

Provincial Infectious
Diseases Advisory
Committee
(PIDAC)

Best Practices For Cleaning, Disinfection and Sterilization

In All Health Care Settings

**This document replaces “Best Practices
For Cleaning, Disinfection and Sterilization
in All Health Care Settings” published
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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, transportation and biological decontamination of contaminated medical equipment/devices.

In this document, “shall” indicates mandatory requirements according to the Canadian Standards Association; “must” indicates best practice, i.e. the minimum standard based on current recommendations in the medical literature.

This document reflects the best expert opinion on the reprocessing of medical equipment/devices in a health care setting. As new information becomes available, the recommendations in this document will be reviewed and updated. Users must be cognizant of the basic principles of reprocessing and safe use of medical equipment/devices when making decisions about new equipment/devices and methodologies that might become available.

Information in this document is consistent with, or exceeds, recommendations from the Public Health Agency of Canada. It also meets standards developed by the Canadian Standards Association and reflects position statements of the Ontario Hospital Association. As such, it may be used as a basis for auditing reprocessing practice in any health care setting in Ontario.

How and When to Use This Document

The best practices for reprocessing medical equipment set out in this document should be practiced in all settings where care is provided, across the continuum of health care. This includes settings where emergency care is provided, hospitals, long term care homes, outpatient clinics, community health centres and clinics, physician offices, dental offices, offices of allied health professionals, Public Health and home health care.

All reprocessing of equipment/devices, regardless of source, must meet these best practices whether the equipment/device is purchased, loaned, physician/practitioner-owned, research equipment/device or obtained by any other method.

Assumptions and General Principles for Infection Prevention and Control

The best practices set out in this document are based on the assumption that health care settings in Ontario have basic infection prevention and control systems or programs in place. If this is not the case, these settings must work with organizations that have infection prevention and control expertise, such as regional academic health science centers, regional networks, public health units that have certified infection prevention and control staff 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) about basic infection prevention and control, these best practices are based on the following assumptions and principles:

1. Health care settings routinely implement best practices to prevent and control the spread of infectious diseases.
2. Health care settings devote adequate resources to infection prevention and control.

3. All staff are, or will be, certified in the Ontario MOHLTC infection prevention and control core competencies.
4. Health care settings provide regular education and support to help staff consistently implement appropriate infection prevention and control practices. Effective education programs emphasize:
 - The risks associated with infectious diseases and their transmission via medical equipment/devices and objects;
 - The importance of immunization against vaccine-preventable diseases;
 - Hand hygiene (including the use of alcohol based hand rubs or hand washing);
 - Principles and components of Routine Practices (Health Canada. Infection Control Guidelines: [*Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care*](#). *Can Commun Dis Rep*. 1999; 25 Suppl 4: 1-149.)
 - Assessment of the risk of infection transmission and the appropriate use of personal protective equipment, including safe application, removal and disposal;
 - Appropriate cleaning and/or disinfection of care equipment, supplies and surfaces or equipment/devices that have been in the healthcare environment;
 - Procedures that are considered high risk and rationale;
 - Individual staff responsibility to keep clients/patients/residents, themselves and fellow staff members safe;
 - Collaboration between Occupational Health and Safety and Infection Prevention and Control departments/individuals.

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 Prevention and Control networks may be a resource and can provide assistance in developing and providing education programs for community settings.

5. All health care settings promote collaboration between occupational health and safety and infection prevention and control in implementing and maintaining appropriate infection prevention and control standards that protect workers.
6. The facility is to be in compliance with the *Occupational Health and Safety Act, R.S.O. 1990, c.O.1* and associated Regulations including the *Health Care and Residential Facilities - O. Reg. 67/93 Amended to O. Reg. 631/05*.
7. All health care settings have established communication with their local public health unit.
8. All health care settings have access to ongoing infection prevention and control advice and guidance to support staff and resolve any uncertainty about the level of reprocessing required for a particular piece of equipment/device or a given situation.
9. **Health care settings have established procedures for receiving and responding appropriately to all international, regional and local health alerts regarding medical equipment/devices.** They also communicate health alerts promptly to all staff responsible for reprocessing medical equipment/devices and provide regular updates. Current alerts are available from local Public Health units, the MOHLTC, Health Canada's medical devices alerts website [http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index_e.html], local regional infection prevention and control networks, etc.
10. All health care settings regularly assess the effectiveness of their infection prevention and control education programs and their impact on practices, and use that information to refine their programs.
11. All health care settings have a process for evaluating personal protective equipment (PPE) to ensure it meets quality standards where applicable.

Abbreviations

AER	Automated Endoscope Reprocessor
CSA	Canadian Standards Association
CJD	Creutzfeldt-Jakob Disease
DIN	Drug Identification Number
HLD	High Level Disinfection
LLD	Low Level Disinfection
MOHLTC	Ontario Ministry of Health and Long Term Care
MSDS	Material Safety Data Sheet
OPA	Ortho-phthalaldehyde
PHAC	Public Health Agency of Canada
PPE	Personal Protective Equipment
QUAT	Quaternary Ammonium Compound
USFDA	United States Food and Drug Administration

Glossary of Terms

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 equipment/device.

Biologic Monitor: Spore-laden strips or vials that are used to monitor the effectiveness of the sterilization process.

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

Cleaning: The physical removal of foreign material (e.g. dust, soil, organic material such as blood, secretions, excretions and microorganisms). Cleaning physically removes rather than kills microorganisms. It is accomplished with water, detergents and mechanical action. Thorough and meticulous cleaning is required before any equipment/device may be decontaminated, disinfected and/or sterilized.

Client/patient/resident: Any person receiving health care within a health care setting.

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

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 process or product that is used on medical equipment/devices which results in disinfection of the equipment/device.

Disinfection: The inactivation of disease-producing microorganisms. Disinfection does not destroy bacterial spores. Medical equipment/devices must be cleaned thoroughly before effective disinfection can take place.

Drug Identification Number (DIN): In Canada, disinfectants are regulated as drugs under the Food and Drugs Act and Regulations. Disinfectant manufacturers must obtain a drug identification number (DIN) from Health Canada prior to marketing, which ensures that labelling and supporting data have been provided and that it has been established by the Therapeutic Products Directorate that the product is effective and safe for its intended use.

Endoscope – Critical: Endoscopes used in the examination of critical spaces, such as joints and sterile cavities. Many of these endoscopes are rigid with no lumen. Examples of critical endoscopes are arthroscopes, laparoscopes and cystoscopes.

Endoscope – Semicritical: Fiberoptic or video endoscopes used in the examination of the hollow viscera. These endoscopes generally invade only semicritical spaces, although some of their components might enter tissues or other critical spaces. Examples of semicritical endoscopes are laryngoscopes, nasopharyngeal endoscopes, transesophageal probes, colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes and enteroscopes.

Enzymatic Cleaner: An enzymatic cleaner is a solution that aids in the removal of proteinaceous material on medical equipment/devices when plain water and/or a detergent solution are considered inadequate.

Hand Hygiene: A process for the removal of soil and transient microorganisms from the hands. Hand hygiene may be accomplished using soap and running water or the use of alcohol-based hand rubs. Optimal strength of alcohol-based hand rubs should be 60% to 90% alcohol.

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

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

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

Infection Prevention and Control: 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 workers, other clients/patients and visitors.

Loaned Equipment: Medical equipment/devices used in more than one facility, including borrowed, shared or consigned equipment/devices, which are used on patients/clients/residents. Reprocessing is carried out at both loaning and receiving sites. Loaned equipment may also be manufacturer-owned and loaned to multiple health care facilities.

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

Low Level Disinfection (LLD): Level of disinfection required when processing noncritical medical equipment/devices or some 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. Medical equipment/devices must be thoroughly cleaned prior to low level disinfection.

Manufacturer: Any person, partnership or incorporated association that manufactures and, under its own name or under a trade mark, design, trade name or other name or mark owned or controlled by it, sells medical equipment/devices.

Medical equipment/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.

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

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

Pasteurization: A high level disinfection process using hot water at a temperature of 75°C for a contact time of at least 30 minutes.

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

Reprocessing Department: A centralized area within the health care setting for cleaning, disinfection and/or sterilization of medical equipment/devices. In community settings, any segregated area where reprocessing of equipment/devices takes place, away from patients and clean areas (e.g. Central Processing Department – CPD, Central Processing Service - CPS, Central Surgical Supply - CSS, Surgical Processing Department - SPD, etc.).

Reusable: A designation given by the manufacturer of medical equipment/devices that allows it, through the selection of materials and/or components, to be reused.

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

Sharps: Objects capable of causing punctures or cuts (e.g. needles, syringes, blades, glass).

Single patient-use: Medical equipment/device that may be used on a single client/patient/resident and may be reused on the same client/patient/resident, but may not be used on other clients/patients/residents.

Single-use/disposable: Medical equipment/device designated by the manufacturer for single-use only. Single-use equipment/devices must not be reprocessed.

Staff: Anyone conducting activities within a health care setting including: all health care providers (e.g. emergency service workers, physicians/practitioners, dentists, chiropractors, nurses, respiratory therapists and other allied health professionals, students); support services (e.g. housekeeping); and volunteers.

Sterilant: A chemical used on medical equipment/devices which results in sterilization of the equipment/device.

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

Ultrasonic washer: A machine that cleans medical equipment/devices by the cavitations produced by ultrasound waves.

Washer-disinfector: A machine that removes soil and cleans medical equipment/devices prior to high level disinfection or sterilization. Noncritical medical equipment/devices that do not require high level disinfection or sterilization may be reprocessed in a washer-disinfector (e.g. bedpans).

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

BEST PRACTICES FOR CLEANING, DISINFECTION AND STERILIZATION IN ALL HEALTH CARE SETTINGS

I. General Principles

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

“Effective reprocessing requires rigorous compliance with recommended protocols.”¹

“All activities included in the reprocessing of medical equipment/devices are based on the consistent application of Routine Practices and Hand Hygiene.”²

The goals of safe reprocessing of medical equipment/devices include:

- Preventing transmission of microorganisms to personnel and clients/patients/residents;
- Minimizing damage to medical equipment/devices from foreign material (e.g. blood, body fluids, saline and medications) or inappropriate handling.

Best practices in reprocessing medical equipment/devices must include the following:

- A corporate strategy for dealing with single-use medical equipment/devices;
- Adequate review by all parties whenever new equipment/devices are being considered for purchase (e.g. reprocessing committee);
- A centralized area for reprocessing or an area that complies with the requirements for reprocessing;
- Training of all staff who do reprocessing;
- Written policies and procedures for each type of medical equipment/device that is reprocessed;
- Validation of cleanliness, sterility and function of the reprocessed equipment/device;
- Continual monitoring of reprocessing procedures to ensure their quality.

Decisions related to reprocessing medical equipment/devices should be made by a **multi-disciplinary reprocessing committee** that includes the individuals responsible for purchasing the equipment/device, reprocessing the equipment/device, maintaining the equipment/device, infection prevention and control, occupational health and safety, and the end-user of the equipment/device.

There must be a clear definition of the lines of authority and accountability with respect to reprocessing, whether done centrally or elsewhere.

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.

When formulating written policies and procedures, the following steps in reprocessing must be addressed:³

- Collection at point of use, containment and transport
- Cleaning
- Inspection
- Disinfection/Sterilization
- Rinsing (following disinfection)
- Drying/aeration
- Clean transportation
- Storage

¹ Health Canada. Hand washing, cleaning, disinfection and sterilization in health care. *Can Commun Dis Rep.* 1998; 24 Suppl 8: i-xi, 1-55.

² Health Canada. Routine practices and additional precautions for preventing the transmission of infection in health care. *Can Commun Dis Rep.* 1999; 25 Suppl 4: 1-149.

³ Canadian Standards Association. *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada.* Toronto, Ont.: Canadian Standards Association; 2000 (R2005). Adapted from Figure 1.

It is essential that an **overall inventory** of all reprocessing practices within the healthcare setting is done and documented where, how and by whom all equipment/devices are being reprocessed and whether current standards are being met, as set out in this document.

All processes must continue to be **audited** on a regular basis (e.g. annually), with clear and known consequences attached to non-compliance. Compliance with the processes must also be audited.

As new reprocessing technologies and processes become available, they must be evaluated against the same criteria as current methodologies. Verify that:

- the process is compatible with the equipment/device being reprocessed;
- the process is compatible with the cleaning products being used;
- environmental issues with the process have been considered (e.g. odours, toxic waste products, toxic vapours);
- occupational health issues with the process have been considered (e.g. are PPE or special ventilation required);
- staff education and training is available (provided by the manufacturer);
- the facility is able to provide the required preventive maintenance;
- the process can be monitored (e.g. there are mechanical, chemical and biologic monitors and indicators available);
- chemical products have a Drug Identification Number (DIN) from Health Canada.

II. Best Practices

1. Single-Use Medical Equipment/Devices

1.1 **Critical and semi-critical medical equipment/devices labeled as single-use must not be reprocessed and reused unless the reprocessing is done by a licensed reprocessor.**^{4,5,6}

Currently there are no licensed reprocessors in Canada. There are reprocessors in the USA licensed by the United States Food and Drug Administration (USFDA).^{5,6}

Health care settings that wish to have their single-use medical equipment/devices reprocessed by a licensed reprocessor should 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 equipment/devices.⁷ In order to have critical or semicritical medical equipment/devices reprocessed by one of these facilities, there must be processes for:

- Equipment/device tracking and labeling
- The ability to recall reprocessed medical equipment/devices
- Proof of sterility or high level disinfection
- Pyrogenicity testing
- Maintenance of equipment/device functionality and integrity
- The presence of quality assurance and quality control programs
- The ability to report adverse events
- Proof of good manufacturing procedures

Whereas reusable medical equipment/devices are sold with instructions for proper cleaning and sterilization, no such instructions exist for single-use medical equipment/devices. Furthermore, manufacturers often have not provided data to determine whether the equipment/device can be thoroughly cleaned, whether the materials can withstand heat or chemical sterilization, or whether delicate mechanical and electrical components will continue to function after one or more reprocessing cycles.⁵

In circumstances where the manufacturer does not approve of reuse, the facility will bear the brunt of legal responsibility in establishing when and under what conditions reuse of medical equipment/devices presents no increased risk to patients and that a reasonable standard of care was adhered to in the reuse of the equipment/device. This would involve written policies, extensive testing of reprocessing protocols and strict adherence to quality assurance investigations.⁴ This is a detailed and expensive process and should only be undertaken if there is a compelling reason to do so.

Single-use medical equipment/devices are usually labeled by the manufacturer with a symbol:



1.2 **Needles must be single-use and must not be reprocessed.**

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 is a patient safety issue as there is no guarantee that the lumen is clean and that the reprocessing is effective.

⁴ Canadian Healthcare Association. *The Reuse of Single-Use Medical Devices: Guidelines for Healthcare Facilities*. Ottawa: CHA Press, 1996.

⁵ Health Canada. Therapeutic Products Directorate. *Reprocessing of Reusable and Single-Use Medical Devices*. Letter to hospital administrators, July 30, 2004. Available online at: http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/annonce-annonce/reprocess_retraitement_let_e.html. Accessed November 9, 2005.

⁶ Ontario Hospital Association. Report of OHA's Reuse of Single-Use Medical Devices Ad-hoc Working Group. Toronto, Ont.: Ontario Hospital Association; 2004. Executive summary available online at: [http://www.oha.com/Client/OHA/OHA_LP4W_LND_WebStation.nsf/resources/ReuseofSingleUse_Medical_Devices_Executive_Summary/\\$file/ReuseofSingleUse_Medical_Devices_Executive_Summary.pdf](http://www.oha.com/Client/OHA/OHA_LP4W_LND_WebStation.nsf/resources/ReuseofSingleUse_Medical_Devices_Executive_Summary/$file/ReuseofSingleUse_Medical_Devices_Executive_Summary.pdf)

⁷ Ontario Hospital Association Bulletin. *Reprocessing of Single Use Medical Devices*. July 8, 2005.

- 1.3** *It is strongly recommended that catheters, drains and other medical equipment/devices with small lumens (excluding endoscopy equipment) be designated single-use and not be reprocessed and reused.*
- 1.4** *Home health care agencies may consider reusing single-use semicritical medical equipment/devices for a single client in their home when reuse is safe and the cost of discarding the equipment/device is prohibitive for the client.*
- a) Equipment/devices owned by the client that are reused in their home must be adequately cleaned prior to reuse. See Section 10, "Disassembling and Cleaning Reusable Medical Equipment" for cleaning requirements.
- 1.5** *The health care setting must have written policies regarding single-use medical equipment/devices.*

2. Purchasing and Assessing Medical Equipment/Devices and/or Products to be Subjected to Disinfection or Sterilization Processes

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

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

Equipment that is used to clean, disinfect or sterilize (e.g. ultrasonic cleaners, pasteurizers, washer-disinfectors, Automated Endoscope Reprocessors - AERs, sterilizers) must also meet standards established by Health Canada/PHAC, the CSA and the standards contained in this document.

- 2.1** *Do not purchase medical equipment/devices that cannot be cleaned and reprocessed according to the recommended standards.*
- 2.2** *When purchasing reprocessing equipment or chemical products for reprocessing, consideration must be given to Occupational Health requirements, patient safety, and environmental safety issues.*
- 2.3** *All medical equipment/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 equipment/devices, trial or research equipment/devices, physician/practitioner-owned, etc.) must meet established quality reprocessing parameters.*
- a) The manufacturer must supply the following:
- i) Information about the design of the equipment/device
 - ii) Manuals/directions for use
 - iii) Device-specific recommendations for cleaning and reprocessing of equipment/device
 - iv) Education for staff on use, cleaning and the correct reprocessing of the equipment/device
 - v) Recommendations for auditing the recommended process

- b) Infection prevention and control as well as reprocessing personnel must make a recommendation regarding the suitability of the equipment/device for purchase after reviewing:
 - i) Manufacturer's directions
 - ii) CSA standards regarding the equipment/device
 - iii) Health Canada/PHAC guidelines regarding the equipment/device
 - iv) MOHLTC best practices for cleaning, disinfection and sterilization
- c) Biomedical engineering must review the equipment/device.
- d) A valid medical device license issued by the Therapeutic Products Directorate of Health Canada [<http://www.mdall.ca/>] or provided by the manufacturer must be available for all medical equipment/devices⁸ 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.⁹
- e) Once the decision to use the equipment/device is made, the following factors must then be addressed:
 - i) Who is accountable to verify that the required protocols are written and in place, staff are adequately trained and certified, and that routine audits will occur to verify that the process is safe?
 - ii) Who will reprocess the equipment/device?
 - iii) Where will the reprocessing be done?
 - iv) What process will be used for reprocessing?
 - v) Are personnel certified to carry out this procedure (this includes training in the procedure, auditing the process, regular re-education and re-certification)?
 - vi) How often will audits be performed?

2.4 Newly purchased non-sterile critical and semicritical medical equipment/devices must first be inspected and reprocessed according to their intended use.

Refer to Table 1, "Spaulding's Classification of Medical Equipment/Devices and Required Level of Reprocessing" for the level of processing that is to be used for medical equipment/devices based on the intended use of the equipment/device.

2.5 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 equipment/devices,⁸ including endoscopes.

- a) In addition to the requirements in Section 2.3, equipment/devices loaned to a health care setting must be disassembled, cleaned and reprocessed by the receiving facility prior to use in the receiving facility.
- b) Ideally, the equipment/device should be received by the facility's reprocessing department at least 24 hours before use. **The facility shall not accept for use any medical equipment/device that does not arrive in sufficient time to allow the receiving health care setting to follow its procedures for inventory, inspection and reprocessing.**
- c) Loaned medical equipment/devices must include written instructions for reprocessing and staff must have received training in reprocessing the equipment/device.
- d) A health care setting that uses loaned, shared and/or leased medical equipment/devices shall have a policy to cover emergencies related to the equipment/devices.
- e) Loaned equipment/devices must be tracked and logged. There must be a tracking mechanism and log book which includes:
 - i) The identification number of the equipment/device must be recorded;
 - ii) The owner of the equipment/device must have a system to track the equipment/device. This information should be given to the user for their records;
 - iii) There must be a record of the client/patient/resident involved with the equipment/device, so that the client/patient/resident may be identified if the equipment/device is recalled;
 - iv) There must be documentation about the reason for using loaned equipment and awareness of the possible consequences.

⁸ Canadian Standards Association. CAN/CSA-Z314.22-04. *Management of Loaned, Shared and Leased Medical Devices*. Toronto, Ont.: Canadian Standards Association; 2004.

⁹ *Food and Drugs Act*, R.S.C. 1985, c. F-27. Available online at: <http://laws.justice.gc.ca/en/F-27/text.html>; *Medical Devices Regulations*, SOR/98-282. Available online at: <http://www.canlii.org/ca/regu/sor98-282/whole.html>

- f) Borrowed equipment/devices must be cleaned and reprocessed before returning it to the owner.
 - g) Organizations that transport loaned, shared and leased medical equipment/devices shall have written procedures for the safe handling and transportation of medical equipment/devices, including provision for maintenance of cleanliness/ sterility, separation of clean and dirty items, and safety of those doing the transport:
 - i) Soiled equipment/devices must be transported in compliance with federal [<http://laws.justice.gc.ca/en/T-19.01/index.html>] and provincial [<http://www.oshforeveryone.org/wsib/external/www.ccohs.ca/legislation/documents/ont/onedgt/onadgte0.htm>] regulations regarding the transport of dangerous goods.
 - ii) Clean equipment/devices must be transported in a manner that does not compromise the integrity of the clean item.
 - h) The use of loaned equipment/devices for neurosurgical procedures is strongly discouraged (see Section 2.6).
- 2.6** *Because of the risks associated with Creutzfeldt-Jakob disease (CJD), surgical instruments that are used on high risk neurological and eye tissue from patients at high risk for CJD must be subjected to rigorous decontamination processes as detailed in the Health Canada/Public Health Agency of Canada infection control guideline, "Classic Creutzfeldt-Jakob Disease in Canada".¹⁰*

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. Special recommendations 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).¹⁰ These instruments should not be pooled with other instruments.

Health Canada/PHAC defines a high risk patient as a patient diagnosed with CJD or a patient with an unusual, progressive neurological disease consistent with CJD (e.g. dementia with myoclonus and ataxia, etc.). High risk tissue includes brain, spinal cord, dura mater, pituitary and eye (including optic nerve and retina).¹⁰

3. Education and Training

- 3.1** *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 equipment/devices.*
- a) Any individual involved in the cleaning, disinfection and/or sterilization of medical equipment/devices must be properly trained and their practice audited on a regular basis to verify that standards are met.
 - b) Training will include information on cleaning, disinfection and sterilization, occupational health and safety issues, and infection prevention and control.
 - c) Orientation and continuing education for all personnel involved in reprocessing of medical equipment/devices will be provided and documented.
 - d) Feedback should be provided to personnel in a timely manner.
- 3.2** *All aspects of reprocessing shall be supervised and shall be performed by knowledgeable, trained personnel.*
- 3.3** *The program director and all supervisors involved in reprocessing must, as a minimum, have completed a recognized qualification/certification course in reprocessing practices. A plan must be in place for each person involved in reprocessing to obtain this qualification within five years.*

¹⁰ Health Canada. Classic Creutzfeldt-Jakob disease in Canada. An infection control guideline. *Can Commun Dis Rep.* 2002; 28 Suppl 5: 1-84.

Refer to [Appendix G](#) for a list of education and training resources.

- a) All staff who are primarily involved in reprocessing must obtain and maintain certification.
- b) Any individual involved in any aspect of reprocessing must obtain education and training specific to the medical equipment/device to be reprocessed (e.g. dental hygienists, radiation technologists, nurses in long term care, nurses in physician offices).
- c) There must be a process in place to ensure continued competency, including continuing education.
- d) It is strongly recommended that recertification be obtained every five years.

4. Written Policies and Procedures

4.1 ***The health care setting will, as a minimum, have policies and procedures for all aspects of reprocessing that are based on current recognized standards/recommendations and that are reviewed at least annually.***

- a) Policies and procedures must be established to ensure that the disinfection processes follow the principles of infection prevention as set out by Health Canada¹¹, the CSA Standards^{12,13} and these Ontario MOHLTC best practices.
- b) Policies and procedures must include the following:
 - i) Responsibilities of management and staff;
 - ii) Qualifications, education and training for staff involved in reprocessing;
 - iii) Infection prevention and control activities;
 - iv) Worker health and safety activities;
 - v) Preventive maintenance requirements with documentation of actions;
 - vi) 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;
 - vii) Annual review with updating as required;
 - viii) Documentation and maintenance of records for each process;
 - ix) Ongoing audits of competency and procedures (who, when, how);
 - x) Management and reporting of incidents where patient safety may have been compromised to administration or appropriate regulatory body.

4.2 ***Manufacturer's information for all medical equipment/devices must be received and maintained in a format that allows for easy access by personnel carrying out the reprocessing activities.***

4.3 ***All policies and procedures for reprocessing medical equipment/devices require review by an individual with infection prevention and control expertise (e.g. facility's infection prevention and control professionals, Public Health staff with certification in infection prevention and control, regional infection control network).***

4.4 ***There must be a procedure established for the recall of improperly reprocessed medical equipment/devices.***

- a) Improper reprocessing includes, but is not limited to, the following situations:
 - i) The load contains a positive biologic monitor;¹¹
 - ii) Incorrect reprocessing method was used on the equipment/device;
 - iii) Print-outs on reprocessing equipment indicate failure to reach correct parameters (e.g. temperature, pressure, exposure time, etc.);
 - iv) Chemical monitoring tape or indicator has not changed colour.
- b) All equipment/devices in each processed load must be recorded to enable tracking in the event of a recall.

¹¹ Health Canada. Hand washing, cleaning, disinfection and sterilization in health care. *Can Commun Dis Rep.* 1998; 24 Suppl 8: i-xi, 1-55.

¹² Canadian Standards Association. *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada.* Toronto, Ont.: Canadian Standards Association; 2000 (R2005).

¹³ Canadian Standards Association. *CAN/CSA-Z314.3-00. Effective Sterilization in Hospitals by the Steam Process.* Toronto, Ont.: Canadian Standards Association; 2001.

4.5 The recall procedure should include assessment of patient risk and a procedure for subsequent notification of clients/patients/residents, other facilities and/or regulatory bodies if indicated.

- a) Where a health care setting has a risk manager, that individual must be involved in any recall procedure.

5. Selection of Product/Process for Reprocessing

5.1 Products used for any/all stages in reprocessing (i.e. cleaning, disinfection, sterilization) must 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 (e.g. facility's infection prevention and control professionals, Public Health staff with certification in infection prevention and control, regional infection control network).

5.2 The reprocessing method and products required for medical equipment/devices will depend on the intended use of the equipment/device and the potential risk of infection involved in the use of the equipment/device.

The classification system developed by Spaulding¹⁴ divides medical equipment/devices into three categories based on the potential risk of infection involved in their use:

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

Classification	Definition	Level of Processing/Reprocessing
Critical Equipment/device	Equipment/device that enters sterile tissues, including the vascular system.	Cleaning followed by Sterilization
Semicritical Equipment/device	Equipment/device that comes in contact with nonintact skin or mucous membranes but do not penetrate them.	Cleaning followed by High Level Disinfection (as a minimum). Sterilization is preferred.
Noncritical Equipment/device	Equipment/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)

5.3 Products used for decontamination must be appropriate to the level of reprocessing that is required for the use of the medical equipment/device.

Refer to Appendix A and Appendix F for guidance in choosing reprocessing products and processes.

5.4 The process and products used for cleaning, disinfection and/or sterilization of medical equipment/devices must be compatible with the equipment/devices.

- a) Compatibility of the equipment/device to be reprocessed to detergents, cleaning agents and disinfection/sterilization processes is determined by the manufacturer of the equipment/device.
- b) The manufacturer must provide written information regarding the safe and appropriate reprocessing of the medical equipment/device.

¹⁴ Spaulding EH. The Role of chemical disinfection in the prevention of nosocomial infections. In: PS Brachman and TC Eickof (ed). *Proceedings of International Conference on Nosocomial Infections*, 1970. Chicago, IL: American Hospital Association: 1971: 254-274.

- 5.5** *All medical equipment/devices that will be purchased and will be reprocessed must have written device-specific manufacturer's cleaning, decontamination, disinfection, wrapping and sterilization instruction. If disassembly or reassembly is required, detailed instructions with pictures must be included. Staff training must be provided on these processes before the medical equipment/device is placed into circulation.*

6. Environmental Issues

- 6.1** *There must be a centralized area for reprocessing medical equipment/devices. Reprocessing performed outside the centralized area must be kept to a minimum and must be approved by the reprocessing committee or those accountable for safe reprocessing practices and must conform to the requirements for reprocessing space.*

Refer to [Appendix B](#) for details regarding recommendations for processing space. The environment where cleaning is performed must:

- a) Have adequate space for the cleaning process and storage of necessary equipment and supplies;
- b) Be distinctly separate from areas where clean/disinfected/sterile equipment/devices are handled or stored;
- c) Have easy access to hand hygiene facilities;
- d) Have surfaces that can be easily cleaned;
- e) Have restricted access from other areas in the setting and ensure one-way movement by staff;
- f) Have air changes, temperature and humidity appropriate to the process/product being used (see manufacturer's recommendations and CSA Standards). Refer to [Appendix B](#);
- g) In health care settings where there are dedicated central reprocessing areas, negative pressure airflow must be used in soiled areas, and positive pressure airflow must be used in clean areas;¹⁵
- h) The health care setting should be aware of the quality of its water supply and develop policies to address known problems (refer to [Appendix B](#));
- i) The health care setting should have written reprocessing contingency plans in place that address loss of potable water, boil water advisories and other situations where the water supply becomes compromised.

- 6.2** *Wherever chemical disinfection/sterilization is performed, air quality must be monitored when using products that produce toxic vapours.*

Many products (e.g. glutaraldehyde) have a maximum ceiling exposure value (CEV) as documented in the Ontario *Occupational Health and Safety Act*.¹⁶ If reprocessing is not carried out in an appropriately vented space, air sampling may be required to ensure that the CEV has not been exceeded for the chemical being used.

7. Occupational Health and Safety Issues

- 7.1** *Occupational Health and Safety for the health care setting will review all protocols for reprocessing medical equipment/devices to verify that worker safety measures are followed and in compliance with the Occupational Health and Safety Act, R.S.O. 1990, c.O.1 and associated Regulations including the Health Care and Residential Facilities - O. Reg. 67/93 Amended to O. Reg. 631/05.*

¹⁵ Canadian Standards Association. Physical requirements for decontamination facilities. In: *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada*. Toronto, Ont.: Canadian Standards Association; 2000 (R2005), Appendix C.

¹⁶ *Occupational Health and Safety Act, R.S.O. 1990, c.O.1; Control of Exposure to Biological or Chemical Agents, R.R.O. 1990, Regulation 833 Amended to O. Reg. 607/05.* [Part 5: Ceiling Exposure Values (CEV) for Biological and Chemical Agents]

The following aspects of the reprocessing procedure must be reviewed by a representative from the facility's Occupational Health and Safety Department:

- a) Sharps are handled appropriately;
- b) Air handling systems adequately protect the worker from toxic vapours;¹⁷
- c) Chemicals are stored and handled appropriately, and MSDS documentation is available as required by the *Workplace Hazardous Materials Information System (WHMIS)*, R.R.O. 1990, Reg. 860 Amended to O. Reg. 36/93 [information on WHMIS is available online from Health Canada website at: http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/index_e.html].

7.2 There is a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics and handling contact lenses in the reprocessing area.

7.3 Appropriate PPE must be worn for all reprocessing activities.

- a) Personnel involved in reprocessing will be trained in Routine Practices¹⁸, the correct use and requirement to wear PPE¹⁹, and hand hygiene.²⁰
- b) Personnel must not wear hand and arm jewellery or nail enhancements.
- c) PPE for cleaning and handling contaminated equipment/devices includes gloves, face protection (e.g. mask, protective eyewear and/or face shield) and impermeable gown or waterproof apron.
- d) When choosing gloves, the following points need to be considered:
 - i) Gloves must be long enough to cover wrists and forearms;
 - ii) Gloves must be of sufficient weight to be highly tear-resistant;
 - iii) Gloves must allow adequate dexterity of the fingers;
 - iv) Disposable gloves are recommended. If reusable gloves are used, they must be decontaminated daily, inspected for tears and holes and be staff-specific.
- e) Personnel must be trained in management of a blood or body fluid spill.

7.4 All personnel working in reprocessing must be immune to Hepatitis B or receive Hepatitis B immunization.^{21,22}

7.5 Procedures shall be written to prevent and manage injuries from sharp objects. In addition, procedures shall be in place for immediate response to worker exposure to blood and body fluids.²²

8. Factors Affecting the Efficacy of the Reprocessing Procedure

8.1 Procedures for Disinfection and Sterilization must 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

¹⁷ Canadian Standards Association. Physical requirements for decontamination facilities. In: *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada*. Toronto, Ont.: Canadian Standards Association; 2000 (R2005), Appendix C.

¹⁸ Health Canada. Routine practices and additional precautions for preventing the transmission of infection in health care. *Can Commun Dis Rep*. 1999; 25 Suppl 4: 1-149.

¹⁹ Canadian Standards Association. Personal protective equipment. In: *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada*. Toronto, Ont.: Canadian Standards Association; 2000 (R2005), Appendix A.

²⁰ Health Canada. Hand washing, cleaning, disinfection and sterilization in health care. *Can Commun Dis Rep*. 1998; 24 Suppl 8: i-xi, 1-55.

²¹ *Occupational Health and Safety Act*, R.S.O. 1990, c.O.1; *Control of Exposure to Biological or Chemical Agents*, R.R.O. 1990, Regulation 833 Amended to O. Reg. 607/05. [Part 5: Ceiling Exposure Values (CEV) for Biological and Chemical Agents]

²² Ontario Hospital Association, the Ontario Medical Association Joint Communicable Diseases Surveillance Protocols Committee. *Blood-borne Diseases Surveillance Protocol for Ontario Hospitals: Publication #206*. (Rev.ed). Toronto, Ont.: Ontario Hospital Association; 2004. Available online at: [http://www.oha.com/client/OHA/OHA_LP4W_LND_WebStation.nsf/resources/BloodBorne/\\$file/Blood_Borne_Revise_dMay2004.pdf](http://www.oha.com/client/OHA/OHA_LP4W_LND_WebStation.nsf/resources/BloodBorne/$file/Blood_Borne_Revise_dMay2004.pdf)

on the efficacy of the process. These procedures must be readily accessible to staff performing the function.

Many factors²³ affect the efficacy of reprocessing, particularly when chemical reprocessing is used. These factors include:

- a) **Cleanliness of the surface of the equipment/device**
 - i) Many chemical disinfectants/sterilants are inactivated by organic material. Cleaning must always precede decontamination.
 - ii) The greater the bioburden, the more difficult it is to disinfect or sterilize the equipment/device.
- b) **Type and concentration of the product**
 - i) Products used for disinfection and/or sterilization must 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 increases.
 - ii) Dry equipment/devices after cleaning, before immersing in disinfectant to prevent dilution of the disinfectant.
 - iii) Discard solutions on or before expiry date. Diluted products are inherently unstable once mixed and the manufacturer's directions as to duration of use must be followed.
 - iv) Use chemical test strips for all high level liquid disinfectants to assess their efficacy. During reuse, the concentration of active ingredients may drop as dilution of the product occurs and organic impurities accumulate (see Section 11.7).
 - v) Use the right disinfectant for the job. Infection prevention and control must approve the product and application.
 - vi) Some microorganisms are more resistant to germicidal chemicals, and this must be taken into consideration when choosing the product/process.
- c) **Duration and temperature of exposure to the product**
 - i) Use Health Canada recommendations for the level of disinfection/sterilization required for the intended use of the equipment/device and minimum exposure time to disinfectants/sterilants to achieve this level (refer to Appendix F).
 - ii) Use manufacturer's recommendations for temperature and for exposure time required to achieve the desired level of disinfection/sterilization. Do not exceed the manufacturer's maximum exposure time as some chemicals may cause damage to the medical equipment/device if used for extended periods of time.
 - iii) Where the manufacturer's recommendations for minimum exposure time conflict with those of Health Canada, an infection prevention and control specialist must be consulted for advice.
 - iv) All surfaces of the article must be in direct contact with the disinfectant/sterilant.
 - v) Contact may be compromised by the complexity of the article and the ability of the disinfectant to penetrate lumens etc.
- d) **Physical and chemical properties of the equipment/device being reprocessed or the surrounding environment**
 - i) Water hardness can affect some disinfectants (refer to Appendix B).
 - ii) Excessive humidity may compromise sterile wrappings (refer to Appendix B, section 7: "Temperature and Humidity").
 - iii) The pH of the solution may be important as extremes of acidity or alkalinity can limit growth of microorganisms or alter the activity of disinfectants and sterilants.
 - iv) Materials such as rubber and plastic may require special treatment.
 - v) Hinges, cracks, crevices on the equipment/device may impede successful disinfection/sterilization.

²³ Health Canada. Hand washing, cleaning, disinfection and sterilization in health care. *Can Commun Dis Rep.* 1998; 24 Suppl 8: i-xi, 1-55

9. Transportation and Handling of Contaminated Medical Equipment/Devices

- 9.1** *Disposable sharps such as needles and blades shall be removed and disposed of in an appropriate puncture-resistant sharps container at point of use, prior to transportation.*
- 9.2** *If cleaning cannot be done immediately, the medical equipment/device must be submerged in tepid water and/or detergent and enzymatic to prevent organic matter from drying on it.*

Gross soil should be removed immediately at point of use if the cleaning process cannot be completed immediately after use.

- 9.3** *Soiled medical equipment/devices must 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.*
- a) Closed carts or covered containers with easily cleanable surfaces should be used for handling and transporting soiled medical equipment/devices.
 - b) Soiled equipment/devices should be transported by direct routes to areas where cleaning will be done.
 - c) Containers or carts used to transport soiled medical equipment/devices should be cleaned after each use.
- 9.4** *A process should be in place that will ensure that medical equipment/devices which have been reprocessed can be differentiated from equipment/devices which have not been reprocessed (e.g. colour coding).*

10. Disassembling and Cleaning Reusable Medical Equipment/Devices

“Cleaning is always essential prior to disinfection or sterilization. An item that has not been cleaned cannot be assuredly disinfected or sterilized.”²⁴

The process of cleaning is to physically remove contaminants from the equipment/device, rather than to kill or damage microorganisms. If an item is not cleaned, soil (e.g. blood, body fluids, dirt) can protect the microorganisms from the action of the disinfection or sterilization process making it ineffective, as well as inactivating the disinfectant or sterilant so that it does not work. Disinfectants that become overloaded with soil can become contaminated and may themselves become a source for transmission of microorganisms.

- 10.1** *Reusable medical equipment/devices must be thoroughly cleaned before disinfection or sterilization.*²⁴
- 10.2** *Factors that affect the ability to effectively clean medical equipment/devices must be considered prior to cleaning.*
- See Section 8.1 for a list of factors that must be considered prior to cleaning medical equipment/devices.
- 10.3** *The process for cleaning should include written protocols for disassembly, sorting and soaking, physical removal of organic material, rinsing, drying, physical inspection and wrapping.*

²⁴ Health Canada. Hand washing, cleaning, disinfection and sterilization in health care. *Can Commun Dis Rep.* 1998; 24 Suppl 8: i-xi, 1-55.

Full PPE must be worn for handling and cleaning contaminated equipment/devices (see Section 7.3). The process used for cleaning should include the following steps:

- a) **Disassembly**
 - i) Unless otherwise recommended by the manufacturer, equipment/devices must be disassembled prior to cleaning.
 - ii) The manufacturer's recommendations shall be followed when disassembling medical equipment/devices prior to washing.
- b) **Sorting and soaking**
 - i) Sort equipment/devices into groups of like products requiring the same processes.
 - ii) Segregate sharps and/or delicate equipment/devices to prevent injury to personnel and damage to the equipment/device.
 - iii) Soak equipment/device in a hospital approved instrument soaking solution to prevent drying of soil, making cleaning easier.
 - iv) Saline should not be used as a soaking solution as it damages some medical equipment/devices.
 - v) Detergent-based products, including those containing enzymes, may be used as part of the soaking process.
 - vi) Ensure that detergents (including enzymatic detergents) are appropriate to the equipment/device being cleaned.
- c) **Physical removal of organic material**
 - i) Completely submerge immersible items during the cleaning process to minimize aerosolization of microorganisms and assist in cleaning.
 - ii) Remove gross soil using tools such as brushes and cloths.
 - iii) Employ manual or mechanical cleaning, such as a washer-disinfector or ultrasonic cleaning, after gross soil has been removed.
 - iv) **Washer-disinfectors** are strongly recommended for medical equipment/devices that can withstand mechanical cleaning, to achieve the required exposure for cleaning and to reduce potential risk to personnel. Washer-disinfectors must meet the requirements of the CSA.²⁵ Manufacturer's instructions must be followed for the use and regular maintenance, cleaning and calibration of the washer-disinfector. Washer-disinfectors may be used for low level disinfection. **Washer-disinfectors are not to be used for high level disinfection.**²⁶
 - v) **Ultrasonic washers** are strongly recommended for any semi-critical or critical medical equipment/device that has joints, crevices, lumens or other areas that are difficult to clean. Manufacturer's instructions must be followed for use of the ultrasonic cleaner. The ultrasonic washing solution should be changed at least daily or more frequently if it becomes visibly soiled.
 - vi) If manual cleaning is performed, physical removal of soil must occur under the water level to minimize splashing.
 - vii) Tools used to assist in cleaning, such as brushes, must be cleaned and disinfected after use.
- d) **Rinsing**

Rinsing following cleaning is necessary as residual detergent may neutralize the disinfectant.

 - i) Rinse all equipment/devices thoroughly after cleaning with water to remove residues which might react with the disinfectant/sterilant.
 - ii) Perform the final rinse for equipment/devices containing lumens with commercially prepared sterile water (note: distilled water is not necessarily sterile).
- e) **Drying**

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 equipment/device.
 - ii) Equipment/devices may be air-dried or dried by hand with a clean, lint-free towel.

²⁵ Canadian Standards Association. *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada*. Toronto, Ont.: Canadian Standards Association; 2000 (R2005).

²⁶ Canadian Standards Association. Mechanical washers. In: *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada*. Toronto, Ont.: Canadian Standards Association; 2000 (R2005), Appendix E.

- iii) Dry stainless steel equipment/devices immediately after rinsing to prevent spotting.
- f) **Inspection**
 - i) Visually inspect all equipment/devices once the cleaning process has been completed and prior to terminal disinfection/sterilization to ensure cleanliness and integrity of the equipment/device (e.g. cracks, defects, adhesive failures).
 - ii) Repeat the cleaning on any item that is not clean.
 - iii) Follow the manufacturer's guidelines for lubrication.
 - iv) Do not reassemble equipment/device prior to disinfection/sterilization.
- g) **Wrapping**
 - i) Equipment/devices that are to be sterilized require wrapping prior to sterilization (except for flash sterilization: see Section 13.8).
 - ii) Materials used for wrapping shall be prepared in a manner that will allow adequate air removal, steam penetration and evacuation.²⁷
- h) **Practice audits**
 - i) Cleaning processes must be audited on a regular basis.
 - ii) A quality improvement process must be in place to deal with any irregularities/concerns resulting from the audit.

11. Disinfection of Reusable Medical Equipment/Devices

“Failure to use disinfection products or processes appropriately has repeatedly been associated with the transmission of healthcare associated infections.”²⁸

Disinfection is the inactivation of disease-producing microorganisms. Disinfection does not destroy bacterial spores or prions. Disinfection of medical equipment/devices falls into two major categories – low level disinfection and high level disinfection.

Methods of Disinfection

There are two major methods of disinfection used in health care settings – liquid chemicals and pasteurization.

Liquid Chemical Disinfection

Low Level Disinfection (LLD)

Low level disinfection eliminates vegetative (“live”) bacteria, some fungi and enveloped viruses. LLD is used for noncritical medical equipment/devices and some environmental surfaces. Low level disinfectants include 3% hydrogen peroxide, 0.5% accelerated hydrogen peroxide, some quaternary ammonium compounds (QUATS), phenolics and diluted sodium hypochlorite (e.g. bleach) solutions. LLD is performed after the equipment/device is thoroughly cleaned and rinsed. The container used for disinfection must be washed, rinsed and dried when the solution is changed. Refer to Appendix A for chemical products that may be used to achieve low level disinfection.

High Level Disinfection (HLD)

High level disinfection eliminates vegetative bacteria, enveloped viruses, fungi, mycobacteria (e.g. Tuberculosis) and non-enveloped viruses. HLD is used for semicritical medical equipment/devices. High level disinfectants include 2% glutaraldehyde, 6% hydrogen peroxide, 0.2% peracetic acid, 7% accelerated hydrogen peroxide and 0.55% ortho-phthalaldehyde (OPA). Pasteurization also achieves high level disinfection. HLD is performed after the equipment/device is thoroughly cleaned and rinsed. Refer to Appendix A and Appendix F for chemical products that may be used to achieve high level disinfection.

²⁷ Canadian Standards Association. CAN/CSA Z314.3-01. *Effective Sterilization in Health Care Facilities by the Steam Process*. Toronto, Ont.: Canadian Standards Association; 2001.

²⁸ Health Canada. Hand washing, cleaning, disinfection and sterilization in health care. *Can Commun Dis Rep*. 1998; 24 Suppl 8: i-xi, 1-55.

- 11.1 Noncritical medical equipment/devices are to be decontaminated using a Low Level Disinfectant.**
- 11.2 Semicritical medical equipment/devices must be decontaminated using, at a minimum, High Level Disinfection. Sterilization is the preferred method of decontamination.**
- 11.3 Noncritical and semicritical medical equipment/devices that are owned by the client and reused by a single client in their home do not require disinfection between uses provided that they are adequately cleaned prior to reuse.**

See Section 10, "Disassembling and Cleaning Reusable Medical Equipment/Devices" for cleaning requirements.

- 11.4 All disinfectants must have a Drug Identification Number (DIN) from Health Canada.²⁹**
- 11.5 The chemical disinfectant used for disinfecting medical equipment/devices must be compatible with both the equipment/device manufacturer's instructions for disinfection and the cleaning products involved in the reprocessing of the equipment/device.**

The following items should be considered when selecting a disinfectant for use in the health care setting:

- a) Compatibility with equipment/device and surfaces to be disinfected;
- b) Compatibility with detergents, cleaning agents, and disinfection and/or sterilization processes;
- c) The intended end use of the equipment/devices to be disinfected;
- d) Personal and environmental safety.

- 11.6 Disinfectant manufacturers must supply recommended usage for the disinfectant to ensure that it is compatible with the medical equipment/devices on which it will be used.**

- a) Manufacturer's recommendations for chemical disinfectants must be followed pertaining to:
 - i) Use
 - ii) Contact time (NOTE: Where the manufacturer recommends a shorter contact time with a particular product than is required to achieve the desired level of disinfection/sterilization, an infection prevention and control specialist must be consulted for advice)
 - iii) Shelf life
 - iv) Storage
 - v) Appropriate dilution
 - vi) Required PPE
- b) If a disinfectant manufacturer is unable to provide compatibility information specific to a piece of medical equipment/device, information may be obtained from Health Canada's drug information website:
[\[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/dpd_index_e.html\]](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/dpd_index_e.html).

- 11.7 The process of high level disinfection requires monitoring and auditing. If a chemical product is used, the concentration of the active ingredient(s) must be verified and a logbook of daily concentration test results is to be maintained.**

- a) Chemical test strips should be used to determine whether an effective concentration of active ingredients is present despite repeated use and dilution.
- b) The frequency of testing should be based on how frequently the solutions are used (i.e. test daily if used daily).
- c) Chemical test strips must be checked each time a new package/bottle is opened to verify they are accurate, using positive (e.g. full strength disinfectant solution) and negative (e.g. tap water) controls. See manufacturer's recommendations for appropriate controls.
- d) Test strips must not be considered a way of extending the use of a disinfectant solution beyond the expiration date.

²⁹ Health Canada. Hand washing, cleaning, disinfection and sterilization in health care. *Can Commun Dis Rep.* 1998; 24 Suppl 8: i-xi, 1-55

- e) A permanent record of processing shall be completed and retained according to the policy of the facility.³⁰ This record shall include, but not be limited to, the identification of the equipment/device to be disinfected; date and time of the clinical procedure; concentration and contact time of the disinfectant used in each process; results of each inspection (and, for endoscopes, each leak test); result of each testing of the disinfectant; and the name of the person completing the reprocessing.
- f) Disinfection practices shall be audited on a regular basis and a quality improvement process must be in place to deal with any irregularities/concerns resulting from the audit.
- g) If manual disinfection is performed, the container used for disinfection must be kept covered during use, and washed, rinsed and dried when the solution is changed.
- h) Rinsing of medical equipment/devices following chemical disinfection requires three separate rinses, using sterile water, and the rinse solutions must be changed after each process.

Pasteurization

Pasteurization is a process of hot water disinfection (75°C for 30 minutes) which is accomplished through the use of automated pasteurizers or washer disinfectors. Semicritical medical equipment/devices suitable for pasteurization include equipment for respiratory therapy and anaesthesia. Equipment/devices require thorough cleaning and rinsing prior to pasteurization.

Advantages of pasteurization include:

- No toxicity
- Rapid disinfection cycle
- Moderate cost of machinery and upkeep

Disadvantages of pasteurization include:

- It may cause splash burns
- There is difficulty validating the effectiveness of the process
- Pasteurizers and related equipment can become contaminated without a good preventive maintenance program and careful monitoring of processes

11.8 *Manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated.*

The process must be monitored with mechanical temperature gauges and timing mechanisms for each load, with a paper printout record. Pasteurizing equipment must have, or be retrofitted for, mechanical paper printout. In addition:

- a) Water temperature within the pasteurizer should be verified weekly by manually measuring the cycle water temperature;
- b) Cycle time should be verified manually and recorded daily;
- c) Calibration of pasteurization equipment will be performed according to the manufacturer's recommendations;
- d) Daily cleaning of pasteurizing equipment is required following the manufacturer's recommendations;
- e) Following pasteurization, medical equipment/devices should be inspected for wear, cracks or soil. Damaged equipment/devices should be handled according to facility procedures. Soiled equipment/devices should be reprocessed;
- f) Following pasteurization, medical equipment/devices shall be handled so as to prevent contamination. Equipment/devices shall be transported directly from the pasteurizer to a clean area for drying, assembly and packaging.

11.9 *A preventive maintenance program for pasteurizing equipment must be implemented and documented.*

³⁰ Canadian Standards Association. *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada*. Toronto, Ont.: Canadian Standards Association; 2000. (R2005).

- 11.10 Following the pasteurizing cycle, medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a HEPA filter and that is used exclusively for the drying of pasteurized equipment/devices.³¹**

A preventive maintenance program for drying cabinets must be implemented and documented.

- 11.11 A logbook of contents, temperature and time is to be maintained for pasteurizing equipment.**

If the pasteurizer produces printed records of the parameters of each cycle, these records shall be retained in accordance with the facility's requirements.

12. Reprocessing Endoscopy Equipment/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 lumen. Examples of critical endoscopes are arthroscopes, laparoscopes and cystoscopes.

Semicritical Endoscope: Fiberoptic or video endoscopes used in the examination of the hollow viscera. These endoscopes generally invade only semicritical spaces, although some of their components might enter tissues or other critical spaces. Examples of semicritical endoscopes are laryngoscopes, nasopharyngeal endoscopes, transesophageal probes, colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes and enteroscopes. Opinions differ regarding the reprocessing requirements for bronchoscopes; a minimum of high level disinfection is required.

Due to the complexity of their design, flexible fibreoptic and video endoscopes ("semicritical endoscopes") require special cleaning and handling.^{31,32}

- 12.1 Individuals responsible for reprocessing endoscopes shall be specially trained and shall meet the facility's written endoscope processing competency requirements, including ongoing education and training.³¹**
- Staff assigned to reprocess endoscopes must receive device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilization.
 - Competency testing of personnel reprocessing endoscopes must be performed on a regular basis.³²
 - Temporary personnel must not be allowed to reprocess endoscopes until competency has been established.³²
- 12.2 Each health care setting in which endoscopic procedures are performed shall have written detailed procedures for the cleaning and handling of endoscopes.³¹**
- 12.3 Ventilation shall be such as to remove toxic vapours³¹ generated by, or emitted from, cleaning or disinfecting agents.**
- The vapour concentration of the chemical disinfectant used shall not exceed allowable limits³² (e.g. 0.05 ppm for glutaraldehyde).
 - Air-exchange equipment (e.g. ventilation system, exhaust hoods) should be used to minimize the exposure of all persons to potentially toxic vapours.³²
 - In-use disinfectant solutions must be maintained in closed, covered, labeled containers at all times.
 - Air quality should be monitored on a scheduled basis to ensure control of vapours.

³¹ Canadian Standards Association. CAN/CSA Z314.8-00. *Decontamination of Reusable Medical Devices: A National Standard of Canada*. Toronto, Ont.: Canadian Standards Association; 2000. (R2005).

³² American Society for Gastrointestinal Endoscopy. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointest Endosc*. 2003;58: 1-8.

12.4 Endoscopic cleaning shall commence immediately following completion of the clinical procedure.³³

Soil residue in endoscope lumens dries rapidly, becoming very difficult to remove. Initial cleaning includes:

- a) The manufacturer's recommendations for cleaning and cleaning products shall be followed;
- b) Soaking and manual cleaning of all immersible endoscope components with water and a recommended cleaning agent shall precede automated or further manual disinfection or sterilization;
- c) Endoscope components (e.g. air/water and suction valves) must be disconnected and disassembled as far as possible and the endoscope and components must be completely immersed in enzymatic detergent;³⁴
- d) All channels and lumens of the endoscope shall be flushed and brushed while submerged to remove debris while minimizing aerosols;
- e) Brushes used for cleaning lumens shall be of an appropriate size, inspected before and after use, and discarded or cleaned, high-level disinfected and dried following use;
- f) Irrigation adaptors or manifolds shall be utilized to facilitate cleaning;
- g) Damaged endoscopes shall be identified and immediately removed from service.
- h) Enzymatic detergent shall be discarded after each use;
- i) Cleaning items shall be disposable or thoroughly cleaned and disinfected/sterilized between uses.³³

12.5 Patency and integrity of the endoscope sheath should be verified through leak testing, performed after each use.^{33,34}

- a) The leak test is performed prior to, and during, immersion of the endoscope.
- b) An endoscope that fails the dry leak test should not undergo the immersion leak test.

12.6 Endoscopic equipment/devices shall be rinsed and dried prior to disinfection or sterilization.³³

- a) Sterile water is recommended for rinsing and flushing.

12.7 Semicritical endoscopes and accessories (excluding biopsy forceps and brushes) must receive at least high-level disinfection after each use.³⁴

- a) Choose a disinfectant that is compatible with the endoscope.³⁴
- b) Completely immerse the endoscope and endoscope components in the high-level disinfectant/sterilant and ensure all channels are perfused.³⁴
- c) Maintain a written log of monitoring test results.
- d) Monitoring of the disinfectant must be carried out before each use with test strips available from the product manufacturer.
- e) Disinfectants must not be used past the expiry date.
- f) Manufacturer's directions must be carefully followed regarding the ambient temperature and duration of contact for disinfectant (e.g. 2% glutaraldehyde = 20 minutes at 20°C).
- g) Following disinfection, rinse the endoscope and flush the channels with water (preferably sterile water).

12.8 Endoscopic accessories (e.g. biopsy forceps and brushes) that break the mucosal barrier must be sterilized after each use.³⁴

- a) Because of the difficulty cleaning biopsy forceps/brushes, **it is strongly recommended that disposable items be used.**
- b) If biopsy forceps/brushes are not disposable, they must be meticulously cleaned prior to sterilization using ultrasonic cleaning.

³³ Canadian Standards Association. *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada*. Toronto, Ont.: Canadian Standards Association; 2000. (R2005).

³⁴ American Society for Gastrointestinal Endoscopy. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointest Endosc*. 2003;58: 1-8.

- 12.9** *If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components are compatible with the AER.*³⁵
- a) Follow the manufacturer's instructions for use of the AER.
 - b) Ensure that the endoscope to be reprocessed is compatible with the AER used.
 - c) Ensure that channel connectors and caps for both the AER and the endoscope are compatible.
 - d) If an AER cycle is interrupted, high level disinfection cannot be assured.
 - e) Brushes and instruments used to clean the equipment/device may be placed in the AER for disinfection.
 - f) Infection prevention and control and reprocessing staff should routinely review Health Canada/OHA alerts and advisories and the scientific literature for reports of AER deficiencies that may lead to infection.³⁵
- 12.10** *Final drying of semicritical endoscopes shall be facilitated by flushing all channels with 70% isopropyl alcohol, followed by forced air purging of the channels.*^{35,36}
- 12.11** *Semicritical 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 floor or bottom of the cabinet while hanging, or stored in their cases.*³⁶
- a) Caps, valves and other detachable components should be removed during storage and reassembled before use.³⁵
 - b) Endoscopic storage cabinets shall be cleaned and disinfected at least weekly³⁶ and should be made of non-porous material that can be cleaned.
 - c) Colonoscopes have a maximum shelf life of 7 days, if stored dry.³⁷ There are no recommendations regarding shelf life of other types of endoscopes.
- 12.12** *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.*³⁵
- a) Sterile water should be used to fill the water bottle.
- 12.13** *A preventive maintenance program for automated endoscope reprocessor (AER) must be implemented and documented.*
- 12.14** *Healthcare settings shall have policies in place providing a permanent record of endoscope use and reprocessing, as well as a system to track endoscopes and patients that includes recording the endoscope number in the patient record.*^{35,36}
- 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 both the endoscope and the AER (if used) to assist in outbreak investigation.^{35,36}
 - b) Retain records according to the policy of the facility.³⁶

13. Sterilization of Reusable Medical Equipment/Devices

Sterilization is the elimination of all disease-producing microorganisms, including spores (e.g. *Clostridium* and *Bacillus* species). Prions are not susceptible to routine sterilization. Sterilization is used on critical medical equipment/devices and, whenever possible, semicritical medical equipment/devices. **The preferred method for heat-resistant equipment/devices is steam sterilization (pre-vacuum sterilizers are preferred).** For equipment/devices that cannot withstand

³⁵ American Society for Gastrointestinal Endoscopy. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointest Endosc.* 2003;58: 1-8.

³⁶ Canadian Standards Association. *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada.* Toronto, Ont.: Canadian Standards Association; 2000, (R2005).

³⁷ Riley R, Beanland C, Bos H. Establishing the shelf life of flexible colonoscopes. *Gastroenterol Nurs.* 2002; 25:114-9.

heat sterilization, some examples of sterilants include 6% hydrogen peroxide, 2% glutaraldehyde (> 10 hours), hydrogen peroxide gas plasma, 0.2% peracetic acid, 7% accelerated hydrogen peroxide and 100% ethylene oxide. Refer to Appendix A and Appendix F for chemical products that may be used to achieve sterilization.

13.1 Critical medical equipment/devices must be sterilized.³⁸

13.2 Whenever possible, semicritical medical equipment/devices should be sterilized.

13.3 All sterilization processes must ensure that they follow the manufacturer's instructions for installation, operation and preventive maintenance of the equipment.

- a) Manufacturers of sterilizers must be contacted for specific instructions on installation and use of their equipment.
- b) Storage and transportation practices must maintain sterility to the point of use.
- c) Manufacturers of sterilizers must be specific as to which medical equipment/devices can be sterilized in their machines and manufacturers of medical equipment/devices must be specific as to the recommended sterilization methods.

13.4 The sterilization process must be validated and documented with written policies and procedures.

- a) Policies and procedures must be established to ensure that the sterilization processes follow the principles of infection prevention and control as set out in Health Canada guidelines³⁸, CSA standards^{39,40} and these MOHLTC best practices.
- b) All sterilization processes must be thoroughly evaluated before being put into service, and at regular intervals thereafter.

13.5 The sterilization process requires testing, monitoring and auditing.

For all sterilizers:

- a) All three of the following parameters must be completed to ensure that effective sterilization has been achieved:
 - i) **Mechanical monitoring** (e.g. time, temperature, pressure graphs);
 - ii) **Chemical monitoring** – each pack must have external chemical indicators. In addition, it is recommended that both internal and external visible chemical indicators be used to detect penetration into the pack. The CSA recommends that “an internal chemical indicator shall be placed inside all packages. This indicator shall be placed in the area of the package least accessible to steam”⁴⁰ or to the sterilizing agent,⁴¹ in order to verify that the sterilant has penetrated the package;
 - iii) **Biologic monitoring** (e.g. spore-laden strips or vials) – include a biologic monitor each day a sterilizer is used. A biologic monitor must be used with each load if implantable equipment/devices are being sterilized.³⁸ Refer to Appendix F for sterilizer-specific criteria. The recommended test microorganisms are:
 - *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*) spores for sterilizers that use steam, hydrogen peroxide gas plasma or peracetic acid, as well as flash sterilizers;
 - *Bacillus atrophaeus* (formerly *Bacillus subtilis*) spores for sterilizers that use dry heat or ethylene oxide;
- b) Staff performing the process must document the daily operation of the sterilizer. This documentation should be reviewed for each operation, and any malfunction should be noted and appropriate action taken to ensure that the product either has been properly treated or is returned for reprocessing.

³⁸ Health Canada. Hand washing, cleaning, disinfection and sterilization in health care. *Can Commun Dis Rep.* 1998; 24 Suppl 8: i-xi, 1-55.

³⁹ Canadian Standards Association. *CAN/CSA Z314.8-00. Decontamination of Reusable Medical Devices: A National Standard of Canada.* Toronto, Ont.: Canadian Standards Association; 2000, (R2005).

⁴⁰ Canadian Standards Association. *CAN/CSA-Z314.3-01. Effective Sterilization in Hospitals by the Steam Process.* Toronto, Ont.: Canadian Standards Association; 2001.

⁴¹ Canadian Standards Association. *CAN/CSA Z15882-04. Sterilization of Health Care Products – Chemical Indicators – Guidance for Selection, Use and Interpretation of Results.* Toronto, Ont.: Canadian Standards Association; 2004.

Additional sterilizer-specific criteria:

- c) Autoclaves must be installed according to the manufacturer's instructions. Tabletop steam sterilizers are recommended for office settings.⁴²
- d) Filter systems should be tested for leakage.
- e) Gas sterilization units should be appropriately validated for such factors as gas concentration, temperature, and relative humidity.
- f) For sterilizers of the dynamic air removal type, three consecutive tests shall also be conducted with the air detection test pack (Bowie-Dick) yielding uniform colour change.
- g) Ethylene oxide is a designated substance under the Occupational Health & Safety Act⁴³:
 - i) Facilities that use 10 kg. or more per year of ethylene oxide for sterilization must comply with guidelines from Environment Canada⁴⁴, specifically:
 - Emissions of ethylene oxide must be reduced by 99% during the sterilization cycle by installing an emission control system;
 - Emissions of ethylene oxide must be reduced by 95% during aeration;
 - Eliminate liquid discharge to avoid releases of ethylene oxide to the local sewer system;
 - Test emissions of ethylene oxide annually;
 - Report annually to Environment Canada.
 - ii) At the conclusion of a sterilization cycle and before the load is removed, the operator shall check the recording chart printout to ensure that required parameters have been met. If the chart or printout indicates a failure of any parameter, the operator shall follow the health care setting's applicable policies and procedures.⁴⁵
 - iii) Medical equipment/devices sterilized with ethylene oxide shall be thoroughly aerated prior to handling or use, according to the equipment/device manufacturer's recommendations. Reprocessing staff shall not interrupt the aeration cycle to retrieve items for use.⁴⁵
- h) Dry heat sterilization must be rigidly monitored with each cycle due to differences in penetration with different items.

13.6 Infection Prevention and Control input must be obtained prior to the purchase of a new sterilizer (e.g. facility's infection prevention and control professionals, Public Health staff with certification in infection prevention and control, regional infection control network).

13.7 Sterilizers must be subjected to rigorous testing and monitoring on installation and following disruptions to their normal activity.

- a) Following installation of a new sterilizer, the sterilizer must pass at least three consecutive cycles with the appropriate challenges (i.e. biological, chemical) placed in an empty sterilizer, as well as at least one cycle challenged with a full test load, before the sterilizer can be put into routine service.
- b) The sterilizer shall not be approved for use if the biologic monitor yields a positive result on any of the tests.⁴⁶
- c) Sterilizers must be monitored with a test load in the following circumstances:
 - i) After major repairs to an existing sterilizer;
 - ii) When there has been construction or relocation in the area;
 - iii) After unexplained sterility failures;
 - iv) After changes in steam supply or delivery.

⁴² The College of Physicians and Surgeons of Ontario. *Infection Control in the Physician's Office*, 2004 ed. Toronto, Ont.: CPSO; 2004.

⁴³ *Occupational Health and Safety Act*, R.S.O. 1990, c.O.1; *Designate Substance –Ethylene Oxide*, R.R.O. 1990, Reg. 840, Amended to O. Reg. 107/04. Available online at: http://www.e-laws.gov.on.ca/DBLaws/Regs/English/900841_e.htm Accessed October 23, 2005.

⁴⁴ Environment Canada. *Guidelines for the Reduction of Ethylene Oxide Releases from Sterilization Applications*. October 1, 2005. Available online at: http://www.chica.org/pdf/EOguidelines_eng.pdf. Accessed November 15, 2005.

⁴⁵ Canadian Standards Association. *CAN/CSA Z314.2-01. Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process*. Toronto, Ont.: Canadian Standards Association; 2001.

⁴⁶ Canadian Standards Association. *CAN/CSA-Z314.3-01. Effective Sterilization in Hospitals by the Steam Process*. Toronto, Ont.: Canadian Standards Association; 2001.

Methods of Disinfection/Sterilization Not Recommended for Routine Use**Flash Sterilization****13.8 Flash sterilization shall only be used in emergency situations and must never be used for implantable equipment/devices.⁴⁷**

- a) Operative scheduling and lack of instrumentation do not qualify as reasons to use flash sterilization. Sterilization is a process, not an event. Effective sterilization is impaired if all the necessary parameters of the process are not met. These include, but are not limited to, the following:
 - i) Decontamination and sterilization areas must meet the requirements for processing space as noted in [Appendix B](#);
 - ii) A record for each piece of equipment/device being subjected to flash sterilization that includes the name of the patient, procedure, physician/practitioner and equipment/device used. The patient record should also reflect this information;
 - iii) A biological monitor must be included daily with each type of cycle and every load configuration (i.e. open tray, rigid flash container, single wrapper) that will be used that day;⁴⁸
 - iv) The load printout must be signed to verify that the required time, temperature and pressure have been achieved;
 - v) Records must be retained according to the facility's policy;
 - vi) There must be a procedure for notification of the patient in the event of a recall (e.g. positive biological indicator). Records should be reviewed on a regular basis to correct issues relating to overuse of flash sterilization.

Boiling**13.9 Boiling is not an acceptable method of sterilization.⁴⁷**

The use of boiling water to clean instruments and utensils is not an effective means of sterilization. Boiling water is inadequate for the destruction of bacterial spores and some viruses. In the home care environment, boiling may be used for high level disinfection for equipment/devices reused on the same client, following adequate cleaning.

Ultraviolet Radiation**13.10 The use of ultraviolet light is not an acceptable method of disinfection/sterilization.⁴⁷**

The germicidal effectiveness of ultraviolet (UV) radiation is influenced by organic matter, wavelength, type of suspension, temperature, type of microorganism and UV intensity, which is affected by distance and dirty tubes. The application of UV light in the hospital is limited to the destruction of airborne organisms (e.g. ventilation ducts) or inactivation of microorganisms located on surfaces (e.g. laboratory hoods).

Glass Bead Sterilization**13.11 Glass bead sterilization is not an acceptable method of sterilization.⁴⁷**

Glass bead sterilizers are difficult to monitor for effectiveness, have inconsistent heating resulting in cold spots, and often have trapped air which affects the sterilization process.

⁴⁷ Health Canada. Hand washing, cleaning, disinfection and sterilization in health care. *Can Commun Dis Rep*. 1998; 24 Suppl 8: i-xi, 1-55.

⁴⁸ Canadian Standards Association. *CAN/CSA-Z314.13-01. Recommended Standard Practices for Emergency (Flash) Sterilization*. Toronto, Ont.: Canadian Standards Association; 2001.

The U.S. Food and Drug Administration has determined that a risk of infection exists with this equipment because of their potential failure to sterilize dental instruments and has required their commercial distribution cease unless the manufacturer files a pre-market approval application.⁴⁹

Chemiclave

13.12 The use of a chemiclave for sterilization poses an environmental risk and must be closely monitored.⁵⁰

Unsaturated chemical-vapour sterilization ("chemiclave") involves heating a chemical solution of primarily alcohol with 0.23% formaldehyde in a closed pressurized chamber. Because of the environmental risks associated with formaldehyde, this method of sterilization is discouraged. Local regulations for hazardous waste disposal must be followed and air sampling for toxic vapours may be indicated.

Microwave Oven Sterilization

13.13 The use of microwave ovens for sterilization is not acceptable.⁵¹

Microwave ovens are unreliable and difficult to monitor for effective sterilization. Home microwaves are unable to achieve sterilization.

14. Storage and Use of Reprocessed Medical Equipment/Devices

14.1 Sterility must be maintained until point of use.⁵¹

The shelf life of a sterile package is event related rather than time related. Event related shelf life is based on the concept that items that have been properly decontaminated, wrapped, sterilized, stored and handled will remain sterile indefinitely, unless the integrity of the package is compromised (i.e. open, wet, dirty).

- a) Medical equipment/devices purchased as sterile must be used before the expiration date if one is given.
- b) Sterile packages that lose their integrity must be re-sterilized prior to use.

14.2 Reprocessed medical equipment/devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage.

- a) Equipment/devices must be handled in a manner that prevents recontamination of the item.
- b) Containers used for storage of clean equipment/devices should be moisture-resistant and cleanable (i.e. cardboard boxes must not be used).
- c) Store equipment/device in a clean, dry, dust-free area (closed shelves), not at floor level, and at least one meter away from debris, drains, moisture and vermin to prevent contamination.
- d) Store equipment/device in an area where it is not subject to tampering by unauthorized persons.
- e) Transport processed equipment/device in a manner that avoids contamination or damage to the equipment/device.

⁴⁹ US Department of Health and Human Services, Food and Drug Administration. 21 CFR Part 872.6730. *Dental devices; endodontic dry heat sterilizer; final rule*. Federal Register 1997;62:2903.

⁵⁰ Kohn WG, Collins AS, Cleveland JL, Harte JA, Eklund KJ, Malvitz DM; Centers for Disease Control and Prevention (CDC). Guidelines for infection control in dental health-care settings – 2003. *MMWR Recomm Rep*. 2003; 52 (RR-17): 1-67.

⁵¹ Health Canada. Hand washing, cleaning, disinfection and sterilization in health care. *Can Commun Dis Rep*. 1998; 24 Suppl 8: i-xi, 1-55.

14.3 At point of use, upon opening the reprocessed medical equipment/device, check for integrity of the packaging and the equipment/device; validate results of chemical monitors if present; and reassemble equipment/device if required.

- a) Provide education to those opening sterile items at point of use. Education should include inspection, interpretation of monitors and reassembly of equipment/devices.
- b) Validate results of chemical tape and internal monitors if present.
- c) Visually inspect the equipment/device for discolouration or soil. If present, remove from service and reprocess.
- d) Check for defective equipment/devices and remove from use.
- e) If sterile package has become damp or wet (e.g. high humidity), reprocessing may be required. Refer to Appendix B, section 7: “*Temperature and Humidity*”.
- f) Reassemble equipment/device if required.

Summary of Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings

(See complete text for rationale)

1. Single-Use Medical Equipment/Devices

- 1.1 *Critical and semi-critical medical equipment/devices labeled as single-use must not be reprocessed and reused unless the reprocessing is done by a licensed reprocessor.*
- 1.2 *Needles must be single-use and must not be reprocessed.*
- 1.3 *It is strongly recommended that catheters, drains and other medical equipment/devices with small lumens (excluding endoscopy equipment) be designated single-use and not be reprocessed and reused.*
- 1.4 *Home health care agencies may consider reusing single-use semicritical medical equipment/devices for a single client in their home when reuse is safe and the cost of discarding the equipment/device is prohibitive for the client.*
- 1.5 *The health care setting must have written policies regarding single-use medical equipment/devices.*

2. Purchasing and Assessing Medical Equipment/Devices and/or Products to be Subjected to Disinfection or Sterilization Processes

- 2.1 *Do not purchase medical equipment/devices that cannot be cleaned and reprocessed according to the recommended standards.*
- 2.2 *When purchasing reprocessing equipment or chemical products for reprocessing, consideration must be given to Occupational Health requirements, patient safety, and environmental safety issues.*
- 2.3 *All medical equipment/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 equipment/devices, trial or research equipment/devices, physician/practitioner-owned, etc.) must meet established quality reprocessing parameters.*
- 2.4 *Newly purchased non-sterile critical and semicritical medical equipment/devices must first be inspected and reprocessed according to their intended use.*
- 2.5 *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 equipment/devices, including endoscopes.*
- 2.6 *Because of the risks associated with Creutzfeldt-Jakob disease (CJD), surgical instruments that are used on high risk neurological and eye tissue from patients at high risk for CJD must be subjected to rigorous decontamination processes as detailed in the Health Canada/Public Health Agency of Canada infection control guideline, "Classic Creutzfeldt-Jakob Disease in Canada".*

3. Education and Training

- 3.1 *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 equipment/devices.*
- 3.2 *All aspects of reprocessing shall be supervised and shall be performed by knowledgeable, trained personnel.*

- 3.3** *The program director and all supervisors involved in reprocessing must, as a minimum, have completed a recognized qualification/certification course in reprocessing practices. A plan must be in place for each person involved in reprocessing to obtain this qualification within five years.*

4. Written Policies and Procedures

- 4.1** *The health care setting will, as a minimum, have policies and procedures for all aspects of reprocessing that are based on current recognized standards/recommendations and that are reviewed at least annually.*
- 4.2** *Manufacturer's information for all medical equipment/devices must be received and maintained in a format that allows for easy access by personnel carrying out the reprocessing activities.*
- 4.3** *All policies and procedures for reprocessing medical equipment/devices require review by an individual with infection prevention and control expertise (e.g. facility's infection prevention and control professionals, Public Health staff with certification in infection prevention and control, regional infection control network).*
- 4.4** *There must be a procedure established for the recall of improperly reprocessed medical equipment/devices.*
- 4.5** *The recall procedure should include assessment of patient risk and a procedure for subsequent notification of clients/patients/residents, other facilities and/or regulatory bodies if indicated.*

5. Selection of Product/Process for Reprocessing

- 5.1** *Products used for any/all stages in reprocessing (i.e. cleaning, disinfection, sterilization) must 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 (e.g. facility's infection prevention and control professionals, Public Health staff with certification in infection prevention and control, regional infection control network).*
- 5.2** *The reprocessing method and products required for medical equipment/devices will depend on the intended use of the equipment/device and the potential risk of infection involved in the use of the equipment/device.*
- 5.3** *Products used for decontamination must be appropriate to the level of reprocessing that is required for the use of the medical equipment/device.*
- 5.4** *The process and products used for cleaning, disinfection and/or sterilization of medical equipment/devices must be compatible with the equipment/devices.*
- 5.5** *All medical equipment/devices that will be purchased and will be reprocessed must have written device-specific manufacturer's cleaning, decontamination, disinfection, wrapping and sterilization instruction. If disassembly or reassembly is required, detailed instructions with pictures must be included. Staff training must be provided on these processes before the medical equipment/device is placed into circulation.*

6. Environmental Issues

- 6.1** *There must be a centralized area for reprocessing medical equipment/devices. Reprocessing done outside the centralized area must be kept to a minimum and must be approved by the reprocessing committee or those accountable for safe reprocessing practices and must conform to the requirements for reprocessing space.*

- 6.2 *Wherever chemical disinfection/sterilization is performed, air quality must be monitored when using products that produce toxic vapours.*

7. Occupational Health and Safety Issues

- 7.1 *Occupational Health and Safety for the health care setting will review all protocols for reprocessing medical equipment/devices to verify that worker safety measures are followed and in compliance with the Occupational Health and Safety Act, R.S.O. 1990, c.0.1 and associated Regulations including the Health Care and Residential Facilities – O. Reg. 67/93 Amended to O. Reg 631/05.*
- 7.2 *There is a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics and handling contact lenses in the reprocessing area.*
- 7.3 *Appropriate PPE must be worn for all reprocessing activities.*
- 7.4 *All personnel working in reprocessing must be immune to Hepatitis B or receive Hepatitis B immunization.*
- 7.5 *Procedures shall be written to prevent and manage injuries from sharp objects. In addition, procedures shall be in place for immediate response to worker exposure to blood and body fluids.*

8. Factors Affecting the Efficacy of the Reprocessing Procedure

- 8.1 *Procedures for Disinfection and Sterilization must 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 must be readily accessible to staff performing the function.*

9. Transportation and Handling of Contaminated Medical Equipment/Devices

- 9.1 *Disposable sharps such as needles and blades shall be removed and disposed of in an appropriate puncture-resistant sharps container at point of use, prior to transportation.*
- 9.2 *If cleaning cannot be done immediately, the medical equipment/device must be submerged in tepid water and/or detergent and enzymatic to prevent organic matter from drying on it.*
- 9.3 *Soiled equipment/devices must 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.*
- 9.4 *A process should be in place that will ensure that medical equipment/devices which have been reprocessed can be differentiated from equipment/devices which have not been reprocessed (e.g. colour coding).*

10. Disassembling and Cleaning Reusable Medical Equipment/Devices

- 10.1 *Reusable medical equipment/devices must be thoroughly cleaned before disinfection or sterilization.*
- 10.2 *Factors that affect the ability to effectively clean medical equipment/devices must be considered prior to cleaning.*
- 10.3 *The process for cleaning should include written protocols for disassembly, sorting and soaking, physical removal of organic material, rinsing, drying, physical inspection and wrapping.*

11. Disinfection of Reusable Medical Equipment/Devices

- 11.1 *Noncritical medical equipment/devices are to be decontaminated using a Low Level Disinfectant.***
- 11.2 *Semicritical medical equipment/devices must be decontaminated using, at a minimum, High Level Disinfection. Sterilization is the preferred method of decontamination.***
- 11.3 *Noncritical and semicritical medical equipment/devices that are owned by the client and reused by a single client in their home do not require disinfection between uses provided that they are adequately cleaned prior to reuse.***
- 11.4 *All disinfectants must have a Drug Identification Number (DIN) from Health Canada.***
- 11.5 *The chemical disinfectant used for disinfecting medical equipment/devices must be compatible with both the equipment/device manufacturer's instructions for disinfection and the cleaning products involved in the reprocessing of the equipment/device.***
- 11.6 *Disinfectant manufacturers must supply recommended usage for the disinfectant to ensure that it is compatible with the medical equipment/devices on which it will be used.***
- 11.7 *The process of high level disinfection requires monitoring and auditing. If a chemical product is used, the concentration of the active ingredient(s) must be verified and a logbook of daily concentration test results is to be maintained.***
- 11.10 *Manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated.***
- 11.11 *A preventive maintenance program for pasteurizing equipment must be implemented and documented.***
- 11.12 *Following the pasteurizing cycle, medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a HEPA filter and that is used exclusively for the drying of pasteurized equipment/devices.***
- 11.13 *A logbook of contents, temperature and time is to be maintained for pasteurizing equipment.***

12. Reprocessing Endoscopy Equipment/Devices

- 12.1 *Individuals responsible for reprocessing endoscopes shall be specially trained and shall meet the facility's written endoscope processing competency requirements, including ongoing education and training.***
- 12.2 *Each health care setting in which endoscopic procedures are performed shall have written detailed procedures for the cleaning and handling of endoscopes.***
- 12.3 *Ventilation shall be such as to remove toxic vapours generated by, or emitted from, cleaning or disinfecting agents.***
- 12.4 *Endoscopic cleaning shall commence immediately following completion of the clinical procedure.***
- 12.5 *Patency and integrity of the endoscope sheath should be verified through leak testing, performed after each use.***
- 12.6 *Endoscopic equipment/devices shall be rinsed and dried prior to disinfection or sterilization.***
- 12.7 *Semicritical endoscopes and accessories (excluding biopsy forceps and brushes) must receive at least high-level disinfection after each use.***

- 12.8 *Endoscopic accessories (e.g. biopsy forceps and brushes) that break the mucosal barrier must be sterilized after each use.*
- 12.9 *If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components are compatible with the AER.*
- 12.10 *Final drying of semicritical endoscopes shall be facilitated by flushing all channels with 70% isopropyl alcohol, followed by forced air purging of the channels.*
- 12.11 *Semicritical endoscopes shall be stored hanging vertically in well-ventilated areas in a manner that minimizes contamination or damage. Endoscopes shall not be coiled, allowed to touch the floor or bottom of the cabinet while hanging, or stored in their cases.*
- 12.12 *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.*
- 12.13 *A preventive maintenance program for automated endoscope reprocessor (AER) must be implemented and documented.*
- 12.14 *Healthcare settings shall have policies in place providing a permanent record of endoscope use and processing, as well as a system to track endoscopes and patients that includes recording the endoscope number in the patient record.*

13. Sterilization of Reusable Medical Equipment/Devices

- 13.1 *Critical medical equipment/devices must be sterilized.*
- 13.2 *Whenever possible, semicritical medical equipment/devices should be sterilized.*
- 13.3 *All sterilization processes must ensure that they follow the manufacturer's instructions for installation, operation and preventive maintenance of the equipment.*
- 13.4 *The sterilization process must be validated and documented with written policies and procedures.*
- 13.5 *The sterilization process requires testing, monitoring and auditing.*
- 13.6 *Infection Prevention and Control input must be obtained prior to the purchase of a new sterilizer (e.g. facility's infection prevention and control professionals, Public Health staff with certification in infection prevention and control, regional infection control network).*
- 13.7 *Sterilizers must be subjected to rigorous testing and monitoring on installation and following disruptions to their normal activity.*
- 13.8 *Flash sterilization shall only be used in emergency situations and must never be used for implantable equipment/devices.*
- 13.9 *Boiling is not an acceptable method of sterilization.*
- 13.10 *The use of ultraviolet light is not an acceptable method of disinfection/sterilization.*
- 13.11 *Glass bead sterilization is not an acceptable method of sterilization.*
- 13.12 *The use of a chemiclave for sterilization poses an environmental risk and must be closely monitored.*
- 13.13 *The use of microwave ovens for sterilization is not acceptable.*

14. Storage and Use of Reprocessed Medical Equipment/Devices

14.1 *Sterility must be maintained until point of use.*

14.2 *Reprocessed medical equipment/devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage.*

14.3 *At point of use, upon opening the reprocessed medical equipment/device, check for integrity of the packaging and the equipment/device; validate results of chemical monitors if present; and reassemble equipment/device if required.*

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Appendix A – Reprocessing Decision Chart

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED			
Level of Processing/Reprocessing	Classification of Equipment/Device	Examples of Equipment/Devices	Products**
<p>Cleaning Physical removal of soil, dust or foreign material. Chemical, thermal or mechanical aids may be used. Cleaning usually involves soap and water, detergents or enzymatic cleaners. Thorough cleaning is required before disinfection or sterilization may take place.</p>	All reusable equipment/devices	<ul style="list-style-type: none"> • All reusable equipment/devices • Oxygen tanks and cylinders 	<p>** concentration and contact time are dependant on manufacturer's instructions</p> <ul style="list-style-type: none"> • Quarternary ammonium compounds (QUATs) • Enzymatic cleaners • Soap and water • Detergents • 0.5% Accelerated hydrogen peroxide
<p>Low level disinfection Level of disinfection required when processing noncritical equipment/devices or some 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>	Noncritical equipment/devices	<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 • Patient lift slings • ECG machines/leads/cups etc. • Sonography (ultrasound) equipment/probes that come into contact with intact skin only • Bladder scanners • Baby scales • Cardiopulmonary training mannequins • Environmental surfaces (e.g. IV poles, wheelchairs, beds, call bells) • Fingernail care equipment that is single-client/patient/resident use 	<p>** concentration and contact time are dependant on manufacturer's instructions</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) • Quarternary ammonium compounds (QUATs) • Iodophors • Phenolics ** (should not be used in nurseries)
<p>High level disinfection The level of disinfection required when processing semicritical equipment/devices. High level disinfection processes destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores.</p>	Semicritical equipment/devices	<ul style="list-style-type: none"> • Flexible endoscopes that do not enter sterile cavities or tissues • Laryngoscopes • Bronchosopes (sterilization is preferred) • Respiratory therapy equipment • Nebulizer cups • Anesthesia equipment • Endotrachial tubes • Specula (nasal, anal, vaginal – 	<p>** concentration and contact time are dependant on manufacturer's instructions</p> <ul style="list-style-type: none"> • 2% Glutaraldehyde (20 minutes at 20°C) • 6% Hydrogen peroxide (30 minutes) • 0.55% Ortho-phthalaldehyde (OPA) (10

<p align="center">MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED</p>			
<p align="center">Level of Processing/Reprocessing</p>	<p align="center">Classification of Equipment/Device</p>	<p align="center">Examples of Equipment/Devices</p>	<p align="center">Products**</p>
		<p>disposable equipment is strongly recommended)</p> <ul style="list-style-type: none"> • Tonometer foot plate • Ear syringe nozzles • Sonography (ultrasound) equipment/probes that come into contact with mucous membranes or non-intact skin (e.g. transrectal probes) • Pessary and diaphragm fitting rings • Cervical caps • Breast pump accessories • Glass thermometers • CPR face masks • Alligator forceps • Cryosurgery tips • Ear cleaning equipment, ear cures, otoscope tips • Fingernail care equipment used on multiple clients/patients/residents 	<p>minutes at 20°C)</p> <ul style="list-style-type: none"> • Pasteurization (30 minutes at 75°C) • 7% Accelerated hydrogen peroxide (20 minutes) • 0.2% Peracetic acid (30-45 minutes)
<p><u>Sterilization</u> The level of reprocessing required when processing critical equipment/devices. Sterilization results in the destruction of all forms of microbial life including bacteria, viruses, spores and fungi.</p>	<p>Critical equipment/devices</p>	<ul style="list-style-type: none"> • Surgical instruments • Foot care equipment • Implantable equipment/devices • Endoscopes that enter sterile cavities and spaces (e.g. arthroscopes, laparoscopes, cystoscopes) • Bronchosopes • Colposcopy equipment • Electrocautery tips • Endocervical cures • Fish hook cutters • Biopsy forceps, brushes and biopsy equipment associated with endoscopy (disposable equipment is strongly recommended) • Eye equipment including soft contact lenses • Transfer forceps • Kimura spatula • Dental equipment including high speed dental handpieces 	<p>** concentration and contact time are dependant on manufacturer's instructions</p> <ul style="list-style-type: none"> • Dry heat • 100% Ethylene oxide • Formaldehyde • 2.5-3.5% Glutaraldehyde (10 hours at 20°C) • Hydrogen peroxide gas plasma (75 minutes at 50°C) • 6-25% Hydrogen peroxide liquid (6 hours) • 7% Accelerated hydrogen peroxide (6 hours at 20°C) • 0.2% Peracetic acid (30-45 minutes) • Steam

**** concentration and contact time are dependant on manufacturer's instructions**

Appendix B – Recommendations for Physical Space for Reprocessing

Sources:

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

Update No. 2. January 2001.

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 (in print).

Personnel Recommendations:

1. Access to decontamination areas shall be restricted to authorized personnel as defined by departmental policies.
2. Eating, drinking, smoking, applying cosmetics or lip balm, and handling of contact lenses shall not take place in decontamination areas.

Space Recommendations:

1. **There must be clear separations between soiled and clean areas**
 - 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
 - Soiled work areas must be physically separated from all other areas of the space.
 - Walls or partitions should be constructed of materials capable of withstanding frequent cleaning
 - Doors to all work areas should be kept closed at all times (self-closing doors are recommended) to restrict access and optimize ventilation control.
 - In healthcare facilities, doors should be pass-through, to ensure one-way movement by staff from contaminated areas to clean areas
 - Adequate space must be provided for decontamination equipment and materials used for cleaning and reprocessing
 - Work surfaces and surrounding areas should be designed to minimize crowding of work space and to facilitate regular cleaning with disinfectants
 - Stainless steel surfaces are recommended
 - Sinks should be deep enough to immerse items to be cleaned
 - Storage of food, drink, or personal effects in decontamination areas shall be prohibited.
2. **There must be easy access to hand hygiene facilities**
 - Dedicated handwashing sinks must be provided
 - Handwashing sinks should be conveniently located in or near all decontamination and preparation areas
 - Handwashing facilities should also be located in all personnel support areas (e.g. change rooms)
 - “Hands-free” operating sinks are recommended
3. **There must be easy access to emergency supplies**
 - Eye-wash stations, deluge showers and spill equipment should be provided as necessary
 - Consult jurisdictional occupational health and safety statutes/regulations
4. **There must be an area for donning or removing Personal Protective Equipment**
 - If staff interchange is required between clean and contaminated areas, PPE shall be carefully removed and hands thoroughly washed.

5. **The reprocessing area is regularly and adequately cleaned**
 - There is an area for storage of dedicated housekeeping equipment and supplies
 - Wet-vacuuming or hand-mopping with a clean mop head and clean, fresh water should be done at least daily
 - Spills are cleaned up immediately
 - There is an area for waste
6. **There is adequate storage space**
 - There is an area for transportation equipment (e.g. carts, trolleys)
 - Clean supplies and PPE must be stored in a separate area from soiled items and cleaning processes
7. **In healthcare facilities ventilation, temperature and humidity of the area meets or exceeds CSA standards**
 - CSA requirements for ventilation:
 - Minimum 10 air changes per hour
 - Minimum 2 outdoor air changes per hour
 - Soiled areas: negative pressure
 - Clean areas: positive pressure
 - Exhaust air vented outdoors and not recirculated
 - Portable fans must not be used in any area of the central processing space
 - CSA recommendations for temperature and humidity
 - Room temperature of all decontamination work areas should be between 18-20°C
 - Relative humidity should be maintained between 30-60%
 - If humidity increases such that sterile packages become damp or wet, the integrity of the package may be compromised and it should be reprocessed.
8. **Water used in the processing area should be tested and be free of contaminants.**

[Refer to Appendix C3 in: "Canadian Standards Association. *Decontamination of Reusable Medical Devices*. CAN/CSA-Z314.8. Update No. 2. January 2001.]

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 equipment/devices, decontamination equipment and detergents should be consulted regarding their particular water quality requirements.

Limiting values of water contaminants:

- Hardness: ≤ 0.1 mmol/L
- pH: 6.5 to 8
- Iron: ≤ 0.2 mg/L
- Phosphate: ≤ 0.5 mg/L
- Chloride: ≤ 3 mg/L
- Lead: ≤ 0.05 mg/L
- Silica: ≤ 2 mg/L
- Evaporation residue: ≤ 15 mg/L
- Conductivity: ≤ 50 μ s/cm

Appendix C – Sample Audit Checklist for Reprocessing of Medical Equipment/Devices

NOTE: This checklist was adapted from Sunnybrook & Women's College Health Sciences Centre and is provided to assist health care settings in developing their own audit tools.

Purpose:

All medical equipment/devices used in health care settings in Ontario is to be reprocessed in accordance with both the Ministry of Health and Long Term Care "*Best Practices for Cleaning, Disinfection and Sterilization*", Public Health Agency of Canada infection control guidelines and current CSA standards.

Definition:

Reprocessing refers to the steps performed to prepare used medical equipment/devices for reuse.

Responsibility:

Each Physician Program Head and/or department manager is responsible to verify that all medical equipment/devices reprocessed in the area for which he/she is responsible is being reprocessed according to the Ministry of Health and Long Term Care Best Practices for Cleaning, Disinfection and Sterilization in Health Care Settings.

Checklist:

Department/Area to be Audited: _____

Item	Yes	No	Partial	Comments
Reprocessing occurs in the area (if no – sign off checklist is complete)				
Single-use medical equipment/devices are not reprocessed				
Personal protective equipment is worn when cleaning reprocessing (eye protection, mask, gown and gloves)				
Cleaning				
Equipment/devices are cleaned using an enzymatic cleaner prior to reprocessing				
Is cleaning done in a separate area from where the instrument will be used (i.e. designated dirty area)				
High Level Disinfection				
Equipment/devices are subjected to high-level disinfection according to manufacturer's instructions, using an approved high-level disinfectant (do not keep high-level disinfectant for more than 2 weeks even if test strip is still okay)				
High-level disinfectant concentration is checked daily				
Quality Control on test strips is carried out as per company guideline				
Test strip bottle is dated when opened				
Test strips are not used past the manufacturer's expiry date				
Log is kept of results of high-level disinfectant quality control				
Log is kept of instruments that receive high-level disinfection				
Log is kept of dates when high-level disinfectant is changed				
Two staff sign off that the correct solution was used when high-level disinfectant is changed				
Automated reprocessor has preventive maintenance program				
Log is kept of all preventive maintenance				
Log is kept of all maintenance associated with reprocessor malfunction				
Using checklist for reprocessing of endoscopes.				
Sterilization				
Equipment/devices are sterilized by an approved sterilization process				
Bowie Dick – done daily – high-vacuum sterilizer				
Sterilizer physical parameters are reviewed after each run				
Log is kept of physical parameters				
Sterilizers monitored with biologic monitor daily (each type of cycle i.e.				

Item	Yes	No	Partial	Comments
<i>flash, long loads)</i>				
Log is kept of biologic monitors				
Sterilizer has a preventive maintenance program				
Log is kept of preventive maintenance				
If biologic monitor is positive, loads are recalled and the positive test is investigated				
Log is kept of all maintenance associated with a positive biologic monitor				
Indicator tape is used on outside each wrapped package				
Multi-parameter indicator used on inside each wrapped package containing 2 or more instruments				
Log is kept of each load and items in load				
If flash sterilization is used, a log is kept of flash sterilizer use				
Flash sterilized equipment/devices are noted in the patient's chart along with reason.				
All logs are to be retained according to facility policy.				
All reprocessed equipment/devices are stored in a manner to keep them clean and dry				
Chemical indicators are checked before equipment/devices are used				
Is there a process in place that clearly identifies a non-reprocessed instrument from one that has been reprocessed to prevent use on a client/patient/resident				
<i>Purchasing & Reprocessing Instructions</i>				
Manager/purchaser is aware of purchasing policy for all medical equipment/devices requiring reprocessing.				
There are explicit written reprocessing instructions from the manufacturer on each equipment/device to be reprocessed.				
Policy & procedure for reprocessing are written. These are compatible with current published reprocessing standards and guidelines.				
<i>Education & Core Competency</i>				
Manager and staff are educated on how to reprocess instruments when: <ul style="list-style-type: none"> o First employed o Minimum of annually o Any authorized change in process o When new equipment is purchased – reprocessor o When new equipment is purchased – medical equipment/devices requiring reprocessing 				
Managers and staff have completed a recognized certification course in reprocessing or there is a plan to obtain this qualification within 5 years.				
There is an audit and follow up process in place for ongoing evaluation of reprocessing. Appropriate people and Infection Prevention & Control are notified when follow up is required.				
Compliance with the Occupational Health and Safety Act, R.S.O. 1990, c.O.1 and associated Regulations including the Health Care and Residential Facilities - O. Reg. 67/93 Amended to O. Reg. 631/05.				

Checklist Auditor: _____

Date: _____

Print name: _____

Dept: _____

Position: _____

Appendix D – Sample Task List for Cleaning and Disinfection/Sterilization of Flexible Endoscopes

NOTE: This checklist is designed for competency verification of staff involved in the reprocessing of flexible endoscopes. This tool was adapted from Sunnybrook & Women's College Health Sciences Centre and is provided to assist health care settings in developing their own audit tools.

Leak Testing	√	Comments
Wear appropriate personal protective equipment (PPE).		
Discard disposable valves.		
Place reusable valves and irrigation ports and removable parts in a beaker of enzymatic solution.		
Fill basin or sink with clean water for leakage testing.		
Perform leakage testing in the decontamination area, prior to reprocessing each endoscope.		
Attach the water resistant cap to cover the electrical socket on the scope (where applicable).		
Connect the leakage tester connector to the output socket on the MU-1 or light source/water resistant cap.		
Check that the leakage tester is emitting air and confirm that the connector cap is dry.		
Attach the leakage tester's connector to venting connector (on cap where applicable) and ensure connection is made.		
Immerse the entire endoscope in the water and observe for 30 sec. Visually inspect for potential leaks.		
Manipulate the angulation knobs to check for potential leaks.		
Remove the endoscope from the water and then turn off the air supply.		
Disconnect the leakage tester from the air supply and allow the endoscope to depressurize.		
Disconnect the leakage tester from the water resistant cap.		
Dry the leakage tester connector cap.		

Reprocessing Checklist for Flexible Endoscopes

Manual Cleaning	√	Comments
Prepare enzymatic solution as per manufacturer's recommendations with regard to dilution rate, temperature and time.		
Completely immerse the entire endoscope in freshly prepared enzymatic detergent solution in basin 16 inches by 16 inches or sink.		
Verify that instrument is totally immersed during entire cleaning process to prevent splashing or aerosolization.		
Verify that the bending section is straight so brushing does not damage endoscope.		
Clean the exterior of the endoscope with a soft brush or lint free cloth.		
Brush biopsy/suction channel in the insertion tube with the appropriate sized channel cleaning brush for the endoscope until all debris is removed.		
Continue brushing biopsy/suction channel with channel cleaning brush until all visible debris is removed. Clean brush in enzymatic each time brush is passed through channel.		
Brush suction valve housing & instrument channel port with channel opening brush until all debris is removed.		
Attach a 30ml. syringe to the adapter and send enzymatic into the channels at least three times.		
Soak the endoscope in the enzymatic solution as per manufacturer's instructions to ensure proper contact time for the enzymatic cleaner.		
Brush and flush the valves and removable parts until all debris is removed.		
Perform the final rinses in clear water followed by air purges using 30 ml. syringes.		
Thoroughly dry the exterior of the endoscope and all removable parts using a clean lint free cloth.		
Inspect the endoscope for residual debris and repeat the manual cleaning process if debris remains.		
Prepare compatible valves, removable parts and cleaning brush prior to HLD or ETO sterilization.		
Prepare endoscope for HLD or ETO sterilization.		

Reprocessing Checklist for Flexible Endoscopes

Manual Disinfection	√	Comments
Test the HLD dilution as per Hospital protocol.		
Immerse the entire endoscope, valves, cleaning brush & removable parts in a basin of HLD solution.		
Using a 30 cc syringe flush the HLD solution to purge air from all channels.		
Soak the endoscope in HLD solution for the recommended time and temperature.		
Flush air through the endoscope channels using adapters (suction cleaning adapters).		
Immerse the endoscope in fresh sterile/potable water.		
Rinse the endoscope and flush all channels with sterile/potable water as per manufacturer's instructions.		
Rinse the valves, brush & removable parts then flush with water as per manufacturer's instructions.		
Perform a channel air flush followed by an alcohol and an air purge. Dry the endoscope with a lint free cloth.		
Record scope number in patient record and logbook with date.		
Manipulate angulation knobs to test scope flexibility. Ensure optical clarity of telescope.		
Dry for ETO sterilization where required.		
Accessories, i.e. biopsy brushes, must be steam sterilized.		

Reprocessing Checklist for Flexible Endoscopes

Automated Disinfection	√	Comments
If applicable test the HLD dilution as per Hospital protocol.		
Properly place the endoscope, valves, cleaning brush & removable parts in the chamber (Note: Monitor endoscope stacking).		
Attach the endoscope connectors/adapters to the AER.		
Run the AER and ensure the endoscope is soaked in HLD solution for the recommended time and temperature.		
Remove the endoscope promptly after the final cycle has been completed.		
Sign off that all AER parameters have been met.		
Perform a channel air flush followed by an alcohol and an air purge. Dry the endoscope with a lint free cloth.		
Record scope number and AER number in patient record. Record scope number in AER logbook with date.		
Manipulate angulation knobs to test scope flexibility. Ensure optical clarity of telescope.		
Dry for ETO sterilization where required.		
Accessories, i.e. biopsy brushes, must be steam sterilized.		

Preparation for ETO Sterilization	√	Comments
Attach ETO cap to venting connector.		
Seal, wrap and label package for ETO gas sterilization according to Hospital protocol.		
Sterilize according to ETO parameters.		
Aerate following manufacturer's guidelines.		
Store on shelf.		

Reprocessing Checklist for Flexible Endoscopes

Handling	√	Comments
Ensure that the insertion tube is not coiled too tightly when handling the endoscope.		
Position the control portion upright, especially if the endoscope is placed on a counter.		
Transport the endoscope using both hands.		

Storage	√	Comments
Complete audit procedure before storage.		
Ensure the endoscope was dried thoroughly before storage.		
Remove all valves and removable parts from the endoscope to prevent the retention of moisture.		
If applicable store the endoscope with the bending section straight, in a ventilated cabinet/container.		
Hang the endoscope with the insertion tube and light guide tube placed vertical (support the body).		

Employee: _____

Auditor: _____

Date: _____

The above checklist was developed in conjunction with the Carsen Medical Imaging Group.

Appendix E – Sample Audit Tool for Reprocessing of Endoscopy Equipment/Devices

NOTE: This audit tool was adapted from Kingston Hospitals and is provided to assist health care settings in developing their own audit tools for endoscopy equipment.

	Recommendation	Specific Procedure	Yes / No/ Or N.A.	M.R.P.	Comment / Strategy for Improvement
1.	There is compliance with endoscope manufacturer's recommendations for cleaning	A. Endoscope is wiped and flushed immediately following procedure			
		B. Removal of debris collected in the scope (brushing)			
		C. Removal of debris collected on the scope (surface cleaning)			
		D. Perform a leak test			
		E. Visually inspect the scope to verify working properly			
2.	Verify that endoscope can be reprocessed in site's automated endoscope reprocessor (AER)	A. Documentation from endoscope manufacturer confirming compatibility of each scope with AER.			
		B. Documentation from AER manufacturer confirming testing of individual scope in system.			
		C. Specific steps before reprocessing endoscope in AER.			
3.	Compare reprocessing instructions provided by AER manufacturer and scope manufacturer and resolve conflicts.	A. Conflicts identified and resolved.			
4.	Adhere to endoscope manufacturer's instructions for manual reprocessing in the absence of specific technical information on AER reprocessing.	A. Manual procedures in place for endoscopes not compatible with AER.			
		B. Compliance with manufacturer's recommendations for hospital approved chemical germicide			
5.	Reprocessing protocol incorporates a final drying step.	A. All channels of reprocessed endoscopes are flushed with alcohol followed by purging with air.			
		B. Scopes are stored in a manner that minimized the likelihood of contamination or collection / retention of moisture.			

	Recommendation	Specific Procedure	Yes / No/ Or N.A.	M.R.P.	Comment / Strategy for Improvement
6.	Staff adhere to facility's procedures for preparing endoscope for client/patient/resident.	A. Confirm AER's processes are applicable to specific endoscope models.			
B. Ensure endoscope-specific reprocessing instructions from AER mfg are correctly implemented.					
C. Written, device-specific instructions for every endoscope model available to reprocessing staff.					
D. Written instructions for reprocessing system are available to reprocessing staff.					
7.	Comprehensive and intensive training is provided to all staff assigned to reprocessing endoscopes.	A. New reprocessing staff receive thorough orientation with all procedures.			
B. Competency is maintained by periodic (annual) hands on training with every endoscope model and AER used in the facility.					
C. Competency is documented following supervision of skills and expertise with all procedures.					
D. Frequent reminders and strict warnings are provided to reprocessing staff regarding adherence to written procedures.					
E. Additional training with documented competency for new endoscope models (or AER).					
8.	A comprehensive quality control program is in place.	A. Periodic visual inspections (monthly) of the cleaning and disinfecting procedures.			
B. A scheduled endoscope preventive maintenance program is in place and documented.					
C. Preventive maintenance program for AER is in place and documented.					
D. Preventive maintenance program for all reprocessing system filters is in place and documented.					
E. AER process monitors are utilized and logged.					
F. Chemical germicide effectiveness level is monitored and recorded in a logbook.					
G. There are records documenting the use of each AER which include the operator identification, client/patient/resident's chart record number, physician code, endoscope serial # and the type of procedure.					
H. There are records documenting the serial # of scopes leaving the					

	Recommendation	Specific Procedure	Yes / No/ Or N.A.	M.R.P.	Comment / Strategy for Improvement
		endoscope reprocessing area (e.g. repairs, loaners, O.R. etc.)			
		I. There is a surveillance system that detects clusters of infections /pseudoinfections associated with endoscopic procedures.			
9.	Staff adhere to Routine Practices.	A. Ensure correct hand hygiene technique is performed in appropriate situations.			
		B. There is compliance with procedures for wearing clean, non-sterile gloves.			
		C. PPE (masks, eye protection, gown/plastic apron) is worn during procedures and client/patient/resident – care activities that are likely to generate splashes or sprays.			
		D. Appropriate PPE is worn during scope cleaning and reprocessing.			
		E. Heavily soiled linen is placed into plastic bag prior to depositing in linen hamper			
		F. Procedures are in place to prevent sharps injury.			
		G. Staff are knowledgeable regarding protocol for follow-up for blood / body fluid exposure.			
10.	Endoscope reprocessing policies and physical space are in compliance with workplace regulations and standards.	H. All procedures are in compliance with the Occupational Health and Safety Act,R.S.O. 1990, c.O.1 and associated Regulations including the Health Care and Residential Facilities - O. Reg. 67/93 Amended to O. Reg. 631/05.			
		I. The reprocessing physical space is in compliance with the Canadian Standards Association standards and with the Occupational Health and Safety Act,R.S.O. 1990, c.O.1 and associated Regulations including the Health Care and Residential Facilities - O. Reg. 67/93 Amended to O. Reg. 631/05.			

Appendix F - Advantages and Disadvantages of Currently Available Reprocessing Alternatives

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED				
PROCESS OPTION	USES/COMMENTS	MONITORING	ADVANTAGES/COMMENTS	DISADVANTAGES/COMMENTS
STERILIZATION	Critical equipment/devices Some semicritical equipment/devices	Effective sterilization must be monitored	Completely kills all forms of microbial life including spores	
Boiling	Not acceptable	None	Not acceptable	
Chemiclave	<ul style="list-style-type: none"> Dental equipment Sterilization is achieved after 20 minutes exposure. It is highly recommended that steam sterilization be used in place of chemiclaves.	<ul style="list-style-type: none"> Mechanical – each cycle/load Chemical – each pack Biologic – daily (<i>Geobacillus stearothermophilus</i> spores) 		<ul style="list-style-type: none"> Toxic chemicals used (chemicals may be considered hazardous waste in some jurisdictions)
Dry Heat Gravity convection Mechanical convection	<ul style="list-style-type: none"> Anhydrous oil Powders, creams Glass Foot care equipment Heat tolerant equipment/devices Temperatures – time 171°C – 60 min 160°C – 120 min 149°C – 150 min 141°C – 180 min 121°C – 12 hours	<ul style="list-style-type: none"> Mechanical – each cycle/load Chemical – each pack Biologic – daily (<i>Bacillus atrophaeus</i> spores) 	<ul style="list-style-type: none"> No corrosive or rusting effect on instruments Reaches surfaces of instruments that cannot be disassembled Inexpensive 	<ul style="list-style-type: none"> Lengthy cycle due to slowness of heating and penetration High temperatures may be deleterious to material Limited packing materials Temperature and exposure times vary, depending on article being sterilized
Ethylene oxide (EtO) gas	<ul style="list-style-type: none"> Heat sensitive equipment/devices Lensed instruments that require sterilization EtO concentration based on manufacturer's	<ul style="list-style-type: none"> Mechanical – each cycle/load Chemical – each pack Biologic – each cycle/load (<i>Bacillus atrophaeus</i> spores) 	<ul style="list-style-type: none"> Not harmful to heat sensitive and lensed instruments 	<ul style="list-style-type: none"> Expensive Toxic to humans Requires monitoring of residual gas levels in environment Requires aeration of sterilized

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED				
PROCESS OPTION	USES/COMMENTS	MONITORING	ADVANTAGES/COMMENTS	DISADVANTAGES/COMMENTS
STERILIZATION	Critical equipment/devices Some semicritical equipment/devices	Effective sterilization must be monitored	Completely kills all forms of microbial life including spores	
Ethylene oxide (EtO) gas, con't.	recommendation Temperature – variable Humidity – 50% Time – extended processing time (several hours)	Routine testing shall include a biologic monitor placed in the centre of each load to be sterilized, and a chemical monitor in each pack. A rapid readout biologic monitor is available (4 hours).		products prior to use <ul style="list-style-type: none"> • Lengthy cycle required to achieve sterilization and aeration • Highly flammable and explosive and highly reactive with other chemicals • Causes structural damage to some medical equipment/devices
Flash sterilization	<ul style="list-style-type: none"> • Should be used only in an emergency • Never use for implantable equipment/devices Sterilization of unwrapped objects at 132°C for 3 minutes at 27-28 lbs. pressure	<ul style="list-style-type: none"> • Mechanical – each cycle/load • Chemical – each pack • Biologic – daily (<i>Geobacillus stearothermophilus</i> spores) Testing should include every type of cycle and every load configuration (i.e. open tray, rigid flash container, single wrapper) that will be used that day. One biologic monitor and a chemical indicator shall be placed in a perforated or mesh bottom surgical tray of appropriate size for the sterilizer to be tested. The test tray shall be placed on the bottom shelf of an otherwise empty sterilizer.	Not recommended	<ul style="list-style-type: none"> • If medical equipment/devices are used before the results of biologic monitors are known, personnel must record which equipment/devices were used for specific clients/patients, so that they can be followed if the load was not processed properly • Difficult to monitor • Efficacy will be impaired if all the necessary parameters are not properly met • Sterility cannot be maintained if the medical equipment/device is not wrapped • Effectiveness is impaired if the medical equipment/device is contaminated with organic matter

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED				
PROCESS OPTION	USES/COMMENTS	MONITORING	ADVANTAGES/COMMENTS	DISADVANTAGES/COMMENTS
STERILIZATION	Critical equipment/devices Some semicritical equipment/devices	Effective sterilization must be monitored	Completely kills all forms of microbial life including spores	
Formaldehyde	<ul style="list-style-type: none"> Limited use as a chemisterilant Sometimes used to reprocess hemodialyzers Gaseous form used to decontaminate laboratory safety cabinets 	<ul style="list-style-type: none"> Biologic monitors are not available Concentration must be monitored 	<ul style="list-style-type: none"> Active in the presence of organic materials 	<ul style="list-style-type: none"> Toxic Carcinogenic Strong irritant Pungent odour Cannot be monitored for sterility
Glass bead sterilizers	Not acceptable	None	Not acceptable	
Glutaraldehyde (2.5%-3.5%)	<ul style="list-style-type: none"> May be used on metals, plastics, rubber, equipment/devices with lens cement May use on heat sensitive equipment/devices <p>Sterilization may be accomplished in 10 hours at 20°C with some products. Refer to product label for time and temperature required to achieve sterilization.</p> <p>Sterilized equipment/devices must be rinsed with sterile water to remove all residual chemical.</p> <p>Sterilized equipment/devices must be handled in a manner that prevents contamination from process through storage to use</p>	<ul style="list-style-type: none"> Exposure time and temperature must be maintained Monitors are available for pH and dilution concentration Biologic monitors are not available <p>Concentration is monitored using test strips provided by the product manufacturer. Testing must be done at least daily.</p> <p>Product is time limited following activation, usually maximum 14 days. During reuse, the concentration may drop as dilution of the product occurs. Chemical test strips are available for determining whether an effective concentration of active ingredients is present despite repeated use and dilution.</p>	<ul style="list-style-type: none"> Heat sensitive equipment/devices Does not coagulate protein 	<ul style="list-style-type: none"> Toxic, sensitizing irritant Need proper ventilation and closed containers- ceiling limit 0.05 ppm Handling provides opportunities for contamination Requires copious rinsing with sterile water Unable to monitor sterility Lengthy process (6-12 hours) Shelf life of 14 days once mixed During reuse, the concentration may drop as dilution of the product occurs

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED				
PROCESS OPTION	USES/COMMENTS	MONITORING	ADVANTAGES/COMMENTS	DISADVANTAGES/COMMENTS
STERILIZATION	Critical equipment/devices Some semicritical equipment/devices	Effective sterilization must be monitored	Completely kills all forms of microbial life including spores	
Accelerated Hydrogen Peroxide (7%)	<ul style="list-style-type: none"> Heat sensitive equipment/devices Sterility is achieved after 6 hours of undiluted solution at 20°C. (refer to product label for time and temperature).	<ul style="list-style-type: none"> Biologic monitors are not available Chemical – test kits to monitor the concentration are available from the manufacturer and must be used for each load 	<ul style="list-style-type: none"> Safe for environment Non-toxic Rapid Inexpensive Active in the presence of organic materials 	<ul style="list-style-type: none"> Contraindicated for use on copper, brass, carbon-tipped devices and anodised aluminum Cannot monitor for sterility
Hydrogen peroxide gas plasma	<ul style="list-style-type: none"> Heat sensitive equipment/devices Sterility is achieved after 75 minutes at 50°C	Follow manufacturer's instructions <ul style="list-style-type: none"> Chemical – each pack Biologic – daily (<i>Bacillus stearothermophilus</i> spores) 	<ul style="list-style-type: none"> Low heat good for heat sensitive equipment/devices Rapid Safe for environment (water and oxygen end products) Non-toxic Lack of corrosion to metals and other materials (except nylon) Compatible with most medical equipment/devices 	<ul style="list-style-type: none"> Special wraps and trays required Limitations on length and lumens of medical equipment/devices that can be effectively sterilized. Long (12") narrow lumens (1/8"/0.38 cm) require a booster Cannot sterilize materials which absorb liquids (e.g. linen, gauze, cellulose/paper) Not approved for flexible endoscopes
Hydrogen peroxide liquid (6-25%)	<ul style="list-style-type: none"> Heat sensitive equipment/devices (e.g. eye equipment) Costly equipment/devices that may be lost in transit Sterility is achieved after 6 hours.	<ul style="list-style-type: none"> Biologic monitors are not available Concentration must be monitored 	<ul style="list-style-type: none"> Less toxic than other chemical sterilants Safe for environment Rapid 	<ul style="list-style-type: none"> Contraindicated for use on copper, zinc, brass, aluminium Store in cool place, protect from light Limitations on length and lumens of medical equipment/devices that can be effectively sterilized Cannot monitor for sterility
Microwave ovens	Not acceptable	None	Not acceptable	

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED				
PROCESS OPTION	USES/COMMENTS	MONITORING	ADVANTAGES/COMMENTS	DISADVANTAGES/COMMENTS
STERILIZATION	<p>Critical equipment/devices Some semicritical equipment/devices</p>	<p>Effective sterilization must be monitored</p>	<p>Completely kills all forms of microbial life including spores</p>	
<p>Peracetic acid (0.2%)</p>	<ul style="list-style-type: none"> Heat sensitive immersible equipment/devices (e.g. endoscopes, dental and surgical instruments) <p>Sterilizes in 30-45 minutes at 50-56°C (time and temperature controlled by cycle and may vary due to water pressure, incoming water temperature, or filter status).</p>	<ul style="list-style-type: none"> Mechanical - diagnostic cycle should be performed each day to ensure that all mechanical components are functioning properly - with each cycle/load there are printouts that document the parameters of the cycle (e.g. temperature, exposure time, etc.) Chemical – each pack Biologic – daily (<i>Geobacillus stearothermophilus</i> spores) 	<ul style="list-style-type: none"> Rapid Automated Leaves no residue Effective in presence of organic matter Sporicidal at low temperatures 	<ul style="list-style-type: none"> Monitoring of efficacy of sterilization cycle with spore strips is questionable Can be used for immersible instruments only Corrosive Material incompatibility with some materials Unstable particularly when diluted <p>In vapour form, PAA is volatile, has a pungent odour, is toxic and is a fire and explosion hazard.</p>
<p>Steam sterilization</p> <p>Small table top sterilizers Gravity displacement sterilizers High-speed vacuum sterilizers</p>	<p>First choice for critical equipment/devices</p> <ul style="list-style-type: none"> Heat tolerant instruments and accessories Linen Liquids Foot care equipment <p>Raised pressure (preset by manufacturer) to increase temperature to 121°C.</p> <p>Time varies with temperature, type of material and whether the instrument is wrapped or not.</p> <p>Steam must be saturated (narrow lumen equipment/devices may require prehumidification)</p>	<ul style="list-style-type: none"> Pre-vacuum sterilizers – include air removal test daily before first cycle of the day, in an empty sterilizer with no dry cycle Mechanical – each cycle/load Chemical – each pack Biologic – daily and on every type of cycle to be used; and with each load of implantable equipment/devices; Place biologic monitor near the drain in a fully loaded sterilizer (<i>Geobacillus stearothermophilus</i> spores). <p>Whenever possible, loads containing implantable devices shall be quarantined until the results of the biologic monitor testing are available.</p>	<ul style="list-style-type: none"> Inexpensive Rapid Efficient Non toxic 	<ul style="list-style-type: none"> Cannot use for heat or moisture sensitive equipment/devices Unsuitable for anhydrous oils, powders, lensed instruments, heat and moisture sensitive materials Some tabletop sterilizers lack a drying cycle

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED				
PROCESS OPTION	USES/COMMENTS	MONITORING	ADVANTAGES/COMMENTS	DISADVANTAGES/COMMENTS
HIGH LEVEL DISINFECTION (HLD)	Semicritical equipment/devices	Monitoring for dilution is recommended	Kills all vegetative forms of microbial life including bacteria, viruses, fungi and mycobacteria.	Does not kill bacterial spores.
Glutaraldehyde (2%)	<ul style="list-style-type: none"> Heat sensitive equipment/devices Lensed instruments that do not require sterilization Endoscopes Respiratory therapy equipment Anaesthesia equipment Fingernail care equipment used on multiple clients/patients/residents <p>High level disinfection is achieved after at least 20 minutes at 20°C. Refer to product label for time and temperature required to achieve high level disinfection.</p>	<ul style="list-style-type: none"> Exposure time and temperature must be maintained Test strips for concentration are available from the manufacturer and must be used at least daily (preferably with each load). <p>Product is time limited following activation, usually maximum 14 days. Chemical test strips are available for determining whether an effective concentration of active ingredients is present. During reuse, the concentration may drop as dilution of the product occurs.</p>	<ul style="list-style-type: none"> Noncorrosive to metal, plastic, rubber, lens cements Active in presence of organic material 	<ul style="list-style-type: none"> Extremely irritating to skin and mucous membranes Need proper ventilation & closed containers- ceiling limit 0.05 ppm Shelf life shortens when diluted (effective for 14-30 days depending on formulation) During reuse, concentration may drop as dilution of the product occurs Acts as a fixative
Accelerated Hydrogen Peroxide (7%)	<ul style="list-style-type: none"> Heat sensitive equipment/devices Delicate equipment/devices <p>Achieves high level disinfection with undiluted 7% solution after at least 20 minutes at 20°C (refer to product label for time and temperature).</p>	<p>Test kits to monitor the concentration are available from the manufacturer and must be used with each load.</p>	<ul style="list-style-type: none"> Safe for environment Non-toxic Active in the presence of organic materials Rapid Inexpensive 	<ul style="list-style-type: none"> Contraindicated for use on copper, brass, carbon-tipped devices and anodised aluminum
Hydrogen peroxide (6%)	<ul style="list-style-type: none"> Semicritical equipment used for home health care Disinfection of soft contact lenses <p>Achieves high level disinfection after at least 30 minutes.</p>	<p>Not currently available</p>	<ul style="list-style-type: none"> Strong oxidant Rapid action Safe for the environment Low cost 	<ul style="list-style-type: none"> Must be stored in cool place, protect from light Contraindicated for use on copper, brass, carbon-tipped devices and aluminum

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED				
PROCESS OPTION	USES/COMMENTS	MONITORING	ADVANTAGES/COMMENTS	DISADVANTAGES/COMMENTS
HIGH LEVEL DISINFECTION (HLD)	Semicritical equipment/devices	Monitoring for dilution is recommended	Kills all vegetative forms of microbial life including bacteria, viruses, fungi and mycobacteria.	Does not kill bacterial spores.
Ortho-phthalaldehyde (OPA) (0.55%)	<ul style="list-style-type: none"> Endoscopy equipment/devices Heat sensitive equipment/devices <p>Achieves high level disinfection after at least 10 minutes at 20°C.</p>	<ul style="list-style-type: none"> Test strips for concentration are available from the manufacturer and must be used at least daily (preferably with each load). 	<ul style="list-style-type: none"> Superior penetration Rapid activity Active in presence of organic materials Non-irritating vapour Does not require activation or dilution 	<ul style="list-style-type: none"> Stains protein, including hands, requiring gloves and gown for use Expensive
Pasteurization	<ul style="list-style-type: none"> Respiratory therapy equipment Anaesthesia equipment <p>Achieves high level disinfection at 75°C for 30 min.</p>	<ul style="list-style-type: none"> The process must be monitored with <u>mechanical temperature gauges and timing mechanisms</u> for each load, with a paper printout record Water temperature within the pasteurizer should be verified weekly by <u>manually</u> measuring the cycle water temperature Cycle time should be verified <u>manually</u> and recorded daily Daily cleaning of pasteurizing equipment is required following the manufacturer's recommendations 	<ul style="list-style-type: none"> Rapid, simple, moderate cost Alternative to chemicals Non-toxic Can be used for some plastics 	<ul style="list-style-type: none"> Dry well & store carefully to prevent contamination Difficult to monitor efficacy of the process Preventive maintenance required

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED				
PROCESS OPTION	USES/COMMENTS	MONITORING	ADVANTAGES/COMMENTS	DISADVANTAGES/COMMENTS
LOW LEVEL DISINFECTION (LLD)	<u>Noncritical medical equipment/devices</u>	<u>Monitoring not required</u>	<u>Inactivates vegetative bacteria and enveloped viruses</u>	<u>Not able to kill fungi, non-enveloped virus, mycobacteria, or bacterial spores.</u>
Alcohols (60-95%)	<ul style="list-style-type: none"> External surfaces of some equipment (e.g. stethoscopes) Noncritical equipment used for home health care Used as a skin antiseptic <p>Disinfection is achieved after 10 minutes of contact.</p> <p>Observe fire code restrictions for storage of alcohol.</p>	Monitoring not required	<ul style="list-style-type: none"> Non-toxic Low cost Rapid action Non-staining No residue Effective on clean equipment/devices that can be immersed 	<ul style="list-style-type: none"> Evaporates quickly - not a good surface disinfectant Evaporation may diminish concentration Flammable - store in a cool well ventilated area; refer to Fire Code restrictions for storage of large volumes of alcohol Coagulates protein; a poor cleaner May dissolve lens mountings Hardens and swells plastic tubing Harmful to silicone; causes brittleness May harden rubber or cause deterioration of glues Inactivated by organic material Use in the Operating Room is contraindicated
Chlorines	<ul style="list-style-type: none"> Hydrotherapy tanks, exterior surfaces of dialysis equipment, cardiopulmonary training manikins, environmental surfaces Noncritical equipment used for home health care Blood spills <p>Dilution of Household Bleach [REF: Health Canada/PHAC: "Hand Washing, Cleaning, disinfection and Sterilization in Health Care". Table 7, page 17]</p> <p><u>Undiluted:</u> 5.25% sodium hypochlorite, 50,000 ppm available chlorine</p>	Monitoring not required	<ul style="list-style-type: none"> Low cost Rapid action Readily available in non hospital settings 	<ul style="list-style-type: none"> Corrosive to metals Inactivated by organic material; for blood spills, blood must be removed prior to disinfection Irritant to skin and mucous membranes Should be used immediately once diluted Use in well-ventilated areas Must be stored in closed containers away from ultraviolet light & heat to prevent deterioration

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED

PROCESS OPTION	USES/COMMENTS	MONITORING	ADVANTAGES/COMMENTS	DISADVANTAGES/COMMENTS
LOW LEVEL DISINFECTION (LLD)	Noncritical medical equipment/devices	Monitoring not required	Inactivates vegetative bacteria and enveloped viruses	Not able to kill fungi, non-enveloped virus, mycobacteria, or bacterial spores.
Chlorines, con't.	<p><u>Blood spill – major:</u> dilute 1:10 with tap water to achieve 0.5% or 5,000 ppm chlorine</p> <p><u>Blood spill – minor:</u> dilute 1:100 with tap water to achieve 0.05% or 500 ppm chlorine</p> <p><u>Surface cleaning, soaking of items:</u> dilute 1:50 with tap water to achieve 0.1% or 1,000 ppm chlorine</p>			<ul style="list-style-type: none"> Stains clothing and carpets
Accelerated Hydrogen Peroxide 0.5% (7% solution diluted 1:16)	<ul style="list-style-type: none"> Isolation room surfaces Clinic and procedure room surfaces <p>Low level disinfection is achieved after 5 minutes of contact at 20°C.</p>	Monitoring not required, however test kits are available from the manufacturer	<ul style="list-style-type: none"> Safe for environment Non-toxic Rapid action Available in a wipe Active in the presence of organic materials Excellent cleaning ability due to detergent properties 	<ul style="list-style-type: none"> Contraindicated for use on copper, brass, carbon-tipped devices and anodised aluminum
Hydrogen peroxide 3%	<ul style="list-style-type: none"> Noncritical equipment used for home health care Floors, walls, furnishings <p>Disinfection is achieved with a 3% solution after 10 minutes of contact.</p>	Monitoring not required	<ul style="list-style-type: none"> Low cost Rapid action Safe for the environment 	<ul style="list-style-type: none"> Contraindicated for use on copper, zinc, brass, aluminum Store in cool place, protect from light
Iodophors (Non-antiseptic formulations)	<ul style="list-style-type: none"> Hydrotherapy tanks Thermometers Hard surfaces and equipment that do not touch mucous membranes (e.g. IV poles, wheelchairs, beds, call bells) <p>DO NOT use antiseptic iodophors as hard surface disinfectants</p>	Monitoring not required	<ul style="list-style-type: none"> Rapid action Non-toxic 	<ul style="list-style-type: none"> Corrosive to metal unless combined with inhibitors Inactivated by organic materials May stain fabrics and synthetic materials

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED

PROCESS OPTION	USES/COMMENTS	MONITORING	ADVANTAGES/COMMENTS	DISADVANTAGES/COMMENTS
LOW LEVEL DISINFECTION (LLD)	Noncritical medical equipment/devices	Monitoring not required	Inactivates vegetative bacteria and enveloped viruses	Not able to kill fungi, non-enveloped virus, mycobacteria, or bacterial spores.
Phenolics	<ul style="list-style-type: none"> Floors, walls and furnishings Hard surfaces and equipment that do not touch mucous membranes (e.g. IV poles, wheelchairs, beds, call bells) <p>DO NOT use phenolics in nurseries</p>	Monitoring not required	<ul style="list-style-type: none"> Leaves residual film on environmental surfaces Commercially available with added detergents to provide one-step cleaning and disinfecting Slightly broader spectrum of activity than QUATs 	<ul style="list-style-type: none"> Do not use in nurseries Not recommended for use on food contact surfaces May be absorbed through skin or by rubber May be toxic if inhaled Corrosive Some synthetic flooring may become sticky with repetitive use
Quaternary ammonium compounds (QUATs)	<ul style="list-style-type: none"> Floors, walls and furnishings Blood spills prior to disinfection <p>DO NOT use QUATs to disinfect instruments</p>	Monitoring not required	<ul style="list-style-type: none"> Non corrosive, non-toxic, low irritant Good cleaning ability, usually have detergent properties Rinsing not required May be used on food surfaces 	<ul style="list-style-type: none"> NOT to be used to disinfect instruments Limited use as disinfectant because of narrow microbicidal spectrum Diluted solutions may support the growth of microorganisms May be neutralized by various materials (e.g. gauze)

Appendix G – Resources for Education and Training

Resources for Infection Prevention and Control

Organizations and Publications

Canadian Standards Association (CSA)

Source for national standards in sterilization and sterilizing equipment.

<http://www.csa.ca/Default.asp?language=english>

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>

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 are in the process of publishing a number of best practice guidelines.

http://www.health.gov.on.ca/english/providers/program/infectious/pidac/pidac_mn.html

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/>

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

Infection Control Guidelines.

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

Professional Associations

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>

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>

The College of Physicians and Surgeons of Ontario

Infection Control in Physician's Office, 2004.

<http://www.cpso.on.ca/Publications/infectioncontrolv2.pdf>

Resources for Reprocessing

Central Service Association of Ontario (CSAO)

Provincial association of hospital central service workers dedicated to standardization of central service practices in hospitals across the province. Offers the "Central Service Techniques Course" at chapters around the province.

<http://www.csaonet/education.htm>

Algonquin College (Ottawa)

Offers course on Sterile Supply Processing.

<http://www.algonquincollege.com/PartTimeStudies/currentOfferings.htm>

Centennial College (Toronto)

Offers certificate course in processing: Introduction to Sterile Supply Processing

<http://db2.centennialcollege.ca/ce/coursedetail.php?CourseCode=AN-100>

Fanshawe College (London)

Offers Sterile Processing Technician certificate course.

<http://www.fanshawec.ca/ce/health.asp>

Ontario Hospitals Association (OHA)

Offers courses for CSAO workers.

<http://www.oha.com>

Sterris

Offers online endoscope reprocessing training.

http://www.steris.com/healthcare/res_education.cfm