualification/certification course in reprocessing and an infection prevention and control practitioner.
- 5.2. All reusable medical devices purchased shall have written device-specific manufacturer's cleaning, decontamination, disinfection, wrapping and sterilization instructions.
 - 5.2.1. The reprocessing processes and products used in the reprocessing of a medical device shall be determined by the intended use of the device in accordance with the Spaulding Classification.
 - 5.2.2. The processes and products used for reprocessing shall be compatible with each other and the medical device.
 - 5.2.3. If disassembly or reassembly is required, the organization shall ensure that manufacturer's instructions used include detailed instructions and diagrams.
 - 5.2.4. Staff training shall be provided on disassembly, reassembly and reprocessing before the medical device is placed into circulation.

6. Disassembling and Cleaning Reusable Medical Devices

- 6.1. Reusable medical devices shall be cleaned before disinfection or sterilization.
- 6.2. The cleaning process shall include disassembly (if required), sorting and soaking, physical removal of organic material, rinsing, drying, physical inspection and wrapping (if required).
- 6.3. In contrast to critical and semi-critical items, most non-critical reusable items may be decontaminated where they are used and do not need to be transported to a central reprocessing area. Low level disinfectants may be used for cleaning non-critical items.⁷

7. Disinfection of Reusable Medical Devices

- 7.1. Non-critical medical devices shall be cleaned using a low level disinfectant between clients and after discharge.
 - 7.1.1. Non-critical medical devices shall be cleaned and disinfected using a low level disinfectant if they become contaminated with blood or body fluids or if they have been exposed to a client with an infectious organism.²⁴
- 7.2. Heat sensitive semi-critical medical devices shall be disinfected using high level disinfection (HLD).
- 7.3. Client-owned non-critical and semi-critical medical devices and foot care instruments reused by a client in the client's own home may not require disinfection between uses provided they are cleaned in accordance with 6.2 prior to reuse for the same client.
- 7.4. All disinfectants used for disinfecting medical devices shall have a Drug Identification Number (DIN) from Health Canada.⁸
- 7.5. HLD for any medical device shall be monitored according to manufacturer's recommendation and results shall be recorded. If a chemical product is used, the concentration of the active ingredient(s) shall be verified and a logbook of daily concentration test results shall be maintained.

Pasteurizing Equipment

- 7.6. Manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment shall be followed to ensure that the machine does not become contaminated.
- 7.7. A preventative maintenance program for pasteurizing equipment shall be implemented and documented.
- 7.8. Following the pasteurization 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 pasteurized medical devices.
- 7.9. A log book of contents, temperature and time shall be maintained for pasteurizing equipment.

8. Reprocessing Endoscopes

- 8.1. The organization shall ensure that all personnel responsible for reprocessing endoscopes are specifically trained and qualified in endoscope reprocessing.
- 8.2. Endoscope cleaning, as recommended by the manufacturer, shall commence immediately, at the point of use, following completion of the clinical procedure.²²
- 8.3. Leak testing shall be done after each use, to verify the patency and integrity of the endoscope sheath.²⁵
- 8.4. Endoscope devices shall be rinsed and dried prior to disinfection or sterilization.
- 8.5. Critical endoscopes shall be sterilized after each use.
- 8.6. Reusable accessories such as biopsy forceps and brushes shall be single use or sterilized after each use.
- 8.7. Semi-critical endoscopes and accessories (excluding biopsy forceps and brushes) shall be at least high level disinfected after each use.
- 8.8. Automated endoscope reprocessors (AERs) shall be compatible with endoscope and endoscope components.²⁵
- 8.9. Final drying of semi-critical endoscopes shall include flushing all channels with 70% isopropyl alcohol, followed by forced air purging of the channel.²²
- 8.10. Semi-critical endoscopes shall be stored hanging vertically in a well-ventilated area.
- 8.11. Endoscope storage cabinets shall be cleaned and disinfected weekly.
- 8.12. The water bottle and its connecting tube, used for cleaning an endoscope lens and irrigation, shall be sterilized daily when used, or if sterilization is not reasonably possible, high level disinfection is acceptable.²
- 8.13. A preventive maintenance program for automated endoscope reprocessors (AER) shall be implemented and documented.
- 8.14. The organization shall maintain:
 - 8.14.1. a permanent record of endoscope use and reprocessing.

8.14.2. a system to track endoscopes and clients that includes recording the endoscope number in the client record.

9. Sterilization of Reusable Medical Devices

- 9.1. Critical medical devices shall be sterilized.⁸
 - 9.1.1. Steam sterilization shall be used for critical or semi-critical medical devices that are compatible with heat and moisture.
 - 9.1.2. All instruments used for foot care shall be sterilized prior to reuse on another client.
- 9.2. All sterilization processes shall follow the manufacturer's instructions for installation, operation, preventative maintenance and quality assurance monitoring of the equipment.
- 9.3. The sterilization process shall be tested, monitored and audited.² For all sterilizers:
 - 9.3.1. The following shall be completed to ensure that effective sterilization has been achieved:
 - Mechanical monitoring including time, temperature, and pressure graphs;
 - Chemical monitoring – each pack must have external chemical indicators; and
 - Biologic monitoring – biologic monitor shall be included each day a sterilizer is used. A biologic monitor shall be used with each load if implantable medical devices are being sterilized.
 - 9.3.2. Daily operation of the sterilizer shall be documented for each operation and any malfunction shall be noted and appropriate action taken to ensure that the product is either properly treated or is returned for reprocessing.
- 9.4. The IPC executive shall approve the purchase of a new sterilizer prior to its purchase.
- 9.5. Sterilizers shall be subjected to rigorous testing and monitoring on installation and following disruptions to their normal activity.
- 9.6. Flash sterilization shall only be used in emergency situations and shall never be used for implantable medical devices.

9.7. The following processes shall not be used for sterilization:

9.7.1. Boiling;

9.7.2. Ultraviolet light;

9.7.3. Glass bead sterilization; or

9.7.4. Microwave ovens.²

10. Storage and Use of Reprocessed Medical Devices

- 10.1. Sterile medical devices shall be maintained as sterile until point of use.
- 10.2. Reprocessed medical devices shall be stored in a clean, dry location in a manner that prevents contamination or damage.
- 10.3. Reprocessed medical devices shall be inspected for integrity upon opening device at point of use. The results of chemical indicators, if present, shall be validated prior to reassembly and use.

11. Transportation and Handling of Contaminated Medical Devices

- 11.1. Disposable sharps shall be removed and disposed of in an appropriate puncture-resistant sharps container at point of use.
- 11.2. If medical devices cannot be cleaned immediately after use, devices shall be kept moist in a transport container by using a wet huck towel moistened with water, or foam, spray or gel product (not saline) specifically intended for this use.
- 11.3. All personnel who handle contaminated medical devices shall handle those devices in a manner which reduces the risk of:
 - exposure and/or injury to self, other personnel and clients,
 - contamination of environmental surfaces.
- 11.3.1. From the point of use, contaminated medical devices shall be taken directly to the area designated for handling contaminated devices and if required, initial disassembly completed.
- 11.3.2. Where there is no dedicated direct access from point of use to the area designated for handling contaminated medical devices, contaminated devices shall be securely contained in a covered container and closed containers or carts shall be used for transport of contaminated materials.
- 11.3.3. Open carts may be used to transport contaminated medical devices where there is a dedicated, direct access from the point of use to the area designated for handling contaminated devices.
- 11.4. Contaminated medical devices which have not been reprocessed shall be clearly labeled as not reprocessed by use of a labeling system such as color coding or tagging.

12. Education and Training

- 12.1. All reprocessing personnel and all reprocessing supervisors shall have qualifications as defined by Alberta Health and Wellness.
- 12.2. If qualified reprocessing personnel are not available, partnerships with other qualified health care facilities and settings/individuals shall be made to ensure supervision of all reprocessing activities by personnel meeting Alberta Health and Wellness qualifications.

13. Occupational Health and Safety Requirements

- 13.1. The organization shall comply with the Alberta *Occupational Health and Safety (OHS) Act, Regulation and Code*.²⁰
 - 13.1.1. The organization shall ensure that a written hazard assessment is completed and appropriate controls are implemented based on the hazard assessment.
 - 13.1.2. The reprocessing area shall be limited to reprocessing activities only and all other activities are prohibited including and without limitation eating or drinking, storage of food, smoking, application of cosmetics or handling of contact lenses in the reprocessing area.
 - 13.1.3. The organization shall ensure that sharps systems are adequate to protect personnel from injury.
 - 13.1.4. The organization shall ensure that air handling systems are adequate to protect personnel from toxic vapors.
 - 13.1.5. The organization shall ensure that chemicals are stored according to manufacturers' instructions, and Material Safety Data Sheets (MSDS) documentation shall be available as required by the Workplace Hazardous Materials Information System (WHMIS).
 - 13.1.6. The organization shall ensure that all persons handling contaminated medical devices wear personal protective equipment (PPE) as per hazard assessment.
 - 13.1.7. The organization shall ensure that all reprocessing personnel are assessed regarding their immunity to Hepatitis B and offered Hepatitis B immunization if required.
 - 13.1.8. The organization shall ensure that a first aid plan, equipment and services are in place.
 - 13.1.9. The organization shall have written policies to prevent exposure to blood and body fluids, exposure to chemicals, and injuries from sharp objects.
 - 13.1.10. Policies shall be in place for immediate response to worker exposure to chemicals.

- 13.1.11. Policies shall be in place for immediate response and post-exposure management of workers exposed to blood and body fluids.
- 13.1.12. Policies shall be in place for immediate response to worker exposure to sharp objects.
- 13.1.13. The organization shall ensure that ventilation is in place to remove toxic vapors generated by, or emitted from, cleaning or disinfecting agents and air quality shall be monitored.

14. Written Policies and Procedures

- 14.1. The organization shall ensure that the reporting structure with individuals who have authorization, responsibility and accountability to develop, approve, monitor and maintain reprocessing policies is documented.
- 14.2. The organization shall develop and maintain written policies and procedures that apply to the transporting, receiving, handling and processing of loaned, shared and leased medical devices.
- 14.3. The organization shall establish written policies to ensure that reprocessing follows manufacturers' directions and Alberta Health and Wellness standards.
- 14.4. The organization shall establish written policies that ensure sterilization processes follow IPC principles as set out in Health Canada, CSA standards and Alberta Health and Wellness standards.
- 14.5. The organization shall ensure that health care facilities and settings in which endoscope procedures are performed shall have detailed written policies for reprocessing endoscopes.
- 14.6. The organization shall establish written policies to ensure the protection and safety of personnel in accordance with the *OHS Act* as outlined in section 13 of this standard.
- 14.7. The organization shall review all policies annually to ensure policies are kept up-to-date with Health Canada, CSA standards and Alberta Health and Wellness standards.

15. References

- ¹ AHW-PSD Monitoring and Compliance Function Useful Definitions. Dictionary.com
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