

18th December 2012

VCH Reprocessing Practices Improvement Project
Contact: reprocessing@vch.ca

VCH complies with the 2011 Ministry of Health Policy Communiqué concerning Reprocessing of Medical Devices and Patient Care Equipment, including new directives concerning research devices to be used on humans. Relevant excerpts are provided below.

Use of research devices on humans at VCH may only be done once the protocol for sterilization of the research device has been approved by the Reprocessing Variance Committee. Membership includes representation from across VCH of Medical Device Reprocessing Department and Client Representatives, Diagnostic Imaging, Healthcare Technology Management, Patient Safety, Quality and Infection Control, Client Relations and Risk Management, and the Reprocessing Practice Improvement Program Coordinator. Reporting to the Reprocessing Operations Committee (which reports to the Executive Team through the VP Medicine, Clinical Quality and Safety), the Variance Committee will meet at the call of the chair (Risk Management).

Those seeking comment by the Reprocessing Variance Committee are asked to complete the document "Proposal for Approval Concerning Reprocessing of a Research Device".

Please provide

- Confirmation of **validated** instructions including documentation from a certified lab (FDA, ISO, Health Canada) concerning:
 - Mechanical Testing- to ensure that the device is not negatively affected by the sterilization technique.
 - Bioburden Testing- to ensure that the device is in fact sterile after sterilization and
 - Dose Mapping- confirmation of the sterilization technique at the parameters determine by bioburden testing.
- Documented comment and input from others who are affected by or can comment on the proposed guidance
 - The users / of the device (effect on budget / workflow?)
 - Medical Device Reprocessing Department (can it be cleaned as proposed?),
 - Infection Control (infection control implications?),
 - Biomedical Engineering (device functionality implications?)
 - Other comments as you deem appropriate.

Once your completed submission is received, we will convene the committee for review, and will invite you as the applicant to attend to explain and discuss the submission with the Committee. Potential outcomes include:

- the proposed approach will be confirmed, revised, or declined, or
- more information may be necessary before a decision can be made.

For discussion or clarification on any of the foregoing, please contact reprocessing@vch.ca

Instructive Excerpts concerning Research Devices from Ministry of Health Policy Communiqué concerning, Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices In BC Health Authorities (Reviewed & revised December 2011).

For recommendations in this document:

- **"Shall"** indicates mandatory requirements based on legislated requirements or national standards (i.e., Canadian Standards Association - CSA);
- **"Should"** indicates a recommendation which is advised but not mandatory.

Page 14 and General Principles, page 20

This document applies to critical and semi-critical reusable medical devices, be they purchased, loaned, physician/practitioner-owned, research devices or obtained by any other method and regardless of where reprocessing occurs.

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All reprocessing of medical devices, regardless of source, **shall** meet best practices whether the device is purchased, loaned, physician/practitioner-owned, used for research, or equipment obtained by any other means, and regardless of where reprocessing occurs.

II. Best Practices

1. Assessment and Purchase of Medical Devices and Reprocessing Equipment

All reusable medical devices that will be purchased shall have **validated** device specific, written manufacturer's instructions. These instructions shall address:

- Cleaning and decontamination;
- Packaging (if required);
- High level disinfection or sterilization; and
- Device maintenance.

The validation shall be specific for the reprocessing equipment that is used in the health care facility (e.g. endoscopes and automatic endoscope reprocessors).

If disassembly or reassembly is required, detailed instructions with pictures shall be included. Staff training shall be provided on these processes before the medical device is placed into circulation.

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Manufacturer's Recommendations:

The manufacturer's information for all medical devices and reprocessing equipment shall be received and maintained in a format that allows for easy access by staff carrying out the reprocessing activities.¹

Information to be provided by the medical device manufacturer shall:

- a) Specify at least one **validated** method for the reprocessing of the medical device;
- b) Determine if there are any limitations and restrictions on reprocessing the device and specify the number of reprocessing cycles that can be tolerated;
- c) Specify the requirements for the preparation at the point of use of the medical device;
- d) specify the requirements for the preparation of the medical device prior to cleaning;
- e) Specify a **validated** manual cleaning method and at least one **validated** automated method unless the medical device cannot withstand this process;
- f) Specify a **validated** non-automatic method of disinfection and at least one **validated** automated method using a washer disinfectant unless the medical device cannot withstand this process;
- g) Specify, if necessary, a **validated** method of drying;
- h) Specify inspection, maintenance and testing methods required at any stage of processing;
- i) Specify a method of packaging that is compatible with the stated sterilization process and the medical device;
- j) Specify a **validated** sterilization method unless the medical device cannot withstand this process;
- k) Specify any limitation for the time or conditions of storage of the medical device prior to use; and
- l) Validate that any process identified in instructions for use are capable of reprocessing the medical device for its intended use.

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A valid medical device license issued by the Therapeutic Products Directorate of Health Canada [<http://www.mdall.ca/>] or provided by the manufacturer shall be available for all medical devices that are class II and higher. Failure to comply with licensing could result in litigation under the Medical Devices Regulations section of the Food and Drugs Act.²

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"Thermal Disinfection is a process of hot water disinfection, which is accomplished through the use of automated pasteurizers or washer disinfectants with a **validated** thermal disinfection cycle."

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Cleaning

Unless otherwise **validated** by the endoscope reprocessor manufacturer and third party research, the following steps should be included in the cleaning procedure:^{3 4 5}

- a) Follow the manufacturer's recommendations for cleaning and cleaning products;
- b) Soak and manually clean all immersible endoscope components in an enzymatic solution prior to automated or further manual disinfection or sterilization;
- c) Disconnect and disassemble endoscope components (e.g., air/water and suction valves) as far as possible and completely immerse the endoscope and components in enzymatic cleaner;
- d) Flush/suction and brush all channels and lumens of the endoscope while it is submerged to remove debris and minimize aerosols;
- e) Ensure that brushes used for cleaning lumens are of an appropriate size, inspected before and after use;
- f) Discard disposable cleaning items or thoroughly clean and high-level disinfect/sterilize reusable items between uses
- g) Use irrigation adaptors or manifolds that are recommended by the manufacturer to facilitate cleaning;
- h) Endoscopic equipment shall be rinsed and excess water removed prior to sterilization or dried prior to disinfection;
- i) Identify damaged endoscopes and immediately remove from service; and
- j) Discard enzymatic cleaner and rinse water after each use.

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Cleaning Procedure

Unless otherwise **validated** by the endoscope reprocessor manufacturer and by third party research, endoscopes shall be manually cleaned after each use. The following steps should be included in the cleaning procedure:^{6 7 8}

- a) Use a detergent that is compatible with the endoscope and accessories
- b) Use fresh, low-sudsing enzymatic cleaning solution and rinse water for each endoscope
- c) Prepare and use the enzymatic cleaning solution according to manufacturer's instructions for use e.g. concentration, temperature
- d) Completely immerse the endoscope in the enzymatic solution for cleaning and allow the appropriate time to soak. Clean the exterior with a soft brush or a lint-free product
- e) Ensure that brushes used for cleaning the channels are of an appropriate size, and are inspected before and after each use
- f) Flush/suction and brush all channels and lumens while the endoscope is completely immersed. Keep the bending section straight to avoid damaging the scope
- g) Use only those irrigation adaptors or manifolds that have been **validated** by the endoscope manufacturer and the manufacturer of the automated reprocessor. Use these according to the manufacturer's instructions
- h) Disconnect and disassemble (as far as possible) all endoscope components e.g. air/water and suction valves
- i) Soak and manually clean all endoscope components in an enzymatic solution j) Rinse the endoscopes and accessories in fresh water k) Ensure that the endoscope and accessories are dried prior to sterilization, or that the excess water is removed prior to disinfection
- j) Use disposable cleaning items, or if reusable items are used, ensure that they are thoroughly cleaned and high-level disinfected/sterilized between uses

Remove damaged endoscopes from service

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Written procedures should be based on the AER manufacturer's instructions for use and shall:⁹

- a) Ensure that the endoscope and endoscope components e.g. channel connectors or caps, are **validated** for reprocessing in the AER;
- b) Ensure that the connectors are clearly labeled to indicate the appropriate connection site on the AER and the endoscope. Connectors shall be labeled to clearly indicate the:
 - Endoscope manufacturer;
 - Model for which they are **validated** for use; and
 - Connection ports for the endoscopes and the AER.

The type of chemical and how it is diluted/dispensed can vary with the automatic endoscope reprocessing system. Some chemicals are ready to use and some require dilution or activation. Chemicals can be single-use or reusable.

The AER manufacturer's instructions for the system shall describe the:

- a) (a) Medical devices that have been **validated** for reprocessing in the system;
- b) (b) Types of HLDs that have been **validated** for use in that specific system; and
- c) (c) Conditions under which those HLDs will be used. These conditions should include, but are not limited to:
 - (i) Contact method (e.g., complete immersion or spray);
 - (ii) Preparation instructions for the system. This can include directions regarding device connections and device positioning;
 - (iii) Preparation instructions for the disinfectant;
 - (iv) In-use requirements such as contact time, temperature, and concentration
 - (v) Monitoring methods;
 - (vi) Rinsing methods. Sub-micron/bacteria free water is preferred for the final rinse.
 - (vii) Chemical spill procedure; and
 - (viii) Contingency plan for water advisories.

If the AER's irrigation adaptors or manifolds do not flush liquid through the elevator wire channel in a duodenoscope, the channel should be manually cleaned and disinfected according to the instructions provided by the scope manufacturer.

Implement and document preventive maintenance program(s) for the AER(s).

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Health care settings shall have written policies and procedures for sterilization processes that:

- a) Follow the principles of infection prevention and control as set out in CSA standards,^{10 11 12}
- b) BC Ministry Best Practice Guidelines and PHAC guidelines¹⁹¹;
- c) Follow manufacturer's instructions for installation, operation, cleaning and preventive maintenance of the sterilization equipment;
- d) Follow manufacturer's instructions for cleaning and preparation of the medical device. The instructions shall be **validated**, written and device specific; and d) Describe the preparation of devices to be sterilized (i.e., disassembly, cleaning, drying, inspection, lubrication, wrapping, sealing and labeling)^{13 14 15}

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Users shall obtain written **validated** device specific instructions from the device manufacturer and sterilizer efficacy testing from the sterilizer manufacturer when utilizing the steam sterilization method.

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ii Packaging

Packaging materials for steam sterilization shall:

- Be **validated** for steam sterilization;

iii. Loading

Steam sterilizers shall be loaded in the following manner to ensure sterilant contact and penetration:

- Package placement to avoid overloading;
- Non-perforated tray and container placed on their edge;
- Packages away from chamber walls;
- Concave devices on an angle to avoid condensate pooling;
- Textile packs perpendicular to the sterilizer cart shelf;
- Steri-peel on its edge with multiple packages being placed paper to plastic; and
- Rigid containers shall not be stacked unless **validated** by the manufacturer for that configuration.

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Containers used for "Immediate Use Steam Sterilization" of devices shall be **validated** for that purpose.

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Packaging material used for chemical sterilization shall be **validated** for that method.

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There are six classes of chemical indicators. When choosing a CI, ensure that the manufacturer supplies documented evidence that the CI has been **validated** for use with North American cycle parameters.

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Used only for the sterilizer type and cycle for which it was designed and **validated**

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Once a package has been opened, additional checks for validation of process shall include:

- Internal chemical indicator change;
- Presence of moisture or watermarks within the package;
- Filter alignment (in rigid container); and
- Presence of foreign debris.

¹ Canadian Standards Association. CAN/CSA-Z314.3-09 Effective Sterilization in Health Care Facilities by the Steam Process. Rexdale, Ont.: Canadian Standards Association; 2009.

² *Food and Drugs Act*. Medical Devices Regulations, SOR/98-282; 1998 June 2, 2009. [cited June 29, 2009]; Available from: <http://laws.justice.gc.ca/en/f-27/sor-98-282/text.html>.

³ Canadian Standards Association. CAN/CSA Z314.8-08 Decontamination of Reusable Medical Devices. Mississauga, Ont.: Canadian Standards Association; 2008.

⁴ Whyman CA, McDonald SA, Zoutman D. Unsuspected dilution of glutaraldehyde in an automatic washer for flexible fiberoptic endoscopes. *Can J Infect Control* 1991;6(4):91-3.

⁵ Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointest Endosc* 2003;58(1):1-8.

⁶ Canadian Standards Association. CAN/CSA Z314.8-08 Decontamination of Reusable Medical Devices. Mississauga, Ont.: Canadian Standards Association; 2008.

⁷ Whyman CA, McDonald SA, Zoutman D. Unsuspected dilution of glutaraldehyde in an automatic washer for flexible fiberoptic endoscopes. *Can J Infect Control* 1991;6(4):91-3.

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¹⁰ Canadian Standards Association. CAN/CSA-Z314.3-09 Effective Sterilization in Health Care Facilities by the Steam Process. Rexdale, Ont.: Canadian Standards Association; 2009.

¹¹ Canadian Standards Association. CAN/CSA Z314.8-08 Decontamination of Reusable Medical Devices. Mississauga, Ont.: Canadian Standards Association; 2008.

¹² Canadian Standards Association. CAN/CSA-Z314.3-09 Effective Sterilization in Health Care Facilities by the Steam Process. Rexdale, Ont.: Canadian Standards Association; 2009.

¹³ Canadian Standards Association. CAN/CSA-Z314.3-09 Effective Sterilization in Health Care Facilities by the Steam Process. Rexdale, Ont.: Canadian Standards Association; 2009.

¹⁴ Canadian Standards Association. CAN/CSA Z314.8-08 Decontamination of Reusable Medical Devices. Mississauga, Ont.: Canadian Standards Association; 2008

¹⁵ Canadian Standards Association. CAN/CSA-Z314.2-09 Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process. Rexdale, Ont.: Canadian Standards Association; 2009.