

Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices

In BC Health Authorities

THIS DOCUMENT IS INTENDED TO DESCRIBE BEST PRACTICES

**HEALTH CARE SETTINGS ARE ENCOURAGED TO WORK TOWARDS THESE BEST PRACTICES IN AN
EFFORT TO IMPROVE QUALITY OF CARE.**

**BC Ministry of Health
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Foreword

This document was originally developed in 2006 by the Ontario Provincial Infectious Diseases Advisory Committee (PIDAC) and was approved by the Ontario Ministry of Health and Long-Term Care (MOHLTC). PIDAC is a multidisciplinary scientific advisory body that provides evidence-based advice to the Chief Medical Officer of Health regarding multiple aspects of infectious disease identification, prevention and control. PIDAC's work is guided by the best available evidence and updated as required. Best practice documents and tools produced by PIDAC reflect consensus positions on what the committee deems prudent practice and are made available as a resource to public health and health care providers.

In 2006, the British Columbia (BC) Ministry of Health (the Ministry) received permission to adopt PIDAC's *Best Practices for Cleaning, Disinfection and Sterilization of Medical Devices*. Permission was also granted at that time for the Ministry to amend contextual material within the document to better fit BC's health services environment. An adapted version of the PIDAC guidelines was issued as BC's provincial policy in 2007. The policy applies to all critical and semi-critical single use and multiple use devices and patient care equipment used within health authority facilities and programs, as well as private and non-profit facilities providing public healthcare services under contract to health authorities.

In February 2010, PIDAC published a revised version of the guidelines and the MOHLTC once again gave permission to the BC Ministry of Health to use its updated best practices document to further improve patient safety in BC. The Ministry extends its thanks and appreciation to its colleagues in Ontario for supporting inter-provincial learning in the area of medical device reprocessing.

Key Revisions in this Document:

- This document incorporates revisions from the following updated Canadian standards:
 - CSA Z314.3-09 Effective Sterilization in Health Care Facilities by the Steam Process
 - CSA Z314.2-09 Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process
 - CSA Z314.8-08 Decontamination of Reusable Medical Devices

- The Provincial Infection Control Network's (PICNet) recommendation for a provincial minimum standard for the reprocessing of flexible endoscopes has been adopted in this revision.

- New information from the Centers for Disease Control and Prevention's '*Guideline for Disinfection and Sterilization in Healthcare Facilities*', published in 2008, is also reflected in this revision.

Key Revisions in BC's Provincial Medical Device Reprocessing Policy:

BC's revised provincial policy for medical device reprocessing (2011) reflects advances in the oversight and delivery of safe, high quality medical device reprocessing services, including:

- Updated "Best Practice Guidelines for Cleaning, Disinfection, and Sterilization of Medical Devices in Health Authorities" (2011);
- Clear requirements for halting activities known to be inconsistent with best practices (e.g., reprocessing of "in-house" manufactured devices);
- Clear expectations regarding the education, training, and competency assessment of reprocessing staff;
- Expanded requirements for ongoing quality assurance planning, risk assessment and remediation;

- Updated requirements for ongoing practice auditing; and
- Clear expectations for submission of status reports and other materials to the Ministry on an ongoing basis.

This updated provincial reprocessing policy also reflects recommendations made by Dr. Douglas Cochrane, Chair of the BC Patient Safety & Quality Council, to the Ministry and health authorities in September 2010.

Acknowledgement

Ontario Ministry of Health and Long-Term Care & the Provincial Infectious Diseases Advisory Committee. Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings. February 2010.

Available at:

http://www.health.gov.on.ca/english/providers/program/infectious/diseases/best_prac/bp_cds_2.pdf

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In February 2010, the BC Ministry of Health was granted permission by PIDAC to adopt and adapt their document entitled '*Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings*'. All updated content is © BC Ministry of Health / BC Health Authorities / Providence Health Care.

The BC Ministry of Health would like to acknowledge the contribution and expertise of PIDAC's subcommittee that developed the original best practice document:

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Abbreviations

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| AER | Automated Endoscope Reprocessor |
| BI | Biological Indicator |
| CI | Chemical Indicator |
| CJD | Creutzfeldt - Jakob disease |
| CSA | Canadian Standards Association |
| DIN | Drug Identification Number |
| ERCP | Endoscopic Retrograde Cholangiopancreatography |
| HEPA | High Efficiency Particulate Air |
| HLD | High-Level Disinfection |
| HSSBC | Health Shared Services BC |
| IPC | Infection Prevention and Control |
| LLD | Low-Level Disinfection |
| MOHLTC | Ontario Ministry of Health and Long Term Care |
| MSDS | Material Safety Data Sheet |
| OPA | Ortho-phthalaldehyde |
| PCD | Process Challenge Device |
| PHAC | Public Health Agency of Canada |
| PPE | Personal Protective Equipment |
| QA | Quality Assurance |
| QUAT | Quaternary Ammonium Compound |
| MDR/SPD | Medical Device Reprocessing/Sterile Processing Department |
| MEC | Minimally Effective Concentration |
| MIFU | Manufacturers Instructions for Use |
| USFDA | United States Food and Drug Administration |
| WHMIS | Workplace Hazardous Materials Information System |

Glossary of Terms

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.

Assessment: A comprehensive review of reprocessing practices to identify gaps in compliance with best practice standards.

Automated Endoscope Reprocessor (AER): Machines designed to assist with the cleaning and disinfection of endoscopes.

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

Biological Indicator (BI): A test system containing viable bacterial spores providing a defined resistance to a specified sterilization process.¹

Chemical Indicator (CI): A system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to the process.²

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

Cleaning: The physical removal of foreign material (e.g., dust, soil) and organic material (e.g., blood, secretions, excretions, microorganisms). Cleaning physically removes rather than kills microorganisms. It is accomplished with water, detergents and mechanical action. Cleaning must be performed before high level disinfection or sterilization.

Client/Patient/Resident: Any person receiving health care within a health care setting.

Critical Medical Devices: Medical devices that enter sterile tissues, including the vascular system (e.g. surgical instruments, 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.

Decontamination: The process of cleaning, followed by the inactivation of microorganisms, in order to render an object safe for handling.³

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 chemical agent that kills most disease-producing microorganisms, but not necessarily bacterial spores. Disinfectants are applied only to inanimate objects. Some products combine a cleaner with a disinfectant.

Disinfection: A process that kills most disease-producing microorganisms. Disinfection does not destroy all bacterial spores. Medical devices must be cleaned thoroughly before effective disinfection can take place. There are 3 levels of disinfection; high, intermediate and low.

Drug Identification Number (DIN): In Canada, disinfectants are regulated as drugs under the Food and Drugs Act and Regulations. Disinfectant manufacturers shall 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 cleaning agent that contains enzymes which break down proteins such as blood, body fluids, secretions and excretions from surfaces and equipment. Most enzymatic cleaners also contain a detergent. Enzymatic cleaners are used to loosen and dissolve organic substances.

Flash Sterilization: see “Immediate Use Steam Sterilization”

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 shall be accomplished using soap and running water or an alcohol-based hand rub (ABHR).

Health Care Provider: Any person delivering care to a client/patient/resident.

Health Care Setting: Any location where health care is provided, including settings where emergency care is provided, hospitals, complex continuing care, rehabilitation hospitals, long-term care homes, mental health facilities, outpatient clinics, community health centres and clinics, physician offices, dental offices, offices of allied health professionals and home health care.

High Efficiency Particulate Air (HEPA) Filter: A filter which has an efficiency of 99.97% in the removal of airborne particles 0.3 microns or larger in diameter.⁴

High-Level Disinfection (HLD): A process capable of killing vegetative bacteria, mycobacteria including *Mycobacterium tuberculosis*, fungi, and lipid and nonlipid viruses, as well as some, but not necessarily high numbers of, bacterial spores. High-level disinfection is considered to be the minimum level of disinfection required for semi-critical medical devices. Medical devices shall be thoroughly cleaned prior to high-level disinfection.

Immediate Use Steam Sterilization (Flash Sterilization): A special steam sterilization cycle, designed to be used only in situation where there is an urgent or unplanned need and when routine sterilization cannot be done.

Infection Prevention and Control (IPC): Evidence-based practices and procedures that, when applied consistently in health care settings, can prevent or reduce the risk of transmission of microorganisms to health care providers, clients/patients/residents and visitors.

Loaned Medical Device: A critical and semi-critical medical device that is used by a health care facility under an arrangement based on lending or trial use of medical devices.⁵

Licensed Reprocessor: A facility licensed by a regulatory authority (e.g., government agency) to reprocess medical devices to the same quality system requirements as manufacturers of the device, resulting in a standard that ensures the device is safe and performs as originally intended.

Low-Level Disinfection (LLD): A process capable of killing most vegetative bacteria, some viruses, and some fungi. This class of disinfection cannot be relied on to kill micro-organisms such as mycobacteria, including *Mycobacterium tuberculosis*, or bacterial spores. Level of disinfection required when processing non-critical medical devices and some environmental surfaces.

Manufacturer's instructions for use (MIFU): 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.⁶

Medical Device: Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap; investigation, replacement, or modification of the anatomy or of a physiological process; or control of conception.

Medical Device Reprocessing/Sterile Processing Department (MDR/SPD): A centralized area within the health care setting for cleaning, disinfection and/or sterilization of medical devices (e.g., Central Processing Department – CPD, Central Processing Service - CPS, Central Surgical Supply – CSS). In smaller settings such as clinics or offices in the community, this refers to any segregated area where reprocessing of devices takes place, away from clients/patients/residents and clean areas.

Noncritical Medical Device: Devices that either touches only intact skin (but not mucous membranes) or do not directly touch the client/patient/resident. Reprocessing of noncritical devices involves cleaning and may also require low-level disinfection (e.g., blood pressure cuffs, stethoscopes).

One way work flow: The practice of ensuring that reprocessing work flows in one direction from the dirtiest to the cleanest to prevent contamination.

Pasteurization: A high-level disinfection process using hot water at a temperature of 71°C for a contact time of at least 30 minutes.

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

Physical Monitor: A device that monitors the physical parameters, such as time, temperature and pressure of a steam sterilizer.

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.⁷ Examples include BI test packs which also contain a chemical indicator, or CI test packs which contain a Class 5 integrating indicator or an enzyme-only indicator.

Reprocessing: The steps performed to prepare used medical devices for reuse (e.g., cleaning, disinfection, sterilization).⁸

Reusable: A term given by the manufacturer of medical devices that allows it, through the selection of materials and/or components, to be re-used.⁹

Semi-critical Medical Device: Medical device that comes in contact with non-intact 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.

Sharps: 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.

Single-use/Disposable: A device designated by the manufacturer for single-use only. Single-use devices shall not be reprocessed except by an approved 3rd party reprocessor.¹⁰

Sterilant: A physical or chemical entity or combination of entities that has sufficient microbiocidal activity to achieve sterility under defined conditions.¹¹

Sterilization: A validated process used to render a product free from viable microorganisms. This is the level of reprocessing required for critical medical devices. Devices must be cleaned thoroughly before sterilization can take place.

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

Washer-Disinfector: A machine intended to clean and disinfect medical devices.

Preamble

About This Document

This document is intended for health care providers to ensure that the critical elements and methods of decontamination, disinfection and sterilization are incorporated into health care facility procedures. The document describes essential elements and methods in the safe handling, monitoring and assessment, transportation and biological decontamination of contaminated medical devices.

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, podiatrists) providing public health care services under contract to health authorities.

Information in this document is consistent with, or exceeds, recommendations from the Public Health Agency of Canada (PHAC). It also meets standards developed by the Canadian Standards Association and reflects position statements of the BC Ministry of Health. As such, it shall be used as a basis for assessing reprocessing practice by health authorities in BC.

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.**

The best practices in this document reflect the evidence and expert opinion on the reprocessing of medical devices available at the time of writing. This document will be reviewed and updated every three years or as new information becomes available.

Users should be cognizant of the basic principles of reprocessing and safe use of medical devices when making decisions about new devices and equipment and methodologies that might become available.

When to Use This Document

The best practices for reprocessing medical devices set out in this document shall be practiced in settings where care is provided, across the continuum of health care. This includes settings where emergency (including pre-hospital) care is provided, hospitals, complex continuing care facilities, rehabilitation facilities, residential care homes, outpatient clinics, community health centres and clinics, physician offices, offices of allied health professionals, public health and home health care.

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.

Assumptions for Best Practice Guidelines

The best practices in this document are based on the assumption that health authorities in BC already have basic infection prevention and control systems and programs in place. This document provides a number of recommendations to health authorities regarding ways to implement best practices in the area of medical device reprocessing. The objective is to protect patient safety, by ensuring that all health authorities are in full compliance with established standards for reprocessing of medical devices and patient care equipment as described by the PHAC and the Canadian Standards Association (CSA). This document can be obtained at:

- BC Ministry of Health. *Best Practices for Cleaning, Disinfection, and Sterilization in Health Authorities*,¹² June 2011, available at:
<http://www.health.gov.bc.ca/library/publications/year/2011/Best-practice-guidelines-cleaning.doc>

The Ministry's Policy Communiqué (2011-03) on the reprocessing of medical devices is available at:
<http://www.health.gov.bc.ca/library/publications/year/2011/Reprocessing-policy-communique.doc>

Health care settings that do not have Infection Control professionals should work with organizations that have infection prevention and control expertise, such as academic health science centres, regional infection control networks, public health units that have professional staff certified in infection prevention and control and local infection prevention and control associations (e.g., Community and Hospital Infection Control Association – Canada chapters), to develop evidence-based programs.

In addition to the general assumption above, these best practices are based on the following additional assumptions and principles:

1. Best practices to prevent and control the spread of infectious diseases are routinely implemented in all health care settings, including:
 - a) Health Canada's '*Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care*' (Can Commun Dis Rep. 1999; 25 Suppl 4:1-142) [under revision],¹³ available at:
<http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/99vol25/25s4/index.html>.
2. Adequate resources are devoted to infection prevention and control in health authorities.
3. Health authorities have implemented programs that promote good hand hygiene practices and ensure adherence to standards for hand hygiene. See:
 - a) BC Centre for Disease Control's Hand Hygiene Fact Sheet,¹⁴ available at:
<http://www.bccdc.ca/prevention/HandHygiene/default.html>
 - b) The Public Health Agency of Canada's, *Handwashing, Cleaning, Disinfection and Sterilization in Health Care*,¹⁵ available at: <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/98pdf/cdr24s8e.pdf>
 - c) Provincial Infection Control Network's Hand Hygiene Resource page¹⁶ available at:
http://www.picnetbc.ca/hand_hygiene.htm#Standards
4. Adequate resources are devoted to Environmental Services/Housekeeping in all health care settings that include written procedures for cleaning and disinfection of client/patient/resident rooms and equipment; education of new cleaning staff and continuing education of all cleaning staff; and ongoing review of procedures. Each health authority publishes the results of Westech's annual independent housekeeping audit on their website. Contact information for each health authority is available at:

<http://www.health.gov.bc.ca/socsec/index.html>

5. Regular education (including orientation and continuing education) and support to help staff consistently implement appropriate infection prevention and control practices is provided across the continuum of care.
6. Effective education programs emphasize:
 - a) The risks associated with infectious diseases, including acute respiratory illness and gastroenteritis;
 - b) Hand hygiene, including the use of alcohol-based hand rubs and hand washing;
 - c) Principles and components of Routine Practices as well as additional transmission-based precautions;
 - d) Assessment of the risk of infection transmission and the appropriate use of personal protective equipment (PPE), including safe application, removal and disposal;
 - e) Appropriate cleaning and/or disinfection of health care equipment, supplies and surfaces or items in the health care environment
 - f) Individual staff responsibility for keeping clients/patients/residents, themselves and co-workers safe; and
 - g) Collaboration between professionals involved in Infection Prevention and Control and Occupational Health and Safety (OHS).

NOTE: Education programs should be flexible enough to meet the diverse needs of the range of health care providers and other staff who work in the health care setting. The local public health unit and regional infection control networks may be a resource and can provide assistance in developing and providing education programs for community settings.

7. Collaboration between professionals involved in OHS and Infection Prevention and Control is promoted in all health care settings to implement and maintain appropriate infection prevention and control standards that protect workers.
8. There are effective working relationships between the health care setting and local Public Health. Clear lines of communication are maintained and Public Health is contacted for information and advice as required and the obligations (under the *Public Health Act*, SBC. 2008, section 73)¹⁷ to report reportable and communicable diseases are fulfilled. Public Health provides regular aggregate reports of outbreaks of any infectious diseases in facilities and/or in the community to health care settings.
9. Infection prevention and control guidance is required for staff support in the decision making process.
10. There are established procedures for receiving and responding appropriately to all international, national, regional and local health advisories in all health care settings. Health advisories are communicated promptly to all staff responsible for reprocessing medical devices and regular updates are provided. Current advisories are available from Public Health, the Ministry of Health, Health Canada and the PHAC websites as well as local regional infection prevention and control networks.
11. Where applicable, there is a process for evaluating PPE in the health care setting, to ensure it meets quality standards.

12. There is regular assessment of the effectiveness of the infection prevention and control program and its impact on practices in the health care setting. The information is used to further refine the program.¹⁸

13. The BC Ministry of Health's Home and Community Care requirements shall be met. Specific legislative requirements for long-term care providers shall be found in:

- The *Community Care and Assisted Living Act*,¹⁹ available at:
http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/00_02075_01
- The *Residential Care Regulation*,²⁰ RSBC 2009, Regulation, available at:
http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/96_2009
- The *Continuing Care Act*,²¹ RSBC 1996, available at:
http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/00_96070_01
- The *Hospital Act Regulation*,²² 2008, available at:
http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/10_121_97
- The *Hospital Insurance Act*,²³ RSBC 1996, available at:
http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/00_96204_01

Note: The *Public Health Act* and *Mental Health Act* apply as referenced in the *Health Authorities Act*.

All HCC residential care facilities are either licensed under the *Community Care and Assisted Living Act*,²⁴ or licensed or designated under the *Hospital Act*, and are subject to regular inspection and monitoring under these Acts. Many facilities are also voluntarily accredited through the Canadian Council on Health Services Accreditation.

The Assisted Living Registrar under the *Community Care and Assisted Living Act*²⁵ has a mandate to protect the health and safety of assisted living residents. The Registrar administers the assisted living provisions of the Act, which require assisted living operators to register their residences and meet provincial health and safety standards. Information on the Assisted Living Registrar is available at:
<http://www.hls.gov.bc.ca/assisted/mandate.html>

In addition, all health authorities have operating agreements with their affiliate residential care operators and have established performance management frameworks within the agreements that include performance indicators against which to measure facility performance.

All long-term care providers shall also comply with all requirements outlined in the Ministry's Home and Community Care Policy Manual.²⁶ The Home and Community Care Policy Manual²⁷ outlines the Ministry's requirements for the provision of long-term care services, programs and supplies for health authorities. There is also a range of legislation and regulation which address facility operator requirements such as environment services (waste management,; pest control; housekeeping services; laundry services and; maintenance services) and risk management (infection control; health and safety; internal and external disaster planning and; monitoring, evaluating and improving quality). This legislative framework includes the Public Health Act²⁸ and Residential Care Regulations.²⁹

In regard to the legislative requirements for staff education in long-term care facilities, health authorities establish their own policies for orientation of staff, and mandatory education programs are established by professional licensing bodies and professional licensing bodies. Health authorities shall also require their staff to participate in education programs on a mandatory basis.

As such, there is range of legislative and regulatory requirements that an operator of a facility should comply with and Licensing Officers, who are delegated by the BC Medical Health Officer are responsible for ensuring that facilities meet the requirements of the Community Care and Assisted Living Act³⁰ as well as all applicable regulations.

- The Home and Community Care Policy Manual is available at:
<http://www.health.gov.bc.ca/hcc/policy.html>

For more information, please contact your respective health authority. Contact information for each health authority is available at: <http://www.health.gov.bc.ca/socsec/index.html>.

14. Occupational Health and Safety requirements shall be met:

Health care facilities are required to comply with applicable provisions of the *Workers Compensation Act, RSBC 1996*, and Occupational Health and Safety Regulations.³¹ Employers, supervisors and workers have rights, duties and obligations under the *Workers Compensation Act*. Specific requirements under the *Workers Compensation Act* are available at:

http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/96492_00.

The *Workers Compensation Act* places duties on many different categories of individuals associated with workplaces, such as employers, constructors, supervisors, owners, suppliers, licensees, officers of a corporation and workers. Additional information regarding the requirements and regulations under the *Workers Compensation Act* are available at:

<http://www2.worksafebc.com/Publications/OHSRegulation/WorkersCompensationAct.asp>.

Specific health and safety requirements for residential facilities shall be found in the *Residential Care Regulation, RSBC 2009, Regulation*, available at:

http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/96_2009

In addition, the *Workers Compensation Act*³² section 115 the 'general duty clause', requires an employer to take every precaution reasonable in the circumstances for the protection of a worker. There is a general duty for an employer to establish written measures and procedures for the health and safety of workers, in consultation with the joint health and safety committee or health and safety representative, if any. Such measures and procedures shall include, but are not limited to, the following:

- Safe work practices
- Safe working conditions
- Proper hygiene practices and the use of hygiene facilities
- The control of infections

At least once a year the measures and procedures for the health and safety of workers shall be reviewed and revised in the light of current knowledge and practice. The employer, in consultation with the joint health and safety committee or health and safety representative, if any, shall develop, establish and provide training and educational programs in health and safety measures and procedures for workers that are relevant to the workers' work.

- A worker who is required by his or her employer or by the *Community Care and Assisted Living Act (CCALA)* to wear or use any protective clothing, equipment or device shall be instructed and trained in its care, use and limitations before wearing or using it for the first time and at regular intervals thereafter and the worker shall participate in such instruction and training. The employer is reminded of the need to be able to demonstrate training, and is therefore encouraged to document the workers trained, the dates training was conducted, and materials covered during training. Under

the *Workers Compensation Act*, a worker should work in compliance with the Act and its regulations, and use or wear any equipment, protective devices or clothing required by the employer.

For more information, please contact your local WorkSafeBC office. A list of local regional WorkSafeBC offices is available at http://www.worksafebc.com/contact_us.

BEST PRACTICE GUIDELINES FOR CLEANING, DISINFECTION AND STERILIZATION OF CRITICAL AND SEMI-CRITICAL MEDICAL DEVICES IN BC HEALTH AUTHORITIES

I. General Principles

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.

The goals of safe reprocessing of medical devices include:

- a) Preventing transmission of microorganisms to personnel and clients/patients/residents;
- b) Minimizing damage to medical devices from foreign material (e.g., blood, body fluids, saline and medications) or inappropriate handling; and
- c) Minimizing impact on the natural environment.

Best practices in reprocessing medical devices should include the following:^{33,34}

- a) Adequate review by all parties whenever new devices are being considered for purchase (e.g., reprocessing committee)
- b) A centralized area for reprocessing or an area that complies with the requirements for reprocessing;
- c) Written policies and procedures for reprocessing each type of medical device;
- d) Training of all staff who perform reprocessing;
- e) Verification of processes to ensure their quality;
- f) A corporate strategy for dealing with single-use medical devices;
- g) Management and reporting of reprocessing incidents, including recall of improperly reprocessed devices;
- h) Management and reporting of safety-related accidents; and
- i) Procedures to be followed in emergency situations (e.g., utilities shutdowns, compromised packaging, biological indicator (BI) testing failures)

“Effective reprocessing requires rigorous compliance with recommended protocols.”
Public Health Agency of Canada

Decisions related to reprocessing medical devices should be made by individuals who are knowledgeable regarding reprocessing standards and practices. Input should be obtained from individuals responsible for purchasing the device, reprocessing the device, maintaining the device, infection prevention and control, occupational health and safety, and the end-user of the device as required.

It is strongly recommended that, wherever possible, reprocessing should be performed in a centralized area that complies with the physical and human resource requirements for reprocessing.

It is strongly recommended that, wherever possible, reprocessing should be performed in a centralized area that complies with the physical and human resource requirements for reprocessing. There should be a clear definition of the lines of authority and accountability with

respect to reprocessing, whether done centrally or elsewhere.

When formulating written policies and procedures, the following steps in reprocessing should be included^{35,36}:

- a) Pre-cleaning and containment at point-of-use;
- b) Soiled Transportation;
- c) Disassembly (if required);
- d) Decontamination;
- e) Preparation and packaging (if required);
- f) Disinfection/sterilization (considering the level of reprocessing required for items, based on the risk class and manufacturer's instructions);
- g) Quarantine or early release of processed devices and loads;
- h) Clean transportation; and
- i) Storage.

It is required that an assessment of all reprocessing practices within the healthcare setting is done, including documentation as to where, how and by whom all devices are being reprocessed and whether current standards are being met, as set out in this document. All processes shall continue to be assessed by health authorities on a regular basis (e.g., annually), with clear and known consequences attached to non-compliance. Compliance with the processes shall also be assessed.

As new reprocessing technologies and processes become available, they should be evaluated against appropriate criteria. Verify that:

- a) The technology or process is compatible with the devices being reprocessed;
- b) The technology or process is compatible with the chemicals being used;
- c) Environmental issues with the process have been considered (e.g., odours, toxic waste products, toxic vapours);
- d) Occupational health issues with the process have been considered (e.g., is PPE or special ventilation required?);
- e) Staff education and training is available (provided by the manufacturer);
- f) Maintenance requirements for the new technology is achievable;
- g) The process/outcome can be monitored;
- h) Disinfectant products have a Drug Identification Number (DIN) from Health Canada; and
- i) Appropriate Health Canada or CSA licensing or approvals are available.

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.³⁷ 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.

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.

A. Device Purchases

The administration of the health care setting is responsible for verifying that any product used in the provision of care to clients/patients/residents is capable of being cleaned, disinfected and/or sterilized according to the most current standards and guidelines from the Canadian Standards Association (CSA), the PHAC/Health Canada as well as these BC Ministry Best Practices. The issuing of a purchase order is a useful point of control for ensuring that appropriate review of the device has taken place prior to purchase.

Equipment that is used to clean, disinfect or sterilize (e.g., ultrasonic washers, pasteurizers, washer-disinfectors, automated endoscope reprocessors / AERs, sterilizers) shall also meet standards established by the CSA³⁸, Health Canada/PHAC and the requirements of this document.

Decision-making prior to purchasing reusable medical devices and reprocessing equipment shall involve representatives from the departments in the health care setting that will use, reprocess and maintain the items and should include, as appropriate^{39,40}:

- a) Medical Device Reprocessing/Sterile Processing (required);
- b) Unit/department that will use the device;
- c) Risk Management;
- d) Infection Prevention and Control (required);
- e) Occupational Health and Safety;
- f) Support services;
- g) Physical plant/maintenance;
- h) Biomedical Engineering; and

- i) Health Shared Services BC (Purchasing).

Reprocessing staff, Infection Prevention and Control, Biomedical Engineering and Occupational Health and Safety shall make recommendations regarding the ability to achieve the appropriate level of reprocessing required for the device according to Spaulding's criteria⁴¹ (see Table 1) and the suitability of the device for purchase, after reviewing:

- a) The manufacturer's instructions for use (MIFU);
- b) Applicable CSA standards regarding the device;
- c) Health Canada/PHAC guidelines regarding the device; and
- d) The Ministry's Best Practices Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-Critical Medical Devices

Prior to purchase of the device, all parties involved should be in agreement that the procedure for reprocessing the device satisfies the required criteria and is achievable in the health care setting. If such a process cannot be defined, consideration should be given to alternate devices that can be adequately reprocessed.

If there is a discrepancy between the reprocessing level recommended by the manufacturer and the intended use of the instrument by Spaulding's criteria, the higher level of disinfection/sterilization shall be used.

Newly purchased non-sterile critical and semi-critical medical devices shall be reprocessed by the health authority prior to being put into circulation.^{42,43} Refer to

Table 1, "*Spaulding's Classification of Medical Devices and Required Level of Reprocessing*" (see page 39) for the level of processing that is to be used for medical devices based on the intended use of the device.

If there is a discrepancy between the reprocessing level recommended by the manufacturer and the intended use of the instrument by Spaulding's criteria, the higher level of disinfection/sterilization shall be used. For example, if the manufacturer recommends high-level disinfection for an item even though it enters a sterile space and would require sterilization by Spaulding's criteria, sterilization shall be chosen.

Prior to purchasing the device, the following questions shall be addressed:

- a) Who is accountable to verify that the required protocols are written and in place?
- b) Who will reprocess the device?
- c) Where will the reprocessing be done?
- d) What process will be used for reprocessing?
- e) Are personnel qualified to carry out this process (this includes training in the procedure, assessing the process, frequency and content of regular re-education and re-qualification)?
- f) How often will assessments be performed?
- g) If there are limits to the number of times the device shall be reprocessed, how is this tracked and by whom?

B. 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.⁴⁴

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 disinfector 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.

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 devices⁴⁵ 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*.⁴⁶

C. Loaned, Shared and Leased Medical Devices

Health authorities shall develop and maintain policies and procedures that apply to the sending, transporting, receiving, handling and processing of loaned, shared and leased medical devices,⁴⁷ including endoscopes. Organizations that include more than one health care facility and that follow common policies and procedures would not be considered to be loaning devices if sharing between sites and/or within the organization. Vendor-owned devices that are remaining within a facility for extended periods should be treated in the same manner as owned devices.

The following should be included in the policy:

- a) In addition to the requirements in Section II.1.A, devices loaned to a health care facility shall be reprocessed prior to use;
- b) Ideally, the device should be received by the facility's Medical Device Reprocessing/Sterile Processing Department (MDR/SPD) at least two business days, three business days if the device is new to the facility, before use; **a facility shall not accept for use any medical device that does not arrive in sufficient time to allow the receiving facility to follow its procedures for inventory, inspection, training/in-servicing for all staff involved, and reprocessing;**
- c) Written instructions for reprocessing of loaned medical devices shall include photos and staff shall have training in reprocessing the device prior to use;
- d) A health care facility that uses loaned, shared and/or leased medical devices shall have a policy to cover emergencies related to the devices;
- e) Loaned devices shall be tracked and logged. Should the owner of the device have a system to track the device, this information may be given to the user for their records. A tracking mechanism within the health care facility shall include records to identify:

A facility shall not accept for use any medical device that does not arrive in sufficient time to allow the receiving facility to follow its procedures for inventory, inspection and reprocessing

- i) The device; and
 - ii) The patient/client/resident on whom the device was used, so that the client/patient/resident can be identified if the device is recalled.
- f) Devices shall be decontaminated (at a minimum) and inspected prior to being returned to the owner;
- g) Organizations that transport loaned, shared and leased medical devices shall have written procedures for the safe handling and transportation of medical devices, including provision for maintenance of cleanliness, sterility, separation of clean and dirty items, and safety of those doing the transport:
- i) Soiled devices shall be transported in compliance with federal and provincial regulations regarding the transport of dangerous goods:
 - *Transportation of Dangerous Goods Act*,⁴⁸ S.C., 1992, c.34. Available at: <http://laws.justice.gc.ca/PDF/Statute/T/T-19.01.pdf>
 - *Transport of Dangerous Good Act, RSBC*, 1996. Available at: http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/00_96458_01.
 - ii) Clean devices shall be transported in a manner that does not compromise the integrity of the clean item.
- h) The use of loaned devices for neurosurgical procedures is strongly discouraged (see Section II.1.D below).

D. Creutzfeldt-Jakob Disease (CJD)

Creutzfeldt-Jakob disease (CJD) is caused by infection with a prion, which is a fragment of protein that is resistant to most of the usual methods of reprocessing and decontamination. Specific recommendations (e.g., quarantine of devices, use of disposable devices) have been made by Health Canada/PHAC for the cleaning and decontamination of instruments and surfaces that have been exposed to tissues considered infective for Creutzfeldt-Jakob disease (CJD).⁴⁹ Refer to your health care facility's infection prevention and control policies Health Canada/PHAC infection control guideline, "Classic Creutzfeldt-Jakob Disease in Canada"⁵⁰; available at: <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/02vol28/28s5/index.html>).

Summary of Section 1 Recommendations

- 1. Do not purchase medical devices that cannot be cleaned and reprocessed according to the recommended standards.**
- 2. When purchasing reprocessing equipment or chemical products for reprocessing, consideration should be given to Occupational Health requirements, client/patient/resident safety and environmental safety issues.**
- 3. All medical devices intended for use on a client/patient/resident that are being considered for purchase or will be obtained in any other way (e.g., loaned devices, trial or research devices, physician/practitioner-owned) shall meet established quality reprocessing parameters. Such equipment shall not be purchased or used until this process is established.**
- 4. Manufacturers' information for all medical devices shall be received and maintained in a format that allows for easy access by personnel carrying out the reprocessing activities.**
- 5. If there is a discrepancy between the reprocessing level recommended by the manufacturer and the intended use of the instrument by Spaulding's criteria, the higher level of disinfection/sterilization shall be used.**

6. **Newly purchased, non-sterile critical and semi-critical medical devices shall first be inspected and reprocessed according to their intended use prior to being put into circulation.**
7. **The organization shall develop and maintain policies and procedures that apply to the sending, transporting, receiving, handling and processing of loaned, shared and leased medical devices, including endoscopes.**
8. **The use of loaned devices for neurosurgical procedures is strongly discouraged.**
9. **Surgical devices at risk for CJD contamination shall be managed following Health Canada/PHAC infection control guideline, "Classic Creutzfeldt-Jakob Disease in Canada".**

2. Environmental Requirements for Reprocessing Areas

A. Physical Space

Access to reprocessing areas shall be restricted to authorized personnel as defined by departmental policies.

There should be a centralized area for reprocessing medical devices. It should conform to the requirements for reprocessing space. In smaller settings, such as clinics or offices in the community, this refers to any segregated area where reprocessing of devices takes place, away from clients/patients/residents and from clean areas.

Reprocessing performed outside the centralized area should be kept to a minimum and shall be approved by the reprocessing committee or those accountable for safe reprocessing practices.

Reprocessing performed outside the centralized area should be kept to a minimum and shall be approved by the reprocessing committee or those accountable for safe reprocessing practices and should conform to the requirements for reprocessing space.

The environment where cleaning/decontamination is performed should^{51,52}:

- a) Be distinctly separate from areas where clean/disinfected/sterile devices are handled or stored;
- b) Have restricted access from other areas in the setting;
- c) Ensure one-way work flow of staff and medical devices;
- d) Have adequate space for the cleaning process and storage of necessary equipment and supplies;
- e) Have surfaces that can be easily cleaned and disinfected;
- f) Have slip-proof flooring that can withstand wet mopping and hospital-grade cleaning and disinfecting products; and
- g) Have easy access to hand hygiene facilities.

Decontamination work areas shall be physically separated from clean and other work areas to control traffic flow and to isolate contaminants generated during the stages of cleaning. Walls or partitions should be cleaned regularly and be constructed of materials that can withstand cleaning and disinfection.⁵³

Decontamination sinks⁵⁴:

- a) Shall be designed and arranged to facilitate soaking, washing and rinsing of devices with minimal movement or delay between steps;

- b) Should be adjacent to waterproof counter tops and a backsplash;
- c) Shall not have an overflow;
- d) Should be at a height that allows workers to use them without bending or straining;
- e) Shall be large enough to accommodate trays or baskets of instruments;
- f) Shall be deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated during cleaning; and
- g) Should be equipped with water ports for the flushing of instruments with lumens, if appropriate.

Hand hygiene facilities shall be located in all personnel support areas and at all entrances to, and exits from, the decontamination area. Hand hygiene facilities should include:

- a) Accessible hand washing sinks with hands-free controls, soap dispensers and paper towels; and/or
 - b) Alcohol-based hand rub (ABHR).
- Refer to Appendix C, 'Recommendations for Physical Space for Reprocessing', for details regarding reprocessing area space requirements.

B. Air Quality

The Occupational Health and Safety Regulation respecting control of exposure to biological and chemical agents made under the *Workers Compensation Act* provides occupational exposure limits such as ceiling exposure value (CEV) for chemical agents (e.g., glutaraldehyde).⁵⁵ A CEV is the maximum airborne concentration of a chemical agent to which a worker is exposed at any time. If control measures are not available during reprocessing involving a chemical agent, air sampling shall be required to ensure that the regulated limit has not been exceeded for the chemical being used.

The health care setting should have air changes; temperature and humidity appropriate to the process/product being used (refer to CSA standards and manufacturer's recommendations for products).

In health care settings where there are dedicated medical device reprocessing departments, in soiled areas negative pressure relative to clean areas shall be maintained, and positive pressure shall be maintained in clean areas. Pressure should be monitored.⁵⁶

- Refer to Appendix C, 'Recommendations for Physical Space for Reprocessing', for specific information regarding reprocessing area ventilation, temperature and humidity requirements

C. Water Quality

The quality of the water supply used for reprocessing shall be known and checked as required. Policies shall be developed to address known problems. There should be written reprocessing contingency plans in place that address loss of potable water, boil water advisories and other situations where the water supply becomes compromised.

- Refer to Appendix C, 'Recommendations for Physical Space for Reprocessing', for information regarding reprocessing area water quality requirements,
- AMMI TIR 34 (2007), Water for the reprocessing of medical devices.⁵⁷

D. Environmental Cleaning in Medical Device Reprocessing/Sterile Processing Departments

The housekeeping department should consult with the management of the Medical Device Reprocessing department and infection prevention and control to establish policies and procedures for cleaning practices and cleaning frequency. As a minimum⁵⁸:

- a) The facility shall have written cleaning procedures with clearly defined responsibilities for all areas in the facility where reprocessing is performed;
- b) All work areas, stands, tables, countertops, sinks and equipment surfaces shall be cleaned and disinfected at least daily;
- c) Floors shall be cleaned at least daily;
- d) If a spill occurs, the affected area shall be cleaned immediately following WorkSafe BC dangerous spills guidelines;
- e) Sinks shall be cleaned each shift at a minimum and more frequently as necessary;
- f) Sinks used for cleaning endoscopes and respiratory equipment shall be cleaned between each use;
- g) The sequence of environmental cleaning shall be from clean areas to soiled areas, from high areas to low areas (e.g. top of walls to floor) and from least contaminated to most contaminated;
- h) Cleaning staff shall not move back and forth between clean and soiled areas; and
- i) Cleaning equipment used in the decontamination area shall not be used in any other area.

- Refer to the MOHLTC's 'Best Practices for Environmental Cleaning for Prevention and Control of Infections in All Health Care Settings' for guidance regarding cleaning in reprocessing areas, available at:

http://www.health.gov.on.ca/english/providers/program/infectious/diseases/ic_enviro_clean.html.

Summary of Section 2 Recommendations

- 10. Reprocessing performed outside the centralized reprocessing area should be kept to a minimum.**
- 11. The decontamination work area shall be physically separated from clean areas.**
- 12. Air quality shall be monitored when using chemical disinfection/sterilization products that produce toxic vapours and mists.**
- 13. The quality of the water supply used for reprocessing shall be known and checked as required.**
- 14. There shall be a regular schedule for environmental cleaning in the Medical Device Reprocessing/Sterile Processing Department that includes written procedures and clearly defined responsibilities.**

3. Policies and Procedures

Policies and procedures should be established to ensure that reprocessing practices follow the principles of infection prevention as set out by the CSA standards,^{59,60} these BC Ministry Best Practice Guidelines, and the PHAC/Health Canada,⁶¹. Completed policies and procedures shall be reviewed by an individual with medical device reprocessing expertise. Other experts shall be involved as appropriate e.g. infection prevention and control, risk management.⁶² Review of reprocessing policies and procedures shall take place regularly.

Reprocessing policies and procedures shall include, but are not limited to, the following⁶³:

- a) Responsibilities of management and staff;
- b) Qualifications, education, training and competency assessment of staff involved in reprocessing;
- c) Infection prevention and control activities;
- d) Worker health and safety activities;
- e) Preventive maintenance requirements with documentation of actions;
- f) Written protocols for each component of the cleaning, disinfection and/or sterilization process that are based on the manufacturer's recommendations and established guidelines for the intended use of the product;
- g) Provision for regular review of policies and procedures with updating as required e.g. every 3 years as per CSA Z314.3-09;
- h) Documentation and record maintenance for each critical process (e.g., high level disinfection, sterilization);
- i) Management and reporting of incidents where client/patient/resident or staff safety may have been compromised ;
- j) Requirements for internal or external subcontractors, if applicable; and
- k) Written procedures for adverse events⁶⁴
 - o See Section II, 13, 'Quality Assurance,' for more information about adverse events and a recall procedure.

Summary of Section 3 Recommendations

- 15. The health care setting shall, as a minimum, have policies and procedures for all aspects of reprocessing based on CSA standards,^{65,66} these BC Ministry Best Practice Guidelines, and the PHAC/Health Canada guidelines⁶⁷ .**
- 16. All policies and procedures for reprocessing medical devices require review by an individual with medical device reprocessing expertise. Other stakeholders shall be consulted as required (e.g., Infection Prevention and Control (IPC) practitioners, Health Shared Services BC (HSSBC), Risk Management)**
- 17. A procedure shall be established for the management of adverse reprocessing events.**

4. Education and Training

Medical Device Reprocessing (MDR) Managers accountable for reprocessing shall have demonstrated knowledge of reprocessing practices and infection prevention and control principles as they relate to medical device reprocessing.⁶⁸ It is the manager's responsibility to ensure that:

- a) Any individual involved in the cleaning, disinfection and/or sterilization of medical devices is properly trained and their practice assessed on a regular basis to verify that standards are met;
- b) Training includes information on cleaning, disinfection and sterilization, occupational health and safety issues, and infection prevention and control principles; and
- c) Orientation and continuing education is provided and documented for all personnel involved in reprocessing of medical devices.

All staff, including supervisors, involved in the reprocessing of medical devices should be supervised and shall be qualified through education, training and experience in the functions they perform.^{69,70}

Reprocessing technicians who routinely perform medical device reprocessing activities shall, at a minimum, have successfully completed a recognized medical device reprocessing technician educational program.

- a) Where attaining the minimum educational requirement is not possible due to program availability, it is recommended that personnel who routinely perform medical device reprocessing activities successfully complete CSA's Certified Medical Device Reprocessing Technician's program or equivalent.
- b) It is strongly recommended that re-certification be obtained every five years.
 - Refer to Appendix E, 'Additional Resources', for a list of education and training resources.

It is strongly recommended that re-certification be obtained every five years.

The policies of the health care setting shall specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical devices and will ensure that:

- a) All staff who are primarily involved in reprocessing obtain and maintain their qualification;
- b) There is a process in place to ensure continued competency, including continuing education provided at regular intervals and periodic competency assessment⁷¹; and
- c) All orientation, training and continuing education is documented.⁷²

Summary of Section 4 Recommendations

- 18. MDR Managers accountable for reprocessing shall have demonstrated knowledge of reprocessing practices and infection prevention and control principles as they relate to medical device reprocessing.**
- 19. All staff, including supervisors, involved in the reprocessing of medical devices should be supervised and shall be qualified through education, training and experience in the functions they perform.**
- 20. Reprocessing technicians who routinely perform medical device reprocessing activities shall, at a minimum, have successfully completed a recognized medical device reprocessing technician educational program.**
- 21. Any individual involved in any aspect of reprocessing shall obtain education, orientation and training specific to the function they perform/medical device to be reprocessed (e.g., medical imaging technologists, respiratory technicians and staff in endoscopy, dental, podiatry, residential care, and physician offices).**
- 22. The policies of the health care setting shall specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical devices.**

5. Occupational Health and Safety for Reprocessing

An Occupational Health and Safety representative for the health care setting should review all protocols for reprocessing medical devices to verify that staff safety measures are followed and are in compliance with the *Workers Compensation Act*, RSBC, 1996 and associated Regulations. This review will verify that:

- a) Sharps are handled appropriately^{73, 74};
- b) Local exhaust ventilation systems adequately protect staff from toxic vapours^{75, 76};

- c) Chemicals are labelled, stored and handled appropriately, and Material Safety Data Sheets (MSDS) are readily available as required by the *Workplace Hazardous Materials Information System (WHMIS)*, R.R.O. 1990, Reg. 860 Amended to O. Reg. 36/93⁷⁷;
- d) An eyewash fountain is installed near to where chemicals are stored or used to treat the eyes after contact with a biological or chemical agent⁷⁸; and
- e) Personal protective equipment appropriate to the task is available and used.

Information on WHMIS is available from the Health Canada website at: http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/index_e.html].

The federal *Hazardous Products Act* and the pursuant *Controlled Products Regulation*, which apply to suppliers, define which materials (i.e., controlled products) are included in the Workplace Hazardous Materials Information System (WHMIS) and what information suppliers should provide to employers for controlled products used in the workplace.

The Workers' Compensation Board administers the requirements of the *Hazardous Products Act* in BC under section 114 of the *Workers Compensation Act*, and WorkSafeBC officers enforce federal requirements on suppliers under the *Hazardous Products Act*.

A. Routine Practices

Routine practices^{79, 80} shall be part of all staff education and training to prevent exposure to body substances. Procedures shall be in place for immediate response to staff exposure to blood and body fluids or injury from sharp objects.⁸¹ All staff that reprocess should be immune to Hepatitis B or receive Hepatitis B immunization.^{82, 83, 84}

Routine practices in reprocessing areas include:

- a) A dress code for all reprocessing areas^{85, 86};
- b) A policy to control traffic in reprocessing areas^{87, 88};
- c) A policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics or lip balm and handling contact lenses in the reprocessing area^{89, 90};
- d) Personal effects, including food and drink, shall not be brought into the reprocessing area¹;
- e) Hand hygiene facilities located at all entrances to, and exits from, reprocessing areas and faucets should be supplied with foot-, wrist- or knee-operated handles or electronic sensors^{91, 92};
- f) Hand hygiene training for reprocessing staff^{93, 94, 95} which includes:
 - i) Hands shall be cleaned before beginning work, before breaks and upon completion of work; after removing gloves; and whenever hands are contaminated;
 - ii) If there is visible soil on the hands, hand hygiene shall be performed with soap and water. If there is no visible soil on the hands, staff shall use either soap and water or an alcohol-based hand rub (ABHR); and
 - iii) Hand or arm jewellery, external body piercings that cannot be covered, or nail enhancements including nail polish, shall not be worn.
- g) Provision for, and wearing of, appropriate PPE for all reprocessing activities.

More information on Routine Practices shall be found in the PHAC following publication:

- 'Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care', available at: <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/99pdf/cdr25s4e.pdf>

B. Personal Protective Equipment (PPE)

Staff involved in reprocessing should be trained in the correct use, wearing, limitations and indications for PPE^{96, 97, 98}:

- a) PPE worn for cleaning and handling contaminated devices includes gloves appropriate to the task, face protection (i.e., full face shield OR fluid-impervious face mask and protective eyewear)⁹⁹ and impermeable gown or waterproof apron; refer to CSA Z314.08-09 Section 6.7.2 and/or for guidance in choosing task specific PPE.

When choosing gloves, the following principles should be considered:

- i. Gloves should be appropriate to the task;
 - ii. Gloves should be long enough to cover wrists and forearms;
 - iii. Gloves should be of sufficient weight to be highly tear-resistant;
 - iv. Gloves should allow adequate dexterity of the fingers; and
 - v. Disposable gloves are recommended; if reusable gloves are used, they should be decontaminated daily, inspected for tears and holes and be staff-specific.
- b) PPE shall be removed on completion of the task for which it was indicated and before moving from soiled to clean areas (e.g., leaving Decontamination area)¹⁰⁰;
 - c) Staff shall be trained in management of a blood, body fluid and chemical spill^{101,102}; and
 - d) Where there is the risk of exposure to biological and/or chemical agents, eye wash stations shall be provided and staff shall be trained in their use.

- Additional information on PPE may be found in the MOHLTC's '*Routine Practices and Additional Precautions for All Health Care Settings*'¹⁰³, available at:

http://www.health.gov.on.ca/english/providers/program/infectious/diseases/ic_routine.html.

C. Safe Handling of Sharps

Procedures shall be in place to prevent injuries from sharp objects such as disposing of sharps at point of use. However, sharps can inadvertently reach the reprocessing area. In this case, staff in the reprocessing area shall¹⁰⁴:

- a) Place disposable sharp objects in puncture-resistant containers;
- b) Take care when handling glass and other fragile objects;
- c) Discard chipped or broken glass devices or arrange to have them repaired;
- d) Not recap used needles or other sharps unless using a recapping device; and
- e) Not manually bend or break needle.

D. Work Restrictions

Reprocessing staff may be subject to some work restrictions¹⁰⁵:

- a) Staff who have respiratory problems (e.g., asthma) should be assessed by Occupational Health and Safety staff prior to working with chemical disinfectants or cleaning agents; and
- b) Staff who have exudative lesions or weeping dermatitis shall refrain from handling client/patient/resident care equipment until the condition is resolved.

Summary of Section 5 Recommendations

23. All activities included in the reprocessing of medical devices shall be based on the consistent application of Routine Practices and hand hygiene.

- 24. There is a policy that prohibits eating/drinking, storage of food, smoking, and application of cosmetics or personal effects in the reprocessing area.**
- 25. Appropriate personal protective equipment (PPE) shall be worn for all reprocessing activities.**
- 26. All staff working in reprocessing shall be offered Hepatitis B immunization unless they have documented immunity to Hepatitis B.**
- 27. Measures and procedures shall be written to prevent and manage injuries from sharp objects.**
- 28. Measures and procedures shall be in place for immediate response to worker exposure to chemicals as well as blood and body fluids.**
- 29. Occupational Health and Safety for the health care setting should review all protocols for reprocessing medical devices to verify that worker safety measures and procedures are in place.**

6. Cleaning (Decontamination) of Reusable Medical Devices

“Cleaning is always essential prior to disinfection or sterilization. An item that has not been cleaned cannot be assuredly disinfected or sterilized.”

Public Health Agency of Canada/Health Canada

Reusable medical devices shall be thoroughly cleaned (decontaminated) before disinfection or sterilization.¹⁰⁶ The process of cleaning physically removes contaminants from the device, rather than killing microorganisms. If an item is not cleaned, soil (e.g., blood, body fluids, dirt) can protect the microorganisms from the action of disinfection or sterilization making the process ineffective, as well as inactivate the disinfectant or sterilant so that it does not work. Disinfectants that become overloaded with soil can become contaminated and may become a source for transmission of microorganisms.

Cleaning is always required prior to disinfection or sterilization. An item that has not been cleaned cannot be adequately disinfected or sterilized.¹⁰⁷

Sharps are devices that can cause occupational injury to a worker. Some examples of sharps which cannot be safely cleaned include needles, lancets, blades and glass. Reprocessing needles is an occupational health hazard. Further, reprocessing needles can be a patient safety issue as there is no guarantee that the lumen is clean and that the reprocessing is effective. Sharps and needles shall be single-use and shall not be reprocessed.

Reusable devices with small lumens or other design characteristics that make them difficult to clean effectively can put clients/patients/residents at risk.^{108, 109} They cannot be checked for cleanliness and sterilant contact cannot be verified. This includes items, such as catheters, tubing, fine cannulae, and burrs. These items should be designated single-use and shall not be reprocessed and re-used.

Despite the fact that some manufacturers' provide instructions for reprocessing, this may be impossible to effectively accomplish due to device design or complexity. In this case, consider treating the device as single use.

Semi-critical medical devices owned by the client that are re-used in their home shall be adequately cleaned prior to reuse. Home health care agencies may consider re-using single-use semi-critical medical devices for a single client in their home when reuse is safe. Critical medical devices owned by clients cannot be reprocessed safely as sterilization cannot be achieved in the home environment. Therefore, critical medical devices remain single use in the home and shall be disposed of after use.

Refer to CSA Z314.8-09 Annex J for further information regarding difficult to cleaning medical devices.

A. Pre-Cleaning At Point of Use

Disposable sharps such as needles and blades shall be removed and disposed of by the user in an appropriate sharps container at the point of use. Reusable devices that are sharp or that incorporate sharp components shall be segregated to prevent injury to personnel.

Immediately after use, the user shall clean medical devices of gross soil by rinsing with water. Devices shall then be sorted and contained. The medical device should be pre-treated to prevent organic matter from drying on it.^{110, 111, 112}

Pre-cleaning (e.g., soak or spray) prevents soil from drying on devices and it makes them easier to clean:

- a) Cleaning products used should be appropriate for medical devices and approved by the device manufacturer;
- b) If detergent based products are used, ensure that they are mixed to the correct in-use dilution;
- c) Avoid prolonged soaking of devices; and
- d) Do not use saline as a soaking solution as it damages some medical devices.

Following point-of-use precleaning, devices should be kept moist in a transport container by adding a towel moistened with water (not saline) or foam, spray, or gel product specifically intended for this use.

PPE shall be worn for handling and cleaning contaminated devices (see Section II.5.B).

B Handling and Transportation of Contaminated Devices

Soiled medical devices shall be handled in a manner that reduces the risk of exposure and/or injury to personnel and clients/patients/residents, or contamination of environmental surfaces:¹¹³

- a) Contaminated devices shall be transported to a designated decontamination area as soon as possible after use.
- b) Contaminated devices shall be transported in covered, fully enclosed, puncture-resistant containers that prevent spill of liquids. Containers shall be decontaminated after each use.
- c) On-site transport for contaminated devices shall follow designated routes to avoid high-traffic and patient-care areas.
- d) All carts and containers containing contaminated devices shall be so identified.

- e) Sterile and soiled devices shall not be transported together (i.e., on the same cart) due to the risk of cross-contamination.

C Preparation for Cleaning of Medical Devices

Once medical devices have been received in the reprocessing area, they should be disassembled and sorted. They may also require pre-treatment prior to cleaning:

- a) **Disassembly** – facilitates access of the cleaning agent, disinfectant and/or sterilant to device surfaces:
 - i) Devices shall be disassembled¹¹⁴ prior to cleaning if there is one or more removable part¹¹⁵, unless otherwise recommended by the manufacturer.
 - ii) Follow the manufacturer's recommendations when disassembling medical devices prior to cleaning.
- b) **Sorting** – keeps medical devices that belong to a set together and streamlines the cleaning process:
 - i) Sort devices into groups of like products requiring the same processes.
 - ii) Segregate reusable sharps and/or delicate devices to prevent injury to personnel and damage to the device.
- c) **Pre-treatment** (e.g., soak or spray) loosens soil that may remain on devices, and it makes them easier to clean:
 - i. Cleaning products should be appropriate for medical devices and approved by the device manufacturer.
 - ii. If detergent based products are used, ensure that they are mixed to the correct in-use dilution.
 - iii. Avoid prolonged soaking of devices.
 - iv. Do not use saline as a soaking solution as it damages some medical devices.

D. Cleaning

Cleaning shall be done manually or using mechanical cleaning machines (e.g., washer-disinfector, ultrasonic washer) after gross soil has been removed. Automated machines may increase productivity, improve cleaning effectiveness and decrease staff exposure to blood and body fluids.¹¹⁶ Manual cleaning may be required for delicate or intricate items.

Devices shall be cleaned with a detergent solution unless otherwise recommended by the device manufacturer. Selection of the detergent shall depend upon:¹¹⁷

- a. Instructions of the device manufacturer;
- b. Instructions of the detergent manufacturer;
- c. The type of residual soil left on the device; and
- d. The water quality.

The device manufacturer's cleaning instructions shall be followed, including specifications for detergent type, water temperature and cleaning methods. The following procedures are included in the cleaning process:

- a) **Manual Cleaning**¹¹⁸
 - Ensure that the device to be cleaned is compatible with the chemical solutions that are being used;

- Completely submerge immersible items during the cleaning process to minimize aerosolization and to assist in cleaning¹¹⁹;
- Remove gross soil using tools such as brushes and cloths;
- Minimize the production of aerosols when cleaning non-immersible devices;
- Clean devices that have lumens with a disposable brush, according to the manufacturer's instructions, then manually or mechanically flush with a detergent solution and rinse with potable water; and
- Check devices with lumens for obstructions and leakage.

b) Mechanical Cleaning¹²⁰

Whenever possible, clean devices by mechanical means:

- i) Use mechanical washers in accordance with the manufacturer's instructions;
- ii) Manually clean heavily soiled devices before mechanical cleaning if necessary;
- iii) Ensure that the device to be cleaned is compatible with the mechanical cleaning equipment, cycle parameters and chemical solutions that are being used;
- iv) Ultrasonic washers are strongly recommended for any semi-critical or critical medical device that has joints, crevices, lumens or other areas that are difficult to clean.
 - The manufacturer's instructions shall be followed for use and routine cleaning and maintenance of the ultrasonic washer.
 - Devices shall be completely immersed in the cleaning solution/bath.
 - After cleaning, devices shall be rinsed thoroughly prior to further reprocessing
 - The ultrasonic solution shall be changed at least daily or more frequently if it becomes visibly soiled or if the manufacturer's instructions specify more frequent changes.
- v) Washer-disinfectors are strongly recommended for medical devices that can withstand mechanical cleaning, to achieve the required exposure for cleaning and to reduce potential risk to personnel. When used:
 - Washer-disinfectors shall meet the requirements of CSA and ISO 15883.
 - The manufacturer's instructions shall be followed for the use, preventative and routine maintenance, cleaning, and calibration of the washer-disinfector.

c) Care of Cleaning Tools

- i) Follow manufacturer's instructions for use, cleaning, disinfection, drying, and storage of cleaning tools¹²¹;
- ii) Inspect brushes and other cleaning equipment for damage after each use, and discard if necessary¹²²; and
- iii) The use of single-use cleaning tools is recommended. If reusable tools are used, they shall be disinfected at least daily.

d) Rinsing

Rinsing following cleaning is necessary to remove loosened soil and residual detergent:

- i) Rinse all devices thoroughly after cleaning with water to remove residues which might react with the disinfectant/sterilant; and
- ii) Perform the final rinse of lumens of intravascular/intrathecal devices with commercially prepared sterile, pyrogen-free water (note: distilled water is not necessarily sterile or pyrogen-free)¹²³.

e) Drying¹²⁴

Drying is an important step that prevents dilution of chemical disinfectants which may render them ineffective and prevents microbial growth:

- i) Follow the manufacturer's instructions for drying of the device;
- ii) Devices shall be air-dried or dried by hand with a clean, lint-free towel;
- iii) Dry lumens with compressed medical grade or HEPA-filtered air at a pressure specified by the device manufacturer. Use a regulator to control pressure; and
- iv) Dry stainless steel devices immediately after rinsing to prevent spotting.

Summary of Section 6 Recommendations

- 30. Disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point-of-use, prior to transportation.***
- 31. Soiled medical devices shall be handled in a manner that reduces the risk of exposure and/or injury to personnel and clients/patients/residents, or contamination of environmental surfaces.***
- 32. Contaminated devices shall not be transported through areas designated for storage of clean or sterile supplies, client/patient/resident care areas or high-traffic areas.***
- 33. Sterile and soiled devices shall not be transported together.***
- 34. Reusable medical devices shall be thoroughly cleaned before disinfection or sterilization.***
- 35. If cleaning cannot be done immediately, the medical device should be pre-treated to prevent organic matter from drying on it.***
- 36. The process for cleaning (decontamination) shall include written protocols for disassembly, sorting, pre-treatment, physical removal of organic material, rinsing, and drying.***
- 37. It is strongly recommended that catheters, tubing and other medical devices with small lumens be designated single-use and not be reprocessed and re-used.***
- 38. Home health care agencies may consider re-using single-use semi-critical medical devices for a single client in their home when reuse is safe.***
- 39. The use of single-use (disposable) cleaning tools is recommended.***

7. Factors Affecting Product Selection and Efficacy of Liquid Chemicals for Disinfection or Manual Sterilization

A. Factors affecting efficacy

Policies and procedures for disinfection and sterilization should include statements and information relating to factors that might affect their effectiveness. These procedures shall be readily accessible to staff doing the reprocessing.

Many factors^{125, 126, 127} affect the efficacy of disinfection and sterilization, particularly when chemical reprocessing is used. These factors include:

- a) **Cleanliness of the surface of the device:**
 - i) ***Bioburden***

- Many chemical disinfectants/sterilants are inactivated by organic material;
 - The greater the bioburden, the more difficult it is to disinfect or sterilize the device;
 - Dried organic material is more difficult to remove.
- ii) **Device characteristics:**¹²⁸
- Long, narrow lumens and channels are difficult to clean;
 - Materials such as rubber, plastic, and some metals (e.g., aluminium) may require special treatment;
 - Rough or porous surfaces may trap microorganisms (e.g., ridges, ribbing, grooves, articulations); and
 - Hinges, cracks, coils, valves, joints, clamps, crevices on the device may impede successful disinfection/sterilization.
- b) **Type and concentration of the product:**
- i. Products used for disinfection and/or sterilization shall be mixed according to the manufacturer's recommendations in order to achieve the correct dilution; if the concentration of the disinfectant is too low, the efficacy will be decreased; if the concentration is too high, the risk of damage to the instrument or toxic effects on the user/patient increases;
 - ii. Dry devices after cleaning, before immersing in disinfectant, to prevent dilution of the disinfectant¹²⁹;
 - iii. Discard solutions on or before their expiry date; diluted products are inherently unstable once mixed and the manufacturer's directions as to duration of use shall be followed
 - iv. Use chemical test strips for all reusable high-level liquid disinfectants to assess their efficacy. During reuse, the concentration of active ingredients may decrease as dilution of the product occurs and organic impurities accumulate¹³⁰;
 - v. Use the appropriate disinfectant/sterilant for the task. Medical device reprocessing representative and infection prevention and control representatives should approve disinfectants and their application; and
 - vi. Some microorganisms are more resistant to disinfectants/sterilants, and this should be taken into consideration when choosing the product/process.
- c) **Duration and temperature of exposure to the product:**
- i. Use Health Canada/PHAC recommendations for the level of disinfection/sterilization required for the intended use of the device (refer to Appendix D, 'Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options');
 - ii. Follow manufacturer's instructions for temperature and for exposure time required to achieve the desired level of disinfection/sterilization;
 - iii. Do not exceed the manufacturer's maximum exposure time, as some chemicals may cause damage to the medical device if used for extended periods of time;
 - iv. All surfaces of the device shall be in direct contact with the disinfectant/sterilant;
 - v. Contact may be compromised by the complexity of the medical device and the ability of the disinfectant to penetrate lumens; and
 - vi. Where the manufacturer's recommendations for minimum exposure time conflict with those of Health Canada/PHAC, an infection prevention and control professional should be consulted for advice.
- d) **Physical and chemical properties of the reprocessing environment:**
- i. Water hardness can affect some disinfectants (refer to Appendix C, 'Recommendations for Physical Space for Reprocessing')¹³¹;

- ii. Excessive humidity may compromise sterile packages (refer to Appendix C, 'Recommendations for Physical Space for Reprocessing')¹³²;
- iii. The pH of the solution can be an important consideration, as extremes of acidity or alkalinity may be incompatible with some medical devices.

B. Product selection

The reprocessing method and products required for medical devices will depend on the intended use of the device and the potential risk of infection involved in the use of the device. The process and products used for disinfection and/or sterilization of medical devices shall be compatible with the devices:

- a) Compatibility of the device with the disinfection/sterilization process, shall be determined by the manufacturer of the device; and
- b) All medical devices that will be purchased and will be reprocessed shall have written device-specific manufacturer's reprocessing instructions. If disassembly or reassembly is required, detailed instructions with pictures should be included. Staff training should be provided on these processes before the medical device is placed into circulation.

C. Terminal Reprocessing

The level of terminal reprocessing required by medical devices is based on the classification system developed by Spaulding¹³³. It divides medical devices into three categories, based on the client/patient/resident's risk of infection due to contact with various types of devices.

Table 1: Spaulding's Classification of Medical Devices and Required Level of Processing/Reprocessing

| Classification | Definition | Level of Processing/Reprocessing | Examples |
|----------------------|---|---|--|
| Critical Device | Device that enters sterile tissues, including the vascular system | Cleaning followed by Sterilization | <ul style="list-style-type: none"> ▪ Surgical instruments ▪ Biopsy instruments ▪ Foot care equipment ▪ Cystoscopes |
| Semi-critical Device | Device that comes in contact with non-intact skin or mucous membranes but do not penetrate them | Cleaning followed by High-Level Disinfection (as a minimum) Sterilization is preferred | <ul style="list-style-type: none"> ▪ Respiratory therapy equipment ▪ Anaesthesia equipment ▪ Tonometer ▪ Cystoscopes |
| Noncritical Device | Device that touches only intact skin and not mucous membranes, or does not directly touch the client/patient/resident | Cleaning followed by Low-Level Disinfection (in some cases, cleaning alone is acceptable) | <ul style="list-style-type: none"> ▪ ECG machines ▪ Oximeters ▪ Bedpans, urinals, commodes |

- Refer to Appendix B, 'Reprocessing Decision Chart', for guidance in choosing reprocessing products and processes.

D. Reprocessing Products

Products used for any/all stages in reprocessing (e.g. disinfection, sterilization) should be:

- a) Appropriate to the level of reprocessing that is required for the use of the medical device; and
- b) Approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise.

Summary of Section 7 Recommendations

- 40. Procedures for disinfection and sterilization should include statements and information regarding the type, concentration and testing of chemical products; duration and temperature of exposure; and physical and chemical properties that might have an impact on the efficacy of the process. These procedures should be readily accessible to staff performing the function.**
- 41. Products used for any/all stages in reprocessing should be approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise**
- 42. The reprocessing method and products required for medical devices will depend on the intended use of the device and the potential risk of infection involved in the use of the device.**
- 43. Products used for disinfection and sterilization should be appropriate to the level of reprocessing that is required for the use of the medical device.**
- 44. The process and products used for disinfection and/or sterilization of medical devices shall be compatible with the devices.**
- 45. The manufacturer shall provide written, validated, device specific information regarding the safe and appropriate reprocessing of the medical device.**

8. Disinfection of Reusable Medical Devices

“Failure to use disinfection products or processes appropriately has repeatedly been associated with the transmission of healthcare associated infections.”

Public Health Agency of Canada/Health Canada

Disinfection is the inactivation of disease-producing microorganisms. Disinfection of medical devices falls into two major categories – low-level disinfection and high-level disinfection.

It is important to note that before any device is disinfected, it should first be thoroughly cleaned. See Section 6, Cleaning (Decontamination) of Reusable Medical Devices for cleaning requirements prior to disinfection.

A. Low-Level Disinfection (LLD)

Low-level disinfection eliminates vegetative bacteria, some fungi and enveloped viruses. LLD is used for **noncritical medical devices**^{23, 28} and some environmental surfaces. Low-level disinfectants include 3% hydrogen peroxide, 0.5% accelerated hydrogen peroxide, quaternary ammonium compounds (QUATS), phenolics and diluted sodium hypochlorite (e.g., bleach) solutions. LLD is usually performed after the device is thoroughly cleaned, rinsed and excess rinse water is removed. Refer to Appendix B, 'Reprocessing Decision Chart', for chemical products that may be used to achieve low-level disinfection.

Noncritical medical devices require decontamination using a low-level disinfectant.

B. High-Level Disinfection (HLD)

High-level disinfection kills vegetative bacteria, enveloped and non-enveloped viruses, fungi, mycobacteria (e.g., tuberculosis) and some, but not all spores. HLD is used for **semi-critical medical devices**. High-level disinfectants include 2% glutaraldehyde, 6% hydrogen peroxide, 0.2% peracetic acid, 7% accelerated hydrogen peroxide and 0.55% ortho-phthalaldehyde (OPA). Thermal disinfection also achieves the equivalent of high-level disinfection. HLD is performed after the device is thoroughly cleaned; rinsed and excess rinse water is removed. Refer to Appendix B, 'Reprocessing Decision Chart', and Appendix D, 'Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options' for chemical products that may be used to achieve high-level disinfection.

Sterilization is the preferred method of terminal processing for semi-critical medical devices.

Semi-critical medical devices require decontamination and a minimum, high-level disinfection.^{134, 135} Sterilization is the preferred method of terminal processing.

C. Methods of Disinfection for Semi-critical Medical Devices

There are two disinfection methods for semi-critical devices used in health care settings – chemical disinfection and thermal disinfection.

1. Chemical Disinfection

When selecting a disinfectant for reprocessing medical devices in the health care setting, consider¹³⁶:

- a) The requirement for disinfectants to have a Drug Identification Number (DIN) from Health Canada¹³⁷;
- b) Efficacy for the intended use;
- c) Compatibility with the device;
- d) The intended end use of the devices;
- e) The methods to be used for monitoring the product concentration, efficacy, temperature, and contact time;
- f) Recommendations for rinsing (e.g., water quality, volume, time);
- g) Safety for use, with minimal toxic and irritating effects to/for staff⁹;
- h) Environmental safety, biodegradability and disposal;
- i) Manufacturer's instructions for use (e.g., contact time, concentration/dilution, water requirements); and
- j) Method of use e.g. manual immersion, automated reprocessor.

The manufacturer's recommendations for chemical disinfectants shall be followed pertaining to:

- a) Usage - disinfectant manufacturers shall supply recommended usage for the disinfectant to ensure that it is compatible with the medical devices on which it will be used;
- b) Contact time;
- c) Shelf life;
- d) Storage;
- e) Appropriate dilution and temperature; and
- f) Environmental and personnel safety e.g. required PPE, ventilation

If a disinfectant manufacturer is unable to provide compatibility information specific to the medical device, information may be obtained from Health Canada's drug information website, available at: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php>.

The process of high-level disinfection requires monitoring and documentation:

- a) Chemical test strips shall be used to determine whether a minimally effective concentration (MEC) of active ingredients is present because of the potential for dilution from repeated reuse:
 - i) The frequency of testing is determined by the MIFUs;
 - ii) Chemical test strips shall be checked each time a new package/bottle is opened to verify their efficacy according to the MIFUs;
 - iii) Test strip results shall not be used to extend the use of a disinfectant solution beyond the in-use expiration date; and
 - iv) Disinfectant solutions shall not be used and shall be discarded if MEC test strip fails prior to the in-use expiration date.
- b) A permanent record of high-level disinfection shall be completed and retained according to the policy of the facility¹³⁸; this record shall include, but not be limited to:
 - i) Name of disinfectant, lot number and expiry date;
 - ii) The identification of the device to be disinfected;
 - iii) Date and time that the device was disinfected;
 - iv) Concentration, contact time, and temperature of the disinfectant used in each process;
 - v) Result of each MEC testing of the disinfectant; and
 - vi) The name of the person completing the reprocessing.

Disinfection practices shall be assessed on a regular basis and a quality improvement process should be in place to deal with any irregularities/concerns resulting from the assessment.

Prepared solutions shall not be topped up with fresh solution.¹³⁹

Rinsing of medical devices following manual chemical disinfection requires three separate water rinses as outlined in the chemical and/or device MIFU. The quality of the water (e.g., potable, sub-micron filtered or sterile) will depend on the intended use of the medical device being reprocessed.

Drying of semi-critical medical devices that have been disinfected and rinsed with pyrogen free water shall be completed using medical grade air or HEPA filtered air¹⁴⁰.

If manual disinfection is performed, the container used for disinfection shall be kept covered, whenever possible, during use¹⁴¹ and washed, rinsed and dried when the solution is changed.

2. Thermal Disinfection (e.g., Pasteurization)

Thermal Disinfection is a process of hot water disinfection, which is accomplished through the use of automated pasteurizers or washer disinfectors with a validated thermal disinfection cycle. The exposure time and temperature will vary with the type of thermal disinfection process. Semi-critical medical devices suitable for thermal disinfection include equipment for respiratory therapy and anaesthesia. Devices require thorough cleaning and rinsing prior to thermal disinfection (see Section II.6, 'Section 6, *Cleaning (Decontamination) of Reusable Medical Devices*, for information about cleaning prior to thermal disinfection).

The manufacturer's instructions for installation, operation and ongoing maintenance of thermal disinfection equipment shall be followed.

- a) If a washer disinfectant is intended to provide the thermal equivalent to pasteurization, the facility shall obtain documentation from the manufacturer (or 3rd party) to confirm that the washer disinfectant has been validated for this use according to CSA/ISO 15883 and is licensed by Health Canada ;
- b) For each cycle, the time, and temperature shall be monitored and recorded; and
- c) The accuracy of the recording devices (for time and temperature) shall be periodically confirmed.

Following thermal disinfection, medical devices shall be handled in a manner that prevents contamination. Devices shall be transported directly from the pasteurizer/disinfectant to a clean area for drying, assembly and packaging. Medical devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air filter (HEPA) and is used exclusively for the drying of pasteurized devices.¹⁴²

Printed records of each cycle (i.e., temperature, time) shall be retained in accordance with the health care facility's requirements.¹⁴³

Summary of Section 8 Recommendations

- 46. Noncritical medical devices shall be low-level disinfected prior to use.**
- 47. Semi-critical medical devices shall be, at a minimum, high-level disinfected prior to use. Sterilization is preferred.**
- 48. Disinfectant manufacturers shall supply compatibility information for the disinfectant to ensure that it is compatible with the medical devices on which it will be used.**
- 49. The process of high-level disinfection requires monitoring. If a reusable liquid chemical product is used, the minimally effective concentration (MEC) of the active ingredient(s) shall be verified using appropriate test strips and shall be documented.**
- 50. Manufacturer's instructions for installation, operation and ongoing maintenance of thermal disinfection equipment shall be followed.**
- 51. Following the thermal disinfection cycle, medical devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and that is used exclusively for the drying of pasteurized devices.**
- 52. A permanent record of disinfecting parameters shall be maintained.**

9. Reprocessing Endoscopy Devices

For the purposes of this document, endoscopes will be considered to be of two types:

Critical Endoscope: Endoscopes used in the examination of critical spaces, such as joints and sterile cavities. Many of these endoscopes are rigid with no lumens. Examples of critical endoscopes are arthroscopes, and laparoscopes. **Critical endoscopes should be sterilized prior to use.**

Semi-critical Endoscope: Fiberoptic or video endoscopes used in the examination of the hollow viscera. These endoscopes generally invade only semi-critical spaces, although some of their components might enter tissues or other critical spaces. Examples of semi-critical endoscopes are laryngoscopes, nasopharyngeal endoscopes, transesophageal probes, colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes and enteroscopes. **Semi-critical endoscopes require a minimum of high-level disinfection prior to use.**

Opinions differ regarding the reprocessing requirements for flexible bronchoscopes and cystoscopes. Since they are entering a sterile cavity, it is preferred that bronchoscopes and cystoscopes be sterilized; however, if the cystoscope or bronchoscope is not sterilized, high-level disinfection is the minimum requirement.

Due to the complexity of their design, flexible fiberoptic and video endoscopes ('semi-critical endoscopes') require meticulous cleaning and handling.^{144, 145}

A. Education and Training

Individuals responsible for reprocessing endoscopes require training and should meet the health care setting's written endoscope processing competency requirements:¹⁴⁶

- a) Staff assigned to reprocess endoscopes should be trained, based on the manufacturer's device-specific instructions for reprocessing, including but not limited to endoscopes, automatic endoscope reprocessors, and accessories;
- b) Competency testing of personnel reprocessing endoscopes should be performed at least annually and documented¹⁴⁷; and
- c) Personnel should not be allowed to reprocess endoscopes until competency has been established.¹⁴⁸

B. Physical Space

The endoscope reprocessing area should be physically separate from patient care areas and procedure rooms. The decontamination area should be separate from clean areas.

The endoscope reprocessing areas should have:^{149,150,151}

- (a) Adequate space for reprocessing activities;
- (b) Proper airflow and ventilation in accordance with local regulations and the Material Safety Data Sheet (MSDS) for the products used to reduce chemical vapours from cleaning or disinfecting agents to safe levels;
- (c) One-way workflow patterns;
- (d) Cleanable work surfaces (wood is not appropriate);

- (e) Adequate task lighting;
- (f) Required utilities such as electrical, medical-grade air (for drying purposes), suction, and water;
- (g) Sinks large enough for the intended uses, and counters large enough to facilitate the handling of the endoscopes;
- (h) Separate drains for automatic reprocessing equipment;
- (i) Appropriate sink(s) for hand hygiene, preferably with hands-free operation;
- (j) Eye-washing facilities; and
- (k) Adequate space for storage.

C. Cleaning Procedures

Each health care setting in which endoscopic procedures are performed should have written detailed procedures for the pre-cleaning (e.g., at the bedside), cleaning and handling of endoscopes.¹⁵²

Endoscope pre-cleaning should take place immediately following completion of the clinical procedure,¹⁵³ as soil residue in endoscope lumens dries rapidly, becoming very difficult to remove.

Pre-cleaning at the Bedside

Immediately following completion of the endoscopy procedure:¹⁵⁴

- Flush and wipe the endoscope at point-of-use; and
- Use a freshly prepared enzymatic cleaning solution or water (as specified by the scope manufacturer)

Place the endoscope and accessories in a covered, leak proof container and transport to the designated decontamination area.

Leak Testing

Perform leak testing after each use, prior to cleaning:

- Perform the leak test according to the manufacturer's instructions;
- An endoscope that fails the dry leak test should not undergo the immersion leak test;
- Identify damaged endoscopes and immediately remove from service

If a leak is detected, follow the endoscope manufacturer's specific instructions about decontaminating and returning the device for repair.

Unless otherwise validated by the endoscope reprocessor manufacturer and third party research, the following steps should be included in the cleaning procedure:^{155,156,157}

- 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.

Manual Cleaning

Follow the endoscope manufacturer's recommendations for model-specific endoscope cleaning protocols and for the cleaning products to be used.

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.^{158,159,160}

- 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
- l) 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

D. Disinfection or Sterilization

Procedures for disinfection or sterilization of endoscopes should ensure that a minimum of high-level disinfection is used for all endoscopes and their accessories, excluding biopsy forceps and brushes which require sterilization.¹⁶¹ The following steps should be included in the disinfection/sterilization procedure.^{162,163,164}

- a) Choose a disinfectant or sterilant that is compatible with the endoscope;
- b) Monitor the efficacy of the disinfectant or sterilant as per the manufacturer's instructions;
- c) Maintain a written log of monitored test results;
- d) Do not use disinfectants or sterilants past their expiry date, shelf life, in-use life, or if the MEC fails;

- e) Carefully follow the manufacturer's directions regarding the temperature, duration, and contact time for the disinfectant or sterilant;
- f) Completely immerse the endoscope and endoscope components in the high-level disinfectant or liquid chemical sterilant and ensure all channels are perfused; and
- g) Following disinfection or liquid chemical sterilization, rinse the endoscope and flush the channels with sub-micron filtered or sterile water.

Disposable sheaths/condoms placed over the endoscope reduce the numbers of microorganisms on the scope **but do not eliminate** the need for cleaning/disinfection/sterilization between uses.

E. Automated Endoscope Reprocessors (AER)

Written procedures should be based on the AER manufacturer's instructions for use and shall:¹⁶⁵

- 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) Medical devices that have been validated for reprocessing in the system;
- (b) Types of HLDs that have been validated for use in that specific system; and
- (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).

F. Drying and Storage of Endoscopes and their Attachments after High Level Disinfection

Steps in the final drying of semi-critical endoscopes should include:¹⁶⁶

- a) Initial purge of all channels with filtered, pressure controlled air;
- b) Flushing all channels with 70% isopropyl alcohol to aid in the drying process; and
- c) Second purge of the channels with filtered, pressure controlled air.¹⁶⁷

Storage procedures should include the following¹⁶⁸:

- a) Caps, valves and other detachable components shall remain disconnected during storage and reassembled just before use¹⁶⁹. Store close to the endoscope in a manner that minimizes contamination;
- b) Store semi-critical endoscopes by hanging vertically in a well-ventilated, closed cabinet in a manner that minimizes contamination or damage;
- c) Store endoscopes that have been terminally sterilized in their sterilization containers;
- d) Do not allow disinfected endoscopes to coil, to touch the sides, the floor or bottom of the cabinet while hanging, or be stored in their cases;
- e) Ensure that endoscope storage cabinets are constructed of non-porous material that can be cleaned; and
- f) Clean and disinfect endoscope storage cabinets at least weekly. Document the cleaning activity.

Flexible endoscopes should be reprocessed if storage exceeds 7 days.^{170,171}

Bronchoscopes that are wrapped and sterilized have an indefinite shelf life. Bronchoscopes that have been immersed in a liquid chemical disinfectant or sterilant but are not used on a routine bases, should be reprocessed immediately prior to use¹⁷²

G. Accessories

Endoscopic accessories (e.g., biopsy forceps and brushes) that break the mucosal barrier shall be sterilized before each use.¹⁷³

- a) Because of the difficulty cleaning biopsy forceps/brushes, **it is strongly recommended that disposable items be used;**
- b) If reusable biopsy forceps/brushes are used, they should be meticulously cleaned (e.g. ultrasonic) prior to sterilization; and
- c) The water bottle, cap and connecting tube, shall be cleaned and at least HLD daily. Sterilization is required prior to each Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure and prior to any procedure that invades sterile tissue.¹⁷⁴ Sterile water shall be used to fill the water bottle.

H. Documentation

An accurate, permanent record of endoscope use and reprocessing should link endoscopes to clients/patients/residents in the event of follow-up of an adverse event:

- a) For each procedure, document the client/patient/resident's name and record number, the date and time of the procedure, the type of procedure, the endoscopist, and the serial number or other identifier of the endoscope to assist in investigation;^{175, 176}
- b) For each endoscope reprocessed, document the scope ID, the reprocessing equipment ID, date and time, HLD or sterilant contact time, MEC test results or chemical indicator result, and the person(s) who completed the reprocessing^{177, 178}; and
- c) Retain records according to the policy of the facility.¹⁷⁹

- For more information regarding reprocessing of endoscopes, see the CSA's 'Z314.8-08 Decontamination of Reusable Medical Devices', Section 13.¹⁸⁰

Summary of Section 9 Recommendations

- 53. Individuals responsible for reprocessing endoscopes should be trained and should meet the facility's written requirements for ongoing education and training, and annual competency assessment.**
- 54. Each health care setting in which endoscopic procedures are performed should have written detailed procedures for the reprocessing and handling of endoscopes.**
- 55. Ventilation should be such as to remove toxic vapours generated by, or emitted from, cleaning or disinfecting agents.**
- 56. Endoscope pre-cleaning shall commence immediately following completion of the clinical procedure.**
- 57. Integrity of the endoscope shall be verified through leak testing, performed after each use following manufacturer's instructions.**
- 58. Endoscopic devices shall be rinsed and dried prior to disinfection or sterilization.**
- 59. Critical endoscopes and emergency bronchoscopes shall be sterilized.**
- 60. Semi-critical endoscopes and accessories (excluding biopsy forceps and brushes) should receive at least high-level disinfection after each use.**
- 61. Endoscopic accessories (e.g., biopsy forceps and brushes) that break the mucosal barrier should be disposable or sterilized after each use.**
- 62. If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components are compatible with the AER.**
- 63. Final drying of semi-critical endoscopes after high level disinfection shall be facilitated by flushing all channels with air, 70% isopropyl alcohol, and medical air.**
- 64. Semi-critical endoscopes shall be stored hanging vertically in a well-ventilated area in a manner that minimizes contamination or damage. Endoscopes shall not be coiled, allowed to touch the sides, the floor or bottom of the cabinet while hanging, or stored in their cases.**
- 65. The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during the procedure, should receive high-level disinfection or sterilization at least daily.**
- 66. Accessory bottle, cap, connection tube shall be sterilized prior to ERCPs or any procedure that invades sterile tissue.**
- 67. A preventive maintenance program for automated endoscope reprocessor (AER) shall be implemented and documented.**
- 68. Healthcare settings shall have policies in place providing a permanent record of endoscope use and reprocessing, as well as a system to link endoscopes and clients/patients/residents that includes recording the endoscope number in the client/patient/resident record.**

10. Sterilization of Reusable Medical Devices

Sterilization is the elimination of all disease-producing microorganisms, including bacterial spores (e.g. *Clostridium* and *Bacillus* species). Prions are not

The preferred method for sterilization of heat-resistant medical devices is pre-vacuum steam sterilization.

susceptible to routine sterilization. Sterilization is used on critical medical devices and, whenever possible, semi-critical medical devices. **The preferred method for sterilization of heat-resistant critical devices is steam sterilization (pre-vacuum sterilization is preferred).**

For devices that cannot withstand steam sterilization, some examples of chemical sterilants include:

- a) Hydrogen peroxide gas plasma;
- b) 0.2% peracetic acid;
- c) 7% accelerated hydrogen peroxide;
- d) 100% ethylene oxide; and
- e) Ozone.

For processes for liquid chemical sterilant manual soaking, follow section 9.D.

- Refer to Appendix B, 'Reprocessing Decision Chart', and Appendix D, 'Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options' for chemical products that may be used to achieve sterilization.

A. Sterilization Process

Medical devices that have contact with sterile body tissues or fluids are considered critical items.¹⁸¹ All critical medical devices shall be cleaned and then sterilized,^{182,183,184,185} because microbial contamination could result in disease transmission. Critical items include, but are not limited to, surgical instruments, implants, foot care equipment, endoscopes that enter sterile cavities and spaces, colposcopy equipment, biopsy forceps and brushes, eye and dental instruments.

Whenever possible, semi-critical medical devices should be sterilized. (Semi-critical medical devices have contact with non-intact skin or mucous membranes but do not penetrate them.¹⁸⁶) When sterilization is not possible, semi-critical devices shall be cleaned, followed by high-level disinfection.¹⁸⁷

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,^{188, 189, 190} BC Ministry Best Practice Guidelines and PHAC guidelines¹⁹¹;
- b) Follow manufacturer's instructions for installation, operation, cleaning and preventive maintenance of the sterilization equipment;
- c) 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 labelling)^{192,193,194}

B. Steam Sterilization Methods

Steam sterilization is a process that uses saturated steam under pressure as the sterilant. It is the preferred method for sterilizing critical medical devices. Written policies and procedures for steam shall include:

- Staff qualification, education/training and competency assessment;
- Preparation and packaging of medical devices;
- Sterilization procedures; and
- Monitoring and documenting of cycle parameters.

The manufacturer's instructions for installation, operation and ongoing maintenance of steam sterilization equipment shall be followed.

For each cycle, the sterilization time and temperature shall be monitored and recorded.

Monitoring of the sterilization cycle shall include:

- Physical (displays and printout);
- Chemical (internal and external indicators); and
- Biological.

There are several types of steam sterilizers that utilize different methods to remove air from packages and the chamber. They are dynamic air removal (prevacuum), gravity, and steam-flush pressure-pulse sterilizers.

Prevacuum sterilizers:

- Use a vacuum pump or water ejector to remove air from the chamber and packaged devices during the preconditioning phase and prior to sterilization;
- Operate at 132°C to 135°C.

Gravity sterilizers:

- Use gravity air displacement to remove air from the sterilizer chamber and packaged devices;
- Operate at 121°C or higher.

Steam-flush pressure-pulse:

- Use a repeated sequence of a steam flush and pressure pulse to remove air from the chamber and packaged items;
- Operate at 121°C to 123°C, 132°C to 135°C or 141°C to 144°C.

Steam sterilizers vary in chamber size from small table top models to large floor loading models. The recommended practices described in this guideline shall apply to all types (and sizes) of steam sterilizers, including table top sterilizers.

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.

i. Device Preparation

Devices shall be prepared for sterilization in the following manner:

- Clean, with excess water removed;
- Jointed instruments in the open or unlocked position;
- Multi-piece or sliding pieces disassembled unless otherwise indicated by the device manufacturer;
- Devices with concave surfaces that will retain water are placed in such a manner that condensate does not collect;
- Instruments with lumens moistened with distilled water immediately prior to sterilization;
- Heavy items arranged as to not damage lighter more delicate items; and
- Sharp instruments with tips protected.

ii. Packaging

Packaging materials for steam sterilization shall:

- Be validated for steam sterilization;
- Contain no toxic ingredients or dyes;
- Be capable of withstanding high temperatures;
- Allow air removal from packages and contents;
- Permit sterilant contact with the package contents;
- Permit drying of the package and contents;
- Prevent the entry of microbes, dust and moisture during storage and handling;
- Have a proven and tamper-proof seal;
- Withstand normal handling and resist tearing or puncturing; and
- Allow for aseptic presentation.

Packaging manufacturer's instructions for use shall be followed.

The total weight of instrument sets and their packaging shall not exceed 10 kg.¹⁹⁵

The total weight of a wrapped basin set shall not exceed 3 kg.¹⁹⁶

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.

The operator responsible for loading and initiating the cycle shall be documented.

iv. Unloading

Upon completion of the cycle, the operator responsible for unloading the sterilizer shall:

- Review the sterilizer printout for the following:
 - Correct sterilization parameters;
 - Cycle time and date; and
 - Cycle number matches the lot control label for the load.
- Verify and initial that the correct cycle parameters have been met;
- Examine the load items for :
 - Any visible signs of moisture; and
 - Any signs of compromised packaging integrity.

Printed records of each cycle parameters (i.e., temperature, time) shall be retained in accordance with the health care setting's requirements.¹⁸

v. Load Cool-Down

Upon removal of the sterilized load the operator shall:

- Visually verify the results of the external chemical indicators;
- Allow the load to cool to room temperature. The amount of time for cooling depends on the Devices that have been sterilized; and
- Ensure cool-down occurs in a traffic free area without strong warm or cool air currents.

vi. Troubleshooting—Wet Pack Problems

Packages are considered wet when moisture in the form of dampness, droplets or puddles are found on or within a package. There are two types of wet packs; those with external wetness and those with internal wetness. Sterility is considered compromised and the package contents considered contaminated when wet packs are found. There are several causes of wet packs. The following is a list of possible causes:

- Packages are improperly prepared or loaded incorrectly;
- Condensation dripping from the sterilizer cart shelf above the item;
- Condensation dripping from rigid sterilization containers placed above absorbent packaging;
- Condensate blowing through the steam lines into the sterilizer chamber;
- Instrument or basin sets that are too dense or lack absorbent material to wick moisture away;
- Linen packs wrapped too tightly; and/or
- Sterilization containers with a low metal-to-plastic ratio.

For a more information on troubleshooting wet packs, refer to:

www.health.qld.gov.au/chrisp/sterilising/section_appendix.pdf

vii. Immediate Use Steam Sterilization (Flash Sterilization)

Immediate Use Steam Sterilization shall be used only for situations where:

- (a) There is an urgent or unplanned need
- (b) There are documented policies and procedures for this practice that shall include:
 - Training of staff performing “Immediate Use Steam Sterilization”;
 - Transport of contaminated devices to decontamination area;
 - Disassembly and decontamination;
 - Preparation and containment;
 - Sterilization procedures; and
 - Monitoring and documenting of cycle parameters.

The physical layout and documented procedures shall assure direct delivery of the sterilized item to the point of immediate use.

Containers used for “Immediate Use Steam Sterilization” of devices shall be validated for that purpose.

“Immediate Use Steam Sterilization” shall not be used to:

- Sterilize implants;
- Sterilize complete sets or trays of instruments; or
- Compensate for inventory shortages or scheduling difficulties.

Procedures for “Immediate Use Steam Sterilization” shall include daily biological indicator testing of the sterilizer used for the cycles.

“Immediate Use Steam Sterilization” cycles shall be documented so that:

- Devices can be traced to the patient should there be an adverse event.(e.g. failed BI);
- Inventory requirement can be monitored; and
- Ways to reduce the need for “Immediate Use Steam Sterilization” can be identified.

Documentation shall contain the reason for “Immediate Use Steam Sterilization”, description of the device, the patient’s name, the surgeon’s name, and the time and date of the procedure. A report shall be prepared, reviewed, and maintained in accordance with the facility’s risk management policy.

For more information regarding the use and requirements of “Immediate Use Steam Sterilization”, refer to CSA Standard Z314.3-09, ‘*Effective Sterilization in Health Care Facilities by the Steam Process*’ [Section 13].¹⁹⁷

viii. Table Top Sterilizers

For detailed information on table top sterilizers, refer to CSA “Plus 1112” *Infection prevention and control in office based health care and allied service (Section 4.4)*.¹⁹⁸ and AAMI ST 55: 2010 *Table top steam sterilizers*.¹⁹⁹

C. Chemical (Low Temperature) Sterilization Methods

Chemical gases (Low Temperature) sterilization shall be used to sterilize heat and moisture sensitive medical devices. Written policies and procedures for chemical sterilization shall include:

- Staff qualification, education/training and competency assessment;
- Preparation and packaging of medical devices;
- Sterilizer operating procedures;
- Monitoring and documenting of chemical or cycle parameters;
- Workplace health and safety protocols specific to the chemical sterilant e.g. WHMIS; and
- Handling, storage and disposal of the sterilant. Consult sterilant manufacturer’s instructions for use and local regulations.

Device compatibility will vary with each low temperature sterilization method. The user shall obtain written functional compatibility information from the device manufacturer and sterilizer efficacy information from the sterilizer manufacturer.

Low temperature (gas) sterilization can be achieved using a number of different chemicals including:

- Hydrogen peroxide gas plasma;
- Ozone;
- Liquid peracetic acid; and
- Ethylene Oxide.

Refer to Appendix D, ‘Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options’ for information about these methods.

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

Liquid chemical sterilization (immersion) is not recommended as a best practice for sterilization of medical devices. Refer to Appendix D, 'Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options' for further information.

However, if liquid chemical sterilization is required, see Section 9.D for guidance.

Ethylene Oxide

In addition to the information found in Appendix D 'Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options', users of ethylene oxide should know that it is a designated substance under the *Worker's Compensation Act*.²⁰⁰ Facilities that use ethylene oxide for sterilization shall comply with the workplace health and safety regulations as well as guidelines from Environment Canada.²⁰¹

Medical devices sterilized with ethylene oxide shall be thoroughly aerated prior to handling or use according to the device manufacturer's recommendations.

The aeration cycle shall not be interrupted for any reason e.g. to retrieve items for use.²⁰²

- For more information regarding sterilizing with ethylene oxide, refer to the CSA's Z314.2-09 'Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process'.²⁰³

D. Sterility Assurance

Physical, biological and chemical monitoring shall be routinely performed to verify the effectiveness of sterilizers and the sterilization process.

1. Physical Monitors

A physical monitor is a device that monitors the physical conditions in a chamber during sterilization (e.g. time, temperature and pressure). These conditions are recorded (as a printout or electronic record) on completion of each cycle.

2. Biological Indicators (BI)

A biological indicator contains viable, non-pathogenic microorganisms (e.g., spore-laden strips or vials) providing a defined resistance to a specified sterilization process.^{204,205} It verifies the lethality of the sterilization process. The BI is generally contained inside a process challenge device (PCD) that simulates the in-use challenges presented by packaged devices. Once sterilized, a BI is removed from the PCD and incubated to see if the microorganism will grow. Growth may be an indication of sterilization failure.

The sterilizer manufacturer's instructions regarding the type of microorganism to be used to challenge a particular sterilizer shall be followed.

The BI shall be used according to the BI manufacturer's instructions for use.

- Refer to the CSA's 'Effective Sterilization in Health Care Facilities by the Steam Process'²⁰⁶ [CSA Z314.3-09 Clause 12.6.4] for more information about biological indicators for steam sterilizers.
- Refer to the CSA's 'Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process'²⁰⁷ [CSA Z314.2-09 Clause 12.6.4] for more information about biological indicators for ethylene oxide sterilizers.

3. Chemical Indicators (CI)

Chemical indicators do not replace the need to use a biological indicator.

A chemical indicator is a system that responds to a change in one or more predefined sterilization parameters.

Chemical indicators indicate that the package has been processed through a sterilization cycle. Chemical indicators do not indicate that a device is sterile and **do not replace the need to use a BI**.

There are six classes of chemical indicators¹ (see Table 2, below '*International Classes of Steam 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.

Table 2: International Classes of Steam Chemical Indicators^{208, 209, 210}

| Class | Definition | Use | Examples |
|---|---|--|---|
| CLASS I: Process Indicators | Process indicators differentiate processed from non-processed items | <ul style="list-style-type: none"> ▪ In individual units (e.g., packs, containers) to indicate that the item has been directly exposed to the sterilant ▪ Usually applied to the outside of packages ▪ Responds to one process variable | <ul style="list-style-type: none"> ▪ Sterilization tape ▪ Indicator labels ▪ Load cards ▪ Some internal chemical indicator strips |
| CLASS II: Indicator for Use in Specific Tests | Indicator for use in specific test procedures as defined in sterilization standards | <ul style="list-style-type: none"> ▪ To verify adequate air removal and steam penetration in vacuum assisted steam sterilizers | <ul style="list-style-type: none"> ▪ Bowie-Dick test |
| CLASS III: Single Variable Indicator | Indicator that reacts to a single critical parameter in the sterilization process to indicate when a stated value has been reached (e.g., temperature) | <ul style="list-style-type: none"> ▪ For package monitoring ▪ Use with caution because most sterilization processes depend on more than one critical variable | <ul style="list-style-type: none"> ▪ Temperature tubes ▪ Some internal indicator strips |
| CLASS IV: Multi-variable Indicator | Indicator that reacts to two or more critical parameters in the sterilization cycle under the conditions specified by the manufacturer | <ul style="list-style-type: none"> ▪ For internal package monitoring | <ul style="list-style-type: none"> ▪ Some internal indicator strips |
| CLASS V: Integrating Indicator | Indicator that reacts to all critical parameters in the sterilization process (e.g. time, temperature, presence of steam) <u>and</u> has stated values that correlate to a BI | <ul style="list-style-type: none"> ▪ For internal package monitoring. ▪ Can be used in a PCD as an additional monitoring tool to release loads that do not contain implants before results of a BI test are known | <ul style="list-style-type: none"> ▪ Some Internal indicator strips |
| CLASS VI: | Indicator that reacts to all | <ul style="list-style-type: none"> ▪ For internal package monitoring | <ul style="list-style-type: none"> ▪ Internal |

| Class | Definition | Use | Examples |
|----------------------------|---|---|------------------|
| Emulating Indicator | <p>critical parameters (time, temperature, presence of steam) for a specified sterilization cycle (e.g., 132 deg C for 4 min, or 10 min, or 20 min).</p> <ul style="list-style-type: none"> ▪ The CI manufacturer will specify the type of cycle and the specific parameters that the Class VI indicator will respond to. Therefore a different Class VI indicator is required for each sterilization cycle time and temperature to be monitored. <p>While Class VI indicators are not correlated to a BI, they are very sensitive to the parameters they are intended to monitor.</p> | <ul style="list-style-type: none"> ▪ For monitoring specific extended cycles | indicator strips |

- Refer to the CSA's 'Effective Sterilization in Health Care Facilities by the Steam Process'²¹¹ [CSA Z314.3-09 Clause 12.6.3] for more information about chemical indicators for steam sterilizers.
- Refer to the CSA's 'Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process'²¹² [CSA Z314.2-09 Clause 12.6.3] for more information about chemical indicators for ethylene oxide sterilizers.

4. **Process Challenge Device (PCD)**

A process challenge device contains a BI and/or CI. During routine monitoring of sterilizers, the PCD is placed in the sterilizer according to the PCD and sterilizer manufacturer's instructions. The PCD is intended to challenge the sterilization process in a manner that is equal to or greater than, the challenge posed by the most difficult item that is routinely processed.²¹³

- A PCD can be commercially manufactured or prepared in-house. Refer to sterilizer manufacturer's instructions or to the CSA's 'Effective sterilization in health care facilities by the steam process'²¹⁴ [CSA Z314.3-09 and *Effective sterilization in health care facilities by the ethylene oxide process (CSA Z314.2-09)*] for more information about in-house preparation of PCDs.

5. **Operational Qualification (OQ) and Performance Qualification of Products (PQ)**

OQ confirms that installed equipment operates within predetermined limits that are set by the sterilizer manufacturer. OQ is performed by the manufacturer (or designate) on installation of the sterilizer. It is also used to requalify sterilizers. (See section 10 F for OQ guidance for new sterilizers).

Requalification of Sterilizers

Sterilizers shall be requalified annually. Refer to CSA Z314.3-09 or Z314.02-09 Section 12.4 for more information on Requalification. Sterilizers shall also be requalified after the following events or conditions:^{215, 216}

- i) Major repairs;
- ii) Construction, relocation or other environmental changes to the sterilizer and/or its services;
- iii) Unexplained sterility failures;
- iv) Changes in sterilant supply or delivery; and
- v) Repairs or modification to the emission control system (for ethylene oxide sterilizers).

Performance Qualification

PQ is conducted by the health care facility to confirm that the installed equipment is able to sterilize the trays and loads that are used by that facility.

For specific information on OQ and PQ requirements, refer to CSA Z314.3-09 section 12.4 and 12.5²¹⁷.

E. Routine Monitoring of Sterilizers

Routine monitoring verifies that the sterilization process is working as expected and that conditions for sterilization have been achieved. The elements of routine monitoring include assessment of:

- a) Physical monitors of the sterilization cycle (printout)
 - Each load
- b) Chemical indicators (external and internal)
 - Each package
 - For dynamic air removal-type sterilizers (e.g. “pre-vac” or vacuum assisted), an air removal test with a Class II chemical indicator (e.g. Bowie Dick) shall be performed every day the sterilizer is used.
- c) Biological indicators
 - At least each day that the sterilizer is used
 - Each type of cycle that is used that day
 - All loads containing implants.
- d) Other routine tests (e.g. diagnostic) shall be performed as specified by the sterilizer manufacturer

When using biological and/or chemical indicators^{218, 219} they shall be:

- a) Used according to the indicator manufacturer’s instructions. This includes
 - The incubator
 - BI Controls
- b) Used only for the sterilizer type and cycle for which it was designed and validated
- c) Interpreted only by qualified staff
- d) Used before the expiration date
- e) Stored in accordance with the manufacturer’s instructions.

The following requirements apply to monitoring with chemical indicators²²⁰:

- a) An internal chemical indicator shall be placed inside each package prior to sterilization. It shall be placed in the area that is least accessible to the sterilant.^{221, 222} This is not necessarily the centre

of the package. The class of indicator chosen shall be based on the parameters to be measured and the degree of precision that is needed;

- b) Each package or container to be sterilized shall have an externally visible chemical indicator. The indicator shall be examined immediately after sterilization and immediately prior to use, to verify that the package has been exposed to the sterilant.

The following requirements apply to biological monitoring²²³:

- a) A biological indicator shall be used to test the sterilizer at least each day that it is used and with each type of cycle that is used that day or as specified by the sterilizer manufacturer
- b) A biological indicator shall be included in every load that is to be sterilized with ethylene oxide²²⁴
- c) A biological indicator shall be included in every load containing implantable devices²²⁵
 - Implantable devices should be quarantined until the results of the BI test are available

Ideally, items in the processed load should not be released until the results of the BI test are available. If quarantine pending BI results is not possible, evaluation of a Class 5 or 6 chemical indicator and the specific cycle physical parameters should be used to justify the release of routine loads.

- Refer to Appendix D, 'Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options' for sterilizer-specific monitoring criteria.

F. New Sterilizers

Appropriate experts shall be consulted prior to the purchase of a new sterilizer (e.g. medical device reprocessing, infection prevention and control, physical plant, biomedical engineering).

Prior to evaluation or purchase of sterilization equipment, accessories or supplies, appropriate approvals and licenses shall be verified, e.g. DIN for chemical sterilants, CSA approval for electrical equipment.

Sterilization equipment shall be installed, operated and maintained according to the sterilizer manufacturer's instructions for use. (Refer to CSA Z314.3-09 section 12.3 Installation Qualification (IQ) and Section 12.4 Operational Qualification (OQ) for further information).²²⁶

Sterilizers shall be tested on installation, in routine use and following disruptions to their normal operation:

- a) Following installation of a new sterilizer, the sterilizer shall pass three consecutive cycles with the appropriate challenges (i.e., biological, chemical) in the empty sterilizer chamber as described in the CSA's '*Effective Sterilization in Health Care Facilities by the Steam Process*'²²⁷ [CSA Z314.3-09 Clause 12.4.]; In sterilizers with multiple cycles, each type of cycle shall be similarly challenged.
- b) For dynamic air removal steam sterilizers (vacuum), three consecutive air removal tests shall be conducted in an empty sterilizer with an air detection test pack (e.g., Bowie-Dick)²²⁸, as described in the CSA's '*Effective Sterilization in Health Care Facilities by the Steam Process*'²²⁹ [CSA Z314.3-09 Clauses 12.4.];
- c) A sterilizer shall not be approved for use if any of the tests fail. If any test fails, the sterilizer manufacturer shall be consulted. (Refer to CSA Z314.3-09 section 12.4.1.7 for further guidance).

G. Unacceptable Methods of Disinfection or Sterilization

The following methods of disinfection or sterilization are **not** acceptable.

- Boiling;
- Chemiclave (formaldehyde vapour);
- Formaldehyde ;
- Glass bead sterilization;
- Microwave oven; and
- Ultraviolet irradiation.

Summary of Section 10 Recommendations

- 69. All critical medical devices shall be cleaned and then sterilized.**
- 70. Whenever possible, semi-critical medical devices should be sterilized. When sterilization is not possible, semi-critical devices shall be cleaned, followed by high-level disinfection.**
- 71. The preferred method for sterilization of heat-resistant medical devices is pre-vacuum steam sterilization.**
- 72. Health care settings shall have written policies and procedures for sterilization processes.**
- 73. The manufacturer's instructions for installation, operation and ongoing maintenance of sterilization equipment shall be followed.**
- 74. For each cycle, the sterilization time and temperature shall be monitored and recorded.**
- 75. Users shall obtain written validated device specific instructions from the device manufacturer and sterilizer efficacy testing from the sterilizer manufacturer when utilizing any sterilization method.**
- 76. "Immediate Use Steam Sterilization" (Flash Sterilization) shall be used only for situations where:**
 - a. There is an urgent or unplanned need**
 - b. There are written policies and procedures**
- 77. Containers used for "Immediate Use Steam Sterilization" of devices shall be validated for that purpose.**
- 78. "Immediate Use Steam Sterilization" shall not be used to:**
 - **Sterilize implants;**
 - **Sterilize complete sets or trays of instruments; or**
 - **Compensate for inventory shortages or scheduling difficulties.**
- 79. Procedures for "Immediate Use Steam Sterilization" shall include daily biological indicator testing of the sterilizer used for the cycles.**
- 80. "Immediate Use Steam Sterilization" cycles shall be documented.**
- 81. Chemical (Low Temperature) sterilization shall be used to sterilize heat sensitive medical devices. Chemical gases are used to sterilize moisture sensitive devices following MIFUs.**

- 82. The user shall obtain written functional compatibility information from the device manufacturer and sterilizer efficacy information from the sterilizer manufacturer when using chemical (low temperature) sterilization methods.**
- 83. Packaging used for chemical sterilization of devices shall be validated for that method.**
- 84. Facilities that use ethylene oxide for sterilization shall comply with the workplace health and safety regulations as well as guidelines from Environment Canada.**
- 85. Physical, biological and chemical monitoring shall be routinely performed to verify the effectiveness of sterilizers and the sterilization process. (NB Chemical indicators do not indicate that a device is sterile and do not replace the need to use a BI)**
- 86. Sterilizers shall be requalified annually.**
- 87. Sterilizers shall also be requalified after the following:**
- **Major repairs;**
 - **Construction, relocation or other environmental changes to the sterilizer and/or its services;**
 - **Unexplained sterility failures;**
 - **Changes in sterilant supply or delivery; and**
 - **Repairs or modification to the emission control system (for ethylene oxide sterilizers).**
- 88. Appropriate experts shall be consulted prior to the purchase of a new sterilizer.**
- 89. Sterilization equipment shall be installed, operated and maintained according to the sterilizer manufacturer's instructions for use.**
- 90. Sterilizers shall be tested on installation, routinely following MIFUs, and following disruptions to their normal operation.**

11. Storage and Use of Reprocessed Medical Devices

The shelf life of a sterile package is event-related.²³⁰ Devices that have been properly reprocessed, stored and handled will remain sterile indefinitely, unless the integrity of the package is compromised (i.e., open, wet, dirty). Some commercially manufactured packages may include an expiry date which shall be adhered to.

Health care settings should have written procedures for storage and handling of clean and sterile medical devices.

A. Storage Areas

Sterile and clean storage should be located in a limited access area.²³¹ If access cannot be controlled, the sterile storage area should be enclosed e.g. cupboard, cabinet, closed cart.²³²

Requirements for sterile and clean storage include;^{233, 234,235}

- a) Storage containers that are moisture-resistant and cleanable (i.e., corrugated cardboard boxes shall not be used);
- b) Clean, dry, and dust-free area, that is easy to clean;
- c) Storage shelving that is non-porous, smooth and cleanable (wood is not acceptable). Open shelves shall be at least 250 mm (10 in) off the floor, 460 mm (18 in) from the ceiling and 50 mm (2 in) from outside walls. Bottom and the top shelves shall be solid;
- d) Adequate space to prevent crushing and damage of packages;
- e) A system to ensure packages are rotated i.e. first in first out (FIFO); and
- f) Handling, pick-up and delivery systems that prevent contamination or damage to the device.

Refer to Appendix C, 'Recommendations for Physical Space for Reprocessing

B. Prior to Using Sterile Devices

At point-of-use, prior to opening, the reprocessed medical device, package shall be checked for:

- Integrity e.g. clean, dry and intact;
- External chemical indicator change; and
- Expiry date (if applicable);
- Rigid containers:
 - Filter (s); and
 - Tamper-proof locks.

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.

Summary of Section 11 Recommendations

91. The shelf life of a sterile package is event-related.

92. Some commercially manufactured packages may include an expiry date which shall be adhered to.

93. Sterile storage should be located in a limited access area.²³⁶ If access cannot be controlled, the sterile storage area should be enclosed e.g. cupboard, cabinet, closed cart.

94. At point-of-use, prior to opening the reprocessed medical device, package shall be checked.

12. Quality Assurance (QA)

A. Other Documentation

All documentation shall be dated and signed by the person completing the documentation and/or verifying the test results.

Documentation of the sterilization process shall include:

- Package label:
 - Name of device (when necessary);
 - Initials of technician packaging the device; and
 - Lot control information which includes a load/cycle number, sterilizer number, and the date of sterilization.
- Detailed list of sterilizer load contents;
- Date, time and results of all tests performed (e.g. printout, CI, BI, Bowie-Dick, leak test):
 - Sterilizer physical parameters shall be verified by the individual responsible for releasing the load prior to load release. Verification shall be documented (e.g. printout is initialed);
 - If any indicator fails, the failure shall be investigated. Loads may be recalled according to the results of the investigation and the facility's recall procedure. All actions associated with an investigation shall be documented.
- A process to address any indicator failure e.g. printout, chemical indicator or biological indicator; and
- Record retention according to corporate administrative directives and/or quality management system requirements.

B. Other Documentation

In addition to documentation of sterilization, a QA plan shall include documentation related to:

- Management roles and responsibilities;
- Resources;
- Staff training, education and competency assessments;
- Internal compliance and Reporting Systems:
 - Adverse events/Incident reports.
- Standards and best practices;
- Reprocessing cycle management:
 - Policies and standard operating procedures (SOPs);
 - Test/monitoring results e.g. cleaning efficacy, BI results for sterilization; and
 - Equipment maintenance.
- Current MIFUs for reprocessing equipment and for medical devices being reprocessed; and
- OH&S including MSDS.

C. Adverse Events

An adverse event is one that creates doubt that all required reprocessing steps were performed correctly.

Examples of reprocessing adverse events include (but are not limited to):

- Incorrect reprocessing method used;
- Reprocessing parameters not met;
- Positive biological indicator;
- Failed chemical indicator;
- High level disinfection failure;
- Release of a non-sterile medical device(s);
- Wet sterilization load;
- Incorrect AER connections used for the wrong endoscope;
- Medical device alert:
 - Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.²³⁷

All adverse events shall be followed up with:

- Investigation, to determine what further actions (if any) are required;
- Documentation and reporting of findings according to facility policy (e.g. notification to risk manager);
- An action plan based on risk assessment (e.g. recall);
- Evaluation of action plan effectiveness; and
- Further intervention as required in response to feedback.

D. Recalls

In certain circumstances, medical devices may need to be recalled due to improper reprocessing. A procedure shall be established for the recall and shall:²³⁸

- a. Be in writing;
- b. Outline the circumstances for issuing a recall order;
- c. Designate the personnel authorized to issue a recall order;
- d. Outline the procedure to be followed; and
- e. Designate the person responsible for reporting the result of the recall.

The recall order shall:

- a. Be in writing;
- b. Identify the medical device(s) to be recalled including type and quantity;
- c. Identify the department(s) to which the order applies;
- d. Specify the action to be taken by the person receiving the order (e.g. return, destroy); and
- e. Be retained according to the health care facility policy.

Report of the recall order shall:

- a) Be in writing;
- b) Identify the circumstances that prompted the recall order;
- c) List the medical device(s) included in the recall order;
- d) List the departments or individuals notified of the recall;
- e) State, in terms of the total number of medical devices intended to be recalled, the percentage of devices actually located;
- f) Include an incident report for devices that were recalled but could not be located;
- g) Specify the corrective action taken to prevent a recurrence; and
- h) Be retained according to the facility policy.
- i)

Summary of Section 12 Recommendations

- 95. All reprocessing documentation shall be dated and signed by the person completing the documentation and/or verifying the test results.**
- 96. The sterilization process shall be documented.**
- 97. A written procedure shall be established for recall.**
- 98. Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.**

13. Single-Use Medical Devices

Health care settings shall have written policies regarding single-use medical devices. Critical and semi-critical medical devices labelled as single-use shall not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor.^{239,240,241} Currently there are no licensed reproprocessors in Canada. There are reproprocessors in the USA licensed by the United States Food and Drug Administration (USFDA).

Health care settings that wish to have their 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.²⁴² In order to have critical or semi-critical medical /devices reprocessed by one of these facilities, there shall be quality assurance processes for:

- a) Good manufacturing procedures (GMP);
- b) Maintenance of device functionality and integrity;
- c) Proof of sterility or high-level disinfection;
- d) Testing for pyrogens;
- e) Tracking and labelling devices;
- f) Recalling improperly reprocessed medical devices;
- g) Reporting adverse events; and
- h) Quality control.

Single-use medical devices are usually labelled by the manufacturer with a symbol:



When purchasing sharps or devices with sharp components that cannot be safely cleaned, single-use devices or components shall be considered.^{243, 244} In the interests of staff safety, devices that cannot be cleaned safely shall be single use.

A. Devices with Small Lumens

Reusable devices with small lumens or other characteristics that make them difficult to clean can put clients/patients/residents at risk. This includes items, such as catheters, drains, fine cannulae. These items should be designated single-use and not be reprocessed and re-used.²⁴⁵

B. Devices in Home Health Care

Semi-critical medical devices owned by the client that are re-used in their home shall be adequately cleaned prior to reuse. Home health care agencies may consider re-using single-use semi-critical medical devices for a single client in their home when reuse is safe. Critical medical devices owned by clients cannot be reprocessed safely as sterilization cannot be achieved in the home environment. Therefore, critical medical devices remain single use in the home and shall be disposed of after use.

Summary of Section 13 Recommendations

99. Health care settings shall have written policies regarding single-use medical devices.

100. Critical and semi-critical medical devices labelled as single-use shall not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor.

- 101. In the interests of staff safety, devices that cannot be cleaned safely shall be single use.**
- 102. Reusable devices with small lumens such as catheters, drains, and fine cannulae should be designated single-use and not be reprocessed and reused.**
- 103. Devices owned by the client that are re-used in their home must be adequately cleaned prior to reuse.**
- 104. Home health care agencies may consider re-using single-use semi-critical medical devices for a single client in their home when reuse is safe.**

Recommendations Summary of Best Practices for Cleaning, Disinfection and Sterilization of Medical Devices in BC Health Authorities

This summary table is intended to assist with self-assessment internal to the health care setting for quality improvement purposes. See complete text for rationale.

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
|--|---|--------------------|---------------|-------------|----------------|
| CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | | |
| 1. Assessment and Purchase of Medical Devices and Reprocessing Equipment | | | | | |
| 1. | <i>Do not purchase medical devices that cannot be cleaned and reprocessed according to the recommended standards.</i> | | | | |
| 2. | <i>When purchasing reprocessing equipment or chemical products for reprocessing, consideration should be given to Occupational Health requirements, client/patient/resident safety and environmental safety issues.</i> | | | | |
| 3. | <i>All medical devices intended for use on a client/patient/resident that are being considered for purchase or will be obtained in any other way (e.g., loaned devices, trial or research devices, physician/practitioner-owned) shall meet established quality reprocessing parameters. Such equipment shall not be purchased or used until this process is established.</i> | | | | |
| 4. | <i>Manufacturers' information for all medical devices shall be received and maintained in a format that allows for easy access</i> | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
|--|---|--------------------|---------------|-------------|----------------|
| | CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | |
| | | | | | |
| 5. <i>If there is a discrepancy between the reprocessing level recommended by the manufacturer and the intended use of the instrument by Spaulding's criteria, the higher level of disinfection/sterilization shall be used.</i> | | | | | |
| 6. <i>Newly purchased, non-sterile critical and semi-critical medical devices shall first be inspected and reprocessed according to their intended use prior to being put into circulation.</i> | | | | | |
| 7. <i>The organization shall develop and maintain policies and procedures that apply to the sending, transporting, receiving, handling and processing of loaned, shared and leased medical devices, including endoscopes.</i> | | | | | |
| 8. <i>The use of loaned devices for neurosurgical procedures is strongly discouraged.</i> | | | | | |
| 9. <i>Surgical devices at risk for CJD contamination shall be managed following Health Canada/PHAC infection control guideline, "Classic Creutzfeldt-Jakob Disease in Canada".</i> | | | | | |
| 2. Environmental Requirements for Reprocessing Areas | | | | | |
| 10. <i>Reprocessing performed outside the centralized reprocessing</i> | | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
|--|-----------|--------------------|---------------|-------------|----------------|
| | | | | | |
| CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | | |
| | | | | | |
| 11. | | | | | |
| 12. | | | | | |
| 13. | | | | | |
| 14. | | | | | |
| 3. Policies and Procedures | | | | | |
| 15. | | | | | |
| 16. | | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
|--|--|--------------------|---------------|-------------|----------------|
| | | | | | |
| CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | | |
| | <i>reprocessing expertise. Other stakeholders shall be consulted as required (e.g., Infection Prevention and Control (IPC) practitioners, Health Shared Services BC (HSSBC), Risk Management)</i> | | | | |
| 17. | <i>A procedure shall be established for the management of adverse reprocessing events.</i> | | | | |
| 4. Education and Training | | | | | |
| 18. | <i>Managers accountable for reprocessing shall have demonstrated knowledge of reprocessing practices and infection prevention and control principles as they relate to medical device reprocessing.</i> | | | | |
| 19. | <i>All staff, including supervisors, involved in the reprocessing of medical devices should be supervised and shall be qualified through education, training and experience in the functions they perform.</i> | | | | |
| 20. | <i>Reprocessing technicians who routinely perform medical device reprocessing activities shall, at a minimum, have successfully completed a recognized medical device reprocessing technician educational program.</i> | | | | |
| 21. | <i>Any individual involved in any aspect of reprocessing shall</i> | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
|--|---|--------------------|---------------|-------------|----------------|
| | CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | |
| <i>obtain education, orientation and training specific to the function they perform/medical device to be reprocessed (e.g., medical imaging technologists, respiratory technicians and staff in endoscopy, dental, podiatry, residential care, and physician offices).</i> | | | | | |
| 22. <i>The policies of the health care setting shall specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical devices.</i> | | | | | |
| 5. Occupational Health and Safety for Reprocessing | | | | | |
| 23. <i>All activities included in the reprocessing of medical devices shall be based on the consistent application of Routine Practices and hand hygiene.</i> | | | | | |
| 24. <i>There is a policy that prohibits eating/drinking, storage of food, smoking, and application of cosmetics or personal effects in the reprocessing area.</i> | | | | | |
| 25. <i>Appropriate personal protective equipment (PPE) shall be worn for all reprocessing activities.</i> | | | | | |
| 26. <i>All staff working in reprocessing shall be offered Hepatitis B immunization unless they have documented immunity to</i> | | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
|---|---|--------------------|---------------|-------------|----------------|
| | CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | |
| | | | | | |
| 27. <i>Measures and procedures shall be written to prevent and manage injuries from sharp objects.</i> | | | | | |
| 28. <i>Measures and procedures shall be in place for immediate response to worker exposure to chemicals as well as blood and body fluids.</i> | | | | | |
| 29. <i>Occupational Health and Safety for the health care setting should review all protocols for reprocessing medical devices to verify that worker safety measures and procedures are in place.</i> | | | | | |
| 6. Cleaning (Decontamination) of Reusable Medical Devices | | | | | |
| 30. <i>Disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point-of-use, prior to transportation.</i> | | | | | |
| 31. <i>Soiled medical devices shall be handled in a manner that reduces the risk of exposure and/or injury to personnel and clients/patients/residents, or contamination of environmental surfaces.</i> | | | | | |
| 32. <i>Contaminated devices shall not be transported through areas designated for storage of clean or sterile supplies,</i> | | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
|--|-----------|--------------------|---------------|-------------|----------------|
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| CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | | |
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| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
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| | CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | |
| 7. Factors Affecting Product Selection and Efficacy of Liquid Chemicals for Disinfection or Manual Sterilization | | | | | |
| 40. <i>Procedures for disinfection and sterilization should include statements and information regarding the type, concentration and testing of chemical products; duration and temperature of exposure; and physical and chemical properties that might have an impact on the efficacy of the process. These procedures should be readily accessible to staff performing the function.</i> | | | | | |
| 41. <i>Products used for any/all stages in reprocessing should be approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise</i> | | | | | |
| 42. <i>The reprocessing method and products required for medical devices will depend on the intended use of the device and the potential risk of infection involved in the use of the device.</i> | | | | | |
| 43. <i>Products used for disinfection and sterilization should be appropriate to the level of reprocessing that is required for the use of the medical device.</i> | | | | | |
| 44. <i>The process and products used for disinfection and/or sterilization of medical devices shall be compatible with the devices.</i> | | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
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| CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | | |
| 45. <i>The manufacturer shall provide written, validated, device specific information regarding the safe and appropriate reprocessing of the medical device</i> | | | | | |
| 8. Disinfection of Reusable Medical Devices | | | | | |
| 46. <i>Noncritical medical devices shall be low-level disinfected prior to use.</i> | | | | | |
| 47. <i>Semi-critical medical devices shall be, at a minimum, high-level disinfected prior to use. Sterilization is <u>preferred</u>.</i> | | | | | |
| 48. <i>Disinfectant manufacturers shall supply compatibility information for the disinfectant to ensure that it is compatible with the medical devices on which it will be used.</i> | | | | | |
| 49. <i>The process of high-level disinfection requires monitoring. If a reusable liquid chemical product is used, the minimally effective concentration (MEC) of the active ingredient(s) shall be verified using appropriate test strips and shall be documented.</i> | | | | | |
| 50. <i>Manufacturer's instructions for installation, operation and ongoing maintenance of thermal disinfection equipment shall be followed.</i> | | | | | |

| Recommendation | | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
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| CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | | | |
| 51. | <i>Following the thermal disinfection cycle, medical devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and that is used exclusively for the drying of pasteurized devices.</i> | | | | | |
| 52. | <i>A permanent record of disinfecting parameters shall be maintained.</i> | | | | | |
| 9. Reprocessing Endoscopy Devices | | | | | | |
| 53. | <i>Individuals responsible for reprocessing endoscopes should be trained and should meet the facility's written requirements for ongoing education and training, and annual competency assessment.</i> | | | | | |
| 54. | <i>Each health care setting in which endoscopic procedures are performed should have written detailed procedures for the reprocessing and handling of endoscopes.</i> | | | | | |
| 55. | <i>Ventilation should be such as to remove toxic vapours generated by, or emitted from, cleaning or disinfecting agents.</i> | | | | | |
| 56. | <i>Endoscope pre-cleaning shall commence immediately following completion of the clinical procedure.</i> | | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
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| CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | | |
| 57. | <i>Integrity of the endoscope shall be verified through leak testing, performed after each use following manufacturer's instructions.</i> | | | | |
| 58. | <i>Endoscopic devices shall be rinsed and dried prior to disinfection or sterilization.</i> | | | | |
| 59. | <i>Critical endoscopes and emergency bronchoscopes shall be sterilized.</i> | | | | |
| 60. | <i>Semi-critical endoscopes and accessories (excluding biopsy forceps and brushes) should receive at least high-level disinfection after each use.</i> | | | | |
| 61. | <i>Endoscopic accessories (e.g., biopsy forceps and brushes) that break the mucosal barrier should be disposable or sterilized after each use.</i> | | | | |
| 62. | <i>If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components are compatible with the AER.</i> | | | | |
| 63. | <i>Final drying of semi-critical endoscopes after high level disinfection shall be facilitated by flushing all channels with air, 70% isopropyl alcohol, and medical air.</i> | | | | |
| 64. | <i>Semi-critical endoscopes shall be stored hanging vertically in</i> | | | | |

| Recommendation | Compliance Status | | | Action Plan | Accountability |
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| | Compliant | Partial Compliance | Non-compliant | | |
| CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | | |
| | <i>a well-ventilated area in a manner that minimizes contamination or damage. Endoscopes shall not be coiled, allowed to touch the sides, the floor or bottom of the cabinet while hanging, or stored in their cases.</i> | | | | |
| 65. | <i>The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during the procedure, should receive high-level disinfection or sterilization at least daily.</i> | | | | |
| 66. | <i>Accessory bottle, cap, connection tube shall be sterilized prior to ERCPs or any procedure that invades sterile tissue.</i> | | | | |
| 67. | <i>A preventive maintenance program for automated endoscope reprocessor (AER) shall be implemented and documented.</i> | | | | |
| 68. | <i>Healthcare settings shall have policies in place providing a permanent record of endoscope use and reprocessing, as well as a system to link endoscopes and clients/patients/residents that includes recording the endoscope number in the client/patient/resident record.</i> | | | | |
| 10. Sterilization of Reusable Medical Devices | | | | | |
| 69. | <i>All critical medical devices shall be cleaned and then sterilized.</i> | | | | |
| 70. | <i>Whenever possible, semi-critical medical devices should be sterilized. When sterilization is not possible, semi-critical</i> | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
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| CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | | |
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| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
|--|---|--------------------|---------------|-------------|----------------|
| | CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | |
| 80. <i>“Immediate Use Steam Sterilization” cycles shall be documented.</i> | | | | | |
| 81. <i>Chemical (Low Temperature) sterilization shall be used to sterilize heat and/or moisture sensitive devices.</i> | | | | | |
| 82. <i>The user shall obtain written functional compatibility information from the device manufacturer and sterilizer efficacy information from the sterilizer manufacturer when using chemical (low temperature) sterilization methods.</i> | | | | | |
| 83. <i>Packaging used for chemical sterilization of devices shall be validated for that purpose.</i> | | | | | |
| 84. <i>Facilities that use ethylene oxide for sterilization shall comply with the workplace health and safety regulations as well as guidelines from Environment Canada.</i> | | | | | |
| 85. <i>Physical, biological and chemical monitoring is routinely done to verify the effectiveness of sterilizers and the sterilization process.</i> | | | | | |
| 86. <i>Sterilizers shall be requalified annually.</i> | | | | | |
| 87. <i>Sterilizers shall also be requalified after the following:</i> <ul style="list-style-type: none"> ▪ <i>Major repairs;</i> ▪ <i>Construction, relocation or other environmental changes to the sterilizer and/or its services;</i> ▪ <i>Unexplained sterility failures;</i> ▪ <i>Changes in sterilant supply or delivery; and</i> ▪ <i>Repairs or modification to the emission control system (for ethylene oxide sterilizers).</i> | | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
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| | CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | |
| 88. <i>Appropriate experts shall be consulted prior to the purchase of a new sterilizer.</i> | | | | | |
| 89. <i>Sterilization equipment shall be installed, operated and maintained according to the sterilizer manufacturer's instructions for use.</i> | | | | | |
| 90. <i>Sterilizers shall be tested on installation, in routine use and following disruptions to their normal operation.</i> | | | | | |
| 11. Storage and Use of Reprocessed Medical Devices | | | | | |
| 91. <i>The shelf life of a sterile package is event-related.</i> | | | | | |
| 92. <i>Some commercially manufactured packages may include an expiry date which shall be adhered to.</i> | | | | | |
| 93. <i>Sterile storage should be located in a limited access area.²⁴⁹ If access cannot be controlled, the sterile storage area should be enclosed e.g. cupboard, cabinet, closed cart.</i> | | | | | |
| 94. <i>At point-of-use, prior to opening the reprocessed medical device, package shall be checked.</i> | | | | | |
| 12. Quality Assurance (QA) | | | | | |
| 95. <i>All reprocessing documentation shall be dated and signed by</i> | | | | | |

| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
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| | CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | |
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| 13. Single-Use Medical Devices | | | | | |
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| Recommendation | Compliant | Partial Compliance | Non-compliant | Action Plan | Accountability |
|--|--|--------------------|---------------|-------------|----------------|
| CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL DEVICES IN HEALTH AUTHORITIES | | | | | |
| | <i>semi-critical medical devices for a single client in their home when reuse is safe.</i> | | | | |

Appendix A: Health Canada Guidance Document: Information to be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices

Details of reprocessing instructions as recommended in CAN/CSA/ISO 17664

Note: This table is intended to serve as a checklist for the manufacturer and should be made available to users in addition to, or in conjunction with, the detailed instructions for use and reprocessing. Manufacturers should indicate whether each of these processes and steps is recommended or not recommended. Attach a copy of the validated, detailed reprocessing instructions where applicable.

Product Name:

Manufacturer:

Product Number (optional):

Contact (Name, telephone number, email address):

Specify the intended use of device and method of reprocessing required by checking the appropriate box or boxes:

Non-critical contact (contacts intact skin only); requires low level disinfection

Semi-critical contact (contacts mucosal surface but does not enter sterile body site); requires high level disinfection

Critical contact (enters sterile body site or is exposed to blood); requires sterilization

If more than one box is checked, separate forms and processes are needed.

| Process | Process Stage | Process Step | Recom'd | Not Recom'd | Specific information to be provided by manufacturer (attach details) |
|------------------------------------|-----------------------------|-----------------|---------|----------------|---|
| Preparation at point of use | Soaking after use | | | | Specify type of detergent or agent to use for soak (for example [e.g.] alkaline, acidic, neutral pH, enzymatic solution, enzymatic foam, or water). |
| | | | | | Specify maximum soak time and volume of rinse solution. |
| Decontamination | Preparation | Disassembly | | | Device specific disassembly instructions with pictures. |
| | Cleaning (includes rinsing) | Manual cleaning | | | Specify any special cleaning brushes or tools needed. |

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| | | | | Specify water quality needed. Specify type of agent to use for cleaning (e.g. alkaline, acidic, neutral pH, enzymatic solution, enzymatic foam, or water). Specify minimum volume of water needed for rinsing. |
| | | Automated (machine) cleaning | | Specify type of detergent to use for cleaning (e.g. alkaline, acidic, neutral pH). |
| | | | | Specify water quality needed and maximum temperature (if applicable) that medical device can withstand. |
| | | Ultrasonic Cleaning | | Specify whether cleaning solution is to be used and if so, specify type (e.g., low sudsing). |
| | | | | Specify (if applicable) duration of exposure of instrument to ultrasonic cleaning. |
| | | | | Specify sonication conditions that medical device can withstand for cleaning. |
| Disinfection | Liquid chemical | Automated or manual | | Specify compatible liquid chemicals that can be used. |
| | | | | Specify validated exposure time to liquid chemical. |
| | | | | Specify water quality for rinse and minimum volume for rinsing. |
| | Thermal | Automated only | | Specify maximum time and temperature that medical device can withstand. |
| | | | | Specify water quality. |
| Drying | | | | Specify how device should be dried (e.g. pressurized air at recommended maximum air pressure, manual wiping, heat, etc.). Specify maximum temperature the medical device can withstand |
| Preparation and packing | Reassembly | | | Provide device-specific reassembly instructions with pictures |
| | | | | Specify whether device is not to be reassembled (or only partially reassembled) prior to sterilization. |
| Maintenance | | | | Specify any requirements for ensuring functionality, e.g., sharpening, lubrication, testing device function, testing sheath integrity. |
| Steam sterilization | Dynamic air | | | Specify time and temperature for which sterilization of device has been |

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| | removal | | | | validated. |
| Steam sterilization | Dynamic air removal | | | | Where possible, specify time and temperature cycles used in North American health care facilities, that is (i.e.), 132°C for 4 minutes or 135°C for 3 minutes. (See CSA Z314.3 and AAMI ST 79). If extended cycles are required, use 132 - 135°C for 10 or 20 minutes. |
| | Gravity displacement | | | | Specify time and temperature for which medical device has been validated |
| | | | | | Where possible, specify time and temperature cycles used in North American health care facilities, i.e., 132°C for 4 minutes or 135° C for 3 minutes. (See CSA Z314.3 and AAMI ST 79.) If extended cycles are required, use 121°C for 40 or 60 minutes. |
| ETO Sterilization | | | | | Validate that EtO residues are acceptable after standard aeration time of 12 hours. |
| Other sterilization processes | | | | | Specify sterilization process including cycle and conditions for which device has been validated. |
| Device to be sterilized in container provided by manufacturer | | | | | Provide attestation that validation of the recommended sterilization process has been performed in the specified containment system. |

Table Information taken from:

Health Canada. Guidance Document: Information to be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices, June 2011: p. 9-11. Available from: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/md-im/applic-demande/guide-ld/md_gd_reprocessing_im_ld_retraitement-eng.pdf

Appendix B: Reprocessing Decision Chart

| MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME SHALL BE FOLLOWED | | | |
|--|---|--|--|
| Level of Reprocessing | Type of Device | Examples of Reusable Devices | Products** |
| <p><u>Cleaning</u> Physical removal of soil, dust or foreign material. Chemical, thermal or mechanical aids may be used. Cleaning usually involves detergents or enzymatic cleaners and water. Thorough cleaning shall take place before disinfection or sterilization.</p> | <p>All reusable devices and equipment</p> | <ul style="list-style-type: none"> ▪ All reusable devices and equipment | <p>** concentration and contact time are dependent on manufacturer's instructions</p> <ul style="list-style-type: none"> ▪ Enzymatic cleaners ▪ Detergents ▪ 0.5% Accelerated hydrogen peroxide |
| <p><u>Low-Level Disinfection</u> Level of disinfection required when processing noncritical equipment and devices or environmental surfaces. Low-level disinfectants kill most vegetative bacteria and some fungi as well as enveloped (lipid) viruses. Low-level disinfectants do not kill mycobacteria or bacterial spores.</p> | <p>Noncritical devices and equipment</p> | <ul style="list-style-type: none"> ▪ Environmental surfaces touched by staff during procedures involving parenteral or mucous membrane contact (e.g. dental lamps, dialysis machines) ▪ Bedpans, urinals, commodes ▪ Stethoscopes ▪ Blood pressure cuffs ▪ Oximeters ▪ Glucose meters ▪ Electronic thermometers ▪ Hydrotherapy tanks ▪ Client/patient/resident lift slings ▪ ECG machines/leads/cups etc. ▪ Sonography (ultrasound) equipment/probes that only contact intact skin ▪ Bladder scanners ▪ Baby scales ▪ Cardiopulmonary training mannequins ▪ Environmental surfaces (e.g. IV poles, wheelchairs, beds, call bells) | <p>** concentration and contact time are dependent on manufacturer's instructions</p> <p>For example:</p> <ul style="list-style-type: none"> ▪ 3% Hydrogen peroxide (10 minutes) ▪ 60-95% Alcohol (10 minutes) ▪ Hypochlorite (1000 ppm) ▪ 0.5% Accelerated hydrogen peroxide (5 minutes) ▪ Quaternary ammonium compounds (QUATs) (10 minutes) ▪ Iodophors ▪ Phenolics (should not be used in nurseries) |

| MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME SHALL BE FOLLOWED | | | |
|--|-----------------------|---|---|
| Level of Reprocessing | Type of Device | Examples of Reusable Devices | Products** |
| | | <ul style="list-style-type: none"> ▪ Nail care equipment that is single-client/patient/resident use | |
| <p>High-Level Disinfection The level of disinfection required when processing semi-critical devices.</p> <p>High-level disinfection processes destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily all bacterial spores.</p> | Semi-critical devices | <ul style="list-style-type: none"> ▪ Flexible endoscopes that do not enter sterile cavities or tissues ▪ TEE probes ▪ Laryngoscopes ▪ Flexible bronchoscopes and flexible cystoscopes (sterilization is preferred) ▪ Respiratory therapy equipment ▪ Nebulizer cups ▪ Anaesthesia equipment ▪ Specula (nasal, anal, vaginal – disposable equipment is strongly recommended) ▪ Tonometer foot plate ▪ Ear syringe nozzles ▪ Sonography (ultrasound) endocavity probes (e.g. transrectal, vaginal probes) ▪ Pessary and diaphragm fitting rings (sterilization is preferred) ▪ Cervical caps ▪ Glass thermometers ▪ CPR face masks ▪ Ear cleaning equipment e.g. ear cures, otoscope tips | <p>** concentration and contact time are dependent on manufacturer's instructions</p> <p>For examples, refer to Appendix D, 'Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options':</p> |
| <p>Sterilization The level of reprocessing required when processing critical device.</p> <p>Sterilization results in the destruction of all forms of microbial life including bacteria, viruses, spores and fungi.</p> | Critical devices | <ul style="list-style-type: none"> ▪ Surgical instruments ▪ Implantable devices ▪ Rigid endoscopes that enter sterile cavities and spaces (e.g., arthroscopes, laparoscopes, cystoscopes) ▪ Flexible bronchoscopes and cystoscopes (sterilization is preferred) ▪ Biopsy forceps, brushes and biopsy equipment associated with endoscopy (disposable equipment is strongly recommended) | <p>** concentration and contact time are dependent on manufacturer's instructions</p> <p>For examples, refer to Appendix D, 'Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options':</p> |

| MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME SHALL BE FOLLOWED | | | |
|---|----------------|---|------------|
| Level of Reprocessing | Type of Device | Examples of Reusable Devices | Products** |
| | | <ul style="list-style-type: none"> ▪ Colposcopy equipment ▪ Electrocautery tips (single use is preferred) ▪ Endocervical curettes ▪ Eye equipment ▪ Dental equipment including high speed dental hand pieces ▪ Nail and foot care equipment used on more than one patient/resident/client | |

Adapted from:

Health Canada's 'Hand Washing, Cleaning, Disinfection and Sterilization in Health Care' [available at: <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/98pdf/cdr24s8e.pdf>].

Center for Disease Control and Prevention's 'Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008' [available at: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf]

Appendix C: Recommendations for Physical Space for Reprocessing

A. Space

- 1. There is adequate space to support all reprocessing activities.**
- 2. There shall be clear separations between soiled and clean areas²⁵⁰:**
 - a) Decontamination work areas should be physically separated from clean and other work areas by walls or partitions to control traffic flow and to contain contaminants generated during the stages of decontamination;
 - b) Walls or partitions shall be constructed of materials capable of withstanding frequent cleaning with the cleaning and disinfecting products used in the health care setting;
 - c) Doors to all work areas should be kept closed at all times. Self-closing doors are recommended to restrict access and optimize ventilation control; and
 - d) Space shall be designed to ensure one-way movement by staff and devices from contaminated areas to clean areas.
- 3. There shall be adequate space provided for decontamination equipment and products used for cleaning and reprocessing²⁵¹:**
 - a) Work surfaces and surrounding areas should be designed to minimize crowding of work space;
 - b) Work surfaces shall be flat, cut-resistant, seamless and composed of a non-porous material so they can be cleaned, disinfected and dried. Stainless steel surfaces and backsplashes are recommended;
 - c) There should be at least two adjacent decontamination sinks. If only one sink is available, precautions should be taken to avoid re-contaminating devices. Decontamination sinks should:
 - i) Be at a height that allows staff to use them without bending or straining;
 - ii) Be deep enough to completely immerse items to be cleaned ;
 - iii) Be large enough to accommodate trays or baskets of instruments;
 - iv) Not have an overflow; and
 - v) Should be equipped with water ports for the flushing of instruments with lumens.
- 4. There should be an area for donning or removing Personal Protective Equipment (PPE):**

PPE shall be carefully removed and hands thoroughly washed before moving from dirty to clean area.

5. There should be easy access to hand hygiene facilities²⁵²:

- a) Dedicated hand washing sinks shall be provided;
- b) Accessible, adequately supplied and properly functioning soap dispensers, towel dispensers and alcohol-based hand rub, shall be made available;
- c) Hand washing sinks should be conveniently located in or near all decontamination and preparation areas and at all entrances to and exits from the reprocessing area;
- d) Hand washing facilities should also be located in all personnel support areas (e.g., change rooms);
- e) “Hands-free” operating sinks are recommended; and
- f) Hand washing sinks shall not be used for other purposes.

6. There shall be easy access to emergency supplies²⁵³:

- a) Eye-wash stations, deluge showers and spill equipment shall be provided as necessary; and
- b) Consult jurisdictional workplace health and safety statutes/regulations.

7. There is adequate storage space.

B. Reprocessing Area Cleaning

1. The reprocessing area is regularly and adequately cleaned^{254, 255}:

- a) There is an area for storage of dedicated housekeeping equipment and supplies;
- b) Wet-vacuuming or hand-mopping with a clean mop head and clean, fresh water shall be done at least daily; and
- c) Spills shall be cleaned up immediately. Waste shall appropriately be contained and disposed of. There shall be a designated area to collect waste.

Recommended cleaning frequencies for reprocessing areas shall include:

- i) Clean and disinfect all countertops, work areas, sinks and equipment surfaces at least daily;
- ii) Clean and disinfect sinks each shift at a minimum and more frequently as necessary. When reprocessing endoscopes, sinks shall be cleaned between each scope;
- iii) Clean floors at least daily;
- iv) Clean shelves daily in sterilization areas, preparation and packing areas and decontamination areas;
- v) Clean shelves every three months in sterile storage areas;
- vi) Clean case carts after every use;

- vii) Clean walls every six months; and
- viii) Clean light fixtures, sprinkler heads and other fixtures every six months.

- For more information about 'Hospital Clean', see the MOHLTC's 'Best Practices for Environmental Cleaning in All Health Care Settings'.²⁵⁶

C. Environmental Controls and Utilities

1. **In healthcare facilities ventilation, temperature and humidity of the Medical Device Reprocessing Department shall meet CSA standards^{257, 258}:**
 - a) CSA requirements for ventilation:
 - i) Minimum 10 air changes per hour for soiled and clean areas. Minimum 2 outdoor air changes per hour for soiled areas, 3 outdoor air changes per hour for clean areas;
 - ii) Soiled areas: negative pressure;
 - iii) Clean areas: positive pressure;
 - iv) Exhaust air vented outdoors and not recirculated; and
 - v) Portable fans should not be used in any reprocessing area.
 - b) CSA requirements for temperature and humidity:
 - i) Room temperature of all decontamination work areas shall be between 18-20°C and between 18-23°C for clean areas and be monitored daily;
 - ii) Relative humidity shall be maintained between 30-60% (preferably 40-50%) and be monitored daily; and

If humidity increases such that sterile packages become damp or wet (e.g., > 70%), the integrity of the package may be compromised.¹ The facility shall have a contingency plan to address humidity problems. Refer to CSA Z 314.3-09 Appendix C for detailed information.

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2. Water used in the processing area should be tested and be free of contaminants:

Water quality can be a significant factor in the success of decontamination procedures. In addition to issues of mineral content (hardness or softness), piped water supplies can also introduce pathogens and unwanted chemicals to decontamination processes. Manufacturers of medical device, decontamination equipment, and detergents should be consulted regarding their particular water quality requirements.

For further information on water quality refer to:

- Annex F in the Canadian Standards Association's '*Decontamination of Reusable Medical Devices*' CAN/CSA-Z314.8-08
- AMMI TIR 34 (2007), Water for the reprocessing of medical devices.

Adapted from:

Canadian Standards Association. '*Decontamination of Reusable Medical Devices*'. CAN/CSA-Z314.8-08. 2008.

Canadian Standards Association. '*Effective Sterilization in Health Care Facilities by the Steam Process*'. CAN/CSA-Z314.3-09. 2009

Canadian Standards Association. '*Special Requirements for Heating, Ventilation, and Air Conditioning (HVAC) Systems in Health Care Facilities*'. February 2003.

The American Institute of Architects Academy of Architecture for Health. '*Guidelines for Design and Construction of Hospital and Health Care Facilities*'. 2006 edition.

Appendix D: Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options

STERILIZATION

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT CONCENTRATION AND EXPOSURE TIME SHALL BE FOLLOWED

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|--|---|---|
| STERILIZATION | | |
| <p>Dry Heat Gravity convection Mechanical convection Ref: ISO 20857</p> | <p>Exposure time and temperature vary, depending on the item being sterilized</p> | <p><u>Indications:</u> For critical devices that will be damaged by moisture, pressure and/or vacuum</p> <p><u>Monitoring</u> Sterilization shall be monitored with biological indicators (at least daily), chemical indicators (each package) and physical indicators (each cycle)</p> <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Non-corrosive • Reaches internal parts that cannot be disassembled for direct sterilant contact (via heat conduction) • Inexpensive <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • Lengthy cycle due to slow heat conduction process • Temperature can be variable especially in gravity convection ovens • High temperatures can damage some materials |

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|---|---|--|
| STERILIZATION | | |
| <p>Ethylene Oxide (EtO) gas</p> | <p>Combined sterilization and aeration (required) times commonly total approx 14 hours.</p> | <p><u>Indications:</u></p> <ul style="list-style-type: none"> For critical devices and some semi-critical devices that will be damaged by moisture and /or heat <p><u>Monitoring</u></p> <ul style="list-style-type: none"> Sterilization shall be monitored with biological indicators (each load), chemical indicators (each package) and physical indicators (each cycle) A BI with a 4 hour read-out time is available <p><u>Advantages</u></p> <ul style="list-style-type: none"> Non-corrosive Has some ability to penetrate some synthetic materials <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> Toxic /carcinogenic to humans Lengthy cycle due to aeration requirements Requires monitoring of the work areas Requires control and monitoring of discharge into the environment Flammable and explosive. Can be highly reactive with other chemicals Expensive compared to steam Incompatible with some materials e.g. silicone |
| <p>Immediate Use Steam Sterilization (also known as Flash Sterilization)</p> | <p>Cycle times will vary depending on the sterilization temperature and the device containment system (e.g. tray, container or wrapper) used.</p> | <p><u>Indications:</u></p> <ul style="list-style-type: none"> For emergency sterilization of critical devices that are heat and moisture tolerant Shall not be used for implantable devices or for complete sets or trays of instruments Any trays or wrappers that are used for Flash sterilization must be validated for that purpose. <p><u>Monitoring</u></p> <ul style="list-style-type: none"> Sterilization shall be monitored with biological indicators (at least daily), chemical indicators (each package) and physical indicators (each cycle) BI testing shall include each type of cycle and load configuration (e.g., open tray, enclosed container, single wrapper) to be used that day. Cycles shall be documented in such a way that the flashed device can be linked to the patient on which it was used should there be an adverse sterilization event e.g. failed BI |

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|---|--|--|
| STERILIZATION | | |
| <p>Glutaraldehyde (GTA) (2.4%-3.5%)</p> <p><i>Product examples include:</i> <i>Metricide 14 days 2.6%</i> <i>Metricide 28 days 2.5%</i> <i>Cidex activated dialdehyde solution 2.4%</i> <i>Cidex Plus 28 day 3.4%</i></p> | <p>Sterilization requires up to 10 hours at 20°C with some products.</p> <p>Refer to product label for time, temperature and glutaraldehyde concentration required to achieve sterilization.</p> | <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Fast <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • Devices cannot be stored because they are still wet on cycle completion • Requirement to follow all of the steps of safe sterilization practice (e.g. decontamination, sterilizer monitoring and maintenance, aseptic transfer to the sterile field) may be onerous or impossible to achieve in some settings. <p>Not recommended as a best practice for sterilization of medical devices</p> <p><u>Indications:</u></p> <ul style="list-style-type: none"> • For immersible, heat sensitive critical devices and some semi-critical devices <p><u>Monitoring</u></p> <ul style="list-style-type: none"> • Test strips to confirm the minimal effective concentration (MEC) of the solution should be used each time the solution is used. • There are no biological indicators or chemical indicators to monitor GTA exposure conditions and demonstrate microbial kill <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Not recommended as a best practice for sterilization of medical devices <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • In-use life may be limited (e.g. 14 days, 28 days). Refer to manufacturer's instructions for use <p>The use of glutaraldehyde as a sterilant is strongly discouraged for the following reasons:</p> <ul style="list-style-type: none"> • Biological and chemical process indicators are not available • Devices must be used immediately as sterility cannot be maintained during storage • Toxic, sensitizing irritant • Needs proper ventilation and closed containers. Refer to Work Safe BC for current ventilation requirements and exposure limits. Handling provides opportunities for contamination • Requires copious rinsing with sterile water • Unable to monitor sterilization • Lengthy process (6-12 hours) • During reuse, the concentration drops as dilution of the product occurs • Disposal may require special handling |

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|--|---------------------------|---|
| STERILIZATION | | |
| <p>Hydrogen Peroxide-Accelerated (7% and 2 %)</p> <p>Product examples include: <i>SciCan Optim CS 7%</i> <i>Accel CS 20 7%</i> <i>Steris Resert 2%</i></p> | | <p>Not recommended as a best practice for sterilization of medical devices</p> <p><u>Indications:</u></p> <ul style="list-style-type: none"> For immersible, heat sensitive critical devices and some semi-critical devices that will be damaged by the various sterilization methods <p><u>Monitoring</u></p> <ul style="list-style-type: none"> Minimal effective concentration (MEC) of solution shall be monitored at least daily, and more often if the solution is heavily used. There are no biological indicators or chemical indicators to monitor hydrogen peroxide exposure conditions <p><u>Advantages</u></p> <ul style="list-style-type: none"> Not recommended as a best practice for sterilization of medical devices <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> In-use life is limited to 21 days or failure of the MEC test, whichever comes first. Refer to product manufacturer's instructions for use Strong oxidizer. Depending on the concentration, it can be corrosive to some materials e.g. copper, brass, carbon-tipped devices and aluminium May cause irritation and chemical burns to eyes or to mouth and throat if swallowed. May cause slight irritation to skin Requires copious rinsing with sterile water to maintain sterility Must be stored in cool place, protected from light <p>The use of hydrogen peroxide as a sterilant is strongly discouraged for the following reasons:</p> <ul style="list-style-type: none"> Biological and chemical process indicators are not available Devices must be used immediately as sterility cannot be maintained during storage Frequent handling of devices provides opportunities for contamination Requires copious rinsing with sterile water Unable to monitor sterilization Lengthy process (e.g. 6 hours) During reuse, the concentration drops as dilution of the product occurs |

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|---|---|---|
| STERILIZATION | | |
| <p>Hydrogen peroxide vapour and gas (may also include plasma)</p> <p><i>Sterilizer examples include:</i> <i>Sterrad—by Advanced Sterilization Products</i> <i>V Pro—by Steris</i> <i>HMTS—by SciCan</i></p> | <p>Cycle time and temperature will vary, depending on the brand and model of sterilizer</p> <p>Current times range from 28-70 min. Cycle temperatures are less than 60 deg C.</p> | <p><u>Indications:</u></p> <ul style="list-style-type: none"> For critical devices and some semi-critical devices that will be damaged by moisture or heat <p><u>Monitoring</u></p> <ul style="list-style-type: none"> Sterilization shall be monitored with biological indicators (at least daily), chemical indicators (each package) and physical indicators (each cycle) <p><u>Advantages</u></p> <ul style="list-style-type: none"> Fast compared to ETO. Some cycles are faster than steam sterilization Safe for environment (water and oxygen end products) Compatible with many medical devices <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> May be incompatible with some devices. Compatibility must be confirmed with both sterilizer and device manufacturers Cannot sterilize materials which absorb hydrogen peroxide (e.g. linen, gauze, cellulose/paper, wood) Wraps and trays must be validated for hydrogen peroxide sterilization (e.g. polypropylene wrappers, Tyvek backed peel pouches). Limitations to length of lumens of medical devices that can be effectively sterilized <ul style="list-style-type: none"> Certain models of sterilizers require “boosters” of hydrogen peroxide to sterilizer lumens. |
| <p>Ozone</p> <p><i>Sterilizer examples include:</i> <i>TSO₃</i></p> | | <p><u>Indications:</u></p> <ul style="list-style-type: none"> For critical devices and some semi-critical devices that will be damaged by moisture or heat <p><u>Monitoring</u></p> <ul style="list-style-type: none"> Sterilization shall be monitored with biological indicators (at least daily), chemical indicators (each package) and physical indicators (each cycle) <p><u>Advantages</u></p> <ul style="list-style-type: none"> Fast compared to ET. Safe for environment (oxygen end products) Compatible with certain medical devices |

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|--|--|---|
| STERILIZATION | | |
| | | <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • May be incompatible with some devices. Compatibility must be confirmed with both sterilizer and device manufacturers • Some material restrictions • Wraps and trays must be validated Ozone sterilization (e.g. polypropylene wrappers, Tyvek backed peel pouches). • Limitations to length of lumens of medical devices that can be effectively sterilized |
| <p>Peracetic acid (0.2%)</p> <p><i>Sterilizer example includes: Steris System 1—by Steris</i></p> | <p>Contact time, temperature and chemical concentration controlled by the processing unit.</p> <p>Total cycle time is about 30-40 min and depends on incoming water quality and temperature.</p> | <p><u>Indications:</u></p> <p>NB. This chemical is used only in a proprietary, controlled system</p> <ul style="list-style-type: none"> • For immersible, heat sensitive critical and semi-critical devices e.g. rigid and flexible endoscopes <p><u>Monitoring</u></p> <ul style="list-style-type: none"> • Sterilization shall be monitored with biological indicators (each day that the unit is used) , chemical indicators (each cycle) and physical indicators (each cycle). • Manufacturer’s instructions for use also require that a daily “Diagnostic” cycle be run at the beginning of the day before any devices are processed. • Cycles shall be documented in such a way that the device can be linked to the patient on which it was used should there be an adverse sterilization event e.g. failed BI <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Fast • Automated cycle ,including rinsing to remove chemical residue <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • Devices must be used immediately. They cannot be stored because they are still wet on cycle completion • Time and temperature are controlled by the unit and may vary due to water pressure, incoming water temperature, or filter status). • Spore strips used for monitoring are not self contained and therefore have the potential for external contamination. • Volatile and has a pungent odour. • Disposal may require special handling • Requirement to follow all of the steps of safe sterilization practice (e.g. decontamination, sterilizer monitoring and maintenance, aseptic transfer to the sterile field) may be onerous or impossible to achieve in some settings. |
| <p>Steam</p> <p>Pre-vacuum sterilizers Gravity displacement</p> | | <p><u>Indications:</u></p> <ul style="list-style-type: none"> • For critical devices and some semi-critical devices that will not be damaged by moisture or heat |

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|--|---------------------------|---|
| STERILIZATION | | |
| sterilizers Small table top sterilizers | | <p><u>Monitoring</u></p> <ul style="list-style-type: none"> • Sterilization shall be monitored with biological indicators (at least daily), chemical indicators (each package) and physical indicators (each cycle) • All loads containing an implantable device shall be monitored with an additional BI and should be quarantined until the results of that biological indicator testing are available. • Additional monitoring of Pre-vacuum sterilizers shall include a dynamic air removal test (daily) <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Inexpensive • Fast • Effective, with a wide margin of safety • Non-toxic • Readily available • Sterilizers are available in many sizes for many applications <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • Unsuitable for anhydrous materials (e.g. oils, powders) wood, and for heat and moisture sensitive materials • Some tabletop sterilizers lack a drying cycle and /or printers (for physical monitoring of each cycle) • Safe use of steam sterilizers requires a sound knowledge of their requirements. Not all settings have this expertise. |

HIGH-LEVEL DISINFECTION

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT CONCENTRATION AND EXPOSURE TIME SHALL BE FOLLOWED

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|---|--|---|
| High Level Disinfection | | |
| <p>Glutaraldehyde (2% or higher)</p> <p><i>Product examples include:</i></p> <p><i>Metricide 14 days 2.6%</i></p> <p><i>Metricide 28 days 2.5%</i></p> <p><i>Cidex activated dialdehyde solution 2.4%</i></p> <p><i>Cidex Plus 28 day 3.4%</i></p> | <p>Refer to product label for time and temperature required to achieve high-level disinfection.</p> | <p><u>Indications:</u> For immersible ,semi- critical devices that will be damaged by the various sterilization methods e.g. flexible GI endoscopes</p> <p><u>Monitoring</u> Minimal effective concentration (MEC) of reusable solutions shall be monitored at least daily, and more often if the solution is heavily used.</p> <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Non-corrosive • Can be used as a manual process, which may minimize costs • Inexpensive <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • Reusable solutions have a limited in-use life i.e. 14-30 days depending on formulation, or failure of the MEC test, whichever comes first. Refer to product manufacturer's instructions for use. • Can act as a protein fixative • Toxic, sensitizing irritating • Needs proper ventilation and closed containers. Refer to WorkSafe BC for current ventilation requirements and exposure limits. • Handling provides opportunities for contamination • Requires copious rinsing with sub-micron filtered water to maintain disinfection level • During reuse, the concentration drops as dilution of the product occurs. In-use life shortens when solution is diluted • Disposal may require special handling |

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|--|--|--|
| High Level Disinfection | | |
| <p>Hydrogen peroxide (7.5%)</p> <p><i>Product examples include:</i> Sporox</p> | <p>Refer to product label for time and temperature required to achieve high-level disinfection.</p> <p>One manufacturer's product information claims high-level disinfection in 30 minutes.</p> | <p><u>Indications:</u> For immersible ,semi- critical devices that will be damaged by the various sterilization methods</p> <p>In the US, the Society for Gastroenterology Nurses and Associates (SGNA) indicates that while 7.5% hydrogen peroxide is approved for use as a high level disinfectant, it is not compatible with endoscopes made by Olympus, Pentax or Fujinon.</p> <p><u>Monitoring</u> Minimal effective concentration (MEC) of reusable solutions shall be monitored at least daily, and more often if the solution is heavily used.</p> <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Can be used in a manual process, which may minimize costs • Relatively inexpensive • Rapid action • Safe for the environment. Breaks down into water and oxygen <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • Reusable solutions have a limited in-use life. (14 days, or failure of the MEC test, whichever comes first). Refer to product manufacturer's instructions for use. • Strong oxidant can be corrosive to some materials e.g. copper, brass, carbon-tipped devices and aluminium • Handling provides opportunities for contamination • Requires copious rinsing with sub-micron filtered water to maintain disinfection level • Must be stored in cool place, protected from light |
| <p>Accelerated Hydrogen Peroxide (7%)</p> <p><i>Product examples include:</i> SciCan Optim CS 7% Accel CS 20 7%</p> | <p>Refer to product label for time and temperature required to achieve high-level disinfection.</p> <p>One manufacturer's product information claims high-level disinfection in 20 minutes.</p> | <p><u>Indications:</u> For immersible ,semi- critical devices that will be damaged by the various sterilization methods</p> <p><u>Monitoring</u> Minimal effective concentration (MEC) of reusable solutions shall be monitored at least daily, and more often if the solution is heavily used.</p> <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Can be used in a manual process, which may minimize costs |

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|---|--|---|
| High Level Disinfection | | |
| | | <ul style="list-style-type: none"> • Relatively inexpensive • Rapid action • Safe for the environment. Breaks down into water and oxygen <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • Reusable solutions have a limited in-use life. (14 days, or failure of the MEC test, whichever comes first). Refer to product manufacturer's instructions for use. • Strong oxidant can be corrosive to some materials e.g. copper, brass, carbon-tipped devices and aluminium • May cause irritation and chemical burns to eyes or to mouth and throat if swallowed. May cause slight irritation to skin • Handling provides opportunities for contamination • Requires copious rinsing with sub-micron filtered water to maintain disinfection level ▪ Must be stored in cool place, protected from light |
| <p>Accelerated Hydrogen Peroxide (2%)</p> <p>Product examples include: <i>Steris Resert 2%</i></p> | <p>Refer to product label for time and temperature required to achieve high-level disinfection.</p> <p>The manufacturer's product information claims high-level disinfection in 5 minutes</p> | <p><u>Indications:</u> For immersible ,semi- critical devices that will be damaged by the various sterilization methods</p> <p><u>Monitoring</u> Minimal effective concentration (MEC) of reusable solution shall be monitored at least daily, and more often if the solution is heavily used.</p> <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Can be used in a manual process, which may minimize costs • Relatively inexpensive • Rapid action • Safe for the environment. Breaks down into water and oxygen <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • Reusable solutions have a limited in-use life. (21 days, or failure of the MEC test, whichever comes first). Refer to product manufacturer's instructions for use. • Strong oxidant can be corrosive to some materials e.g. copper alloys, iron and other heavy metals • Mild irritant to eyes, slight irritant to skin • Handling provides opportunities for contamination • Requires copious rinsing with sub-micron filtered water to maintain disinfection level • Must be stored in cool place, protected from light |

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|--|--|--|
| High Level Disinfection | | |
| <p>Ortho-phthalaldehyde (OPA)--(0.55%)</p> <p>Product examples include: <i>Cidex OPA-by Advanced Sterilization Products</i></p> | <p>Refer to product label for time and temperature required to achieve high-level disinfection.</p> | <p><u>Indications:</u> For immersible ,semi- critical devices that will be damaged by the various sterilization methods e.g. flexible GI endoscopes</p> <p><u>Monitoring</u> Minimal effective concentration (MEC) of reusable solutions shall be monitored at least daily, and more often if the solution is heavily used.</p> <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Non-corrosive • Can be used as a manual process, which may minimize costs • Less toxic, sensitizing irritating than glutaraldehyde • Short exposure time (10 min at 20 Deg C) • Does not require activation • Stains protein, , which can be used as an indicator of inadequate cleaning/residual protein <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • More expensive than glutaraldehyde • Reusable solution has a limited in-use life. (14 days or failure of the MEC test, whichever comes first). Refer to product manufacturer’s instructions for use. • Contraindicated for urology instruments to be used on patients with a history of bladder cancer.²⁵⁹ • Handling provides opportunities for contamination • Requires copious rinsing • During reuse, the concentration drops as dilution of the product occurs. In-use life shortens when solution is diluted |
| <p>Thermal disinfection (e.g. Pasteurization)</p> | <p>Refer to manufacturer’s instructions for use for time and temperature required to achieve thermal disinfection</p> <p>Examples of times at temperatures include:</p> <ul style="list-style-type: none"> • immersion at 71°C for 30 min, • hot water flush process at , 80 deg C for 10 min • hot water flush process at , | <p><u>Indications:</u> Achieves the equivalent of high-level disinfection using hot water in a proprietary, controlled system For immersible ,semi- critical devices that will be damaged by the various sterilization methods e.g. respiratory therapy or anaesthesia devices</p> <p><u>Monitoring</u> Physical monitoring of exposure time and temperature documented via printed and/or electronic record</p> <p><u>Advantages</u></p> <ul style="list-style-type: none"> • Non-toxic alternative to HLD chemicals |

| PROCESS OPTION | CONTACT AND/OR CYCLE TIME | COMMENTS |
|-------------------------|---------------------------|---|
| High Level Disinfection | 90deg C for 1min | <ul style="list-style-type: none"> • Low cost per cycle, once equipment has been purchased <p><u>Disadvantages</u></p> <ul style="list-style-type: none"> • Some synthetic materials melt • Regular, manual verification of the thermometer and timing mechanisms of a pasteurizer are required • Handling provides opportunities for contamination |

The following chemicals are intermediate and low level disinfectants and as such are not covered by this table:

- Alcohol (60-95%)
- Hypochlorites e.g. bleach,
- Accelerated hydrogen peroxide (0.5%)
- Hydrogen peroxide (3%)
- Iodophors
- Phenolics
- Quaternary ammonium chlorides (QUATs)

Table information is adapted from:

Health Canada's 'Hand Washing, Cleaning, Disinfection and Sterilization in Health Care' [currently under revision] [available at: <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/98pdf/cdr24s8e.pdf>].

Center for Disease Control and Prevention's 'Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008' [available at: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf]

Appendix E:
Cross-Reference Table – Accreditation Canada’s Reprocessing and Sterilization of Reusable Medical Devices and British Columbia’s Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|---|-------------------|----------------|-----------------------|
| | | Section | Page # | |
| 1.0 | The organization designs its reprocessing services to meet the needs of the organization and partner organizations. | I | 20-25 | N/A |
| 1.1 | The organization collects information at least annually about service volumes and patterns of medical device use | 3 9H | 28-29 48 | 15, 68 |
| 1.2 | The organization reviews its operational plan and the information it collects about service volumes and equipment use to decide which sterilization and reprocessing services are offered within the organization. | 1A 3 | 22-23 28-29 | 1, 2, 15, 16 |
| 1.3 | The team works with others in the organization to limit the use of flash sterilization to emergencies only, and never for complete sets or implantable devices. | 10B vii | 53 | 76, 77, 78 |
| 1.4 | The organization designates a trained and competent individual with the accountability for coordinating all reprocessing and sterilization activities across the organization, including those performed outside the reprocessing unit or area. | GP* 4 | 20-21 29-30 | 18 |
| 1.5 | The designated person reports directly to the organization’s senior management or the executive office. | GP | 20-21 | 18 |
| 1.6 | The organization has the right number and mix of staff to carry out its reprocessing and sterilization activities. | 4 | 29-30 | 18-22 |

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|--|-------------------|-------------------|-----------------------|
| | | Section | Page # | |
| 1.7 | Where sterilization and reprocessing services are contracted to external providers, the organization establishes and maintains a contract with each provider that requires consistent levels of quality and adherence to accepted standards of practice. | GP 3 | 20-21 29 | 18-22 |
| 1.8 | Where sterilization and reprocessing services are contracted to external providers, the organization regularly monitors the quality of services provided. | GP 3 | 20-21 29 | 18-22 |
| 1.9 | Where sterilization and reprocessing services are contracted to external providers, the organization annually reviews each contract and records all aspects of the contract and negotiations in its files. | GP | 20-21 | N/A |
| 2.0 | The organization educates, trains, and evaluates the competency of its reprocessing team members. | 4 | 29-30 | 18-22 |
| 2.1 | The organization orients all staff members about safe work practices, including patient safety, occupational health and safety, and infection prevention and control. | 4 5 | 29 31 | 18-29 |
| 2.2 | The sterilization team receives training about how to reprocess reusable medical devices when they are first employed and whenever there is a change in the sterilization process. | 4 7B (b) | 29-30 39 | 19-22 |
| 2.3 | The team's training includes how to reprocess new devices and equipment used in the organization. | 1A 4 7B | 23 29-30 39 | 6, 19-22 |
| 2.4 | Supervisors and staff members involved in reprocessing have completed a recognized course in reprocessing and sterilization. | 4 | 30 | 19, 20 |
| 2.5 | The organization conducts baseline and annual competency evaluations of staff members involved in reprocessing and sterilization. | 4 9A | 29-30 44 | 22 53 |
| 2.6 | The organization provides follow-up education, training, and supervision for staff who have been involved in critical incidents or adverse events. | 3 12B+C | 29 62-63 | 17, 53 98 |
| 2.7 | The organization documents and retains records of education, training, and competency assessments. | 4 9H | 29-30 48 | 22 53 |

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|--|-------------------|-------------------------|------------------------------|
| | | Section | Page # | |
| | | 12B | 62 | |
| 3.0 | The physical layout of the sterilization unit or area allows for high quality reprocessing and the smooth flow of reusable medical devices and equipment. | 2 9B Appx C | 26-28 44-45 89-91 | 11 |
| 3.1 | When planning and designing the layout of the sterilization unit or area, the organization considers the volume and types of reprocessing and sterilization services, flow of devices and equipment, and traffic patterns. | 2A 9B | 26 44-45 | 10-14 |
| 3.2 | The sterilization unit or area limits access to the overall unit or area to unit or area staff members, and posts clear signage limiting access at all entry points. | 2A 9B | 26 44-45 | 10-14 |
| 3.3 | The physical space prevents cross-contamination of sterilized and contaminated devices or equipment, isolates incompatible activities, and clearly separates different work areas. | 2A 9B | 26 44-45 | 10-14 |
| 3.4 | The physical space has a specific, closed area for decontamination that is separate from other areas of the processing unit or area and the rest of the organization. | 2A 9B | 26 44-45 | 11 |
| 3.5 | The organization regulates the air quality, ventilation, temperature, and relative humidity, and lighting in decontamination, reprocessing, and storage areas. | 2B 9B | 27 44-45 | 12, 55 |
| 3.6 | The organization selects materials for the floors, walls, ceilings, fixtures, pipes, and work surfaces that limit contamination, promote ease of washing and decontamination, and will not shed particles or fibres. | 2A 9B | 26 44 | |
| 3.7 | The reprocessing and sterilization team works with others in the organization to properly clean the sterilization unit or area. | 2D | 28 | 14 |
| 4.0 | The team follows policies, procedures, and manufacturers' instructions for the sterilization unit or area and the reprocessing of reusable equipment and devices. | 3 7A 10A+B | 28-29 37 49-50 | 15, 16, 17 40-45 72-73 |
| 4.1 | The organization sets and follows policies that address the management of the unit or area, the team, all aspects of the sterilization process, safety, infection control, | 3 10A | 28-29 49-50 | 15, 16, 17, 72,73 |

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|--|-------------------|-------------------------|-------------------------|
| | | Section | Page # | |
| | and quality control. | | | |
| 4.2 | When establishing or updating the team's infection prevention and control policies, the team works closely with the organization's IPAC staff, team, or committee. | 3 | 28 | 15, 16 |
| 4.3 | The team follows a process to establish and maintain its Standard Operating Procedures (SOPs) for sterilization and reprocessing. | 3 10B 12B | 28 50-59 62 | 15-17 72,73 95-98 |
| 4.4 | The team writes its SOPs in a clear, concise, and consistent way. | 3 | 28 | |
| 4.5 | The team maintains up-to-date manufacturers' information, instructions, and recommendations for each medical device. | 1B 7 10A | 23-25 37-40 49-50 | 45 1-9 73 |
| 4.6 | The team documents and maintains policies, SOPs, standards of practice, and manufacturers' instructions in a manual. | 1B 7A | 25 37 | 4 45 |
| 4.7 | All team members have access to the manual. | 3 4 7A | 28 30 37 | 15-17 40 |
| 4.8 | The team trains staff prior to implementing a new or amended policy, SOP, practice standard, or manufacturers' instruction. | 3 4 | 28-29 29-30 | 15, 16, 17 18-22 |
| 4.9 | Team leaders review and update the policies and procedures on a regular basis and in response to critical incidents or adverse events; changes in laws, regulations, or standards; results of internal or external audits; and new evidence-based information. | 3 | 28-29 | 15, 16, 17 |
| 4.10 | The team tracks changes to policies, SOPs, standards of practice, and manufacturers' instructions using a document control procedure. | 3 | 28-29 | 16 |
| 4.11 | New and changed SOPs are approved in writing by the team leaders. | 3 | 28-29 | 15,16 |
| 5.0 | The team complies with occupational health and safety (OHS) requirements to make sure staff are safe in the reprocessing and sterilization | 5 9B | 30-33 44-45 | 23-29, 53 |

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|--|-------------------|-------------------------|--|
| | | Section | Page # | |
| | unit or area. | | | |
| 5.1 | The reprocessing area is equipped with hand hygiene facilities at entrances to and exits from the reprocessing units or areas, including support areas. | 2A 5A 9B | 27 31 44-45 | 23 |
| 5.2 | The unit or area's hand hygiene facilities are equipped with faucets supplied with foot-, wrist-, or knee-operated handles, or electric eye controls. | 5A 9B | 31 44-45 | 23 |
| 5.3 | Staff members receive training on proper hand hygiene techniques. | 4 5A | 29-30 31 | 18, 22, 23 |
| 5.4 | Staff members have access to the supplies needed to support proper hand hygiene, including properly supplied and functioning soap and towel dispensers or waterless, alcohol-based hand rubs in the working environment. | N/A | N/A | N/A |
| 5.5 | Staff members apply proper hand hygiene technique before beginning and after completing work activities, as well as at other key points to prevent infection. | 5A | 31 | 23 |
| 5.6 | The team follows policies that prohibit eating and drinking, food storage, smoking, the application of cosmetics, and the handling of contact lenses in the reprocessing unit or area. | 5A | 31 | 24 |
| 5.7 | The team follows a detailed dress code while in the clean reprocessing unit or area that addresses clothing, hair, jewellery, artificial fingernails of any form, and covered footwear. | 5A | 31 | 23, 25 |
| 5.8 | The team wears the appropriate and properly maintained personal protective equipment (PPE) when in the decontamination work areas. | 5A+B | 31-32 | 25 |
| 5.9 | The team regularly conducts workplace assessments of its sterilization and reprocessing units or areas for ergonomics and occupational health and safety (OHS). | 5 | 30-31 | 29 |
| 6.0 | The team keeps up-to-date and accessible documentation and records of its sterilization processes. | 3 10E 12 | 28-29 57-58 62-64 | 15, 74, 95, 96, 97 72-75, 80 95-98 |
| 6.1 | The team maintains a complete record of each sterilization cycle, including the load control label, recording chart or printout, process-recording record, and sterility | 10E 12A | 57-58 62 | 95, 96 |

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|--|-------------------------|----------------------------------|---------------------------|
| | | Section | Page # | |
| | record. | | | |
| 6.2 | The record includes details of the sterilization cycle, including date and time; exposure time; temperature; pressure; sterility test results; and the kind, quantity, and origin of the devices sterilized. | 10B 12A | 50 62 | 74 95, 96 |
| 6.3 | The record allows team members to track individual items or devices associated with a sterilizer or sterilization cycle. | 1D 12A | 25 62 | 9 97, 98 |
| 6.4 | The organization stores and retains its sterilization records according to its policies, and any applicable laws and regulations. | 12A | 62 | |
| 7.0 | The organization selects, installs, and maintains reprocessing equipment so that it is safe to use and functions according to manufacturers' specifications. | 1 10A+B 10F 13 | 22-25 49-50 58-59 64-65 | 1, 2, 3, 73, 88, 89 |
| 7.1 | The organization follows a process to select and purchase equipment based on reprocessing and sterilization requirements, input from staff and service providers, and considerations for maintenance, cleaning, and infection control. | 1 10F | 22-23 58-59 | 1, 2, 3, 88 |
| 7.2 | The organization has a documented preventive maintenance and cleaning program for its decontamination and sterilization equipment. | 3 9H 10A+B | 28-29 48 49-50 | 15, 67, 72, 73 |
| 7.3 | The organization has access to a complete record of maintenance and inspection procedures for reprocessing and sterilization devices and equipment. | 3 9H 10A+B 12B | 28-29 48 49-50 62-63 | 15 67 73, 95, 96 |
| 7.4 | When installing reprocessing equipment, the organization follows the manufacturers' instructions and contacts the manufacturer directly for clarification or additional information, as needed. | 10A 10F | 49-50 58-59 | 89 73 |
| 7.5 | Before releasing a sterilizer for use, the organization completes appropriate installation testing for sterility assurance using a process challenge device (PCD) | 10D&F | 54-59 | 73,89, 90 |

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|---|--------------------------|----------------------------------|-----------------------------------|
| | | Section | Page # | |
| | equipped with chemical and biological indicators. | | | |
| 8.0 | The team properly prepares contaminated equipment for reprocessing. | 6 | 33-37 | 31, 32, 34, 35, 36 |
| 8.1 | The team prevents the on-site reprocessing or sterilization of single-use devices (SUDs). | 13 | 64 | 99, 100 |
| 8.2 | The team follows safe work practices and infection control precautions when handling contaminated devices and equipment. | 3 5 6B 9 | 28-29 30-33 34 44-48 | 18, 23, 29, 31-35, 54-58 |
| 8.3 | If prion contamination is suspected, e.g. Creutzfeldt-Jakob disease, the team follows accepted guidelines from the Public Health Agency of Canada to handle, quarantine, and incinerate the device, as appropriate. | 1D | 25 | 9 |
| 8.4 | Prior to decontamination, the team follows manufacturers' recommendations to clean and rinse equipment and devices. | 6 9C | 33-35 45-46 | 35, 56 |
| 8.5 | The team follows manufacturers' instructions to select and perform appropriate cleaning methods. | 6 9C | 33-37 45-46 | 34 54, 57, |
| 8.6 | The team follows manufacturers' instructions and accepted standards of practice to perform manual cleaning. | 6D 9C | 35-36 45-46 | 36, 54, 57, 58 |
| 8.7 | The team verifies that detergents, solutions, and disinfectants are compatible with the devices being reprocessed, the equipment used for washing or sterilization, and the decontamination or sterilization processes used. | 6D 7A+B 8C 9D | 35-37 37-39 41-43 46 | 40-45 48 |
| 8.8 | For each detergent, solution and disinfectant, the team follows manufacturers' recommendations for use, contact time, shelf life, storage, appropriate dilution, testing for appropriate concentration and effectiveness, and required PPE. | 6D 7A+B 8C 9C+D | 35-37 37-39 41-42 45-46 | 40-45 48, 50 |
| 8.9 | Following cleaning, and prior to additional reprocessing, the team inspects each device for cleanliness, functionality, and defects such as breaks, chips, or cracks, | 6D 9C | 35-36 45-46 | N/A |

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|---|---------------------|-------------------------|-----------------------|
| | | Section | Page # | |
| | and follows up with additional cleaning or maintenance if required. | | | |
| 8.10 | The team prepares each device or set of devices for sterilization according to manufacturers' instructions, including drying, lubrication, and disassembly. | 6 10 | 33-37 49-52 | 36 69, 70, 72, |
| 8.11 | The team packages each device or set of devices for sterilization using an appropriate packaging material and process. | 10A+B | 49-53 | 83 |
| 8.12 | The package or container has an externally visible chemical indicator to differentiate between processed and unprocessed packages. | 10B 10E | 50 57-58 | 85 |
| 8.13 | The team places an internal chemical indicator in each package or container, according to the organization's quality control processes, to verify that sterilizer penetration has occurred. | 10B 10D+E 11B | 50 55-58 61-62 | 85 |
| 9.0 | The team operates the sterilization equipment and conducts the sterilization safely and accurately. | 3 5 10 | 28-29 30-32 49-59 | 15, 16, 29 72, |
| 9.1 | The team uses its most complex or challenging pack or container to verify that all devices can be sterilized. | 10D&E | 57-58 | 85, 90 |
| 9.2 | The team follows the SOPs, the sterilizer's operating manual, and manufacturers' instructions for devices and equipment when loading the sterilizer. | 10B ii+iii | 51-52 | 75 |
| 9.3 | An appropriate team member verifies the configuration of the load before beginning the sterilization. | 10B | 50-52 | N/A |
| 9.4 | The team follows manufacturers' instructions while operating the sterilizer. | 10 | 50-59 | 89,72 |
| 9.5 | Following the sterilization cycle and before unloading, the appropriate team member verifies that the required parameters have been met. | 10B iv 10D | 52 54-58 | 74 |
| 9.6 | During unloading, the team inspects all packs, including the results of external chemical indicators. | 10B iv+v | 52 | N/A |
| 9.7 | The team repeats reprocessing for any items with a damaged pack or seal, or those that are compressed, torn, wet, or have been dropped on the floor. | 11 & 12A | 61-62 | 93,94 |

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|---|---------------------------|----------------------------|-----------------------|
| | | Section | Page # | |
| 10.0 | The team prevents the contamination of reprocessed devices. | 9F 11 | 47 61-62 | 64 93 |
| 10.1 | The reprocessing unit or area has an appropriate area for the storage of sterilized medical devices. | 9F 11A | 47 61 | 93 |
| 10.2 | The organization limits and monitors access to the storage area to appropriate team members. | 11A | 61 | 93 |
| 10.3 | When cleaning the sterile storage area, staff members minimize the amount of air turbulence and excess moisture. | 2B 2D 11A | 27 28 61 | N/A |
| 10.4 | The organization maintains the integrity of each sterile package. | 11A&B | 61-62 | 92-94 |
| 10.5 | Trained team members follow established procedures for handling and distributing sterile devices. | 11A&B | 61-62 | 93 |
| 10.6 | The team transports sterile devices and equipment using clean, enclosed, or covered carts and bins, or plastic bags. | 1C 8 11A | 25 43 61 | 7, 32, 33, 93 |
| 11.0 | The team tracks sterilized loads and performs appropriate recalls, as needed. | 12 | 62-64 | 95-98 |
| 11.1 | The team follows policies and procedures for inventory control of sterilized devices. | 1C 10B vii 11 12 | 24 53 61-62 62-64 | 15 93,94 |
| 11.2 | The sterilized packages are clearly identifiable and distinguished from nonsterilized items. | 6B 10Bv 12A | 34-35 52 62 | 33, 95 |
| 11.3 | The team is able to track all sterilized items in storage or transported to client care areas, units, or other organizations. | 1C 12A | 24-25 62 | 9 98 |
| 11.4 | The organization maintains a dedicated bank of neurosurgical and ortho-spine devices. | 1C&D | 25 | 8, 9 |

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|--|-------------------|----------------------|-----------------------|
| | | Section | Page # | |
| 11.5 | The team follows accepted standards of practice to identify when there may be a problem with sterilization and when a recall may be necessary. | 3 12 | 28, 29 62-64 | 17 97, 98 |
| 11.6 | The team follows an established procedure to recall sterilized items that may have been compromised. | 3 12C&D | 28, 29 63-64 | 17 97, 98 |
| 11.7 | For each recall, the team issues a written, complete notification to all areas of the organization that use reprocessed medical devices that identifies the items to be recalled and the actions needed to recall the items. | 3 12C&D | 28, 29 63-64 | 17 97, 98 |
| 11.8 | The team issues a complete and written report of all recalls. | 3 12C&D | 28, 29 63-64 | 17 97, 98 |
| 11.9 | The team follows a policy to retain recall orders and reports in its files. | 3 12C&D | 28-29 63-64 | 17 97, 98 |
| 12.0 | The team has an integrated approach to quality and risk management for its reprocessing and sterilization services. | 3 12 | 28-29 62-64 | 15, 16, 17 |
| 12.1 | The team has a documented quality management system for its reprocessing and sterilization services that integrates principles of quality assurance, risk management, and continual improvement. | 12A 12C | 62 63 | N/A |
| 12.2 | As part of the quality management system, the reprocessing team engages in an annual review of reprocessing and sterilization activities, with formal reports provided to the organization's senior management. | GP | 20 | 86 |
| 12.3 | The quality management system documents are accessible to staff and team members. | 4 12A&B | 29, 30 62, 63 | N/A |
| 12.4 | As part of its quality management system, the team trains staff to identify, assess, prioritize, reduce, and communicate risks in the reprocessing unit or area. | 4 12C | 29-30 63 | 18 98 |
| 12.5 | The team monitors compliance with policies and procedures, safe work practices, and OHS requirements in the reprocessing unit or area. | P 3 5 | 18 28-29 30-32 | 23-29 15, 16 |
| 12.6 | The team verifies and documents the quality of reprocessing services provided in other areas, or by contracted services or subsidiaries. | GP | 20-21 | N/A |

| ACCREDITATION STANDARDS | | BC BEST PRACTICES | | RECOMMENDATION NUMBER |
|-------------------------|--|-------------------|----------------|-----------------------|
| | | Section | Page # | |
| | | 12A+B | 62-63 | |
| 12.7 | The team identifies, investigates, evaluates, and takes appropriate corrective action for deviations from normal operating procedures or safe work practices, including critical incidents/accidents and adverse events. | 3 12C+D | 28-29 63-64 | 15, 16, 17, 97, 98 |
| 12.8 | Team leaders review the quality management system regularly. | P 12A | 17 62 | N/A |
| 12.9 | The team participates in periodic audits. | GP | 20-21 | N/A |
| 12.10 | The team identifies areas for improvement and makes appropriate changes or improvements. | P 12 | 14-19 62-64 | N/A |

Appendix F: Additional Resources

1. Organizations and Publications

Canadian Standards Association (CSA)

Source for national standards in medical device reprocessing e.g. decontamination, steam sterilization

<http://www.csa.ca/cm/home>

BC Ministry of Health

Best Practice Guidelines for the Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities

<http://www.health.gov.bc.ca/library/publications/year/2011/Best-practice-guidelines-cleaning.doc>

Provincial Infectious Diseases Advisory Committee (PIDAC)

PIDAC was established by the Ontario Ministry of Health and Long-term Care and provides advice on protocols to prevent and control infectious diseases, emergency preparedness for an infectious disease outbreak, and immunization programs. They have published a number of best practice guidelines.

<http://www.pidac.ca/>

Public Health Agency of Canada (PHAC)

Public Health Agency of Canada. Guidelines – Infectious Diseases. Infection Control Guidelines – Hand Washing, Cleaning, Disinfection and Sterilization in Health Care. Canada Communicable Disease Report. 1998; 27(Suppl 8): i-xi, 1-55.

<http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/98pdf/cdr24s8e.pdf>

Public Health Agency of Canada. Guidelines – Infectious Diseases. Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care – Revisions of Isolation and Precaution Techniques, 1999. Canada Communicable Disease Report 1999; 25(Suppl 4): 1-142.

<http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/99vol25/25s4/>

Infection Prevention and Control Guideline for Flexible gastrointestinal Endoscopy and Flexible Bronchoscopy

<http://www.phac-aspc.gc.ca/nois-sinp/guide/endo/index-eng.php>

Infection Control Guidelines: Foot Care by Health Care Providers

<http://www.collectionscanada.gc.ca/webarchives/20071212094643/www.phac-aspc.gc.ca/publicat/ccdr-rmtc/97vol23/23s8/index.html>

U.S. Centers for Disease Control and Prevention (CDC)

Guidelines for Disinfection and Sterilization in Health Care Facilities (2008).

<http://www.cdc.gov/ncidod/dhqp/index.html>

PubMed

PubMed is the National Library of Medicine's search service that provides access to over 15 million citations in biomedical and life sciences journals.

<http://www.pubmed.com>

Society of Gastroenterology Nurses and Associates (SGNA)

The Society of Gastroenterology Nurses and Associates (SGNA) is a professional organization of nurses and associates dedicated to the safe and effective practice of gastroenterology and endoscopy nursing through education, research, advocacy, and collaboration.

www.sgna.org

Association for the Advancement of Medical Instrumentation (AAMI)

The Association for the Advancement of Medical Instrumentation (AAMI) is a non-profit whose mission is to increase the understanding and beneficial use of medical instrumentation through effective standards and educational programs, and publications.

www.aami.org

Provincial Infection Control Network (PICNet)

The BC Provincial Infection Control Network (PICNet) is a collaborative of many health care disciplines working together to prevent and control health care-associated infections (HAI) across the continuum of care.

<http://www.picnetbc.ca/>

Accreditation Canada

Accreditation Canada is a not-for-profit, independent organization that provides health organizations with an external peer review to assess the quality of their services based on standards of excellence.

<http://www.accreditation.ca/accreditation-programs/qmentum/standards/reprocessing-and-sterilization-of-reusable-medical-devices/>

2. Professional Associations

IAHSCMM – International Association of Healthcare Central Service Materiel Management

IAHSCMM offers professional certification programs that are recognized throughout the healthcare industry and are available to members of the Association and healthcare facilities.

<http://www.iahcsmm.org/>

ORNAC – Operating Room Nurses Association of Canada

ORNAC is an Associate member of the Canadian Nursing Association that aims to enhance and advance the practice of perioperative Registered Nurses.

<http://www.ornac.ca/>

CHICA - Canada. Community and Hospital Infection Control Association - Canada

National association for infection prevention and control professionals in Canada. Offers a number of Position Statements and expertise in infection prevention and control.

<http://www.chica.org>

APIC- Association for Professionals in Infection Control and Epidemiology (U.S.)

Association for Professionals in Infection Control and Epidemiology (APIC). APIC Text of Infection Control and Epidemiology, 2005 Edition. Available for purchase from [APIC online store](#).

<http://www.apic.org/AM/Template.cfm?Section=Store>

The College of Physicians and Surgeons of BC

With respect to Non-Hospital Medical/Surgical Facilities (also known as “private clinics”) the College has adopted the Ministry’s 2007 *‘Best Practice Guidelines for the Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities’* as mandatory policy at all non- hospital facilities. The College notified private clinics of this policy in February of 2008.

With respect to physician offices generally (i.e. not including NHMSFs) the College strongly advises physicians to become familiar with the following guidelines:

The College of Physicians and Surgeons of BC. Infection Prevention and Control (IPAC) in Physician’s Offices, Resource Manual. Available from:

<https://www.cpsbc.ca/files/u6/Infection-Prevention-and-Control-in-Physician-Offices.pdf>

Barry C., Boyd N., Cleator N., et al. Infection prevention and control: best practices for long term care, home and community care including health care offices and ambulatory clinics [Internet]. Canadian Committee on Antibiotic Resistance; 2007 Jun [cited 2011 June 20]. Available from:

<http://www.phac-aspc.gc.ca/amr-ram/ipcbp-pepci/index-eng.php>

PICNet: Provincial Infection Control Network of BC [Internet]. Vancouver (BC): Provincial Infection Control Network of BC; c2007-2011 [cited 2011 June 20]. Available from: <http://www.picnetbc.ca/>

3. Resources for Reprocessing Education

College of New Caledonia

The College of New Caledonia, in partnership with the Vancouver Community College, offer a Medical Device Reprocessing/Sterile Processing Technician certificate program at the University of Northern BC.

http://www.cnc.bc.ca/shared/assets/Sterile_Supply_Technician_-_Health18220.pdf

Okanagan College

Offers a Medical Device Reprocessing/Sterile Processing and Distribution certificate program.

http://www.okanagan.bc.ca/departments/cs/programs/all-certificates/Health_Programs/Sterile_Processing_and_Distribution_Certificate.html

Vancouver Community College

The Vancouver Community College offers a Medical Device Reprocessing/Sterile Processing Technician certificate program.

http://www.vcc.ca/programs-courses/details.cfm?area=CS_HEALTH&prog=STERSUPPLY

Vancouver Island University (Duncan and Nanaimo)

Offers a full-time Sterile Supply Technician certificate program.

<http://www.viu.ca/ccs/certificates/sst.asp>

Canadian Standards Association (CSA) – Certified Medical Device Reprocessing Technician (CMDRT)

CSA Standards has developed the first national personnel certification program, the Certified Medical Device Reprocessing Technician (CMDRT), based on Canadian standards and best practices for technicians reprocessing reusable medical devices in Canada.

http://www.csa-america.org/personnel_certification/cmdrt/

IAHSCMM – International Association of Healthcare Central Service Materiel Management

IAHSCMM offers professional certification programs that are recognized throughout the healthcare industry and are available to members of the Association and healthcare facilities.

<http://www.iahscmm.org/Certification/training.html>

CBSPD – Certification Board for Sterile Processing and Distribution, Inc.

The Certification Board for Sterile Processing and Distribution, Inc. (CBSPD) is a non-profit Certification Board which plans, develops and administers competency-based "International" certification examinations for personnel performing cleaning, disinfection, sterilization and inventory management activities.

<http://www.sterileprocessing.org/cbspd.htm>

Endnotes

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http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/00_96204_01

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