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Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization

This assessment tool applies to community-based offices using tabletop steam sterilization for reprocessing of reusable medical devices.

Adapted with the permission of Public Health Ontario

REGISTRANT OFFICE INFORMATION

Registrant name: _____ CPSID: _____

Location name: _____

Location address: _____ City: _____ Province: _____ Postal code: _____

Location contact name: _____

Position: _____ Phone: _____ Email: _____

Date of assessment: _____ Assessor name: _____

Reason for assessment: _____

RISK LEGEND

LR	Legislated requirement	Must be compliant with the relevant Act or regulation (e.g. *Occupational Health and Safety Act*).
H	High risk	Immediate health hazard exists. Stop practice and correct immediately. The act or failure to act immediately may lead to the transmission of infection or risk of illness or injury. Practices that cannot be corrected immediately must be stopped until the health hazard is observed to have been eliminated. Specific actions will be directed from the program within two business days.
M	Medium risk	Signifies practices that must be corrected. Timelines for compliance or agreement on alternate process determined through consultation with the program or during assessment.

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

1.0	INSTRUCTIONS FOR USE AND TRAINING IN REPROCESSING PRACTICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
1.1	Written manufacturer instructions for use (MIFU) for each medical device are available with validated information that steam sterilization is appropriate.		M	**Requirements:** • All reprocessed devices must be validated by the manufacturer for steam sterilization. Ensure MIFU are followed. Devices that cannot be reprocessed safely or which do not have validated MIFU for reprocessing must be considered single use/disposable and discarded after use. **Note:** Verbal instructions from medical supply vendors are not sufficient as MIFU. • Disposable fabrics or devices such as gauze, cotton balls, tongue depressors, cotton-tip applicators and syringes must never be packaged and sterilized in steam or included in procedure trays/kits prior to sterilization in steam. These items have not been validated by the manufacturer for steam sterilization. These items are available from medical suppliers sterile and pre-packaged. Note that manufacturers do not use steam to sterilize these prepackaged items. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

1.0	INSTRUCTIONS FOR USE AND TRAINING IN REPROCESSING PRACTICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
1.2	Written MIFU of the sterilizer are available.		M	**Recommendations:** • Manufacturer instruction manuals are available online or from medical supply vendors • MIFUs will include maintenance and testing requirements as well as safety information **Assessor comments:**	--	**Response:** **Date change in effect:**

1.3	Material safety data sheets are available for all detergents/ enzymatic cleaners and disinfectants.		M	**Recommendations:**
				• MSDS information can be found online from manufacturers or from medical supply vendors
				• MSDS written materials provide information on:
				  ○ risks to staff when using products
				  ○ first aid precautions in the event of exposure or spill
				  ○ safety requirements (using personal protective equipment, ventilation requirements)
				
				Assessor comments:
					--	**Response:**
						
						Date change in effect:

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

1.0	INSTRUCTIONS FOR USE AND TRAINING IN REPROCESSING PRACTICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
1.4	Cleaning products/ detergents/enzymatic cleaners are labelled with the manufacturer expiry date.		M	**Requirements:** • Staff can locate and identify manufacturer expiry dates on all products which carry them • Detergents/enzymatic cleaners are not used past manufacturer expiry dates **Assessor comments:**	--	**Response:** **Date change in effect:**

1.5	All products labeled as disinfectants have a drug identification number (DIN) from Health Canada.		M	• For disinfectant products, a DIN uniquely identifies:
				  ○ the manufacturer
				  ○ product name
				  ○ active ingredient(s)
				  ○ strength
				• A DIN indicates that the product has undergone and passed a review of its formulation, labeling and instructions for use
				• Medical grade disinfectants available for purchase in Canada must have a DIN
				
				Assessor comments:
					--	**Response:**
						
						Date change in effect:

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

1.0	INSTRUCTIONS FOR USE AND TRAINING IN REPROCESSING PRACTICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
1.6	Staff assigned to reprocessing medical devices has completed education and training in reprocessing.		M	**Recommendation:** Registrants and staff responsible for medical device reprocessing (MDR) must possess the necessary knowledge to ensure safe and effective MDR. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

1.0	INSTRUCTIONS FOR USE AND TRAINING IN REPROCESSING PRACTICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
1.7	The clinical office is able to complete all aspects of medical device reprocessing in a timely manner whenever medical devices are used.		H	**Requirement:** • A sufficient number of staff members possess the necessary knowledge and skill set to perform safe and effective MDR during clinic operational hours when in situations where reusable medical devices are used • For example, if the most responsible staff member for MDR is on vacation, there must be another person available that has the minimum knowledge and skill set to handle used/dirty medical devices Some examples include the following scenarios: • Staff clean, rinse and dry used/dirty medical devices in a timely manner to prevent hardening of organic matter (correct product, soaking time, use of brushes) • Any time the sterilizer is used, all quality assurance parameters are met such as when and how to perform and document biological indicator testing, chemical indicators and physical parameters **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

1.0	INSTRUCTIONS FOR USE AND TRAINING IN REPROCESSING PRACTICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
1.8	Staff responsible for reprocessing of reusable medical devices has been trained in basic hand hygiene and know when to perform hand hygiene during reprocessing activities.		M	**Requirements:** Routine indications for hand hygiene during reprocessing activities include: • after handling dirty/contaminated instrument • after blood/bodily fluid exposure risk • before putting on personal protective equipment (PPE) (includes gloves, face protection, gown) • after taking off PPE • before handling clean or sterile instruments **Note:** If hands are visibly soiled (blood, bodily fluids), clean hands using liquid soap and running water. **Recommendation:** • Complete the provincial module on hand hygiene: https://learninghub.phsa.ca/Courses/5360/provincial-hand-hygiene-basics-picnet • Review Ministry of Health *Best Practices for Hand Hygiene* document: http://www.health.gov.bc.ca/library/publications/year/2012/best-practice-guidelines-handhygiene.pdf **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

2.0	POLICIES AND PROCEDURES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
2.1	Written procedures on all aspects of reprocessing medical devices are available for staff.		M	**Recommendations:** Written procedures should: • be specific to site/clinic office/facility • be reviewed and revised regularly and/or as new information becomes available • include step-by-step instructions for cleaning, rinsing, drying and packaging medical devices • include instructions on how to use the sterilizer • include how to perform sterilization monitoring • be based on the *BC Best Practices for Cleaning, Disinfection and Sterilization for Critical and Semi-Critical Medical Devices (2011)* **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

2.0	POLICIES AND PROCEDURES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
2.2	The clinical office has a written policy and procedure for the recall of improperly reprocessed equipment.		M	**Requirements:** A written policy exists outlining: • how to identify improperly reprocessed equipment • how to retrieve improperly reprocessed equipment • the reporting process to record which equipment was recalled; which equipment was not able to be recalled; who is responsible for initiating the recall and investigating the cause of the reprocessing/sterilization failure • the requirement that all recalled devices are repackaged and re-sterilized **Assessor comments:**	--	**Response:** **Date change in effect:**
2.3	There is a policy that requires scheduled preventative maintenance of sterilizer with written documentation that this has occurred.		M	**Requirement:** The sterilizer must be serviced regularly by a trained technician. • Sterilizers older than 10 years must be serviced annually • Many newer sterilizers require servicing after five to ten years of use—check sterilizer MIFUs for servicing requirements • Retain all records of servicing and maintenance **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

3.0	PHYSICAL SPACE FOR REPROCESSING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
3.1	Reprocessing takes place in a physical space solely dedicated for that purpose.		M	**Recommendation:** • There should be a centralized area for reprocessing; the area should be segregated away from patients and clean areas **Rationale:** • A centralized area allows for safe handling of used/dirty medical devices, standardizes processes and reduces possibility of cross contamination **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

3.0	PHYSICAL SPACE FOR REPROCESSING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
3.2	If reprocessing occurs in a dual-purpose space (e.g. exam room) patients are never present when the activities of reprocessing take place.		M	**Recommendations:** • A dual-purpose space may be used when patients are not present during reprocessing activities such as manual cleaning and rinsing as these reprocessing activities may generate risk of splash or spray in the environment. • Some detergent products such as enzymatic cleaners release fumes into the environment which can be harmful to staff and patients. • In addition, the work area (e.g. countertop, sink) in the dual-purpose space should be cleaned and disinfected prior to reprocessing activities being performed, and after, prior to the space being used again for patient care. This reduces the possibility of cross contamination between patient care and reprocessing activities. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

3.0	PHYSICAL SPACE FOR REPROCESSING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
3.3	Eating/drinking, storage of food, application of cosmetics or storage of personal effects does not occur in the reprocessing area.		M	**Requirements:** • Reprocessing does not take place in kitchen, food prep areas or in bathrooms • Food contributes to contamination; makeup and personal effects carry contamination and are sources of foreign matter for medical devices • The detergents used during reprocessing as well as contamination from used/dirty medical devices can contaminate food, food utensils, and food prep surfaces **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

3.0	PHYSICAL SPACE FOR REPROCESSING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
3.4	All reprocessing area surfaces, such as countertops, sinks, floors, can be cleaned and disinfected.		M	**Requirements:** • No carpeting on floors • Limit storage of supplies on open countertops • Countertops and floors are made of non-porous materials that can withstand regular cleaning and disinfection • Cleaning and disinfectant products must be appropriate for work surfaces • Use an appropriate disinfectant product (medical grade low-level disinfectant • Work surface must withstand medical -grade disinfectants used for environmental cleaning • Cleaner and disinfectant may be one combined product **Assessor comments:**	--	**Response:** **Date change in effect:**
3.5	There is sufficient non-porous counter space to handle the volume of work.		M	**Requirement:** • Countertop space must be large enough to allow for a space for receiving soiled devices and for a separate space for cleaned devices • If the space is insufficient counters which have received dirty/soiled devices much be cleaned and disinfected prior to placing clean devices on the counter **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

3.0	PHYSICAL SPACE FOR REPROCESSING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
3.6	There is a clear one-way workflow pattern moving from dirty to clean to prevent cross-contamination.		H	**Requirements:** One-way workflow patterns must be in place in the reprocessing area: • One-way workflow is the practice of ensuring that reprocessing work flows in one direction from the dirtiest to the cleanest to prevent recontamination • For example: Clean medical devices are never placed back onto a dirty/soiled surface or clean devices are not stored next to used/dirty devices awaiting reprocessing **Assessor comments:**	--	**Response:** **Date change in effect:**
3.7	There is a sink or designated container sufficient in size and depth for cleaning and rinsing medical devices in the reprocessing area.		M	**Recommendation:** • Sink or basin must be of a sufficient size to allow medical devices to be submerged in cleaning solutions **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

3.0	PHYSICAL SPACE FOR REPROCESSING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
3.8	Staff has a means to perform hand hygiene in the reprocessing area either using alcohol-based hand rub or running water and soap.		M	**Recommendations:** Best practices state that hand hygiene should not be performed in the reprocessing sink for several reasons: • the sink may be heavily contaminated as it is used for the cleaning of used/dirty medical devices • if there are used/dirty medical devices soaking in detergent solution in the sink, performing hand hygiene with soap and water may interfere with the efficacy of the cleaning process (diluting detergent solution, emollients in hand soap adhering to devices) To safely perform hand hygiene in the reprocessing area, there are two options: • Option 1: If the sink has two adjacent sinks, use one sink for hand hygiene and the other for cleaning/rinsing of medical devices • Option 2: If the clinical office has only a single-unit sink it should be dedicated for the cleaning/rinsing of reusable medical devices, and therefore use alcohol-based hand rub for hand hygiene, or clean and disinfect sink prior to and after using it for reprocessing **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

3.0	PHYSICAL SPACE FOR REPROCESSING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
3.9	There is a documented regular schedule for cleaning/disinfection of the reprocessing area(s).		M	**Requirements:** • Documentation should include date, and initials of staff **Assessor comments:**	--	**Response:** **Date change in effect:**
3.10	There are written instructions for the cleaning/disinfection of the reprocessing area(s).		M	**Requirements:** • Develop cleaning instructions for the reprocessing area for staff that include the type of cleaner/disinfectant to use and how often cleaning is done • Medical grade environmental cleaner and low-level disinfectant may be combined in one product • If cleaning services are outsourced, the clinical office should have a copy of the company's written procedures for environmental cleaning **Assessor comments:**	--	**Response:** **Date change in effect:**
3.11	There is a documented regular schedule for cleaning/disinfection of storage areas/ cupboards/drawers where sterilized packaged devices are kept.		M	**Requirements:** • Documentation should include date, and initials of staff **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

3.0	PHYSICAL SPACE FOR REPROCESSING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
3.12	There are written instructions for the cleaning/disinfection of the storage areas/ cupboards/drawers.		M	**Requirements:** • Develop cleaning instructions for storage areas for staff that include the type of cleaner/disinfectant to use and how often cleaning is done **Assessor comments:**	--	**Response:** **Date change in effect:**
3.13	All cleaning products/ detergents/ enzymatic cleaners are stored in a manner that ensures containers do not become damaged and chemicals can be safely accessed.		M	**Recommendations:** • Avoid storing detergents/enzymatic cleaners on countertops where they could be accessed by the public or splash onto other items on the counter • Avoid storing heavy bottles/containers of any chemical products on upper shelves/cabinets due to risk of physical harm to staff handling them **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

4.0	SINGLE-USE DISPOSABLE MEDICAL DEVICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
4.1	Single-use disposable medical devices are not reused or reprocessed.		M	**Requirements:** • Single-use disposable medical devices must be discarded after use and must be dedicated to only one patient • Single-use devices have indications on packaging or on the device itself that they are single use: and/or or "Do Not Reuse/Reprocess" • Some packages of disposable devices will have the words "Single Use Disposable" written on them **Note**: Common examples of single-use disposable devices that are inappropriately reprocessed include skin staple removers (both plastic and metal) and respiratory devices such as aerochambers and humidifying masks. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

5.0	PRE-CLEANING AT POINT OF USE					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
5.1	Prior to pre-cleaning, medical devices are sorted and disassembled.		H	**Requirement:** Sorting and disassembly includes: • removing and discarding any scalpel blades and needles • opening and/or disassembling medical devices (e.g. scissors and Kelly forceps, vaginal speculum) in preparation for pre-cleaning to minimize risk of injury and for all surfaces of device to have contact with detergent solution **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

5.0	PRE-CLEANING AT POINT OF USE					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
5.2	At point of use, pre-cleaning of used/dirty medical devices is performed to remove gross soil/organic matter immediately.		H	**Requirement:** Used/dirty medical devices must be cleaned immediately after use to prevent hardening of protein soil/organic matter • Detergent or enzymatic solution may be used for pre-cleaning or • Devices may be wiped with a water moistened cloth or gauze • If decontamination/cleaning begins immediately after the patient procedure pre-cleaning may not be necessary; it is always advisable to remove any gross soil prior to decontamination/cleaning **Recommendation:** • Protein soil can harbor and protect microorganisms from further reprocessing steps such as sterilization • Placing used/dirty devices directly into a decontamination cleaning solution can cause a buildup of soil and microorganisms and reduce the effectiveness of the cleaning solution **Note:** Alcohol wipes are not appropriate for pre-cleaning as the alcohol will adhere the protein soil to the device and make it difficult to remove. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

5.0	PRE-CLEANING AT POINT OF USE					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
5.3	Any pre-cleaning solutions used (e.g. detergent solution in soak basin/sink) are discarded and not reused for the cleaning step.		H	**Requirements:** • Pre-cleaning solutions are never reused for the cleaning/decontamination step • Soiled cloths are never placed back into a container of detergent solution used for pre-cleaning ("double dipping") **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

6.0	TRANSPORT OF MEDICAL DEVICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
6.1	Soiled/used medical devices are handled and transported in a manner which reduces the risk of exposure and/or injury to personnel and patients, or contamination of environmental surfaces.		M	**Recommendation:** • Used devices which are transported to another area for reprocessing should be confined and contained in a leak-proof container with a lid • Used devices reprocessed in a dual-purpose space, such as a patient exam room, must be handled in a manner that follows one-way workflow principles in order to minimize environmental contamination • For situations where reprocessing will occur later due to timing (e.g. reprocessing will occur at end of the work day or reprocessing space is dual purpose), the dirty/used devices must be treated with detergent/enzymatic pre-soak solution to prevent organic matter from hardening **Note:** Soiled/used devices which will be transported off site for reprocessing must be contained in a sealed plastic bag; placed in a leak-proof container with a lid; labeled *soiled/biohazard*; and transported in a timely manner to the reprocessing site. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

6.0	TRANSPORT OF MEDICAL DEVICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
6.2	Sterilized medical devices which have been reprocessed off-site are protected during transportation back to the facility.		H	**Requirements:** • Sterilized medical devices must be sealed in a clean plastic bag (preferably double bagged), placed in a secure container with a lid, and transported in a timely manner to the originating site **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

7.0	CLEANING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
7.1	Detergents/enzymatic cleaners used are medical grade products.		H	**Requirements:** • For the cleaning step, product selection must be either a medical grade detergent or enzymatic cleaner. Detergents: Must be medical-grade with label claims that it is intended for the cleaning of medical devices/instruments. Enzymatic cleaners: Detergent with enzymatic properties to break down organic matter with label claims that it is intended for the cleaning of medical devices/instruments. **Recommendation:** It is important to read label claims to ensure the right product is being used for the intended purpose. **Note:** • Cleaner/disinfectant products intended for use as surface cleaners for counters, sinks, beds, etc. are not acceptable products for cleaning medical devices • Household cleaners/disinfectants are not acceptable for cleaning of medical devices **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

7.0	CLEANING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
7.2	Detergents/enzymatic cleaners are prepared and used according to manufacturer's instructions for use (MIFU).		H	**Requirements:** • All detergents/ enzymatic cleaners are prepared and used according to MIFU for dilution, temperature, water, use, shelf-life and storage conditions • Staff instructions/procedures include a statement on the correct dilution of cleaning products **Assessor comments:**	--	**Response:** **Date change in effect:**
7.3	During cleaning medical devices are fully immersed in prepared detergent/enzymatic cleaner.		M	**Recommendation:** Medical devices are fully immersed in detergent/enzymatic solutions unless otherwise indicated by the MIFU for the device. **Assessor comments:**	--	**Response:** **Date change in effect:**
7.4	Medical devices/ instruments are scrubbed with a cleaning brush/tool to remove any organic matter.		H	**Recommendation:** • Sponges with abrasive pads can leave grit and fibres on medical devices and should not be used **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

7.0	CLEANING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
7.5	Medical devices with lumens are flushed with detergent/ enzymatic cleaner and brushed with an appropriate-sized brush during cleaning.		H	**Requirements:** Devices with lumens must be: • cleaned according to the MIFU • manually flushed with detergent solution and brushed with appropriate size brush that can enter the lumen • post-cleaning, inspected to ensure lumens are clean and unobstructed **Assessor comments:**	--	**Response:** **Date change in effect:**
7.6	Cleaning tools (e.g. brushes) used to manually clean medical devices are either disposable or sterilized at the end of the day.		H	**Requirements:** • Check MIFU to confirm whether the cleaning tools can be sterilized, otherwise they must be disposed of at the end of the day they are used **Recommendations:** • Single-use cleaning tools are recommended • If reusable cleaning tools are used (only as validated by manufacturer as reusable), they should be cleaned and sterilized at least at the end of the day • Never leave any cleaning brushes sitting in detergent solution or on the side of the sink for prolonged periods of time; this can lead to microorganism growth on the cleaning tools **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

7.0	CLEANING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
7.7	Detergent/enzymatic cleaner is discarded at least daily or when visibly soiled.		M	**Recommendation:** • Follow MIFU for detergent/enzymatic cleaner • Reusing the same prepared solution of detergent/enzymatic cleaner increases the likelihood of microorganism growth **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

7.0	CLEANING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
7.8	Medical devices are immersed/soaked in detergent/enzymatic cleaner as indicated by the MIFU label.		M	**Recommendation:** Consult detergent/enzymatic cleaner instructions for use to determine minimum soaking time. Avoid prolonged (overnight) soaking of medical devices in cleaning solution as it promotes potential growth of microorganisms, biofilm, damage to instruments, and rust. If sterilization is not possible before the end of day, there are two options for managing the unsterilized devices: • Option 1: The preferred option is to clean, rinse, manually dry the devices with cloth/paper towel, and package them (with internal chemical indicator) until next day. • Option 2: At a minimum, clean, rinse and leave devices to air dry until the next day. Devices should be air dried in a low traffic area and away from sinks to minimize the risk of splash or spray. Devices should be covered with a dry towel to protect them while they are drying. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

8.0	RINSING AND DRYING AFTER CLEANING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
8.1	Following cleaning, all medical devices must be rinsed with water.		H	**Requirement:** • The MIFU of the medical device must be followed for type of water to use for rinsing **Recommendations:** • Two adjacent sinks, one for cleaning and the other for rinsing. If the sink is a single sink, options are to clean and disinfect the sink before the rinsing step or use a separate basin for the rinsing step • Rinsing can be achieved under running water or submerged in rinse water in sink or a basin in the sink **Assessor comments:**	--	**Response:** **Date change in effect:**
8.2	Any medical device with lumens must be flushed with water following cleaning.		H	**Recommendation:** • A disposable syringe may be used to flush lumens, however ensure that the syringe is discarded each day **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

8.0	RINSING AND DRYING AFTER CLEANING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
8.3	Following rinsing, the device is thoroughly dried with a cloth or air-dried in preparation for packaging and sterilization.		H	**Recommendations:** In preparation for packaging and sterilization devices must be dry. • Packaging wet devices will compromise the packaging material and can result in wet loads in the sterilizer • Air drying medical devices is acceptable, as long as items are placed on a clean surface and protected from contamination (see 7.8) **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

9.0	PACKAGING AND LABELING PRE-STERILIZATION					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
9.1	Only packaging materials specifically designed for sterilization is used.		H	**Requirements:** Packaging/wrapping material for steam sterilization: • must be medical grade and validated for steam sterilization • permit drying of the package and contents at the end of the sterilization cycle • prevent the entry of microbes, dust and moisture during storage and handling post sterilization • have a proven and tamper-proof seal • withstand normal handling and resist tearing or puncturing and allow for aseptic presentation **Recommendation:** Appropriate packaging/wrapping include: • Disposable non-woven wrappers (pack wrap) made from medical-grade paper or polypropylene ○ consult MIFU for disposable wrappers to determine how many wrappers are needed for each package to protect sterile content; some types of pack wrap require the use of two sheets for each package • Medical-grade paper/plastic pouches (self-sealing easiest option) **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

9.0	PACKAGING AND LABELING PRE-STERILIZATION					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**

9.2	An external chemical (CI) indicator is applied or embedded on the outside of the pouch/package.		H	**Requirement:**
				• External CI must be used for each pouch/packaged medical device to be sterilized
				• Check the expiry date on autoclave tape—often located on the inside of the roll
				• Examples of external CI:
				  ○ autoclave tape applied to outside of package
				  ○ peel back/pouch style packaging has built in external CI located on the edges of the packaging
				• Color change = items have been exposed to steam
				• No color change = items have **not** been exposed to steam
				
				Note: An external CI does not replace the need for an internal CI nor a biological indicator.
				
				Assessor comments:
					--	**Response:**
						
						Date change in effect:

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

9.0	PACKAGING AND LABELING PRE-STERILIZATION					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**

9.3	An internal chemical indicator (CI) is placed in each pouch/pack-wrapped device to be sterilized (unless already part of the pouch/pack wrap).		H	**Requirement:**
				• Internal CI must be used for each pouch/packaged medical device to be sterilized
				  ○ Color change = successful steam penetration to inside of package
				  ○ No color = unsuccessful steam penetration to inside of package
				
				Note: An internal CI **does not** replace the need to use an external CI, nor a biological indicator.
				
				All peel-back style packaging and pouches contain a built-in external CI. Some forms of this packaging have an internal CI built into the material as well. MIFU for these packages will clearly state that they contain both internal and external indicators. Ensure that all instructions for use are reviewed to determine if packaging includes both types of indicators (external and internal).
				
				Assessor comments:
					--	**Response:**
						
						Date change in effect:

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

9.0	PACKAGING AND LABELING PRE-STERILIZATION					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
9.4	All reusable **critical** medical devices are packaged prior to sterilization in steam.		H	**Requirement:** • Packaging all critical medical devices prior to sterilization is required in order to keep devices sterile until point of use • Packaging along with the use of quality assurance testing (chemical and biological indicators and monitoring physical parameters) fulfills the requirements for sterilization monitoring and quality assurance **Assessor comments:**	--	**Response:** **Date change in effect:**
9.5	All reusable **semi-critical** medical devices are packaged prior to sterilization in steam.		H	**Requirements:** • All reusable semi-critical devices must be packaged in medical grade packaging prior to sterilization • Packaging ensures that devices are intact and uncontaminated until point of use • Packaging along with the use of quality assurance testing (chemical and biological indicators and monitoring physical parameters) fulfills the requirements for sterilization monitoring and quality assurance **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

9.0	PACKAGING AND LABELING PRE-STERILIZATION					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
9.6	Medical devices are placed in the package in an open position.		M	**Recommendation:** • Jaws of instruments must be open to allow exposure to steam • Scissors should be opened to expose at least half of the length of the blade **Assessor comments:**	--	**Response:** **Date change in effect:**
9.7	Medical devices are placed in the package in the unlocked position.		M	**Recommendation** • Devices that have ratchets or locking handles must be packaged with the ratchets and handles in the unlocked position **Assessor comments:**	--	**Response:** **Date change in effect:**
9.8	Medical devices are packaged disassembled if indicated in MIFU.		H	**Recommendation** • Review MIFU for any instructions for disassembling devices. Examples of devices that may require disassembly include reusable metal ear syringes, and vaginal speculum **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

9.0	PACKAGING AND LABELING PRE-STERILIZATION					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
9.9	Medical devices are distributed evenly in packages.		H	**Recommendations** Avoid placing too many medical devices in one package as it: • minimizes effectiveness of steam sterilization process • may result in wet packages at the end of a sterilization cycle **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

9.0	PACKAGING AND LABELING PRE-STERILIZATION					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
9.10	All medical device packages are labelled with: • date of sterilization • initials of the person who packaged the device • name of the device or set if device is not visible through packaging • if more than one load is performed a day: load number • If more than one sterilizer is in use: sterilizer number		H	**Requirements:** • Appropriately labelling the package that contains medical devices fulfills the quality assurance and load monitoring requirements based on national and provincial medical device reprocessing best practice standards and guidelines **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

10.0	LOADING THE STERILIZER					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
10.1	Packaged devices are loaded in the steam sterilizer in a manner that ensures steam contact and penetration.		H	**Requirement:** Load packages correctly to prevent water from collecting in the packages Consult MIFU for the sterilizer for loading requirements. 1. Paper/plastic pouches: multiple packages are placed side by side, paper to plastic 2. Packages should **not** be stacked 3. Packages should be placed away from chamber walls 4. Avoid overloading the sterilizer **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

11.0	STEAM STERILIZATION PROCESS					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
11.1	The clinic uses an appropriate and Canada-licensed tabletop steam sterilizer.		H	**Requirements:** The only approved method of sterilization in the community-based office is steam sterilization for heat-resistant reusable medical devices. The following requirements must be met: 1. The sterilizer must be approved and licensed as a class 2 medical device by Health Canada. 2. The sterilizer must have a Canadian Standard Association (CSA) electrical safety inspection sticker (look for CSA or a UL sticker on sterilizer). 3. The sterilizer must be able to sterilize **packaged** devices as stated in the manufacturer instructions for use (MIFU). Non-acceptable methods of sterilization include: • boiling • dishwasher • glass bead sterilization • chemiclave (formaldehyde vapour) • microwave oven • ultraviolet radiation • dry heat sterilizer • pressure cooker style sterilizer To verify licensing status of your steam sterilizer, see the Medical Devices Active Licence Listing. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

11.0	STEAM STERILIZATION PROCESS					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
11.2	Appropriate sterilization cycle is selected for the medical devices being sterilized based on MIFU.		M	**Requirements:** • Newer tabletop sterilizers may have different cycles—follow MIFU for correct cycle selection for wrapped and packaged medical devices • Older sterilizers require that the operator set the time and temperature—follow sterilizer MIFU for correct settings • Generally cycle selection depends on the MIFU for the sterilizer and the medical device being sterilized (for example some packaged/wrapped medical devices require longer cycle times) **Assessor comments:**	--	**Response:** **Date change in effect:**
11.3	Flash or immediate-use steam sterilization of unwrapped medical devices is not performed.		H	**Requirements:** • As per standard items 9.4 and 9.5 all reusable critical and semi critical medical devices are packaged prior to sterilization in steam • Flash cycle/just-in-time sterilization is **not** acceptable due to the increased risk of contamination following the sterilization cycle **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

12.0	BIOLOGICAL MONITORING OF THE STERILIZER					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
12.1	A biological indicator (BI) test is performed at least once each day the sterilizer is used.		H	**Requirements:** • A BI test must be performed each day the sterilizer is used, typically on the first load of the day. • The BI test must be placed in packaging along with an internal chemical indicator (CI). The packaging and the internal CI must be the same ones used to package reusable medical devices for steam sterilization, for example peel-back packages. • Always place the package containing the BI test and the internal CI in an area of the sterilizer **determined by the manufacturer** to be the most challenging location for sterilization, for example, at the front, on the bottom shelf of the sterilizer. Consult sterilizer manufacturer instructions for use (MIFU). **Note:** Packaging and then placing the BI test vial in the most difficult area of the sterilizer during sterilization provides a challenge for the sterilizer. If the BI test vial is properly sterilized even in this "challenge test pack," it indicates that the other packages in the load have been successfully sterilized. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

12.0	BIOLOGICAL MONITORING OF THE STERILIZER					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
12.2	When the sterilization load is complete, the BI test is immediately incubated in the BI incubator.		H	**Requirement:** • The MIFU for the BI test must be reviewed and followed • Different brands and models for BI tests will have specific minimum incubation times (varies from 10 to 48 hours) • The specific incubation time must be followed for the model/brand of BI test used **Assessor comments:**	--	**Response:** **Date change in effect:**

12.3	For each day that a BI test is performed, a control BI test is performed at the same time.		H	**Requirements:**
				• The control BI test vial is not placed in the sterilizer; however, it is incubated at the same time as the BI test vial that was sterilized
				• The purpose of the control BI test is to:
				  ○ demonstrate spore viability
				  ○ demonstrate the capability of the media to promote growth
				  ○ confirm that the incubator is functioning properly
				• Review BI MIFU for the appropriate use of a positive control BI test
				
				Assessor comments:
					--	**Response:**
						
						Date change in effect:

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

12.0	BIOLOGICAL MONITORING OF THE STERILIZER					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
12.4	BI control and the tested BI should have the same lot number.		H	**Requirement:** • The sterilized BI test vial and the unsterile control BI test vial must come from the same lot and the same box so that spore viability of the test can be confirmed **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

12.0	BIOLOGICAL MONITORING OF THE STERILIZER					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
12.5	All sterilized devices are not released for use until the final BI test result is available and confirmed to be negative for growth.		M	**Requirement:** Confirmation of a negative BI test prior to release of sterilized devices ensures that unsterile devices are not used on patients. **Note:** The use of a class (type) 5 internal chemical indicator (also known as an integrator) may be used in order to release sterilized loads prior to the full incubation of a BI test. Based on national standards (Canadian Standards Association) with the use of a class 5 indicator, the following requirements must be adhered to: 1. A class 5 integrating indicator is used inside each package containing medical devices 2. A full and complete sterilization record is kept for each load in the sterilizer 3. A BI test is run each day the sterilizer is used, the test is always fully incubated for the required time and a full record of these tests is kept 4. All packaged medical devices are clearly labeled with the date of sterilization, and the sterilizer identification and load number; this is important if more than one sterilizer is in use and/or if more than one load is run in a day **The use of a class (type) 5 indicator does not remove the need for BI testing.** **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

12.0	BIOLOGICAL MONITORING OF THE STERILIZER					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
12.6	Final readouts of the BI (both test and control) is reviewed by staff and documented.		H	**Requirement:** Reviewing of the BI test and control test results must be reviewed by trained staff and documented. • **Purple** indicates a **successful** sterilized BI test vial • **Yellow** indicates an **unsuccessful** BI test vial which means there is growth of microorganisms • The control BI test **always remains yellow** as it did not undergo sterilization in the sterilizer **Assessor comments:**	--	**Response:** **Date change in effect:**
12.7	If a BI test indicates spore growth (positive/yellow result), all medical devices sterilized since the last negative BI test are quarantined and not used.		H	**Requirement:** • Following sterilization, a positive/yellow BI test indicates a failure in the sterilization process. • Due to this failed result, all devices that were sterilized since the last negative/purple BI test must be recalled and not used. Once the sterilizer has been investigated and the issue corrected all the recalled devices **must** be re-sterilized before use. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

13.0	CHEMICAL MONITORING OF THE STERILIZER					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
Internal Chemical Indicators						
13.1	At completion of sterilization cycle the **internal chemical indicator** (CI) in each package is inspected and the result is documented.		H	**Requirement:** • **Internal** CI must be reviewed, if visible, and documented on load records for each package at end of cycle when packages are being removed from the sterilizer • For wrapped packages where CIs are not visible, the CI is reviewed upon opening the package at point of use **Assessor comments:**	--	**Response:** **Date change in effect:**
13.2	If a failed **internal CI** is found, the contents of the package are not used.		H	**Assessor comments:**	--	**Response:** **Date change in effect:**
External Chemical Indicators						
13.3	At completion of the sterilization cycle, the **external chemical indicator** (CI) for each package is inspected and the result is documented on the load record.		H	**Requirement:** • **External** CI must be reviewed and documented for each package at the end of the sterilization cycle when packages are being removed from the sterilizer **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

13.0	CHEMICAL MONITORING OF THE STERILIZER					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
13.4	If a failed **external CI** is found, the contents of the package are not used.		H	**Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

14.0	PHYSICAL MONITORING OF THE STERILIZER					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
14.1	Physical parameters (time, temperature and pressure) of each cycle are monitored.		H	**Requirement:** • Documenting the physical parameters is required • Some sterilizers provide a printout of the physical parameters that can be reviewed, initialed and saved as part of the record keeping; most sterilizers do not have a printout capability, therefore the physical parameters must be observed and documented manually in sterilization log sheet **Physical parameters** **Time**: The length of time of the **sterilization portion of a cycle**, not the full cycle from start to finish. Refer to the sterilizer MIFU to select appropriate sterilization time for packaged medical devices. **Temperature**: The minimum temperature required to achieve sterilization. **Pressure (if available)**: The pressure reading of the sterilizer. Note that not all sterilizers without printers will provide a pressure reading. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

15.0	RECORD KEEPING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
15.1	A written log of sterilizer test and monitoring results are maintained.		M	**Requirement:** Information must be documented in the sterilization records on: • internal and external chemical indicator results • biological indicator and biological control results • physical parameters – if your sterilizer produces a printout you may attach the printout directly onto the sterilization log sheet **Assessor comments:**	--	**Response:** **Date change in effect:**
15.2	A written log of all sterilizer cycles (loads) and their contents is maintained.		M	**Requirement:** • Sterilizer records allow the clinic/facility to identify and retrieve any packages that may need to be reprocessed due to suspected sterilization failure • Test results log and the sterilizer load record may be combined into one document **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

15.0	RECORD KEEPING					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
15.3	A written log of all preventative maintenance of the sterilizer is maintained including regular cleaning schedule.		M	**Requirement:** • Review the MIFU for the sterilizer for information on maintenance and cleaning requirements • Perform and document any maintenance and cleaning as required by the manufacturer **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

16.0	UNLOADING THE STERILIZER					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
16.1	Following completion of cycle, as each package is removed from the sterilizer it is verified for absence of moisture and integrity of packaging.		H	**Requirements:** Do not unload sterilized packages until they are cooled to room temperature. Handling hot packages can compromise the integrity of the packaging which compromises the sterility of the medical device. In addition: • ensure packages are intact when being removed from sterilizer • packages cannot be wet; there should be no visible signs of moisture; newer sterilizers have a drying phase programmed into their cycle; if the sterilizer does not have a drying phase consult the sterilizer user manual or MIFU for information on drying • place unloaded packages on a clean surface **Note:** Packages must always be handled with clean hands—gloves are not required during this step. **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

17.0	UNSUCCESSFUL OUTCOMES/ STERILIZATION FAILURE					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
17.1	All sterilization monitoring indicator failures are investigated.		H	**Requirements:** Examples of reprocessing adverse events and sterilization failure include (but are not limited to): • incorrect reprocessing method used • reprocessing parameters not met • positive/failed biological indicator • failed internal or external chemical indicator • release of a non-sterile medical device(s) • wet sterilization load(s) • medical device alert (the clinical office must have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies In the event of an adverse event, the clinical office must: 1. report to medical director or delegate 2. record follow-up actions 3. re-package 4. re-sterilize **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

18.0	STORAGE OF STERILIZED MEDICAL DEVICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
18.1	Devices that underwent sterilization are stored in their sterile packaging until time of use.		M	**Recommendations:** Maintaining a device in packaging: • protects devices from contamination • allows the user to read external and internal indicators and confirm sterility of the device prior to use • allows the device to be located in the event of a recall due to sterilization failure; label on packaging has date and load number to facilitate recall **Assessor comments:**	--	**Response:** **Date change in effect:**
18.2	Packaged sterilized devices are stored securely in a manner that keeps them clean, dry and prevents contamination.		M	**Requirements:** Storage requirements for sterilized packaged devices: • store in an area that is clean and dry (the garbage or dirty utility room is **not** acceptable) • store in enclosed space (cupboards and drawers) to reduce dust and debris exposure; if necessary a clean bin with a lid may be used to store sterile packages • do not store near sinks or water source due to risk of splash or spray • do not store under sink or in office, lab, or high traffic areas **Assessor comments:**	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

18.0	STORAGE OF STERILIZED MEDICAL DEVICES					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
18.3	Packaged sterilized devices are not stored in corrugated cardboard boxes.		M	**Requirement:** Corrugated cardboard can harbor microorganisms, dust and mold. It cannot be cleaned appropriately. **Assessor comments:**	--	**Response:** **Date change in effect:**

19.0	PERSONAL PROTECTIVE EQUIPMENT					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
19.1	PPE (personal protective equipment) appropriate to the task is available and applied as required.	LR	H	**General requirements:** PPE must be worn when handling/transporting used/dirty medical devices, and when cleaning and/or rinsing medical devices. • All PPE should be immediately available in the area in which it will be used (e.g. gloves in exam room to handle dirty/contaminated devices after use) • PPE should be removed as soon as the task is complete **PPE for medical device reprocessing includes**: Gloves • Chemical and fluid resistant gloves, such as nitrile gloves, must be used during reprocessing activities • Vinyl (sandwich) gloves are not acceptable for reprocessing activities as they do not provide adequate protection • Gloves should be disposable and not reused once they are removed	--	**Response:** **Date change in effect:**

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

19.0	PERSONAL PROTECTIVE EQUIPMENT					
	Standard	**LR**	**Risk**	**Requirements and/or recommendations**	**Compliant**	**Registrant response to correct deficiency**
				Facial protection • Facial protection protects face and mucous membranes from splash or spray of fluids during reprocessing activities such as cleaning, disinfection, and rinsing • Facial protection includes fluid-resistant mask with goggles or face shield Gown • Fluid-resistant gown – protects from splash or spray of fluids during reprocessing activities such as during cleaning, and rinsing) • Gowns should be fluid-resistant, long sleeved, and cover neck to mid-thigh **Note:** Ensure hand hygiene has been performed prior to packaging clean medical devices or when removing sterilized items from the sterilizer. PPE is not required for these activities. **Assessor comments:**		

Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

GENERAL COMMENTS

REGISTRANT SIGN-OFF

Name: _____ Signature: _____ Date: _____

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Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization *continued*

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