



MINISTRY OF HEALTH
POLICY COMMUNIQUÉ

COMMUNIQUÉ

TO: All Health Authorities

TRANSMITTAL DATE: DEC 19 2011

COMMUNIQUÉ NUMBER: 2011-03

CLIFF NUMBER: 858935

SUBJECT: Updated Provincial Reprocessing Policy

DETAILS: Cover letter to all Health Authority Chief Executive Officers

EFFECTIVE DATE: Immediately

MINISTRY CONTACT: Director of Patient Safety, Health Authorities Division

Graham Whitmarsh
Deputy Minister
Ministry of Health

MINISTRY OF HEALTH POLICY
REPROCESSING OF MEDICAL DEVICES - 2011

Policy Objective

- This policy is intended to protect patient safety by ensuring that all health authorities are in full compliance with established standards for medical device reprocessing, as stated by Health Canada, the Canadian Standards Association (CSA), and British Columbia's 'Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities (2011)'.

Scope

- The policy applies to all critical and semi-critical, single-use and multiple-use medical devices used within health authority facilities and programs, as well as private or non-profit facilities and/or providers (e.g., dentists and podiatrists) providing public health care services under contract to health authorities.

Policy

- Health authorities shall reprocess medical devices according to current standards set by Health Canada, the Canadian Standards Association, and British Columbia's 'Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities (2011)'. BC's best practice guideline document is attached as Appendix 1. While it is expected that health authorities are meeting best practices for medical device reprocessing, due diligence is required to ensure ongoing compliance.

Standards

- **Single use devices** – Health care settings shall have written policies regarding single-use medical devices. Critical and semi-critical medical devices labeled as "single-use" shall not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor. Currently there are no licensed reprocessors in Canada. There are reprocessors in the USA licensed by the United States Food and Drug Administration.
- Health care settings that wish to have single-use medical devices reprocessed by a licensed reprocessor shall ensure that the reprocessor's facilities and procedures have been certified by a regulatory authority or an accredited quality system auditor to ensure the cleanliness, sterility, safety and functionality of the reprocessed devices.
- Sharps and needles shall be single-use and shall not be reprocessed. "Sharps" refer to any item capable of cutting or piercing the skin (e.g., injection needles, trocars, cautery tips, scalpel blades, drill bits, saw blades, shavers). To maximize worker safety, sharps and needles must be handled in compliance with WorkSafe BC standards. Sharps and needles deemed 'single-use only' by the manufacturer shall not be reprocessed.
- Reusable devices with small lumens or other characteristics that make them difficult to clean, such as fine cannulae (excluding endoscopy equipment), should be designated single-use and should not be reprocessed and re-used, even if designated as reusable by the manufacturer.
- **Multiple use devices** – Health authorities shall ensure that reprocessing practices in all health authority facilities and programs comply with current standards for medical device reprocessing, as stated by Health Canada, CSA, and BC's 'Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities (2011)'.
- **Education, Training, and Competency Assessment** -- It is expected that all persons performing medical device reprocessing activities have appropriate education, training, and competency assessment.
 - Medical device reprocessing technicians who routinely perform medical device reprocessing activities shall, at a minimum, have successfully completed a recognized medical device reprocessing technician educational program or certificate course.

- Health authorities are encouraged to phase in appropriate certification (e.g. CSA and International Association of Healthcare Central Service Materiel Management) as a supplementary educational requirement for all reprocessing technicians, in accordance with organizational quality assurance planning and priorities.
- **Quality assurance** – Health authorities shall maintain an appropriate and responsive reprocessing quality assurance system to ensure ongoing safety and quality of reprocessing activities. The quality assurance system shall include:
 - Clear roles and accountabilities for management of reprocessing activities;
 - Appropriate staffing and resources to ensure reprocessing standards are met;
 - Appropriate ongoing staff training, education, and competency assessment;
 - Ongoing maintenance and monitoring of equipment used for reprocessing to ensure proper function;
 - Internal compliance assessment and reporting;
 - Ongoing processes to identify and implement changes to standards and best practices as they become available;
 - A formal policy that promotes and facilitates the immediate communication of quality-related issues to reprocessing managers;
 - Protocols for communicating shared learnings from adverse events to provincial colleagues, whenever possible and appropriate;
 - An action plan for addressing quality assurance items that includes risk assessment, timelines and accountability for remediation work; and
 - A mechanism for tracking flash sterilization (also referred to as immediate use steam sterilization).

Implementation

- Effective immediately, all health authorities shall adopt the 'Best Practices for Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities (2011)'.
- All health authorities shall demonstrate compliance with current standards by means of internal assessment for critical and semi-critical medical devices.
 - Areas that perform medical device reprocessing or have been deemed high risk by the health authority are to be assessed on an annual basis.
 - Areas that perform reprocessing not deemed high risk by the health authority - including residential and tertiary care sites - are to be assessed once every three years. Health authorities should assess one third of these sites each year.
 - Annual assessment cycles will start the first day of every new fiscal year.
- Submission of reprocessing practice audit results to the Ministry shall occur on an annual basis.
 - Assessment reports are due to the Ministry on the first Friday in May of the following fiscal year.
 - The most recent audit results from all sites shall be included in every report to the Ministry, even if audit data is not from the current fiscal year.
- On April 1, 2012, all health authorities shall transition to the updated 2011/12 Reprocessing Practice Audit Tool. Health authorities shall continue to use the 2008/09 Reprocessing Practice Audit Tool in the interim.
- Health authorities shall submit updated quality assurance plans to the Ministry of Health on an annual basis.
 - Quality assurance plans are due to the Ministry on the first Friday in November.
 - Submissions are to include an Executive Summary highlighting key developments and an action plan for addressing quality assurance items that includes risk assessment, timelines and accountability for remediation work.
- Health authorities shall implement recommendations from third party and external reviews, as required.
- By January 2012 health authorities shall eliminate the following practices:
 - The re-use of semi-critical "single-use" medical devices, unless reprocessing is performed by a licensed third party reprocessor;
 - Flash sterilization (immediate use steam sterilization) in non-emergency situations.
 - The return of used "single use" medical devices to clinicians for disposal.
- By September 2012 health authorities shall eliminate the following practices:
 - Reprocessing of "in-house" manufactured devices lacking validated reprocessing instructions.

Accountability

- The Ministry will monitor and provide feedback on health authority policy implementation and quality assurance plan implementation through annual submissions and bi-annual update calls.
- The Ministry will monitor assessment results on an annual basis.

Review

- This policy is subject to review as standards and best practices are revised every three years, or as required.