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COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Offsite Reprocessing of Medical Devices

Duties of the Originating & Offsite Reprocessing Locations

Self-Assessment Tool

Infection Prevention & Control (IPAC) Program

Last updated February 2024

Purpose

This self-assessment tool is a companion to CPSA Guidance on Offsite Reprocessing of Medical Devices and a supplement to CPSA's Reusable and Single-Use Medical Device Requirements for Medical Clinics ("Requirements"). This tool can assist both clinics and offsite locations in determining that reprocessing requirements are being met and mirrors the tool used by CPSA Assessors during assessments of reprocessing in medical clinics and offsite locations.

This tool is a general breakdown of duties that typically fall to either the originating clinic or offsite reprocessing locations. However, there may be instances where requirements typically set out for the originating clinic are completed at the offsite location or vice versa. Physicians at the originating clinic are ultimately responsible for ensuring that all requirements are met for their reusable medical devices.

For assistance or more information, please contact the CPSA IPAC Program at ipac@cpsa.ab.ca or 780-969-5004.

Glossary of Terms

Originating clinic: The clinic where the reusable devices are used on patients. In this context, the originating clinic sends their contaminated devices to another "offsite" location to be reprocessed. Once reprocessed, the clinic receives their reprocessed devices back from the offsite location.

Offsite location: The location that receives contaminated devices from the originating clinic for the purpose of reprocessing them and returning them to the clinic where they will be used. Offsite locations are typically other medical clinics or community hospital settings.

Offsite reprocessing facility: Sometimes referred to as "third-party reprocessing." This term refers to a partnership between two locations where contaminated devices are transported from one location to another so that cleaning and disinfection, or sterilization, of reusable devices can occur. Once reprocessing is complete, the devices are safely transported back to the originating clinic.

Assessment Measurement

Yes	In compliance with requirements
No	Not in compliance with requirements
CDA	Corrected during the assessment
N/A	Not applicable to this medical clinic

PART 1. DUTIES OF THE ORIGINATING CLINIC LOCATION

SECTION	REQUIREMENTS	YES	NO	CDA	N/A
PART A: SINGLE-USE MEDICAL DEVICES					
Section 1: Single-use medical devices					
1.1	Single-use medical devices shall only be used on a single patient for a single procedure and then shall be discarded.				
1.2	A single-use medical device shall not be used beyond the expiry date specified by the manufacturer.				
1.3	A sterile critical single-use medical device shall be maintained as sterile until point of use.				
1.4	Opened but unused single-use medical devices shall be discarded unless the manufacturer provides validated manufacturer's instructions for use (MIFU) for reprocessing.				
1.5	Prior to using a single-use medical device that was purchased in a non-sterile state, that single-use medical device shall be inspected and processed according to the validated MIFU.				
COMMENTS					
PART B: REPROCESSING OF REUSABLE MEDICAL DEVICES					
Section 3. Procurement of reusable medical devices & reprocessing equipment and supplies					
3.1	The decision to purchase or trial reusable medical devices, reprocessing equipment and supplies, or reusable surgical textiles shall involve representatives from the personnel in the clinic who will use, reprocess, and maintain the items.				
3.2	Prior to purchasing or trialing a medical device, including medical device reprocessing equipment, the clinic shall confirm that the device has a valid medical device license issued under the Government of Canada's Medical Devices Regulations. The clinic shall not purchase or trial a reusable medical device that does not have a valid medical device license.				

SECTION	REQUIREMENTS	YES	NO	CDA	N/A
3.3	Prior to purchasing or trialing a reusable critical or semi-critical medical device, personnel accountable for medical device reprocessing (MDR) shall review the written, validated MIFU to determine that the recommended reprocessing procedures can be achieved, given the clinic's reprocessing resources.				
COMMENTS					
Section 4. General reprocessing requirements					
4.1	Reusable medical devices that have been used shall be reprocessed. Contaminated reusable medical devices that have not undergone reprocessing shall be clearly identified.				
4.2	Reusable medical devices that come from an opened or compromised package shall be reprocessed prior to use.				
4.3	Newly purchased reusable critical and semi-critical medical devices shall be reprocessed before initial use unless they are packaged and sterilized by the manufacturer.				
COMMENTS					
Section 5. Pre-cleaning & transportation of contaminated reusable medical devices					
5.1	Personnel shall pre-clean used reusable medical devices immediately after use and prior to transportation and further manual or automated cleaning.				
5.2	At the point of use, single-use sharps shall be removed from reusable medical devices and disposed of in a puncture-resistant sharps container.				
5.3	Organic matter shall not be allowed to dry on reusable medical devices. Reusable medical devices shall be kept moist by using foam, spray, or gel specifically intended for this use, or by using a towel moistened with water, and in accordance with the manufacturer's instructions for use (MIFU).				
5.4	Contaminated items shall be transported in covered, fully enclosed, leak-proof containers or closed carts that are designed to prevent the spill of liquids, protect reusable medical devices from damage, and allow for effective decontamination after each use.				

SECTION	REQUIREMENTS	YES	NO	CDA	N/A
5.5	Sterile or clean reusable medical devices and soiled reusable medical devices shall be transported in a manner that prevents cross-contamination (i.e., in separate containers and carts).				
5.6	All containers and carts containing contaminated medical devices shall be so identified.				
5.7	Contaminated reusable medical devices shall be transported to the medical device reprocessing (MDR) area in such a way so as not to contaminate the surrounding environment.				
COMMENTS					
Section 7. Disinfection of reusable medical devices					
7.1	Disinfection of reusable medical devices shall take place in accordance with the manufacturer's instructions for use (MIFU) of the device and shall also follow the MIFU for the disinfection process, equipment, and products.				
7.2	Only chemical disinfectants that have a Health Canada drug identification number (DIN) or a medical device licence (MDL) issued by Health Canada shall be used in clinics and settings for the disinfection of reusable medical devices.				
7.3	A liquid chemical disinfectant shall not be used beyond its expiry date and in-use life.				
7.4	Reusable liquid chemical disinfectant solutions shall be:				
7.4.1	Clearly identified with the expiry date included.				
7.4.2	Stored in containers that are cleaned, disinfected, and dried prior to changing the solution.				
7.4.3	Kept covered with a tight-fitting lid, except when introducing or removing a medical device to or from the solution.				
Section 7. Non-critical devices					
7.5	Non-critical reusable medical devices shall be disinfected between patient uses using an intermediate-level disinfectant (ILD) or low-level disinfectant (LLD).				

SECTION	REQUIREMENTS	YES	NO	CDA	N/A
7.5.1	ILD or LLD wipes shall be moist enough to thoroughly wet the surface for the indicated contact time, and a new wipe shall be used if the area to be disinfected cannot be completely wetted with a single wipe.				
Section 7. Semi-critical medical devices					
7.6	If a reusable semi-critical device cannot be sterilized, then it shall, at a minimum, be high level disinfected between patient uses.				
COMMENTS					
Section 8. Sterilization of Reusable Medical Devices					
8.5	Packaging of reusable medical devices for sterilization shall take place in accordance with the MIFU of the device, the sterilization equipment, and the sterilization packaging manufacturer, and when packaging is required, it shall be done using a validated sterile barrier system (e.g., pouches, wrappers, or rigid sterilization container systems).				
8.6	Packages shall be labelled with sterilizer load identification information, including the sterilizer number, the load number in that sterilizer, and the sterilization date.				
8.6.2	For pouches, a label shall be placed on the transparent portion of the packaging.				
8.6.3	For wrapped packages, writing shall be on the closure tape, not directly on the wrappers.				
Chemical indicators					
8.10.2	Both internal and external chemical indicators shall be included with each package prepared for sterilization.				
8.10.2.1	The internal chemical indicator shall be placed in the area of the package that is least susceptible to sterilizing agent penetration. If a multi-layer container is being used, chemical indicators shall be placed at each level.				

SECTION	REQUIREMENTS	YES	NO	CDA	N/A
Biological Indicators					
8.14	Documentation of sterility assurance shall include a printout or electronic cycle parameter record, a load control label, a load contents record, and associated chemical or biological indicator test results for each cycle.				
COMMENTS					
Section 9. Storage					
9.1	Reprocessed critical and semi-critical medical devices shall be protected from contamination by:				
9.1.1	Rotating stock via first-in, first-out.				
9.1.2	Keeping items clean, dry, and protected.				
9.1.3	Keeping items well-separated from soiled items and soiled areas via barriers and/or distance.				
9.1.4	Ensuring they are not stored on the floor or a windowsill, under sinks or near water sources, in open corridors or patient rooms, or in the same area as hazardous materials.				
COMMENTS					
Section 10. Education & training					
10.1	The clinic shall ensure all personnel involved in the reprocessing of critical and semi-critical medical devices are appropriately educated and trained for the reprocessing duties/tasks that they perform.				
10.2	The clinic shall document and maintain records of education, training, orientation, and competency assessments of personnel who reprocess critical and semi-critical medical devices.				
COMMENTS					

SECTION	REQUIREMENTS	YES	NO	CDA	N/A
PART C: QUALITY MANAGEMENT SYSTEMS					
Part 11. Quality management systems					
11.1	The clinic shall have clear accountability and lines of responsibility for all aspects of medical device reprocessing (MDR), wherever MDR takes place in the clinic, and the appropriate use of single-use medical devices.				
11.2	The clinic shall have written policies and procedures in place that meet or exceed appropriate provincial and national standards and guide the clinic through relevant aspects of MDR. The clinic's medical device reprocessing policies and/or procedures shall include (but not be limited to):				
11.2.1	All relevant steps in the reprocessing of reusable medical devices, based on MIFU.				
11.2.1	Pre-cleaning and transportation.				
11.2.1	Sterility assurance, including physical, chemical, and biological.				
11.2.1	Storage.				
11.2.2	Education and training.				
11.2.3	Recall procedures.				
11.2.4	Specific, detailed procedures for medical devices that present unique and complex challenges for reprocessing, such as flexible endoscopes, based on manufacturer's instructions for use (MIFU).				
11.3	The clinic shall have a written policy regarding single-use medical devices that is consistent with Part A of the Requirements.				
11.4	The clinic shall conduct a regularly scheduled review of all written policies and procedures.				
Documentation					
11.6	The MIFU for medical devices, equipment, and supplies shall be received and maintained in printed form (e.g., in binders, manuals, or monographs) or in electronic format and be readily accessible to those needing access and shall be updated as required.				

SECTION	REQUIREMENTS	YES	NO	CDA	N/A
11.7	If reprocessing of reusable medical devices is being performed by an external or internal subcontractor, the subcontractor shall comply with the Requirements.				
COMMENTS					

PART 2. DUTIES OF THE OFFSITE REPROCESSING LOCATION

REQUIREMENTS		YES	NO	CDA	N/A
PART B: REPROCESSING OF REUSABLE MEDICAL DEVICES					
Section 2. Environmental & structural requirements for a medical device reprocessing area					
2.1	The medical device reprocessing (MDR) area shall be a designated area, separate from patient care, and activity in the area shall be restricted to the reprocessing of reusable medical devices.				
All MDR areas shall:					
2.2.1	Have physical separation of clean and dirty areas. In existing clinics and settings where physical separation (i.e., with walls or partitions) of reprocessing areas is not possible, spatial separation and a one-way workflow pattern shall be established to limit cross-contamination.				
2.2.2	Have at least two adjacent sinks, large enough to immerse the largest piece of equipment, to clean and rinse soiled items. In existing smaller clinics where two adjacent sinks dedicated for equipment cleaning and rinsing are not possible, a dedicated basin for rinsing equipment after cleaning in a dedicated sink is an acceptable alternative. The dedicated basin shall be large enough to fully submerse the item being rinsed.				
2.2.3	Have hand hygiene stations—either hand hygiene sinks or alcohol-based hand rub (ABHR) dispensers with products that have a Health Canada Drug Identification Number (DIN) or Natural Product Number (NPN) and contain 60% to 90% alcohol—at all entrances to, and exits from, the MDR area and readily available within the MDR area.				
2.2.3.1	Designated hand hygiene sinks shall have properly functioning soap dispensers and paper towel dispensers.				
2.2.3.2	Designated hand hygiene sinks shall be used for the purpose of hand hygiene only.				
2.2.4	Have surfaces that can be cleaned. All work surfaces and surrounding area shall be intact, cut-resistant, and seamless, and shall be composed of non-porous, non-shedding material capable of withstanding frequent cleaning.				

REQUIREMENTS		YES	NO	CDA	N/A
2.2.5	Restrict access to areas where reprocessing occurs. In existing smaller clinics, where MDR areas may also be used for other purposes, access shall be restricted during reprocessing activities and until the area has been appropriately cleaned.				
2.2.6	Be designed to facilitate one-way workflow.				
2.2.7	Have adequate lighting for the tasks being performed in all work locations.				
2.2.8	Use a water source which meets the equipment manufacturer's specifications for water and steam quality.				
COMMENTS					
Cleaning accessories					
4.4	Cleaning accessories shall be inspected before use to ensure they are not damaged. Damaged cleaning accessories shall not be used.				
4.5	Reusable cleaning accessories shall be reprocessed after use in accordance with the manufacturer's instructions for use (MIFU), inspected for damage, and stored in a clean, dry place.				
4.6	Single-use cleaning accessories shall be discarded following use.				
COMMENTS					
Section 6. Preparation & Cleaning of Reusable Medical Devices					
Sorting & disassembly					
6.1	All contaminated medical devices shall be inspected and sorted before reprocessing to ensure that the appropriate cleaning agents and procedures are applied to the correct devices.				
6.2	All medical devices consisting of multiple components (e.g., minimally invasive surgical medical devices) shall be disassembled in accordance with the manufacturer's instructions for use (MIFU).				

REQUIREMENTS		YES	NO	CDA	N/A
Cleaning					
6.3	Each medical device shall be thoroughly cleaned prior to disinfection or sterilization.				
6.4	Cleaning methods shall be consistent with the medical device's manufacturer's instructions for use (MIFU) and appropriate for the type of medical device and the amount of soil to be removed.				
Manual cleaning					
6.5	If manual cleaning is required, the medical device's manufacturer's instructions for use (MIFU) for reprocessing shall be followed, including any specifications for detergent type, water type, or water temperature and cleaning methods.				
6.6	Immersible medical devices shall be completely submerged during cleaning to prevent the generation of aerosols and non-immersible medical devices shall be cleaned according to the manufacturer's instructions for use (MIFU).				
Automated cleaning					
6.7	Automated washers and ultrasonic cleaners used for cleaning shall be used in accordance with the manufacturer's instructions for use (MIFU).				
6.7.1	The performance of the automated cleaning system (e.g., automated washers) shall be tested each day that it is in use, using commercially available indicators or test kits.				
6.7.2	Ultrasonic cleaners shall be tested for sonication performance (e.g., commercial methods or the foil test) at least weekly.				
6.7.3	The ultrasonic detergent solution shall be changed at least daily or more frequently when visibly soiled or if the ultrasonic cleaner or solution MIFU specifies more frequent changes (e.g., with every cycle).				
6.8	The medical device's MIFU shall be followed to ensure medical devices are compatible with the automated washer's process conditions (e.g., moisture, temperature, chemicals, water quality, and pressure).				

REQUIREMENTS		YES	NO	CDA	N/A
Rinsing & drying					
6.9	Chemical residues and loosened soil shall be completely rinsed from the medical device prior to disinfection or sterilization. Rinsing may be included as a final step in an automated cleaning process. If not, the medical device shall be rinsed manually.				
6.10	Reusable medical devices shall be dried prior to disinfection or sterilization, as directed by the manufacturer's instructions for use (MIFU). Unless dried using an automated process, the exterior surfaces of medical devices shall be manually dried with a clean, lint-free or low-lint soft-absorbent towel.				
Reassembly					
6.11	Decontaminated medical devices shall be reassembled according to the manufacturer's instructions for use (MIFU). Reassembly shall take place in a clean and dry area.				
Inspection					
6.12	Medical devices shall be visually inspected for cleanliness, damage, integrity, and functionality prior to disinfection, sterilization, or subsequent use.				
6.12.1	Cleaned medical devices that are visibly soiled shall be cleaned again.				
6.12.2	Medical devices that are damaged or in poor working condition shall be removed from service, labelled, and segregated from usable medical devices. Such medical devices shall either be repaired or disposed of in accordance with the documented procedures.				
COMMENTS					
Section 8. Sterilization of Reusable Medical Devices					
8.2.1	Sterilization of reusable medical devices shall take place in accordance with the manufacturer's instructions for use (MIFU) of the device.				
8.2.2	Sterilization of reusable medical devices shall take place in accordance with the MIFU for the sterilization process, equipment, and products.				

REQUIREMENTS		YES	NO	CDA	N/A
Qualification					
8.3	Installation qualification of sterilization equipment (including large chamber and table-top steam sterilizers and chemical sterilizers) shall be performed and documented according to the manufacturer's specifications.				
8.4	Operational qualification and requalification shall take place at least annually and following a major sterilizer repair, sterilizer relocation, an unexplained sterility failure, and, for steam sterilizers, following any disruption to steam supply or change to steam pressures.				
8.4.1	Operational qualification and requalification testing shall include a verification of each cycle used by the clinic, according to the MIFU for testing.				
8.4.2.1	Operational qualification and requalification testing shall be conducted by running three consecutive cycles in an empty chamber using process challenge devices (PCDs) with biological indicators. For table-top steam sterilizers, testing will take place in a fully loaded chamber.				
8.4.2.2	In dynamic air removal sterilizers that use pre-vacuum cycles, operational qualification and requalification testing shall be conducted by ensuring that the sterilizer meets the requirements of an air removal test and leak-rate test and is tested with three consecutive air removal tests (e.g., Bowie-Dick) in an otherwise empty sterilizer.				
Packages & labels					
8.5	Packaging of reusable medical devices for sterilization shall take place in accordance with the MIFU of the device, the sterilization equipment, and the sterilization packaging manufacturer, and when packaging is required, it shall be done using a validated sterile barrier system (e.g., pouches, wrappers, or rigid sterilization container systems).				
8.6	Packages shall be labelled with sterilizer load identification information, including the sterilizer number, the load number in that sterilizer, and the sterilization date.				
8.6.1	Labelling systems shall be validated for the sterilization process.				
8.6.2	For pouches, a label shall be placed on the transparent portion of the packaging.				
8.6.3	For wrapped packages, writing shall be on the closure tape, not directly on the wrappers.				

REQUIREMENTS		YES	NO	CDA	N/A
COMMENTS					
Loading & unloading					
8.7	Packages shall be placed in the sterilizer chamber in a manner that facilitates air removal, sterilizing agent penetration, sterilant evacuation, and, in the case of steam sterilization, drying.				
8.7.1	Wrapped items shall not contact the interior walls of the sterilizer chamber, as contact can damage the wrapper.				
8.7.2	Pouches and wrapped packages shall not be stacked or compressed.				
8.7.3	Between packages, there shall be adequate space to ensure effective sterilizing agent penetration, evacuation, and drying.				
8.8	Sterile packages shall be cooled to room temperature before handling.				
8.9	During unloading, packages shall be inspected for package integrity, dryness, presence of a label, the correct change in an external chemical indicator, an intact seal if used, and evidence of potential contamination. If a package does not meet the inspection criteria, the contents shall not be used.				
Sterility assurance					
8.10	Sterilization indicators shall be used only for the sterilizer type and sterilization cycle for which they were designed and validated and shall be used according to the sterilizer and indicator manufacturer's instructions for use (MIFU).				
8.10.1	Sterilization indicators shall not be used beyond their expiry date and shall be stored according to the MIFU.				
Chemical Indicators					
8.10.2	Both internal and external chemical indicators shall be included with each package prepared for sterilization.				

REQUIREMENTS		YES	NO	CDA	N/A
8.10.2.1	The internal chemical indicator shall be placed in the area of the package that is least susceptible to sterilizing agent penetration. If a multi-layer container is being used, chemical indicators shall be placed at each level.				
Air removal testing					
8.10.3	For dynamic air removal-type sterilizers (pre-vacuum cycles), an air removal test shall be performed every day the sterilizer is used.				
Biological indicators					
8.10.4	A biological indicator contained within a process challenge device (PCD) shall be used to test the sterilizer for each type of cycle used (e.g., dynamic air removal, gravity) and at the shortest exposure time, within a full load. This test shall be done at least daily when the sterilizer is in use.				
8.10.4.1	If a steam sterilizer will be used for multiple types of cycles, each type of cycle used shall be tested daily.				
8.11	At the conclusion of a sterilization cycle and before the load is removed, the operator shall confirm that the required parameters and all phases of the sterilization cycle, including aeration (if required), have been met.				
8.12	If a package is released based on monitored physical parameters and internal chemical indicator results, the internal chemical indicator shall be Type 5 or Type 6.				
8.13	All sterilizers used in Alberta clinics and settings shall come equipped with a printer or electronic record that records cycle parameters effective January 1, 2023.				
8.14	Documentation of sterility assurance shall include a printout or electronic cycle parameter record, a load control label, a load contents record, and associated chemical or biological indicator test results for each cycle.				
Section 10. Education & training					
10.1	All personnel involved in the reprocessing of critical and semi-critical medical devices must be appropriately educated and trained for the reprocessing duties/tasks that they perform.				

REQUIREMENTS		YES	NO	CDA	N/A
10.1.1	Personnel who reprocess critical and semi-critical medical devices, but are not employed as medical device reprocessing technicians, shall receive training in a formal medical device reprocessing training program recognized by the clinic, or comprehensive in-house training, and shall successfully complete competency testing.				
10.2	Records of education, training, orientation, and competency assessments of personnel who reprocess critical and semi-critical medical devices are documented and maintained.				
COMMENTS					
PART C: QUALITY MANAGEMENT SYSTEMS					
Section 11. Quality management systems					
11.1	There is clear accountability and lines of responsibility for all aspects of medical device reprocessing (MDR), wherever MDR takes place and the appropriate use of single-use medical devices.				
11.2	There are written policies and procedures in place that meet or exceed appropriate provincial and national standards and guide the clinic through all aspects of MDR.				
The clinic's medical device reprocessing policies and/or procedures shall include (but not be limited to):					
11.2.1	All steps in the reprocessing of reusable medical devices, based on MIFU. • Pre-cleaning and transportation • Sorting, disassembly, and soaking • Manual and/or automated cleaning • Rinsing • Drying Inspection • Packaging and labelling • Sterilization • Sterility assurance, including physical, chemical, and biological monitoring • Storage				
11.2.2	Education and training.				

REQUIREMENTS		YES	NO	CDA	N/A
11.2.3	Recall procedures.				
11.2.4	Specific, detailed procedures for medical devices that present unique and complex challenges for reprocessing, such as flexible endoscopes, based on manufacturer's instructions for use (MIFU).				
11.2.5	The required occupational health and safety activities, including use of appropriate personal protective equipment (PPE) when performing MDR and when using single-use medical devices. • Facial protection (eye protection with mask or full face shield) • Disposable, moisture impervious gown • Tear and chemical-resistant gloves • Cleaning and disinfection of reusable PPE				
11.4	A regularly scheduled review of all written policies and procedures shall be conducted.				
COMMENTS					
Documentation					
11.5	Records of reprocessing shall be retained.				
Reprocessing records shall include, but not be limited to, the following:					
11.5.1	Preventative maintenance of reusable medical devices and equipment.				
11.5.2	Results of installation, operational qualification and requalification, and routine testing of reprocessing equipment and products.				
11.6	The MIFU for medical devices, equipment, and supplies shall be received and maintained in printed form (e.g., in binders, manuals, or monographs) or in electronic format and be readily accessible to those needing access and shall be updated as required.				
11.7	If reprocessing of reusable medical devices is being performed by an external or internal subcontractor, the subcontractor shall comply with CPSA Requirements.				

REQUIREMENTS	YES	NO	CDA	N/A
COMMENTS				