Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization

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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	--	
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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:

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2.0	POLICIES AND PROCEDURES					
	Standard	LR	Risk	Requirements and/or recommendations	Compliant	Registrant response to correct deficiency
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2.0 POLICIES AND PROCEDURES

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Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization continued

3.0	PHYSICAL SPACE FOR REPROCESSING

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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

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			

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Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization continued

7.0	CLEANING	
	Standard	Page

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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: Requirement 380.996380.47(f)3337.73 465.94 Td [(m)3.996 (u)-3.996 (s)-6.004 (t)-3.996 (b) Internal CI must be used for each pouch/packaged medical device to be sterilized o	--	

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9.0	[redacted]GING 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 requireme(m)-5(p)(t)-4(h)-4(e)4(r)-2(5	--	
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Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization continued

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9.0	PACKAGING AND LABELING PRE-STERILIZATION

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Physician Office Medical Device Reprocessing Assessment Tool for Steam Sterilization continued

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14.0	PHYSICAL MONITORING OF THE STERILIZER			
	Standard	LR	Risk	
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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:

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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:

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response to correct

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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

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19.0	PERSONAL PROTECTIVE EQUIPMENT		
	Standard	LR	Risk

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GENERAL COMMENTS

REGISTRANT SIGN-OFF

Name: _____ Signature: _____ Date: _____

References

1. British Columbia Ministry of Health. Best practice guidelines for cleaning, disinfection and sterilization of critical and se

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The information in this form is collected under the authority of section 26.1 of the Health Professions Act, RSBC 1996, c.183 (the Act) and Part 9 of the Bylaws and will be