INFECTION PREVENTION AND CONTROL AUDIT for Medical Device Reprocessing in Ambulatory Clinic or Physician's Office

Name of Facility:

Location: _____ Date: YYYY_____ MM_____ DD_____

Time: _____hours / ____AM ____PM Manager: _____

Auditor (print): _____ Signature: _____

NOTE: This audit tool does not include audit elements related to general infection prevention and control practices in clinics or physician offices, or dental offices. Refer to the '*General IP&C Practices in Ambulatory Clinic or Physician's Office*' and Dentistry audit tools for these items. Refer to '*Endoscopy*' audit tool for reprocessing endoscopes.

Abbreviations:

ABHR	Alcohol-Based Hand Rub
BI	Biological Indicator
CI	Chemical Indicator
CSA	Canadian Standards Association
DIN	Drug Identification Number
HLD	High-Level Disinfection
IP&C	Infection Prevention and Control
MSDS	Materials Safety Data Sheet
N/A	Not Applicable
PCD	Process Challenge Device
PPE	Personal Protective Equipment
RP	Routine Practices
WHMIS	Workplace Hazardous Materials Information System

Revised March 19, 2015

Glossary:

Alcohol-Based Hand Rub (ABHR): A liquid, gel or foam formulation of alcohol (e.g. ethanol, isopropanol) which is used to reduce the number of microorganisms on hands in clinical situations when the hands are not visibly soiled. ABHRs contain emollients to reduce skin irritation and are less time-consuming to use than washing with soap and water.

Bioburden: The number and types of viable microorganisms that contaminate a medical device.

Biological Indicator (BI): A sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to have a high resistance to the mode of sterilization being monitored.

Certification in Reprocessing: Completion of a recognized certification course in reprocessing practices administered by an accredited body, such as the Canadian Standards Association (CSA).

Chemical Indicator (CI): A sterilization monitoring assistive device used to monitor certain parameters of a sterilization process by means of a characteristic color change (e.g. chemically treated paper, pellet sealed in a glass tube, pressure-sensitive tape). A CI does not verify sterility, but does allow the detection of potential sterilization failures due to factors such as incorrect packaging, incorrect loading of the sterilizer, or equipment malfunction.

Chemiclave: A machine that sterilizes medical devices with high-pressure, high-temperature water vapour, alcohol vapour and formaldehyde vapour (occasionally used in offices).

Cleaning: Physical removal of foreign (e.g., dust, soil) and organic (e.g., blood, secretions, excretions, microorganisms) materials. Cleaning physically removes rather than kills microorganisms. It is accomplished with water, detergents and mechanical action.

Cold Chain: The process used to maintain optimal conditions during the transport, storage and handling of vaccines.

Critical Medical Devices: Medical equipment/devices that enter sterile tissues, including the vascular system (e.g. biopsy forceps, foot care equipment, dental hand pieces, etc.). Critical medical devices present a high risk of infection if the device is contaminated with any microorganisms, including bacterial spores. Reprocessing critical devices involves meticulous cleaning followed by sterilization.

Dedicated Hand Washing Sink: A sink for cleaning soiled hands that is not used for any other purpose (e.g., cleaning of equipment, emptying of solutions).

Detergent: A synthetic cleansing agent that can emulsify oil and suspend soil. A detergent contains surfactants that do not precipitate in hard water and may also contain protease enzymes (see *Enzymatic Cleaner*) and whitening agents.

Disinfectant: A product that is used on medical devices or environmental surfaces which results in disinfection of the device/surface. Disinfectants are applied only to inanimate objects. Some products combine a cleaner with a disinfectant.

Drug Identification Number (DIN): In Canada, disinfectants are regulated as drugs under the Food and Drugs Act and Regulations. Disinfectant manufacturers must obtain a drug identification number (DIN) from Health Canada prior to marketing, which ensures that labelling and supporting data have been provided and that the product has undergone and passed a review of its formulation, labelling and instructions for use.

Enzymatic Cleaner: A pre-cleaning agent that contains protease enzymes that break down proteins such as blood, body fluids, secretions and excretions from surfaces and medical devices. Most enzymatic cleaners also contain detergents. Enzymatic cleaners are used to loosen and dissolve organic substances prior to reprocessing.

FDA-Approved 3rd Party Reprocessor: An establishment (outside of a health care facility) that reprocesses single-use medical devices according to guidelines established by the U.S. Food and Drug Administration. There are currently no approved 3rd party reprocessors in Canada.

Foil Test: A simple test for ultrasonic cleaner efficacy, involving running the equipment while holding a piece of aluminum foil in the tank for up to 15 seconds. If foil surfaces are uniformly perforated, cleaning is effective.

Hand Hygiene: A general term referring to any action of hand cleaning. Hand hygiene relates to the removal of visible soil and removal or killing of transient microorganisms from the hands. Hand hygiene may be accomplished using soap and running water or an alcohol-based hand rub. Hand hygiene includes surgical hand antisepsis.

Hand Washing: The physical removal of microorganisms from the hands using soap (plain or antimicrobial) and running water.

High-Level Disinfectant: A chemical product that is used to achieve high-level disinfection.

High-Level Disinfection (HLD): The level of disinfection required when processing semicritical medical devices. High-level disinfection processes destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores. Devices must be thoroughly cleaned prior to high-level disinfection.

Indicator: A chemical which reveals a change in one or more of the sterilization process parameters. Indicators do not verify sterility, but they do allow the detection of potential sterilization failures due to factors such as incorrect packaging, incorrect loading of the sterilizer, or equipment malfunction.

Manufacturer's Instructions: The written directions provided by the manufacturer or distributor of a product that contain the necessary information for the safe and effective use of the product.

Packaging: A step in the sterilization process in which a medical device is enclosed in materials or a container designed to allow the penetration and removal of the sterilant during sterilization and protect the device from contamination and other damage following sterilization and during storage.

Personal Protective Equipment (PPE): Clothing or equipment worn by staff for protection against hazards.

Process Challenge Device (PCD): A test device intended to provide a challenge to the sterilization process that is equal to, or greater than, the challenge posed by the most difficult item routinely processed.

Qualification in Reprocessing: At minimum, a certificate indicating successful completion of a recognized training course in reprocessing.

Quality Monitoring: A system to provide assurance that sterilization practices are providing the highest possible degree of safety. A quality system includes written policies and procedures that are regularly reviewed, updated and monitored; identifies staff responsibility, qualifications and ongoing competence; and includes processes to measure and monitor installation, operational and performance qualifications, including routine daily monitoring and documentation.

Reprocessing: The steps performed to prepare used medical equipment/devices for use (e.g., cleaning, disinfection and sterilization).

Routine Practices (RP): The system of infection prevention and control practices recommended by the Public Health Agency of Canada to be used with all clients/patients/residents during all care to prevent and control transmission of microorganisms in all health care settings.

Semi-Critical Medical Device: Medical device that comes in contact with nonintact skin or mucous membranes but ordinarily does not penetrate them (e.g., respiratory therapy equipment, transrectal probes, specula). Reprocessing semi-critical devices involves meticulous cleaning followed by, at a minimum, high-level disinfection.

Single-Use/Disposable: Medical device designated by the manufacturer for single-use only. Single-use devices must not be reprocessed except by an approved and FDA cleared 3rd party reprocessor.

Sterilant: A chemical product that is used to achieve sterilization.

Sterilization: The level of reprocessing required when processing critical medical devices. Sterilization results in the destruction of all forms of microbial life including bacteria, viruses, spores and fungi. Devices must be cleaned thoroughly before effective sterilization can take place.

Topping-up: Refilling a partially filled container with fresh solution.

Ultrasonic Washer: A machine that cleans medical devices by the cavitations produced by ultrasound waves.

Washer-Disinfector: A machine that removes soil and cleans medical devices prior to high-level disinfection or sterilization.

Washer-Sterilizer: A machine that washes and sterilizes medical devices. Saturated steam under pressure is the sterilizing agent. If used as a sterilizer, quality processes must be observed as with all sterilization procedures (e.g., use of chemical and biologic monitors, record-keeping, wrapping, drying, etc.).

Workplace Hazardous Materials Information System (WHMIS): The Workplace Hazardous Materials Information System (WHMIS) is Canada's national hazard communication standard. The key elements of the system are cautionary labelling of containers of WHMIS 'controlled products', the provision of Material Safety Data Sheets (MSDSs) and staff education and training programs.

Medical Device Reprocessing

Reprocessing Methods (✓ check all methods used)				
Cleaning	☐	Manual Cleaning		
	☐	Automated washer/ disinfector	Name:	Model:
	☐	Ultrasonic washer	Name:	Model:
Sterilization	☐	Liquid chemical	Sterilant Name: DIN #: Yes ☐ No ☐	Active Ingredient:
	☐	Steam	Name:	Model:
	☐	Other	Name:	Model:
Chemical High-level Disinfection (HLD)	☐	Manual Disinfection	Product Name: DIN #: Yes ☐ No ☐	Active Ingredient:
	☐	Automated Disinfection	Product Name: DIN #: Yes ☐ No ☐	Active Ingredient:
Thermal High-level Disinfection	☐	Automated Disinfection	Pasteurizer:	Model:
			Washer-disinfector with validated semi-critical cycle:	Model:
			Other automated method:	Model:

Reprocessing Staff (✓ indicate all persons involved in reprocessing)

Performed by:	☐	Medical Assistant	☐ Nurse	☐	Other (specify):
Qualified?	☐	Yes	☐ No		Date of qualification:
Performed by:	☐	Medical Assistant	☐ Nurse	☐	Other (specify):
Qualified?	☐	Yes	☐ No		Date of qualification:
Performed by:	☐	Medical Assistant	☐ Nurse	☐	Other (specify):
Qualified?	☐	Yes	☐ No		Date of qualification:

INFECTION PREVENTION AND CONTROL AUDIT for Medical Device Reprocessing in Ambulatory Clinic or Physician's Office

NOTE: See the **Table of Contents** for additional audit tools that expand on individual elements of these audit tools (e.g., Hand Hygiene, PPE, Routine Practices, Occupational Health, Foot Care)

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
1.0 Policies and Procedures					
1.1	There are written policies and procedures for all aspects of reprocessing that are based on current recognized standards				
1.2	The department maintains written infection prevention and control (IPAC) policies and procedures and reviews them every 3 years and as necessary to remain current				
1.3	Office manager or individual(s) responsible for all aspects of reprocessing has/ have completed a recognized qualification/certificate course in reprocessing				
1.4	There are ongoing audits with documentation of competency of staff involved in reprocessing medical devices				
1.5	There are written instructions for cleaning, packaging and sterilizing each item to be reprocessed that include pictures for staff to follow for each item to be sterilized				
1.6	There is a policy that requires scheduled maintenance of equipment, with written documentation that this has occurred				
1.7	There is a policy and procedure for quality monitoring and documentation of the reprocessing process (e.g., biological indicators, chemical indicators, preventive maintenance)				
1.8	There is a policy requiring loaned, shared, leased or practitioner-owned medical devices to be reprocessed prior to use.				
1.9	There is a policy prohibiting the reuse of single-use devices unless reprocessed by an approved and FDA cleared 3rd party reprocessor				
1.10	Staff have been screened for immunity to hepatitis B and offered vaccination if warranted				
2.0 Education and Training					
2.1	Staff assigned to reprocess medical devices have completed a recognized qualification/ certificate course, or are certified by an accredited body, in reprocessing				
2.2	Reprocessing staff receive: • education and training on hire				
2.3	• supervision until competency is demonstrated and documented				

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
2.4	• annual competency testing				
2.5	• education and training on any authorized change in process				
2.6	• education and training when new medical devices are purchased that require reprocessing				
2.7	• principles of basic reprocessing techniques that minimize cross-contamination, such as one-way work flow progressing from least soiled to most soiled (*see Appendix*)				
2.8	All staff training and education is documented				
2.9	All staff training and education is evaluated				
3.0 General Procedures					
3.1	Written manuals for all reprocessing equipment are readily available				
3.2	There is a dedicated hand washing sink in the reprocessing area and/or ABHR is available for hand hygiene				
3.3	The hand washing sink has controls that minimize contamination of hands (e.g., knee/foot--operated, "winged" taps, electronic eye) or correct procedures are used to minimize contamination of hands (e.g., turning off taps with paper towel)				
3.4	Personal protective equipment (PPE) is available and accessible in appropriate sizes at point of use				
3.5	Gloves are removed immediately after decontamination procedures, before touching clean items and surfaces				
3.6	Face protection (well-fitted mask, eye protection) is worn for procedures that are likely to result in sprays or splashes of blood or other body fluids				
3.7	PPE (gloves, mask, eye protection) are worn during medical device reprocessing activities				
3.8	A puncture-resistant sharps container is accessible at point-of-use				
3.9	Sharps containers are changed when contents reach the fill line and are not overfilled				
3.10	Devices are cleaned in a designated area that is physically separate from direct care areas and from where clean, disinfected or sterile items are handled or stored				
3.11	There is a one-way work flow from dirty to clean to prevent cross-contamination (*see Appendix*)				

Element			No	N/A	Deficiency Noted
3.12	If chemical disinfection or sterilization is performed, appropriate ventilation controls are in place as per CSA Standards and Occupational Health and Safety regulations				
3.13	Chemical products used for disinfection/sterilization: • have a drug identification number (DIN) from Health Canada				
3.14	• are prepared and used according to the manufacturer's instructions for dilution, temperature, water hardness, use, shelf life and storage conditions				
3.15	• have WHMIS information and a Materials Safety Data Sheet (MSDS) readily available				
3.16	• are properly labelled with the expiry date				
3.17	• are stored in a manner that ensures containers do not become damaged and chemicals can be safely accessed				
3.18	• are stored above the floor on appropriate shelving and at an accessible height; if containers are used, they are washable (i.e., no cardboard containers)				
3.19	Chemical products are compatible with both the reprocessing equipment and the devices being reprocessed, according to manufacturer's instructions				
3.20	Manufacturer's written instructions for operating equipment are followed (e.g., sterilizers, pasteurizers, ultrasonic washers)				
3.21	Manufacturer's written instructions for reprocessing are followed for each device (e.g., assembly, disassembly, lubrication, wrapping)				
3.22	Single-use medical devices are not reprocessed				
4.0 Pre-cleaning					
4.1	A sink for cleaning medical devices is located near the work area				
4.2	Dirty devices are kept separate from clean devices				
4.3	Gross soil is removed from devices at point-of-use				

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
4.4	Immediately after use, device is immersed in an appropriately diluted cleaning solution (e.g., enzymatic cleaner) to avoid drying of secretions or body fluids; or treated with an agent that prevents hardening of bioburden				
4.5	Device is disassembled, if applicable, according to manufacturer's instructions				
5.0 Cleaning					
5.1	Device is cleaned manually with an enzymatic solution, in an ultrasonic washer, or in an automated washer-disinfector				
5.2	Device is rinsed with clean, fresh tap water, or distilled water if water hardness is a factor				
5.3	Devices with lumens are: • cleaned according to manufacturer's instructions				
5.4	• manually flushed with enzymatic cleaner				
5.5	• rinsed				
5.6	• inspected to ensure lumens are clean and unobstructed				
5.7	Special cleaning equipment (e.g., sponges, brushes), if used, is: • disposable, or thoroughly cleaned and disinfected with a high-level disinfectant or sterilized between uses				
5.8	• of an approved material that will not damage the device				
5.9	If an ultrasonic washer is used: • it is tested for efficacy at least weekly or according to manufacturer's recommendations (e.g., 'foil test' – *see Glossary*)				
5.10	• it is operated with the lid closed				
5.11	• there is documented preventive maintenance and performance monitoring of the ultrasonic washer				
5.12	• gross soil is removed prior to ultrasonic cleaning				
5.13	• device is thoroughly rinsed after ultrasonic cleaning				
5.14	• cleaning solution is changed at least daily, or when visibly soiled				

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
5.15	Device is dry prior to HLD or sterilization (e.g., dried with a lint-free cloth)				
5.16	Detergent or enzymatic cleaning solution is discarded after each use				
6.0 Inspection					
6.1	Device is inspected for any damage, operating ability, pitting, corrosion, etc.				
6.2	There is a process for removing faulty devices until repaired or replaced				
6.3	Device is lubricated according to manufacturer's instructions, if required				
7.0 Medical Devices Receiving High-Level Disinfection (HLD)					
7.1	Semi-critical medical devices receive HLD				
7.2	Devices receive HLD according to the device and disinfectant manufacturer's instructions (e.g., temperature, time, concentration)				
7.3	The minimum effective concentration of disinfectant is monitored daily before first use with test strips available from the disinfectant product manufacturer				
7.4	High-level disinfectant test strips specific to the product are checked for efficacy when each bottle is opened				
7.5	Disinfectant test strip bottles are dated when opened and discarded as per the manufacturer's instructions				
7.6	A log is kept of devices that receive HLD including: • date and time of HLD				
7.7	• length of contact time with disinfectant				
7.8	• person responsible for checking and recording the information				
7.9	A written log of disinfectant concentration monitoring is maintained				
7.10	If an automated reprocessor is used, there is a documented preventive maintenance program				
7.11	If chemical disinfection is performed, appropriate PPE is worn by staff who are performing decontamination and HLD (e.g., gloves, mask, eye protection)				
7.12	If manual disinfection is performed: • device is totally submerged in the disinfectant for the time specified by the disinfectant manufacturer				

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
7.13	• device is rinsed with at least three separate rinses with sterile or bacteria-free (e.g., achieved by submicron filtration) water				
7.14	• if rinsing a lumen, it is flushed with a volume of water at least three times the volume of the lumen				
7.15	• device is dried following disinfection				
7.16	• the disinfectant container is kept covered during use				
7.17	• the disinfectant container is washed, rinsed and dried when the solution is changed				
8.0 Medical Devices Receiving Sterilization					
8.1	Critical devices are sterilized or are disposable				
8.2	Critical devices are sterilized by an approved sterilization process (e.g., dry heat, autoclave, chemisterilant) for the device; *Note: inappropriate methods include immediate use (flash) sterilization, glass bead sterilization, boiling water and microwave ovens*				
8.3	Device is packaged according to the device manufacturer's instructions (e.g., devices are opened, disassembled) and sealed				
8.4	Packaging is validated for the sterilization method				
8.5	Internal and external pouch/pack chemical indicators (CI) are placed appropriately in and/ or on each package (if not part of the pouch/pack wrap)				
8.6	Device packages are labelled with name of item(s), date of sterilization and load number (if more than one sterilizer load is run per day) and includes operator's initials				
8.7	If more than one device is being sterilized in a pack and/or more than one pack is in the load, the pack is placed in the sterilizer according to the detailed steps recommended by the manufacturer				
8.8	Device is placed in a steam sterilizer according to manufacturer's instructions (e.g., in the open position)				
8.9	Sterilizer mechanical printout is checked and signed each cycle by the person responsible for releasing the load				
8.10	Sterilizer is tested with a biological indicator (BI) each day the sterilizer is used				
8.11	BIs are placed inside a process challenge device (PCD)				

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
8.12	If a dynamic air removal-type sterilizer is used, an air-detection PCD (Bowie-Dick test pack) is used				
8.13	Records are kept to document that **all** sterilization parameters have been met (e.g., BIs, CIs, time/temperature/pressure readings)				
8.14	A medical device is not used until the CI(s) is/are checked				
8.15	Medical devices are not used until the BI is checked				
8.16	There is documentation of the sterilizer's preventive maintenance program, including a regular cleaning schedule, according to manufacturer's instructions				
9.0 Storage					
9.1	Sterile items are stored in their sterile packaging until time of use				
9.2	Sterile items are handled in a manner that prevents contamination of the item				
9.3	Packaged, sterilized devices are stored securely in a manner that keeps them clean, dry and prevents contamination (e.g., drawer, upper cupboard)				
9.4	Storage of medical equipment/devices in the home care office (including containers that contain medical equipment/devices) is at least: • 25 cm/10 inches off the floor (10 cm/4 inches) if shipping pallets are used)				
9.5	• 45 cm/18 inches from the ceiling				
9.6	• 5 cm/2 inches from walls				
9.7	Open storage units have a solid bottom shelf				
9.8	Items stored on top shelves are protected from moisture and dust contamination				
9.9	**Visual inspection by the auditor**: A processed package is randomly opened and visually inspected: • external indicators show that processing has taken place (e.g., tape, label)				
9.10	• there are no signs of compromise of packs (e.g., moisture)				
9.11	• device is visually clean and free of pitting or corrosion (e.g., rust)				

Compliance Score (see calculation below)				
Total number of 'Yes'				**Compliance Score:**
Total number of 'No'				
Total number of items ('Yes' and 'No', exclude 'N/A')				

Scoring:

$$\frac{\text{Total number of 'yes'}}{\text{Total number of 'yes' and 'no'}} \times 100 = \%\ \text{compliance (compliance score)}$$

Feedback on Compliance:

There is a process in place to address audit deficiencies and to provide timely feedback, on a priority basis (e.g., safety issues would be addressed immediately).

Additional Comments:

Appendix – Sample Reprocessing Area Set-up

All Areas: Alcohol-based Hand Rub, Hand Wash Sink, Liquid Soap, Paper Towels (in dispensers)

DIRTY AREA*	CLEAN AREA*	CLEANEST AREA*
Decontamination, Disassembly, Cleaning and Rinsing	**Inspection, Drying, Reassembly and Packaging**	**High-Level Disinfection (HLD), Sterilization and Storage**

DIRECTION OF WORK FLOW: WORK PROGRESSES FROM "DIRTY" TO "CLEAN" TO "CLEANEST"

Ultrasonic Cleaner	"Dirty" Sink	Washer-disinfector		Clean Drying and Inspection Area/ Counter		Sterilization	
Sharps Container		Hand Hygiene Station		Clean Supplies Storage		High-Level Disinfection (HLD) (Thermal / Chemical)	
Decontamination, disassembly, cleaning PROCEDURE MANUAL				Inspection, reassembly, packaging PROCEDURE MANUAL		Sterilization / HLD PROCEDURE MANUAL	Quality Monitoring

SUPPLIES:	SUPPLIES:	SUPPLIES:
■ Covered containers for contaminated equipment transport ■ PPE (gowns, masks, eye protection, hair covers, shoe covers, gloves) ■ Enzymatic/ detergent solutions ■ Disposable brushes, pipe cleaners etc. ■ Sink(s) ■ Filtered or distilled water ■ Hand wash sink, hand soap	■ Clean counter/ work space ■ Clean work attire, hair covering ■ Lint-free drying cloths ■ Sterilization pouches/ wraps/ containers (all required sizes) ■ Chemical indicators ■ Indicator tape ■ Approved marking pens ■ Medical air for drying	■ PPE (gowns, gloves, masks, eye protection) ■ Approved HLD ■ HLD testing strips ■ Biological indicators ■ Process challenge devices ■ Bowie-Dick air removal test ■ Separate storage area for sterile/ clean equipment

All Areas: Garbage and laundry containers by door and approved environmental cleaning/disinfecting agents and equipment readily available

**** NOTE: This sample layout can be adjusted to fit into one, two or more room locations based on space availability***

IDEALLY, high-level disinfection and sterilization are done in different areas/rooms.

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