

Provincial Infectious
Diseases Advisory
Committee
(PIDAC)

Best Practices For Cleaning, Disinfection and Sterilization of Medical Equipment/Devices

In All Health Care Settings

THIS DOCUMENT IS INTENDED TO PROVIDE BEST PRACTICES ONLY.

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

**Ministry of Health and Long-Term Care
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Disclaimer for Best Practice Documents

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

Revisions to 'Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings', originally published April 2006:

- This document incorporates revisions from the following updated Canadian standards:
 - CSA Z314.3-09 Effective Sterilization in Health Care Facilities by the Steam Process
 - CSA Z314.2-09 Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process
 - CSA Z314.8-08 Decontamination of Reusable Medical Devices
- New information from the Centers for Disease Control and Prevention's '*Guideline for Disinfection and Sterilization in Healthcare Facilities*', published in 2008, is also reflected in this revision.

New material from these documents is highlighted in grey in the text.

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Table of Contents

TABLE OF CONTENTS	4
TABLES	5
ABBREVIATIONS.....	6
GLOSSARY OF TERMS.....	6
PREAMBLE	11
1. ABOUT THIS DOCUMENT.....	11
2. EVIDENCE FOR RECOMMENDATIONS.....	11
3. HOW AND WHEN TO USE THIS DOCUMENT	11
4. ASSUMPTIONS FOR BEST PRACTICES IN INFECTION PREVENTION AND CONTROL	12
I. GENERAL PRINCIPLES.....	17
II. BEST PRACTICES.....	19
1. PURCHASING AND ASSESSING MEDICAL EQUIPMENT/DEVICES AND/OR PRODUCTS FOR DISINFECTION OR STERILIZATION PROCESSES	19
A. Equipment/Device Purchases	19
B. Manufacturer's Recommendations	20
C. Loaned, Shared and Leased Medical Equipment/Devices	21
D. Creutzfeldt-Jakob Disease (CJD)	22
2. ENVIRONMENTAL REQUIREMENTS FOR REPROCESSING AREAS	23
A. Physical Space.....	23
B. Air Quality.....	24
C. Water Quality	24
D. Environmental Cleaning in Sterile Processing Departments.....	24
3. POLICIES AND PROCEDURES	25
4. EDUCATION AND TRAINING.....	26
5. OCCUPATIONAL HEALTH AND SAFETY FOR REPROCESSING	27
A. Routine Practices	27
B. Personal Protective Equipment (PPE)	28
C. Safe Handling of Sharps.....	28
D. Work Restrictions	29
6. TRANSPORTATION AND HANDLING OF CONTAMINATED MEDICAL EQUIPMENT/DEVICES.....	29
7. FACTORS AFFECTING THE EFFICACY OF THE REPROCESSING PROCEDURE	30
8. DISASSEMBLY, INSPECTION AND CLEANING OF REUSABLE MEDICAL EQUIPMENT/DEVICES	31
A. Pre-Cleaning	32
B. Cleaning	32
C. Post-Cleaning	34
9. SELECTION OF PRODUCT/PROCESS FOR REPROCESSING	35
A. Reprocessing Process.....	35
B. Reprocessing Products.....	36
10. DISINFECTION OF REUSABLE MEDICAL EQUIPMENT/DEVICES	36
A. Low-Level Disinfection (LLD)	37
B. High-Level Disinfection (HLD).....	37
C. Methods of Disinfection for Semicritical Medical Equipment/Devices	37
11. REPROCESSING ENDOSCOPY EQUIPMENT/DEVICES.....	40
A. Education and Training.....	41

B. Physical Space	41
C. Cleaning Procedures	41
D. Endoscope Disinfection and Sterilization	42
E. Accessories	43
F. Automated Endoscope Reprocessor (AER)	43
G. Drying and Storage of Endoscopes	43
H. Equipment Used for Cleaning	44
I. Record-keeping	44
12. STERILIZATION OF REUSABLE MEDICAL EQUIPMENT/DEVICES	45
A. Sterilization Process	45
B. New Sterilizers	46
C. Monitors and Indicators	47
D. Routine Monitoring of Sterilizers	49
E. Ethylene Oxide (ETO)	50
13. FLASH STERILIZATION	51
14. UNACCEPTABLE METHODS OF DISINFECTION/STERILIZATION	52
A. Boiling	52
B. Ultraviolet Irradiation	52
C. Glass Bead Sterilization	52
D. Chemiclave	52
E. Microwave Oven Sterilization	53
15. CONTINUED MONITORING AND SYSTEM FAILURES	53
Recalls	53
16. SINGLE-USE MEDICAL EQUIPMENT/DEVICES	54
A. Sharps	55
B. Equipment/Devices with Small Lumens	55
C. Equipment/Devices in Home Health Care	55
17. STORAGE AND USE OF REPROCESSED MEDICAL EQUIPMENT/DEVICES	55
A. Sterile Storage Areas	56
B. Maintaining Sterility	56
C. Using Sterile Equipment/Devices	56
SUMMARY OF BEST PRACTICES FOR CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS	58
APPENDIX A: REPROCESSING DECISION CHART	75
APPENDIX B: RECOMMENDATIONS FOR PHYSICAL SPACE FOR REPROCESSING	78
APPENDIX C: SAMPLE AUDIT CHECKLIST FOR REPROCESSING OF MEDICAL EQUIPMENT/DEVICES	82
APPENDIX D: SAMPLE PROGRAM AUDIT TOOL FOR ENDOSCOPE REPROCESSING	85
APPENDIX E: SAMPLE OBSERVATIONAL AUDIT TOOL/ USER TASK LIST FOR CLEANING, DISINFECTION AND/OR STERILIZATION OF FLEXIBLE ENDOSCOPES	89
APPENDIX F: ADVANTAGES AND DISADVANTAGES OF CURRENTLY AVAILABLE REPROCESSING OPTIONS	94
APPENDIX G: RESOURCES FOR EDUCATION AND TRAINING	105
REFERENCES	107

TABLES

TABLE 1: Spaulding's Classification of Medical Equipment/Devices and Required Level of Processing/Reprocessing	35
TABLE 2: International Classes of Steam Chemical Indicators	48

Abbreviations

AER	Automated Endoscope Reprocessor
BI	Biological Indicator
CI	Chemical Indicator
CJD	Creutzfeldt-Jakob Disease
CSA	Canadian Standards Association
DIN	Drug Identification Number
HEPA	High Efficiency Particulate Air
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
PCD	Process Challenge Device
PHAC	Public Health Agency of Canada
PPE	Personal Protective Equipment
QUAT	Quaternary Ammonium Compound
SPD	Sterile Processing Department
USFDA	United States Food and Drug Administration
WHMIS	Workplace Hazardous Materials Information System

Glossary of Terms

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

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.

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

Chemical Indicator (CI): A system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to the process.¹

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

CHICA-Canada: The Community and Hospital Infection Control Association of Canada, a professional organization of persons engaged in infection prevention and control activities in health care settings. CHICA-Canada members include infection prevention and control professionals from a number of related specialties including nurses, epidemiologists, physicians, microbiology technologists, public health and industry. The CHICA-Canada website is located at: <http://www.chica.org>.

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

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.¹

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

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

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. See also, *Disinfectant*.

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

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 and laparoscopes.

Endoscope – Semicritical: Fibreoptic 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: A pre-cleaning agent that contains protease enzymes that break down proteins such as blood, body fluids, secretions and excretions from surfaces and equipment. Most enzymatic cleaners also contain a detergent. Enzymatic cleaners are used to loosen and dissolve organic substances prior to cleaning.

Hand Hygiene: A general term referring to any action of hand cleaning. Hand hygiene relates to the removal of visible soil and removal or killing of transient microorganisms from the hands. Hand hygiene

may be accomplished using soap and running water or an alcohol-based hand rub (ABHR). Hand hygiene also includes surgical hand antisepsis.

Health Care Provider: Any person delivering care to a client/patient/resident. This includes, but is not limited to, the following: emergency service workers, physicians, dentists, nurses, respiratory therapists and other health professionals, personal support workers, clinical instructors, students and home health care workers. In some non-acute settings, volunteers might provide care and would be included as health care providers. See also, *Staff*.

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

High Efficiency Particulate Air (HEPA) Filter: A filter which has an efficiency of 99.97% in the removal of airborne particles 0.3 microns or larger in diameter.²

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: A system that reveals a change in one or more of the sterilization process parameters. Indicators do not verify sterility, but they do allow the detection of potential sterilization failures due to factors such as incorrect packaging, incorrect loading of the sterilizer, or equipment malfunction. See also, *Biological Indicator* and *Chemical Indicator*.

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 providers, other clients/patients/residents 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 non-invasive medical equipment (i.e., non-critical equipment) and some environmental surfaces. Equipment and surfaces must be thoroughly cleaned prior to low-level disinfection.

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

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.¹

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 71°C for a contact time of at least 30 minutes.

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

Process Challenge Device (PCD): A test device intended to provide a challenge to the sterilization process that is equal to, or greater than, the challenge posed by the most difficult item routinely processed.¹ Examples include BI test packs which also contain a chemical indicator, or CI test packs which contain a Class 5 integrating indicator or an enzyme-only indicator.

Reprocessing: The steps performed to prepare used medical equipment/devices for use (e.g., cleaning, disinfection, sterilization).¹

Reusable: A term given by the manufacturer of medical equipment/devices that allows it, through the selection of materials and/or components, to be re-used.¹

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). 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, lancets, blades, clinical glass).

Single Patient Use: A term given to medical equipment/devices that may be used on a single client/patient/resident and may be re-used on the same client/patient/resident, but may not be used on other clients/patients/residents.

Single-use/Disposable: A term given to medical equipment/devices designated by the manufacturer for single-use only. Single-use equipment/devices must not be reprocessed.¹

Staff: Anyone conducting activities in settings where health care is provided, including but not limited to, health care providers. See also, *Health Care Providers*.

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

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

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).

Workplace Hazardous Materials Information System (WHMIS)³: The Workplace Hazardous Materials Information System (WHMIS) is Canada's national hazard communication standard. The key elements of the system are cautionary labelling of containers of WHMIS 'controlled products', the provision of Material Safety Data Sheets (MSDSs) and staff education and training programs.

Preamble

1. *About This Document*

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

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.

For recommendations in this document:

- ***'shall'*** indicates mandatory requirements based on legislated requirements or national standards (i.e., Canadian Standards Association - CSA);
- ***'must'*** indicates best practice, i.e., the minimum standard based on current recommendations in the medical literature;
- ***'should'*** indicates a recommendation or that which is advised but not mandatory; and
- ***'may'*** indicates an advisory or optional statement.

2. *Evidence for Recommendations*

The best practices in this document reflect the best evidence and expert opinion on the reprocessing of medical equipment/devices available at the time of writing. As new information becomes available, 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.

3. *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 (including pre-hospital) care is provided, hospitals, complex continuing care facilities, rehabilitation facilities, 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.

4. Assumptions for Best Practices in Infection Prevention and Control

The best practices in this document are based on the assumption that health care settings in Ontario already have basic infection prevention and control systems and programs in place, such as those outlined in the following document:

- Ministry of Health and Long-Term Care's '*Recommendations for Infection Prevention and Control Programs in Ontario in All Health Care Settings*',⁴ available at:
http://www.health.gov.on.ca/english/providers/program/infectious/diseases/best_prac/bp_ipcp_20080905.pdf).

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

In addition to the general assumption (*above*) about basic infection prevention and control, these best practices are based on the following additional assumptions and principles:

1. Best practices to prevent and control the spread of infectious diseases are routinely implemented in all health care settings, including:
 - a) Health Canada's '*Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care*' (Can Commun Dis Rep. 1999; 25 Suppl 4:1-142) [under revision],⁵ available at:
<http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/99vol25/25s4/index.html>.
 - b) Ministry of Health and Long-Term Care's '*Routine Practices and Additional Precautions in All Health Care Settings*',⁶ available at:
http://www.health.gov.on.ca/english/providers/program/infectious/diseases/ic_routine.html.
2. Adequate resources are devoted to infection prevention and control in all health care settings. See the Ministry of Health and Long-Term Care's '*Best Practices for Infection Prevention and Control Programs in Ontario*',⁴ available at:
http://www.health.gov.on.ca/english/providers/program/infectious/diseases/best_prac/bp_ipcp_20080905.pdf.
3. Programs are in place in all health care settings that promote good hand hygiene practices and ensure adherence to standards for hand hygiene. See:
 - a) Ministry of Health and Long-Term Care's '*Best Practices for Hand Hygiene in All Health Care Settings*',⁷ available at:
http://www.health.gov.on.ca/english/providers/program/infectious/diseases/ic_h.html.
 - b) Ontario's hand hygiene improvement program, '*Just Clean Your Hands*',⁸ available at:
<http://www.justcleanyourhands.ca>.
4. Adequate resources are devoted to Environmental Services/Housekeeping in all health care settings that include written procedures for cleaning and disinfection of client/patient/resident rooms and equipment; education of new cleaning staff and continuing education of all cleaning

staff; and ongoing review of procedures. See the MOHLTC's 'Best Practices for Environmental Cleaning in All Health Care Settings',⁹ available at:

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

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

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

7. Collaboration between professionals involved in OHS and Infection Prevention and Control is promoted in all health care settings to implement and maintain appropriate infection prevention and control standards that protect workers.
8. There are effective working relationships between the health care setting and local Public Health. Clear lines of communication are maintained and Public Health is contacted for information and advice as required and the obligations (under the *Health Protection and Promotion Act*, R.S.O. 1990, c.H.7)¹⁰ to report reportable and communicable diseases is fulfilled. Public Health provides regular aggregate reports of outbreaks of any infectious diseases in facilities and/or in the community to all health care settings.
9. Access to ongoing infection prevention and control advice and guidance to support staff and resolve differences is available to the health care setting.
10. There are established procedures for receiving and responding appropriately to all international, national, regional and local health advisories in all health care settings. Health advisories are communicated promptly to all staff responsible for reprocessing medical equipment/devices and regular updates are provided. Current advisories are available from Public Health, the Ministry of Health and Long-Term Care (MOHLTC), Health Canada and the Public Health Agency of Canada websites as well as local regional infection prevention and control networks.

11. Where applicable, there is a process for evaluating personal protective equipment (PPE) in the health care setting, to ensure it meets quality standards.
12. There is regular assessment of the effectiveness of the infection prevention and control program and its impact on practices in the health care setting. The information is used to further refine the program.⁴
13. The Ministry of Health and Long-Term Care's Long-Term Care Home Compliance and Enforcement Program requirements shall be met. Specific legislative requirements for long-term care providers may be found in:
 - The *Nursing Homes Act*,¹¹ available at:
http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90n07_e.htm
 - The *Nursing Homes Act*, R.R.O. 1990, Regulation 832, available at:
http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900832_e.htm
 - The *Homes for the Aged and Rest Homes Act*,¹² available at:
http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90h13_e.htm
 - The *Homes for the Aged and Rest Homes Act*, R.R.O. 1990, Regulation 637, available at:
http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900637_e.htm
 - The *Charitable Institutions Act*,¹³ available at:
http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90c09_e.htm
 - The *Charitable Institutions Act*, R.R.O. 1990, Regulation 69, available at:
http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900069_e.htm

In addition, all long-term care providers shall comply with all requirements outlined in the MOHLTC's '*Long-Term Care Homes Program Manual*',¹⁴ which is the core text governing the operation of long-term care homes in the province of Ontario. This manual contains policies, standards and norms covering various aspects of the LTC Homes Program such as:

- a) Risk Management, including:
 - infection control
 - health and safety
 - internal and external disaster planning
 - monitoring, evaluating and improving quality
 - b) Environmental Services, including:
 - waste management
 - pest control
 - housekeeping services
 - laundry services
 - maintenance services
 - c) Education, including:
 - orientation
 - ongoing in-service education
 - mandatory education programs
- The Long-Term Care Program Manual is available at:
http://www.health.gov.on.ca/english/providers/pub/manuals/ltc_homes/ltc_homes_mn.html#full.

- For more information, please contact your local Ministry of Health Service Area Office. A list of these offices is available at:

<http://www.infogo.gov.on.ca/infogo/office.do?actionType=telephonedirectory&infoType=telephone&unitId=UNT0028407&locale=en>.

14. Occupational Health and Safety requirements shall be met:

Health care facilities are required to comply with applicable provisions of the *Occupational Health and Safety Act* (OHSA), R.S.O. 1990, c.0.1 and its Regulations.¹⁵ Employers, supervisors and workers have rights, duties and obligations under the OHSA. Specific requirements under the OHSA are available at:

http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90o01_e.htm.

The *Occupational Health and Safety Act* places duties on many different categories of individuals associated with workplaces, such as employers, constructors, supervisors, owners, suppliers, licensees, officers of a corporation and workers. A guide to the requirements of the *Occupational Health and Safety Act* is available at:

<http://www.labour.gov.on.ca/english/hs/ohsaguide/index.html>.

Specific requirements for certain health care and residential facilities may be found in the *Regulation for Health Care and Residential Facilities*, available at:

http://www.e-laws.gov.on.ca/html/regis/english/elaws_regs_930067_e.htm.

In addition, the OHSA section 25(2)(h), the 'general duty clause', requires an employer to take every precaution reasonable in the circumstances for the protection of a worker. There is a general duty for an employer to establish written measures and procedures for the health and safety of workers, in consultation with the joint health and safety committee or health and safety representative, if any. Such measures and procedures may include, but are not limited to, the following:

- safe work practices
- safe working conditions
- proper hygiene practices and the use of hygiene facilities
- the control of infections

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

A worker who is required by his or her employer or by the *Regulation for Health Care and Residential Facilities* to wear or use any protective clothing, equipment or device shall be instructed and trained in its care, use and limitations before wearing or using it for the first time and at regular intervals thereafter and the worker shall participate in such instruction and training. The employer is reminded of the need to be able to demonstrate training, and is therefore encouraged to document the workers trained, the dates training was conducted, and materials covered during training. Under the *Occupational Health and Safety Act*, a worker must work in compliance with the Act and its regulations, and use or wear any equipment, protective devices or clothing required by the employer.

For more information, please contact your local Ministry of Labour office. A list of local Ministry of Labour offices in Ontario is available at <http://www.labour.gov.on.ca/>.

BEST PRACTICES FOR CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES 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..

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

- a) preventing transmission of microorganisms to personnel and clients/patients/residents; and
- b) 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^{1, 16}:

- a) adequate review by all parties whenever new equipment/devices are being considered for purchase (e.g., reprocessing committee);
- b) a centralized area for reprocessing or an area that complies with the requirements for reprocessing;
- c) written policies and procedures for reprocessing each type of medical equipment/device;
- d) training of all staff who perform reprocessing;
- e) validation of cleanliness, sterility and function of the reprocessed equipment/device;
- f) continual monitoring of reprocessing procedures to ensure their quality;
- g) a corporate strategy for dealing with single-use medical equipment/devices;
- h) management and reporting of medical incidents;
- i) management and reporting of safety-related accidents;
- j) recall of improperly reprocessed devices; and
- k) procedures to be followed in emergency situations (e.g., utilities shutdowns, compromised packaging, biological indicator (BI) testing failures)

“Effective reprocessing requires rigorous compliance with recommended protocols.”

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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.

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

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

respect to reprocessing, whether done centrally or elsewhere.

When formulating written policies and procedures, the following steps in reprocessing must be included¹⁶.

- a) collection at point-of-use, containment and transport;
- b) disassembly (if required);
- c) inspection;
- d) cleaning;
- e) disinfection/sterilization (including establishment of the level of reprocessing required for items, based on the risk class and manufacturer's instructions);
- f) rinsing (following disinfection);
- g) drying/aeration;
- h) reassembly and functional testing;
- i) quarantine of non-implantable items in processed loads pending results of biological indicator (BI) testing (if load quarantine is not possible, evaluation of a Class 5 or 6 chemical indicator (CI) and specific cycle physical parameters may be used to justify the release of loads);
- j) quarantine of each load containing implantable devices pending results of BI testing;
- k) clean transportation; and
- l) storage.

It is essential that an **overall inventory** of all reprocessing practices within the healthcare setting is done, including documentation as to 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:

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

II. Best Practices

1. Purchasing and Assessing Medical Equipment/Devices and/or Products for 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.

A. Equipment/Device Purchases

The administration of the health care setting is responsible for verifying that any product used in the provision of care to clients/patients/residents is capable of being cleaned, disinfected and/or sterilized according to the most current standards and guidelines from the Canadian Standards Association (CSA), the 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 washers, pasteurizers, washer-disinfectors, automated endoscope reprocessors/AERs, sterilizers) must also meet standards established by Health Canada/PHAC, the CSA¹⁶ and the requirements of this document.

Decision-making prior to purchasing medical equipment/devices and reprocessing equipment shall involve representatives from the departments in the health care setting that will use, reprocess and maintain the items and should include^{1, 16}:

- a) Sterile Processing;
- b) Purchasing;
- c) Operating Room or other unit/department that will use the device;
- d) Risk Management;
- e) Infection Prevention and Control;
- f) Occupational Health and Safety;
- g) client/patient/resident care services;
- h) support services;
- i) physical plant/maintenance; and
- j) Biomedical Engineering.

Reprocessing staff, Infection Prevention and Control, Biomedical Engineering and Occupational Health and Safety must make recommendations regarding the ability to achieve the appropriate level of reprocessing required for the equipment/device according to Spaulding's criteria¹⁷ (see Table 1) and the suitability of the equipment/device for purchase, after reviewing:

- a) the manufacturer's directions;
- b) applicable CSA standards regarding the equipment/device;
- c) Health Canada/PHAC guidelines regarding the equipment/device; and
- d) MOHLTC best practices for cleaning, disinfection and sterilization.

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

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

Newly purchased non-sterile critical and semicritical medical equipment/devices shall first be inspected and decontaminated according to their intended use prior to being put into circulation.¹⁶ Refer to Table 1, "Spaulding's Classification of Medical Equipment/Devices and Required Level of Reprocessing" (see page 35) for the level of processing that is to be used for medical equipment/devices based on the intended use of the equipment/device.

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

B. Manufacturer's Recommendations

The manufacturer's information for all medical equipment/devices and decontamination equipment must be received and maintained in a format that allows for easy access by staff carrying out the reprocessing activities.¹⁶ The manufacturer must supply the following:

- a) information about the design of the equipment/device;
- b) written and/or electronic manuals/directions for use^{1, 16};
- c) device-specific recommendations for disassembly, cleaning and reprocessing of equipment/device, including evidence that the device has been validated for disinfection/sterilization using the recommended process(-es)^{1, 16};
- d) recommended detergents, enzymatic cleaners, disinfectants/sterilants and lubricants for use with the equipment/device;
- e) recommended equipment/device exposure time to chemical agents;
- f) education for staff on use, cleaning and the correct reprocessing of the equipment/device;
- g) limitations related to number of times the equipment/device may be reprocessed without degradation^{1, 16}; and
- h) recommendations for auditing the recommended process.

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/devices¹⁸ 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*.¹⁹

Once the decision to use the equipment/device is made, the following questions must then be addressed:

- a) 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?
- b) Who will reprocess the equipment/device?
- c) Where will the reprocessing be done?
- d) What process will be used for reprocessing?

- e) Are personnel certified to carry out this procedure (this includes training in the procedure, auditing the process, regular re-education and re-certification)?
- f) How often will audits be performed?
- g) If there are limits to the number of times the equipment/device may be reprocessed, how is this tracked and by whom?

C. Loaned, Shared and Leased Medical Equipment/Devices

Health care facilities 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,¹⁸ including endoscopes. The following should be included in the policy:

- a) in addition to the requirements in Section II.1.A, equipment/devices loaned to a health care facility 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 Sterile Processing Department (SPD) at least 24 hours before use; **a facility shall not accept for use any medical equipment/device that does not arrive in sufficient time to allow the receiving facility 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 facility 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) a record of the identification number of the equipment/device;
 - 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; and
 - iv) there must be documentation about the reason for using loaned equipment and awareness of the possible consequences;
- f) borrowed equipment/devices must be cleaned and reprocessed before being returned 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 and provincial regulations regarding the transport of dangerous goods:
 - *Transportation of Dangerous Goods Act*,²⁰ S.C., 1992, c.34. Available at: <http://laws.justice.gc.ca/PDF/Statute/T/T-19.01.pdf>;
 - *Dangerous Goods Transportation Act*, R.S.O. 1990, c. D.1. Available at: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90d01_e.htm;
 - ii) clean equipment/devices must be transported in a manner that does not compromise the integrity of the clean item.

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

- h) the use of loaned equipment/devices for neurosurgical procedures is strongly discouraged (see Section II.1.D).

D. Creutzfeldt-Jakob Disease (CJD)

Creutzfeldt-Jakob disease (CJD) is caused by infection with a prion, which is a fragment of protein that is resistant to most of the usual methods of reprocessing and decontamination. Specific recommendations 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).²¹ 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).^{21, 22}

Because of the risks associated with Creutzfeldt-Jakob disease (CJD), surgical instruments that are used on high risk neurological and eye tissue from clients/patients/residents 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"²¹; available at: <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/02vol28/28s5/index.html>.

Recommendations:

- 1. Do not purchase medical equipment/devices that cannot be cleaned and reprocessed according to the recommended standards.**
- 2. When purchasing reprocessing equipment or chemical products for reprocessing, consideration must be given to Occupational Health requirements, client/patient/resident safety and environmental safety issues.**
- 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) must meet established quality reprocessing parameters. Such equipment should not be purchased or used until this process is established.**
- 4. Manufacturers' 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.**
- 5. Newly purchased, non-sterile critical and semicritical medical equipment/devices shall first be inspected and reprocessed according to their intended use.**
- 6. 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.**
- 7. Because of the risks associated with Creutzfeldt-Jakob disease (CJD), surgical instruments that are used on high risk neurological and eye tissue from clients/patients/residents 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".**

2. Environmental Requirements for Reprocessing Areas

A. Physical Space

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. In smaller settings, such as clinics or offices in the community, this refers to any segregated area where reprocessing of equipment/devices takes place, away from clients/patients/residents and clean areas.

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.

The environment where cleaning/decontamination is performed must^{1, 16}:

- 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 and disinfected;
- e) have slip-proof flooring that can withstand wet mopping and hospital-grade cleaning and disinfecting products; and
- f) have restricted access from other areas in the setting and ensure one-way movement by staff.

Decontamination work areas shall 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 cleaning. Walls or partitions should be cleaned regularly and be constructed of materials that can withstand cleaning and disinfection.¹⁶

Decontamination sinks¹⁶:

- a) shall be designed and arranged to facilitate soaking, washing and rinsing of equipment/devices with minimal movement or delay between steps;
- b) should be adjacent to waterproof counter tops and a backsplash;
- c) shall not have an overflow;
- d) should be at a height that allows workers to use them without bending or straining;
- e) should be large enough to accommodate trays or baskets of instruments;
- f) should be deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated during cleaning; and
- g) should be equipped with water ports for the flushing of instruments with lumens, if appropriate.

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

- a) accessible hand washing sinks with hands-free controls, soap dispensers and paper towels; and/or
- b) alcohol-based hand rub (ABHR).

➤ Refer to Appendix B, 'Recommendations for Physical Space for Reprocessing', for details regarding reprocessing area space requirements.

B. Air Quality

The Regulation respecting Control of Exposure to Biological and Chemical Agents (O. Reg. 833/90) made under the *Occupational Health and Safety Act* provides occupational exposure limits such as ceiling exposure value (CEV) for chemical agents (e.g., glutaraldehyde). A CEV is the maximum airborne concentration of a chemical agent to which a worker is exposed at any time. If control measures are not available during reprocessing involving a chemical agent, air sampling may be required to ensure that the regulated limit has not been exceeded for the chemical being used.

The health care setting must have air changes, temperature and humidity appropriate to the process/product being used (refer to manufacturer's recommendations for products and CSA Standards). In health care settings where there are dedicated central reprocessing areas, negative pressure airflow must be maintained in soiled areas and positive pressure airflow must be maintained in clean areas and be monitored.¹⁶

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

C. Water Quality

The health care setting should be aware of the quality of its water supply and develop policies to address known problems. There should be written reprocessing contingency plans in place that address loss of potable water, boil water advisories and other situations where the water supply becomes compromised.

- Refer to Appendix B, '*Recommendations for Physical Space for Reprocessing*', for information regarding reprocessing area water quality requirements

D. Environmental Cleaning in Sterile Processing Departments

The housekeeping department should consult with the management of the sterile processing department and infection prevention and control to establish policies and procedures for cleaning practices and cleaning frequency. As a minimum¹⁶:

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

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

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

Recommendations:

8. ***There must be a centralized area for reprocessing medical equipment/devices.***
9. ***The decontamination work area shall be physically separated from clean areas by walls or partitions.***
10. ***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.***
11. ***Wherever chemical disinfection/sterilization is performed, air quality must be monitored when using products that produce toxic vapours and mists.***
12. ***There must be a regular schedule for environmental cleaning in the Sterile Processing Department that includes written procedures and clearly defined responsibilities.***

3. Policies and Procedures

Policies and procedures must be established to ensure that the disinfection processes follow the principles of infection prevention as set out by the Public Health Agency of Canada/Health Canada,²³ the CSA standards^{1, 16} and these Ontario MOHLTC best practices. Completed policies and procedures should be reviewed by an individual with infection prevention and control expertise¹⁶ (e.g., facility's infection prevention and control professionals, public health staff with certification in infection prevention and control, Regional Infection Control Network). Review of reprocessing policies and procedures must take place at least annually.

Reprocessing policies and procedures shall include the following¹⁶:

- a) responsibilities of management and staff;
 - b) qualifications, education and training for staff involved in reprocessing;
 - c) infection prevention and control activities;
 - d) worker health and safety activities;
 - e) preventive maintenance requirements with documentation of actions;
 - f) written protocols for each component of the cleaning, disinfection and/or sterilization process that are based on the manufacturer's recommendations and established guidelines for the intended use of the product;
 - g) provision for annual review of policies and procedures with updating as required;
 - h) documentation and maintenance of records for each process;
 - i) ongoing audits of competency and procedures (who, when, how);
 - j) management and reporting to administration or appropriate regulatory body of incidents where client/patient/resident safety may have been compromised;
 - k) requirements for internal or external subcontractors, if applicable;
 - l) written procedures for the recall and reprocessing of improperly reprocessed medical equipment/devices¹; and
 - m) a protocol that prevents the release of loads containing implantable devices pending results of BI testing.
- See Section II.15, 'Continued Monitoring and System Failures', for more information about the recall procedure.

Recommendations:

- 13. 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.**
- 14. All policies and procedures for reprocessing medical equipment/devices require review by an individual with infection prevention and control expertise.**
- 15. A procedure shall be established for the recall of improperly reprocessed medical equipment/devices.**

4. Education and Training

The manager and all supervisors involved in reprocessing must, as a minimum, have completed a recognized qualification/certification course in reprocessing practices.¹⁶ A plan must be in place for each person involved in reprocessing to obtain this qualification.

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

- Refer to Appendix G, 'Resources for Education and Training', for a list of education and training resources.

Supervisory staff must be competent through education, training and experience in the reprocessing of reusable medical equipment/devices.^{1, 16} It is the supervisor's responsibility to ensure that:

- a) any individual involved in the cleaning, disinfection and/or sterilization of medical equipment/devices is properly trained and their practice audited on a regular basis to verify that standards are met;
- b) training includes information on cleaning, disinfection and sterilization, occupational health and safety issues, and infection prevention and control;
- c) orientation and continuing education is provided and documented for all personnel involved in reprocessing of medical equipment/devices; and
- d) feedback is provided to reprocessing staff in a timely manner.

All staff involved in reprocessing of medical equipment/devices must be supervised and shall be qualified through education in a formally recognized course for sterilization technology, training and experience in the functions they perform.^{1, 16} 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 and will ensure that:

- a) all staff who are primarily involved in reprocessing obtain and maintain certification;
- b) any individual involved in any aspect of reprocessing obtains education, orientation 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 is a process in place to ensure continued competency, including continuing education provided at regular intervals and periodic competency assessment¹; and
- d) all orientation, training and continuing education is documented.¹⁶

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

- Refer to the CSA's 'Z314.8-08 Decontamination of Reusable Medical Devices'¹⁶ for details regarding specific requirements of training, orientation and continuing education programs for reprocessing staff.

Recommendations:

- 16. 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.**
- 17. All aspects of reprocessing shall be supervised and shall be performed by knowledgeable, trained personnel.**
- 18. Managers, supervisors and staff involved in reprocessing shall have completed a recognized qualification/certification course in reprocessing practices.**
- 19. A plan must be in place for each person involved in reprocessing to obtain certification qualification.**

5. Occupational Health and Safety for Reprocessing

Occupational Health and Safety for the health care setting must review all protocols for reprocessing medical equipment/devices to verify that staff safety measures are followed and 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. 495/09*.¹⁵ This review will verify that:

- a) sharps are handled appropriately^{1, 24};
- b) local exhaust ventilation systems adequately protect staff from toxic vapours^{16, 25};
- c) chemicals are labelled, stored and handled appropriately, and Material Safety Data Sheets (MSDS) are readily available as required by the *Workplace Hazardous Materials Information System (WHMIS)*, R.R.O. 1990, Reg. 860 Amended to O. Reg. 36/93³;
- d) an eyewash fountain is installed to prevent a potential hazard to the eye due to contact with a biological or chemical agent²⁶; and
- e) personal protective equipment such as elbow length impervious gloves (insulated if using a steam autoclave) for unloading the autoclave are present and comply with regulatory requirements.

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

A. Routine Practices

Routine practices^{5, 6} must be part of all staff education and training to prevent exposure to body substances. Procedures must be in place for immediate response to staff exposure to blood and body fluids or injury from sharp objects.²⁷ All staff working in reprocessing must be immune to Hepatitis B or receive Hepatitis B immunization.^{1, 25, 27}

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

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Routine practices in reprocessing areas include:

- a) a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics or lip balm and handling contact lenses in the reprocessing area^{1, 16};
- b) no storage of personal effects, including food and drink, in the reprocessing area¹;
- c) hand hygiene facilities located at all entrances to, and exits from, reprocessing areas and faucets should be supplied with foot-, wrist- or knee-operated handles or electronic sensors^{1, 16};
- d) training of staff involved in reprocessing in hand hygiene^{1, 7, 16}.

- i) hands are cleaned before beginning work, before breaks and upon completion of work; after removing gloves; and whenever hands are contaminated with body substances;
 - ii) if there is visible soil on the hands, hand hygiene is performed with soap and water; if there is no visible soil on the hands, staff may use either soap and water or an alcohol-based hand rub (ABHR);
 - iii) hand and arm jewellery or nail enhancements are not worn; and
- e) provision for, and wearing of, appropriate PPE for all reprocessing activities.
- More information on Routine Practices may be found in the MOHLTC's *'Routine Practices and Additional Precautions for All Health Care Settings'*⁶, available at:
http://www.health.gov.on.ca/english/providers/program/infectious/diseases/ic_routine.html.

B. Personal Protective Equipment (PPE)

Staff involved in reprocessing must be trained in the correct use, wearing, limitations and indications for PPE^{1, 6, 16}:

- a) PPE worn for cleaning and handling contaminated equipment/devices includes gloves appropriate to the task, face protection (i.e., full face shield OR fluid-impervious face mask and protective eyewear)¹ and impermeable gown or waterproof apron; refer to the MOHLTC's *'Routine Practices and Additional Precautions for All Health Care Settings'*⁶, Appendix M, for guidance in choosing task-specific PPE;
 - b) 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;
 - c) PPE is removed on completion of the task for which it was indicated and before leaving the reprocessing area¹;
 - d) staff must be trained in management of a blood or body fluid spill^{1, 16}; and
 - e) where there is the risk of exposure to biological and/or chemical agents, eye wash stations must be provided and staff must be trained in their use.
- More information on PPE may be found in the MOHLTC's *'Routine Practices and Additional Precautions for All Health Care Settings'*⁶, available at:
http://www.health.gov.on.ca/english/providers/program/infectious/diseases/ic_routine.html.

C. Safe Handling of Sharps

Procedures shall be in place to prevent injuries from sharp objects. When working with sharps, staff in the decontamination area shall¹⁶:

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

D. Work Restrictions

Reprocessing staff are subject to some work restrictions¹:

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

Recommendations:

- 20. Occupational Health and Safety for the health care setting will review all protocols for reprocessing medical equipment/devices to verify that worker safety measures and procedures to eliminate or minimize the risk of exposure are followed and are in compliance with the Occupational Health and Safety Act, R.S.O. 1990, c.O.1 and its Regulation including the Health Care and Residential Facilities - O. Reg. 67/93 amended to O. Reg. 631/05.**
- 21. There is a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics or lip balm and handling contact lenses in the reprocessing area.**
- 22. Appropriate personal protective equipment (PPE) shall be worn for all reprocessing activities.**
- 23. All staff working in reprocessing shall be offered Hepatitis B immunization unless they have documented immunity to Hepatitis B.**
- 24. Measures and procedures shall be written to prevent and manage injuries from sharp objects.**
- 25. Measures and procedures shall be in place for immediate response to worker exposure to blood and body fluids.**

6. Transportation and Handling of Contaminated Medical Equipment/Devices

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 surfaces¹⁶:

- a) closed carts or covered containers designed to prevent the spill of liquids, with easily cleanable surfaces, shall be used for handling and transporting soiled medical equipment/devices;
- b) soiled equipment/devices shall be transported by direct routes, that avoid high-traffic, clean/sterile storage and client/patient/resident care areas, to areas where cleaning will be done;
- c) containers or carts used to transport soiled medical equipment/devices shall be cleaned after each use; and
- d) disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point-of-use, prior to transportation.

Recommendations:

- 26. Disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point-of-use, prior to transportation.**
- 27. 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.**

- 28. A process shall 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).**
- 29. Contaminated equipment/devices shall not be transported through areas designated for storage of clean or sterile supplies, client/patient/resident care areas or high-traffic areas.**
- 30. Sterile and soiled equipment/devices shall not be transported together.**

7. Factors Affecting the Efficacy of the Reprocessing Procedure

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

Many factors^{16, 23, 28} 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) **Characteristics of equipment/device¹⁶:**
 - i) long, narrow lumens and channels are difficult to clean;
 - ii) materials such as rubber and plastic may require special treatment;
 - iii) rough or porous surfaces may trap microorganisms (e.g., ridges, ribbing, grooves, articulations);
 - iv) hinges, cracks, coils, valves, joints, clamps, crevices on the equipment/device may impede successful disinfection/sterilization.
- c) **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 disinfectant²⁹;
 - 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 decrease as dilution of the product occurs and organic impurities accumulate²⁹ (see 13, 'Flash Sterilization');
 - v) use the appropriate disinfectant/sporicide for the task; infection prevention and control must approve disinfectants and their application; and
 - vi) some microorganisms are more resistant to disinfectants/sporicides, and this must be taken into consideration when choosing the product/process;
- d) **Duration and temperature of exposure to the product:**
 - i) use Health Canada/PHAC recommendations for the level of disinfection/sterilization required for the intended use of the equipment/device and minimum exposure time to disinfectants/sterilants to achieve this level (refer to Appendix F, 'Advantages and Disadvantages of Currently Available Reprocessing Options');

- ii) use manufacturer's recommendations for temperature and for exposure time required to achieve the desired level of disinfection/sterilization;
 - iii) do not exceed the manufacturer's maximum exposure time, as some chemicals may cause damage to the medical equipment/device if used for extended periods of time;
 - iv) where the manufacturer's recommendations for minimum exposure time conflict with those of Health Canada/PHAC, an infection prevention and control professional must be consulted for advice;
 - v) all surfaces of the article must be in direct contact with the disinfectant/sterilant; and
 - vi) contact may be compromised by the complexity of the article and the ability of the disinfectant to penetrate lumens etc.;
- e) **Physical and chemical properties of the reprocessing environment:**
- i) water hardness can affect some disinfectants (refer to Appendix B, 'Recommendations for Physical Space for Reprocessing');
 - ii) excessive humidity may compromise sterile wrappings (refer to Appendix B, 'Recommendations for Physical Space for Reprocessing'); and
 - iii) the pH of the solution may be an important consideration, as extremes of acidity or alkalinity can limit growth of microorganisms or alter the activity of disinfectants and sterilants.

Recommendations:

31. ***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.***

8. Disassembly, Inspection and Cleaning of 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."

Public Health Agency of Canada/Health Canada

Reusable medical equipment/devices must be thoroughly cleaned before disinfection or sterilization.²³ The process of cleaning physically removes contaminants from the equipment/device, rather than killing microorganisms. If an item is not cleaned, soil (e.g., blood, body fluids, dirt) can protect the microorganisms from the action of the disinfection or sterilization process making it ineffective, as well as inactivate the disinfectant or sterilant so that it does not work. Disinfectants that become overloaded with soil can become contaminated and may become a source for transmission of microorganisms.

Cleaning is always essential prior to disinfection or sterilization. An item that has not been cleaned cannot be adequately disinfected or sterilized.²³

A. Pre-Cleaning

Gross soil (e.g., faeces, sputum, blood) shall be removed immediately at point-of-use.¹⁶ If cleaning cannot be done immediately, the medical equipment/device must be submerged in tepid water and detergent or enzymatic cleaner to prevent organic matter from drying on it.^{1, 23, 28}

Factors that affect the ability to effectively clean medical equipment/devices must be considered prior to cleaning. See Section II.7, '*Factors Affecting the Efficacy of the Reprocessing Procedure*', for a list of factors that must be considered prior to cleaning medical equipment/devices.

Policies and procedures for cleaning medical equipment/devices shall be based on the manufacturer's instructions and must be developed in consultation with Infection Prevention and Control, Occupational Health and Safety, Biomedical Engineering and Environmental Services.^{1, 16} Full PPE shall be worn for handling and cleaning contaminated equipment/devices (see Section II.5.B).

Once medical equipment/devices have been received in the reprocessing area/department, they must be disassembled, sorted and soaked:

- a) **Disassembly** – facilitates access of the cleaning agent, disinfectant and/or sterilant to device surfaces:
 - i) equipment/devices shall be disassembled¹⁶ prior to cleaning if there is one or more removable part²⁸, unless otherwise recommended by the manufacturer; and
 - ii) follow the manufacturer's recommendations when disassembling medical equipment/devices prior to washing.
- b) **Sorting** – keeps medical equipment/devices that belong to a set together and streamlines the cleaning process:
 - i) sort equipment/devices into groups of like products requiring the same processes; and
 - ii) segregate sharps and/or delicate equipment/devices to prevent injury to personnel and damage to the equipment/device.
- c) **Soaking** – prevents soil from drying on equipment/devices and makes them easier to clean:
 - i) soak equipment/device in a hospital approved instrument soaking solution;
 - ii) do not use saline as a soaking solution as it damages some medical equipment/devices;
 - iii) use detergent-based products, including those containing enzymes, as part of the soaking process;
 - iv) ensure that detergents (including enzymatic cleaners) are appropriate to the equipment/device being cleaned (products used must be approved by the equipment/device manufacturer)¹⁶; and
 - v) avoid prolonged soaking (e.g., overnight) of equipment/devices.

B. Cleaning

Cleaning may be done manually or using mechanical cleaning machines (e.g., washer-disinfector, ultrasonic washer, washer-sterilizer) after gross soil has been removed. Automated machines may increase productivity, improve cleaning effectiveness and decrease staff exposure to blood and body fluids.²⁸ Manual cleaning may be required for delicate or intricate items.

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

a) Physical Removal of Organic Materials

- i) completely submerge immersible items during the cleaning process to minimize aerosolization of microorganisms and assist in cleaning¹⁶;
- ii) minimize the production of aerosols when cleaning non-immersible equipment/devices;
- iii) remove gross soil using tools such as brushes and cloths;

b) Manual Cleaning¹⁶

- i) clean equipment/devices that have lumens with a brush, according to the manufacturer's instructions, then manually or mechanically flush with a detergent solution and rinse;
- ii) check equipment/devices with lumens for obstructions and leakage;

c) Mechanical Cleaning¹⁶

Whenever possible, clean equipment/devices by mechanical means:

- i) use mechanical washers in accordance with the manufacturer's instructions;
- ii) manually clean heavily soiled equipment/devices before mechanical cleaning;
- iii) Ensure that the equipment/device to be cleaned is compatible with the mechanical cleaning equipment and chemical solutions that are being used;
- iv) 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:
 - the manufacturer's instructions must be followed for use and routine cleaning and maintenance of the ultrasonic washer
 - equipment/devices shall be completely immersed in the washing solution
 - after cleaning, equipment/devices shall be rinsed thoroughly prior to further reprocessing
 - the ultrasonic washing solution should be changed at least daily or more frequently if it becomes visibly soiled or if the manufacturer's instructions specify more frequent changes
- v) washer-disinfectors are strongly recommended for medical 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
 - the manufacturer's instructions must be followed for the use and routine 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**

d) Care of Cleaning Tools

- i) inspect brushes and other cleaning equipment for damage after each use, and discard if necessary¹⁶;
- ii) clean, disinfect, dry and store tools used to assist in cleaning (e.g., brushes, cloths)¹⁶;

e) 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, pyrogen-free water (note: distilled water is not necessarily sterile or pyrogen-free);

f) Drying¹⁶

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;
- iii) dry lumens with compressed air that has been filtered and dried;
- iv) dry stainless steel equipment/devices immediately after rinsing to prevent spotting.

C. Post-Cleaning

Once medical equipment/devices have been reprocessed, there must be a process to ensure that they can be differentiated from equipment/devices which have not been reprocessed. Sterilized items may be identified using external chemical indicators (CIs), such as autoclave tape, which changes colour during sterilization. Equipment/devices which receive high-level disinfection should also be labelled, tagged or colour-coded to indicate that they have been reprocessed.

The following procedures must be included following the cleaning process^{1, 16}:

a) Reassembly and 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) do not reassemble equipment/device prior to disinfection/sterilization; if the equipment/device manufacturer's instructions specify reassembly at this stage in the reprocessing, it shall take place in a clean area and be performed in accordance with the manufacturer's instructions;

b) Lubrication

- i) follow the manufacturer's guidelines for lubrication;
- ii) equipment/devices requiring lubrication shall be lubricated prior to sterilization;
- iii) lubricants shall be compatible with the device and with the sterilization process;
- iv) discard lubricants on or before the expiry date or when visibly soiled or contaminated;

c) Wrapping

- i) equipment/devices that are to be sterilized require wrapping prior to sterilization (except for flash sterilization - see Section II.13, 'Flash Sterilization');
- ii) materials used for wrapping shall be prepared in a manner that will allow adequate air removal, steam penetration and evacuation to all surfaces;
 - Refer to CSA Z314.3-09, 'Effective Sterilization in Health Care Facilities by the Steam Process' for information on packaging materials, containers and methods.¹

d) 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.

Recommendations:

- 32. Reusable medical equipment/devices must be thoroughly cleaned before disinfection or sterilization.**
- 33. If cleaning cannot be done immediately, the medical equipment/device must be submerged in tepid water and detergent or enzymatic cleaner to prevent organic matter from drying on it.**
- 34. Factors that affect the ability to effectively clean medical equipment/devices must be considered prior to cleaning.**

35. The process for cleaning should include written protocols for disassembly, sorting, soaking, physical removal of organic material, rinsing, drying, physical inspection, lubrication and wrapping.

36. Audits of the cleaning process must be done on a regular basis.

9. Selection of Product/Process for Reprocessing

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

- 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; and
- the manufacturer must provide written information regarding the safe and appropriate reprocessing of the medical equipment/device.

A. Reprocessing Process

The classification system developed by Spaulding¹⁷ 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	Examples
Critical Equipment/Device	Equipment/device that enters sterile tissues, including the vascular system	Cleaning followed by Sterilization	- Surgical instruments - Biopsy instruments - Foot care equipment
Semicritical Equipment/Device	Equipment/device that comes in contact with non-intact skin or mucous membranes but do not penetrate them	Cleaning followed by High-Level Disinfection (as a minimum) Sterilization is preferred	- Respiratory therapy equipment - Anaesthesia equipment - Tonometer
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)	- ECG machines - Oximeters - Bedpans, urinals, commodes

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

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.

B. Reprocessing Products

Products used for any/all stages in reprocessing (i.e., cleaning, disinfection, sterilization) must be:

- a) appropriate to the level of reprocessing that is required for the use of the medical equipment/device; and
- b) approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise (e.g., facility's infection prevention and control professionals, public health staff with certification in infection prevention and control, regional infection control network).

Recommendations:

- 37. 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.**
- 38. 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.**
- 39. Products used for decontamination must be appropriate to the level of reprocessing that is required for the use of the medical equipment/device.**
- 40. The process and products used for cleaning, disinfection and/or sterilization of medical equipment/devices must be compatible with the equipment/devices.**
- 41. 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.**

10. 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."

Public Health Agency of Canada/Health Canada

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.

Noncritical and semicritical medical equipment/devices that are owned by the client and re-used by a single client in their home do not require disinfection between uses,

Noncritical and semicritical medical equipment/devices that are owned by the client and re-used by a single client in their home do not require disinfection between uses, provided they are adequately cleaned prior to reuse.

provided that they are adequately cleaned prior to re-use.

- See Section II.8, “*Disassembly, Inspection and Cleaning of Reusable Medical Equipment/Devices*”, for cleaning requirements prior to disinfection.

A. 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, rinsed and excess rinse water is removed. The container used for disinfection must be washed, rinsed and dried when the solution is changed. Refer to Appendix A, ‘*Reprocessing Decision Chart*’, for chemical products that may be used to achieve low-level disinfection.

Noncritical medical equipment/devices require decontamination using a low-level disinfectant.^{23, 28}

B. 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, rinsed and excess rinse water is removed. Refer to Appendix A, ‘*Reprocessing Decision Chart*’, and Appendix E, ‘*Advantages and Disadvantages of Currently Available Reprocessing Options*’ for chemical products that may be used to achieve high-level disinfection.

Sterilization is the preferred method of decontamination for semicritical medical equipment/devices.

Semicritical medical equipment/devices require decontamination using, at a minimum, high-level disinfection.^{23, 28} Sterilization is the preferred method of decontamination.

C. Methods of Disinfection for Semicritical Medical Equipment/Devices

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

1. Liquid Chemical Disinfection

When selecting a disinfectant for reprocessing medical equipment/devices in the health care setting, consider¹⁶:

- a) the requirement for disinfectants to have a Drug Identification Number (DIN) from Health Canada²³;
- b) efficacy for the intended use;
- c) compatibility with the equipment/device and surfaces to be disinfected;
- d) compatibility with detergents, cleaning agents and disinfection and/or sterilization processes;
- e) the intended end use of the equipment/devices to be disinfected;

- f) the method for monitoring the product concentration;
- g) recommendations for rinsing (e.g., water quality, volume, time);
- h) safety for use, with minimal toxic and irritating effects to/for staff⁹; and
- i) environmental safety and biodegradability.⁹

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

- a) usage - 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;
- b) 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 professional must be consulted for advice);
- c) shelf life;
- d) storage;
- e) appropriate dilution; and
- f) required PPE.

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, available at: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php>.

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

- a) chemical test strips should be used to determine whether an effective concentration of active ingredients is present, despite repeated use and dilution:
 - i) the frequency of testing should be based on how frequently the solutions are used (i.e., test daily if used daily);
 - ii) 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;
 - iii) test strips must not be considered a way of extending the use of a disinfectant solution beyond the expiration date;
- b) a permanent record of processing shall be completed and retained according to the policy of the facility¹⁶; this record shall include, but not be limited to:
 - i) the identification of the equipment/device to be disinfected;
 - ii) date and time of the clinical procedure;
 - iii) concentration and contact time of the disinfectant used in each process;
 - iv) results of each inspection (and, for endoscopes, each leak test);
 - v) result of each testing of the disinfectant; and
 - vi) the name of the person completing the reprocessing.
- c) 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;
- d) prepared solutions shall not be topped up with fresh solution¹⁶;
- e) if manual disinfection is performed, the container used for disinfection shall be kept covered during use¹⁶ and washed, rinsed and dried when the solution is changed; and
- f) 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.

2. Pasteurization

Pasteurization is a process of hot water disinfection (minimum 71°C /160°F for 30 minutes¹⁶), 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 (see Section II.8, 'Disassembly, Inspection and Cleaning of Reusable Medical Equipment/Devices', for information about cleaning prior to pasteurization).

Advantages of pasteurization include:

- a) no toxicity;
- b) rapid disinfection cycle; and
- c) moderate cost of machinery and upkeep.

Disadvantages of pasteurization include:

- a) may cause splash burns;
- b) difficulty validating the effectiveness of the process; and
- c) pasteurizers and related equipment can become contaminated without a good preventive maintenance program and careful monitoring of processes.

The manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated:

- a) 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;
- b) water temperature within the pasteurizer should be verified weekly by manually measuring the cycle water temperature;
- c) cycle time should be verified manually and recorded daily;
- d) calibration of pasteurization equipment will be performed according to the manufacturer's recommendations;
- e) daily cleaning of pasteurizing equipment is required following the manufacturer's recommendations; and
- f) following pasteurization, medical equipment/devices should be inspected for wear, cracks or soil:
 - i) damaged equipment/devices shall be handled according to facility procedures; and
 - ii) soiled equipment/devices shall be reprocessed.

Following pasteurization, medical equipment/devices shall be handled in a manner that prevents contamination. Equipment/devices shall be transported directly from the pasteurizer to a clean area for drying, assembly and packaging. Medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and is used exclusively for the drying of pasteurized equipment/devices.¹⁶ A preventive maintenance program for drying cabinets must be implemented and documented.

Printed records of each cycle (i.e., temperature, time) shall be retained in accordance with the health care setting's requirements.¹⁶

Recommendations:

42. Noncritical medical equipment/devices are to be decontaminated using a low-level disinfectant.

43. Semicritical medical equipment/devices must be decontaminated using, at a minimum, high-level disinfection. Sterilization is the preferred method of decontamination.

44. **Noncritical and semicritical medical equipment/devices that are owned by the client and re-used by a single client in their home do not require disinfection between uses, provided that they are adequately cleaned prior to re-use.**
45. **All disinfectants must have a Drug Identification Number (DIN) from Health Canada.**
46. **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.**
47. **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.**
48. **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.**
49. **Manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated.**
50. **A preventive maintenance program for pasteurizing equipment must be implemented and documented.**
51. **Following the pasteurizing cycle, medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and that is used exclusively for the drying of pasteurized equipment/devices.**
52. **A log of contents, temperature and time is to be maintained for each pasteurizer cycle.**

11. 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 and laparoscopes. **Critical endoscopes shall be sterilized prior to use.**

Semicritical Endoscope: Fibreoptic 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. **Semicritical endoscopes require a minimum of high-level disinfection prior to use.**

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

Due to the complexity of their design, flexible fibreoptic and video endoscopes ('semicritical endoscopes') require special cleaning and handling.^{16,30}

A. Education and Training

Individuals responsible for reprocessing endoscopes require training and must meet the health care setting's written endoscope processing competency requirements, which include ongoing education and training:¹⁶

- a) staff assigned to reprocess endoscopes must receive device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilization;
- b) competency testing of personnel reprocessing endoscopes shall be performed at least annually¹⁶; and
- c) temporary personnel shall not be allowed to reprocess endoscopes until competency has been established.³⁰

B. Physical Space

The area used to reprocess endoscopes must include^{16, 30, 31}:

- a) adequate space for the storage and holding of clean and soiled materials that is separate from other activities and controlled to prohibit public contact;
- b) dedicated processing room(s) for cleaning and decontaminating instruments that are physically separated from clean areas, client/patient/resident care areas and procedure rooms;
- c) within processing/decontamination rooms, utility sink(s) appropriate to the volume of work and method of decontamination;
- d) dedicated hand hygiene sink(s);
- e) eye-washing facilities;
- f) sufficient cleanable counter space to handle the volume of work;
- g) space and utility connections for automatic endoscope reprocessor(s) (AER), if used;
- h) ventilation system that will remove toxic vapours generated by, or emitted from, cleaning or disinfecting agents;
 - i) the vapour concentration of the chemical disinfectant used shall not exceed allowable limits²⁵ (e.g., 0.05 ppm for glutaraldehyde);
 - ii) air-exchange equipment (e.g., ventilation system, exhaust hoods) should be used to minimize the exposure of all persons to potentially toxic vapours³⁰;
 - iii) in-use disinfectant solutions must be maintained in closed, covered, labelled containers at all times; and
 - iv) air quality should be monitored on a scheduled basis to ensure control of vapours; and
- i) clean equipment room(s), including storage, should protect the clean equipment from contamination.

C. Cleaning Procedures

Each health care setting in which endoscopic procedures are performed shall have written detailed procedures for the cleaning and handling of endoscopes.¹⁶ Endoscopic cleaning shall take place immediately following completion of the clinical procedure,¹⁶ as soil residue in endoscope lumens dries rapidly, becoming very difficult to remove.

Immediately following completion of the endoscopy procedure¹⁶:

- a) flush and wipe the endoscope at point-of-use;
- b) use a freshly prepared enzymatic cleaning solution; and

- c) place the endoscope and accessories in a covered, leak proof container and transport to the designated decontamination area.

The following steps must be included in the cleaning procedure^{16, 28, 30}:

- a) follow the manufacturer's recommendations for cleaning and cleaning products;
- b) perform leak testing after each use, prior to cleaning:
 - i) verify the patency and integrity of the endoscope sheath through leak testing, performed prior to, and during, immersion of the endoscope;
 - ii) perform the leak test according to the manufacturer's instructions;
 - iii) an endoscope that fails the dry leak test should not undergo the immersion leak test;
- c) soak and manually clean all immersible endoscope components with water and a recommended cleaning agent prior to automated or further manual disinfection or sterilization;
- d) disconnect and disassemble endoscope components (e.g., air/water and suction valves) as far as possible and completely immerse the endoscope and components in enzymatic cleaner;
- e) flush and brush all channels and lumens of the endoscope while submerged to remove debris and minimize aerosols;
- f) ensure that brushes used for cleaning lumens are of an appropriate size, inspected before and after use, and discarded or cleaned, high-level disinfected and dried following use;
- g) consider irrigation adaptors or manifolds that may be recommended by the manufacturer to facilitate cleaning;
- h) thoroughly rinse endoscope and all components with clean, fresh tap water prior to disinfection/sterilization and remove excess rinse water;
- i) identify damaged endoscopes and immediately remove from service;
- j) discard enzymatic cleaner after each use; and
- k) discard disposable cleaning items or thoroughly clean and high-level disinfect/sterilize nondisposable items between uses.

D. Endoscope Disinfection and Sterilization

Procedures for disinfection and sterilization of endoscopes must ensure that a minimum of high-level disinfection is used for all endoscopes and their accessories, excluding biopsy forceps and brushes (which require sterilization).³⁰ The following steps must be included in the disinfection/sterilization procedure^{16, 28, 30}:

- a) choose a disinfectant that is compatible with the endoscope;
- b) monitor the efficacy of the disinfectant before each use with test strips available from the product manufacturer;
- c) maintain a written log of monitoring test results;
- d) do not use disinfectants past their expiry date;
- e) carefully follow the manufacturer's directions regarding the ambient temperature and duration of contact for the disinfectant (e.g., 2% glutaraldehyde = 20 minutes at 20°C);
- f) completely immerse the endoscope and endoscope components in the high-level disinfectant/sterilant and ensure all channels are perfused; and
- g) following disinfection, rinse the endoscope and flush the channels with bacteria-free or sterile water.

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

E. Accessories

Endoscopic accessories (e.g., biopsy forceps and brushes) that break the mucosal barrier must be sterilized after each use³⁰:

- a) because of the difficulty cleaning biopsy forceps/brushes, **it is strongly recommended that disposable items be used**; and
- b) if reusable biopsy forceps/brushes are used, they must be meticulously cleaned prior to sterilization using ultrasonic cleaning.

F. Automated Endoscope Reprocessor (AER)

If an automated endoscope reprocessor (AER) is used, the following must be included in the procedure³⁰:

- a) follow the manufacturer's instructions for use of the AER;
- b) ensure that the endoscope and endoscope components to be reprocessed are compatible with the AER used;
- c) ensure that channel connectors and caps for both the AER and the endoscope are compatible;
- d) place brushes and instruments used to clean the endoscope in the AER for disinfection;
- e) do not open or stop the AER once started; if an AER cycle is interrupted, high-level disinfection cannot be assured;
- f) routinely review Health Canada/OHA alerts and advisories and the scientific literature for reports of AER deficiencies that may lead to infection (reprocessing and infection prevention and control staff); and
- g) implement and document preventive maintenance program(s) for the AER(s).

G. Drying and Storage of Endoscopes

Steps in the final drying of semicritical endoscopes include¹⁶:

- a) initial flushing of all channels with medical or filtered air;
- b) flushing all channels with 70% isopropyl alcohol to aid in the drying process; and
- c) second flushing of the channels with medical or filtered air.¹⁶

Storage procedures must include the following¹⁶:

- a) remove caps, valves and other detachable components during storage and reassemble just before use³⁰; store close to the endoscope in a manner that minimizes contamination;
- b) store semicritical endoscopes by hanging vertically in a well-ventilated area in a manner that minimizes contamination or damage;
- c) **store endoscopes that have been sterilized in their sterilization containers**;
- d) do not allow endoscopes to coil, touch the floor or bottom of the cabinet while hanging, or be stored in their cases;
- e) ensure that endoscope storage cabinets are constructed of non-porous material that can be cleaned; and
- f) clean and disinfect endoscope storage cabinets at least weekly.

Colonoscopes have a maximum shelf life of 7 days, if stored dry.³² There are no recommendations regarding shelf life of other types of endoscopes.

H. Equipment Used for Cleaning

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.³⁰ Sterile water shall be used to fill the water bottle.

I. Record-keeping

An accurate, permanent record of endoscope use and reprocessing will assist in tracking endoscopes and clients/patients/residents in the event of a recall or follow-up:

- 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^{16, 30};
- b) record the endoscope number in the client/patient/resident record^{16, 30}; and
- c) retain records according to the policy of the facility.¹⁶

- For more information regarding reprocessing of endoscopes, see the CSA's 'Z314.8-08 Decontamination of Reusable Medical Devices', Section 13.¹⁶

Recommendations:

- 53. 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 and annual competency testing.**
- 54. Each health care setting in which endoscopic procedures are performed shall have written, detailed procedures for the cleaning and handling of endoscopes.**
- 55. Ventilation shall be such as to remove toxic vapours generated by, or emitted from, cleaning or disinfecting agents.**
- 56. Endoscope cleaning shall commence immediately following completion of the clinical procedure.**
- 57. Patency and integrity of the endoscope sheath should be verified through leak testing, performed after each use.**
- 58. Endoscopic equipment/devices shall be rinsed and dried prior to disinfection or sterilization.**
- 59. Critical endoscopes shall be sterilized.**
- 60. Semicritical endoscopes and accessories (excluding biopsy forceps and brushes) must receive at least high-level disinfection after each use.**
- 61. Endoscopic accessories (e.g., biopsy forceps and brushes) that break the mucosal barrier must be disposable or sterilized after each use.**
- 62. If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components are compatible with the AER.**
- 63. Final drying of semicritical endoscopes shall be facilitated by flushing all channels with 70% isopropyl alcohol, followed by forced air purging of the channels.**
- 64. 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.**

65. **The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during the procedure, should receive high-level disinfection or sterilization at least daily.**
66. **A preventive maintenance program for automated endoscope reprocessor (AER) must be implemented and documented.**
67. **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 clients/patients/residents that includes recording the endoscope number in the client/patient/resident record.**

12. Sterilization of Reusable Medical Equipment/Devices

Sterilization is the elimination of all disease-producing microorganisms, including spores (e.g. *Clostridium* and *Bacillus* species) and prions. 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 decontamination of heat-resistant equipment/devices is steam sterilization (pre-vacuum sterilizers are preferred).**

The preferred method for decontamination of heat-resistant medical equipment/devices is steam sterilization.

For equipment/devices that cannot withstand heat sterilization, some examples of chemical sterilants include:

- a) 6% hydrogen peroxide;
- b) 2% glutaraldehyde (> 10 hours);
- c) hydrogen peroxide gas plasma;
- d) 0.2% peracetic acid;
- e) 7% accelerated hydrogen peroxide; and
- f) 100% ethylene oxide.

- Refer to Appendix A, 'Reprocessing Decision Chart', and Appendix E, 'Advantages and Disadvantages of Currently Available Reprocessing Options' for chemical products that may be used to achieve sterilization.

A. Sterilization Process

Medical equipment/devices that have contact with sterile body tissues or fluids are considered critical items.¹⁷ All critical medical equipment/devices must be sterilized,^{1, 17, 23, 33} because microbial contamination could result in disease transmission. Critical items include surgical instruments, implants, foot care equipment, endoscopes that enter sterile cavities and spaces, colposcopy equipment, biopsy forceps and brushes, eye equipment and dental equipment.

Semicritical medical equipment/devices have contact with nonintact skin or mucous membranes but do not penetrate them.¹⁷ Whenever possible, semicritical medical equipment/devices should be sterilized. When sterilization is not possible, semicritical equipment/devices shall be cleaned, followed by high-level disinfection.¹⁶

Health care settings shall have written policies and procedures for sterilization of medical equipment/devices processes that:

- a) ensure that the sterilization processes follow the principles of infection prevention and control as set out in Health Canada guidelines,²³ CSA standards^{1, 16, 33} and these MOHLTC best practices;
- b) ensure that manufacturer's instructions for installation, operation, cleaning and preventive maintenance of the equipment are followed;
- c) include clearly defined responsibilities^{1, 33};
- d) include cleaning, decontamination, drying, inspection, lubrication, disassembly, wrapping, sealing and labelling^{1, 16, 33}; and
- e) include a thorough evaluation of all sterilization processes before being put into service, and at regular intervals thereafter.

B. New Sterilizers

Input from a professional with infection prevention and control expertise must be obtained prior to the purchase of a new sterilizer. There must be good communication between the health care setting and the manufacturer of the sterilizer to ensure that^{1, 33}:

- a) manufacturers of sterilizers provide specific, written instructions on installation and use of their equipment;
- b) storage and transportation practices maintain sterility to the point of use; and
- c) manufacturers of sterilizers are specific as to which medical equipment/devices can be sterilized in their machines and the recommended sterilization methods.

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

- a) autoclaves must be installed according to the manufacturer's instructions^{1, 33};
- b) tabletop steam sterilizers are recommended for office settings³⁴;
- c) 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;
- d) for sterilizers of the dynamic air removal type (vacuum), three consecutive air removal tests shall be conducted in an empty sterilizer with the air detection test pack (e.g., Bowie-Dick)²⁸, as described in the CSA's *'Effective Sterilization in Health Care Facilities by the Steam Process'*¹ [CSA Z314.3-09 Clauses 12.4.3.2 to 12.4.3.4];
- e) a sterilizer shall not be approved for use if the biological indicator (BI) yields a positive result on any of the tests¹;
- f) sterilizers must be monitored with a test load and be fully re-qualified in the following circumstances^{1, 33}:
 - i) after major repairs to an existing sterilizer;
 - ii) when there has been construction, relocation or other environmental changes in the area;
 - iii) after unexplained sterility failures;
 - iv) after changes in steam and/or ethylene oxide supply or delivery; and
 - v) after repairs or modification to the emission control system.

For more information regarding requirements for new sterilizers, see the CSA's:

- Z314.3-09, *'Effective Sterilization in Health Care Facilities by the Steam Process'*¹
- Z314.2-09, *'Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process'*³³

C. Monitors and Indicators

Physical, biological and chemical monitoring is done to verify the effectiveness of sterilizers and the sterilizing process. Monitoring is done when a sterilizer is first installed before it is put into general use and to assess routine performance thereafter. See Section II.12.D, 'Routine Monitoring of Sterilizers', for more information about routine monitoring. Performance monitoring using all three types of indicators/monitors must be completed in all sterilizers to ensure that effective sterilization has been achieved.

1. Physical Monitors

A physical monitor is a device that monitors the physical parameters of a sterilizer, such as time, temperature and pressure that are measured during the sterilization cycle and recorded (as a printout or electronic record) on completion of each cycle.

All sterilizers must be tested for performance using physical, chemical and biological monitors and indicators.

2. Biological Indicators (BI)

A biological indicator is a test system containing viable microorganisms (e.g., spore-laden strips or vials) providing a defined resistance to a specified sterilization process.^{1, 28} The BI is generally contained inside a process challenge device (PCD) that simulates the in-use challenges presented by packaged devices. Once sterilized, a BI is incubated to see if the microorganism will grow, which indicates a failure of the sterilizer.

The manufacturer's instructions regarding the type of BI to be used in a particular sterilizer should be followed. The recommended test microorganisms generally used as BIs are:

- a) *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*) spores for sterilizers that use steam, hydrogen peroxide gas plasma or peracetic acid, as well as flash sterilizers; and
- b) *Bacillus atrophaeus* (formerly *Bacillus subtilis*) spores for sterilizers that use dry heat or ethylene oxide.

The BI is incubated according to the manufacturer's instructions. Most BIs require up to 48 hours of incubation before the test is complete. Recently, however, **rapid readout biological indicators** have become available that provide BI results in one hour. These indicators detect enzymes of *Geobacillus stearothermophilus* (the test organism for steam sterilizers) by reading a fluorescent product produced by the enzymatic breakdown of a nonfluorescent substrate.²⁸ Studies have shown that the sensitivity of rapid-readout tests for steam sterilization (1 hour for 132°C gravity sterilizers, 3 hours for 121°C gravity and 132°C vacuum sterilizers) parallels that of the conventional sterilization-specific BIs.^{35, 36}

- Refer to the CSA's 'Effective Sterilization in Health Care Facilities by the Steam Process'¹ [CSA Z314.3-09 Clause 12.6.4] for more information about biological indicators for steam sterilizers.
- Refer to the CSA's 'Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process'³³ [CSA Z314.2-09 Clause 12.6.4] for more information about biological indicators for ethylene oxide sterilizers.

3. Chemical Indicators (CI)

A chemical indicator is a system that responds to a change in one or more predefined process variables with a chemical or physical change. There are six classes of chemical indicators¹ (see Table 2, 'International Classes of Steam Chemical Indicators').

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

Chemical indicators do not necessarily indicate that a device is sterile and do not replace the need to use a BI, but do indicate that the package has been processed through a sterilization cycle.²⁸

Table 2: International Classes of Steam Chemical Indicators^{1, 37, 38}

Class	Definition	Use	Examples
CLASS I: Process Indicators	Process indicators differentiate processed from non-processed items	- Used with individual units (e.g., packs, containers) to indicate that the item has been directly exposed to the sterilization process - Usually applied to the outside of packages - Respond to one or more critical process variables	- Indicator tapes - Indicator labels - Load cards
CLASS II: Indicator for Use in Specific Tests	Indicator for use in specific test procedures as defined in sterilizer/sterilization standards (e.g., air-detection, steam penetration)	Used for equipment control to evaluate the sterilizer performance	Bowie-Dick test
CLASS III: Single Variable Indicator	Indicator that reacts to a single critical variable in the sterilization process to indicate when a stated value has been reached (e.g., temperature at a specific location in the chamber)	- May be used for pack control monitoring but not as useful as class IV or class V indicators - May be used for exposure control monitoring (e.g., temperature at a specific location in the chamber)	Temperature tubes
CLASS IV: Multi-variable Indicator	Indicator that reacts to two or more critical variables in the sterilization cycle under the conditions specified by the manufacturer	May be used for pack control	Paper strips
CLASS V: Integrating Indicator	Indicator that reacts to all critical variables in the sterilization process (time, temperature, presence of steam) <u>and</u> has stated values that correlate to a BI at three time/temperature relationships	- Responds to critical variables in the same way that a BI responds - Equivalent to, or exceeds, the performance requirements of BIs - Used for pack control - May be used as an additional monitoring tool to release loads that do not contain implants	
CLASS VI: Emulating Indicator	Indicator that reacts to all critical variables (time, temperature, presence of steam) for a specified sterilization cycle (e.g., 10 min., 18 min., 40 min.)	- Used as internal CI for pack control - A different Class VI emulating indicator is required <u>for each</u> sterilization cycle time and temperature used - Cannot be used as an additional monitoring tool to release loads that do not contain implants	

- Refer to the CSA's '*Effective Sterilization in Health Care Facilities by the Steam Process*'¹ [CSA Z314.3-09 Clause 12.6.3] for more information about chemical indicators for steam sterilizers.

- Refer to the CSA's '*Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process*'³³ [CSA Z314.2-09 Clause 12.6.3] for more information about chemical indicators for ethylene oxide sterilizers.

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

A process challenge device is a test device intended to provide a challenge to the sterilization process that is equal to, or greater than, the challenge posed by the most difficult item routinely processed.¹ Examples include BI test packs which also contain a chemical indicator, or CI test packs which contain a Class 5 integrating indicator or an enzyme-only indicator.

During routine monitoring of sterilizers, the BI and/or CI is usually placed within a PCD and placed in the sterilizer. A PCD can be commercially manufactured or prepared in-house.

- Refer to the CSA's '*Effective Sterilization in Health Care Facilities by the Steam Process*'¹ [CSA Z314.3-09 Clause 12.12] for more information about in-house preparation of PCDs.
- Refer to the CSA's '*Effective Sterilization in Health Care Facilities by the Steam Process*'¹ [CSA Z314.3-09 Clause 12.2.2] for more information about PCDs.

D. Routine Monitoring of Sterilizers

Routine monitoring verifies that the sterilization process is working as expected and that medical equipment/devices achieve sterility. Routine monitoring of sterilizers involves the assessment of physical parameters of the sterilizer cycle, chemical indicators and biological indicators. All monitoring must comply with the manufacturer's instructions.

The following are included in routine monitoring^{1, 33}:

- a) record and initial results of physical, chemical and biological parameters (see Section II.12.C, '*Monitors and Indicators*', for more information on indicators);
- b) document daily operation of the sterilizer:
 - i) review physical monitoring parameters for each operation (e.g., printed or electronic records);
 - ii) note any malfunction and take appropriate action to ensure that the product either has been properly treated or is returned for reprocessing;
- c) test filter systems for leakage;
- d) validate gas sterilization units for such factors as gas concentration, temperature, and relative humidity;
- e) conduct three consecutive tests with the air detection test pack (Bowie-Dick) for sterilizers of the dynamic air removal type; and
- f) monitor dry heat sterilization with each cycle due to differences in penetration with different items.

When using sterilization indicators^{1, 33}:

- a) indicator shall be used according to the indicator manufacturer's instructions;
- b) indicator shall be used only for the sterilizer type and cycle for which it was designed and validated;
- c) indicator shall be interpreted only by qualified staff who have been trained to do so;
- d) indicator shall not be used beyond the expiration date; and
- e) indicator shall be stored in accordance with the manufacturer's instructions.

The following requirements apply to chemical monitoring¹:

- a) an internal chemical indicator shall be placed inside each package, container or bundle that is undergoing sterilization in the area judged to be least accessible to steam penetration or to the sterilizing agent^{33, 39}; this may not necessarily be at the centre of the package; the class of indicator chosen is based on the parameters being measured and the degree of precision that is needed;
- b) each package or container to be sterilized shall have an externally visible Class I chemical indicator, which is examined immediately after sterilization to make sure that the item has been exposed to the sterilization process; and
- c) for dynamic air removal-type sterilizers, an air removal test with a Class II chemical indicator shall be performed every day the sterilizer is used (see *Section II.12.D.e*);

The following requirements apply to biological monitoring¹:

- a) a biological indicator shall be used to test the sterilizer each day that it is used and with each type of cycle that is used that day;
 - b) a biological indicator shall be included in every load that is to be sterilized with ethylene oxide³³;
 - c) a biological indicator shall be included in every load containing implantable devices²³;
 - d) items in the processed load should not be released until the results of the BI test are available; if quarantine pending BI results is not possible, evaluation of a Class 5 or 6 chemical indicator and the specific cycle physical parameters may be used to justify the release of routine loads; and
 - e) implantable devices should be quarantined until the results of the BI test are available.
- Refer to Appendix F, 'Advantages and Disadvantages of Currently Available Reprocessing Options' for sterilizer-specific monitoring criteria

E. Ethylene Oxide (ETO)

Ethylene oxide is a designated substance under the *Occupational Health & Safety Act*⁴⁰. Facilities that use ethylene oxide for sterilization must comply with the requirements of the designated substance regulation – ethylene oxide (O. Reg. 841/90), made under the OHSA; as well as guidelines from Environment Canada⁴¹, specifically:

- a) emissions of ethylene oxide must be reduced by 99% during the sterilization cycle by installing an emission control system;
- b) emissions of ethylene oxide must be reduced by 95% during aeration;
- c) eliminate liquid discharge to avoid releases of ethylene oxide to the local sewer system;
- d) test emissions of ethylene oxide annually; and
- e) report annually to Environment Canada.

In order to safely operate an ethylene oxide sterilizer, the following must be included in the process³³:

- a) product-specific WHMIS documentation shall be obtained from the manufacturer;
- b) handling, storage and disposal of ethylene oxide cylinders and cartridges shall be in accordance with the manufacturer's instructions;
- c) 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 procedures³³; and
- d) 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.³³

- For more information regarding sterilizing with ethylene oxide, refer to the CSA's 'Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process'³³.

Recommendations:

- 68. Critical medical equipment/devices must be sterilized.**
- 69. All sterilization processes must ensure that they follow the manufacturer's instructions for installation, operation and preventive maintenance of the equipment.**
- 70. The sterilization process must be validated and documented with written policies and procedures.**
- 71. The sterilization process requires testing, monitoring with results recorded and auditing.**
- 72. A biological indicator shall be used to test the sterilizer each day and for each type of cycle that it is used; in every load subjected to ethylene oxide sterilization; and in every load containing implantable devices.**
- 73. Input from a professional with infection prevention and control expertise must be obtained prior to the purchase of a new sterilizer.**
- 74. Sterilizers must be subjected to rigorous testing and monitoring on installation and following disruptions to their normal activity.**

13. Flash Sterilization

Flash sterilization shall only be used in emergency situations and shall not be used for implantable equipment/devices^{1, 23} or on complete sets or trays of instruments.¹ Sterilization is a process, not an event. Operative scheduling and lack of instrumentation do not qualify as reasons to use flash sterilization.

Effective sterilization is impaired if all the necessary parameters of the process are not met. These include, but are not limited to, the following:

- a) decontamination and sterilization areas must meet the requirements for processing space as noted in [Appendix B](#) ('Recommendations for Physical Space for Reprocessing') and shall not be located in the operative procedure room or near any potential source of contamination, such as sinks, hoppers, linen or trash disposal areas¹;
- b) a record for each piece of equipment/device being subjected to flash sterilization that includes the name of the client/patient/resident, procedure, physician/practitioner and equipment/device used¹; the client/patient/resident record should also reflect this information;
- c) if, in an emergency situation, a flash sterilizer is used, a biological monitor must be included at least once daily and with each type of cycle¹ and every load configuration (i.e., open tray, rigid flash container, single wrapper) that will be used that day;
- d) the load printout must be signed to verify that the required time, temperature and pressure have been achieved;
- e) records must be retained according to the facility's policy¹;
- f) there must be a procedure for notification of the client/patient/resident in the event of a recall (e.g., positive biological indicator); and
- g) records should be reviewed on a regular basis to correct issues relating to overuse of flash sterilization.

- For more information regarding the use and requirements of flash sterilization, refer to CSA Standard Z314.3-09, 'Effective Sterilization in Health Care Facilities by the Steam Process' [Section 13].

Recommendations:

75. Flash sterilization shall only be used in emergency situations and must never be used for implantable equipment/devices.

14. Unacceptable Methods of Disinfection/Sterilization

The following methods of disinfection/sterilization are not recommended.

A. Boiling

The use of boiling water to clean instruments and utensils is not an effective means of sterilization.²³ 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 re-used on the same client, following adequate cleaning.

B. Ultraviolet Irradiation

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.²⁸ The application of UV light in the health care setting is limited to the destruction of airborne organisms (e.g., ventilation ducts) or inactivation of microorganisms located on surfaces (e.g., laboratory hoods). It is not an acceptable method of disinfection/sterilization for medical equipment/devices.²³

C. Glass Bead Sterilization

Glass bead sterilizers use small glass beads and high temperature for brief exposure times to inactivate microorganisms.²⁸ 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.

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 until the device has received FDA clearance.^{28, 42} Glass bead sterilization is not an acceptable method of sterilization for medical equipment/devices.^{23, 43}

D. Chemiclave

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. If used, it must be closely monitored⁴⁴ and local regulations for hazardous waste disposal must be followed and air sampling for toxic vapours may be indicated.

E. Microwave Oven Sterilization

Microwave ovens are unreliable and difficult to monitor for effective sterilization. Home microwaves have been shown to inactivate bacteria, viruses, mycobacteria and some spores, however there may not be even distribution of microwave energy over the entire device.²⁸ More research and testing is required to validate the use of microwave ovens for sterilization. The use of microwave ovens for sterilization of medical equipment/devices is not currently acceptable.^{23, 28}

Recommendations:

- 76. Boiling is not an acceptable method of sterilization.**
- 77. The use of ultraviolet light is not an acceptable method of disinfection/sterilization.**
- 78. Glass bead sterilization is not an acceptable method of sterilization.**
- 79. The use of a chemiclave for sterilization poses an environmental risk and must be closely monitored.**
- 80. The use of microwave ovens for sterilization is not acceptable.**

15. Continued Monitoring and System Failures

Recalls

Improper reprocessing includes, but is not limited to, the following situations:

- a) the load contains a positive BI²³;
- b) an incorrect reprocessing method was used on the equipment/device;
- c) print-outs on reprocessing equipment indicate failure to reach correct parameters (e.g., temperature, pressure, exposure time);
- d) CI or monitoring tape has not changed colour; and
- e) there is doubt about the sterility of medical equipment/devices.¹

A written procedure must be established for the recall and reprocessing of improperly reprocessed medical equipment/devices.¹ All equipment/devices in each processed load must be recorded to enable tracking in the event of a recall. The recall procedure should include:

- a) designation of department and staff responsible for executing the recall¹;
- b) identification of the medical equipment/devices to be recalled¹; if recall is due to a failed BI, the recall shall include the medical devices in the failed load as well as all other devices processed in the sterilizer since the last successfully sterilized load¹;
- c) assessment of client/patient/resident risk;
- d) procedure for subsequent notification of physicians, clients/patients/residents, other facilities and/or regulatory bodies, if indicated; and
- e) involvement of the facility's risk manager, if applicable.

Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.¹⁶

Recommendations:

- 81. If a failed chemical indicator is found, the contents of the package shall be reprocessed before use.**

- 82. A procedure must be established for the recall of improperly reprocessed medical equipment/devices.**
- 83. The recall procedure should include assessment of client/patient/resident risk and a procedure for subsequent notification of physicians, clients/patients/residents, other facilities and/or regulatory bodies if indicated.**
- 84. Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.**

16. Single-Use Medical Equipment/Devices

Health care settings must have written policies regarding single-use medical equipment and devices. Critical and semi-critical medical equipment/devices labelled as single-use must not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor.⁴⁵⁻⁴⁷ Currently there are no licensed reproducers in Canada. There are reproducers in the USA licensed by the United States Food and Drug Administration (USFDA).

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.⁴⁸ In order to have critical or semicritical medical equipment/devices reprocessed by one of these facilities, there must be processes for:

- a) tracking and labelling equipment/devices;
- b) recalling improperly reprocessed medical equipment/devices;
- c) assuring proof of sterility or high-level disinfection;
- d) testing for pyrogens;
- e) maintenance of equipment/device functionality and integrity;
- f) quality assurance and quality control;
- g) reporting adverse events; and
- h) provision 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.⁴⁶

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



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 clients/patients/residents 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.⁴⁵ This is a detailed and expensive process and should only be undertaken if there is a compelling reason to do so.

A. Sharps

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

When purchasing sharps or devices with sharp components that cannot be safely cleaned, single-use devices or components shall be considered.^{1, 16}

B. Equipment/Devices with Small Lumens

Reusable equipment/devices with small lumens or other characteristics that make them difficult to clean effectively can put clients/patients/residents at risk, as they cannot be cleaned effectively or be adequately checked for cleanliness during reprocessing.^{1, 16} This includes items, such as catheters, drains, fine cannulae (excluding endoscopy equipment). These items should be designated single-use and not be reprocessed and re-used, even if designated as reusable by the manufacturer.

C. Equipment/Devices in Home Health Care

Equipment/devices owned by the client that are re-used in their home must be adequately cleaned prior to reuse. Home health care agencies may consider re-using single-use semicritical medical equipment/devices for a single client in their home when reuse is safe and the cost of replacing the equipment/device is prohibitive for the client.

- See Section II.8, “Disassembly, Inspection and Cleaning of Reusable Medical Equipment”, for cleaning requirements.

Recommendations:

- 85. The health care setting must have written policies regarding single-use medical equipment/devices.**
- 86. Critical and semi-critical medical equipment/devices labelled as single-use must not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor.**
- 87. Needles must be single-use and must not be reprocessed.**
- 88. 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 re-used, even if designated as reusable by the manufacturer.**
- 89. Home health care agencies may consider re-using single-use semicritical medical equipment/devices for a single client in their home when reuse is safe and the cost of replacing the equipment/device is prohibitive for the client.**

17. Storage and Use of Reprocessed Medical Equipment/Devices

The shelf life of a sterile package is event-related rather than time-related.¹ 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. Sterile Storage Areas

The sterile storage area should be located adjacent to the sterilization area, preferably in a separate, enclosed, limited-access area.¹ Requirements for this area include^{1, 23}:

- a) containers used for storage of clean equipment/devices should be moisture-resistant and cleanable (i.e., cardboard boxes must not be used);
- b) equipment/devices are stored 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;
- c) equipment/devices are stored in an area where they are not subject to tampering by unauthorized persons;
- d) equipment/devices are transported in a manner that avoids contamination or damage to the equipment/device; and
- e) supplies and materials not used for reprocessing will not be stored in sterile processing areas.

B. Maintaining Sterility

Health care settings must have procedures for storage and handling of clean and sterile medical equipment/devices that include^{1, 23}:

- a) medical equipment/devices purchased as sterile must be used before the expiration date, if one is given;
- b) reprocessed medical equipment/devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage¹⁶;
- c) sterility must be maintained until used²³;
- d) sterile packages that lose their integrity shall be re-sterilized prior to use; and
- e) equipment/devices must be handled in a manner that prevents recontamination of the item.

C. Using Sterile Equipment/Devices

At point-of-use, upon opening the reprocessed medical equipment/device, a check must be made for integrity of the packaging and the equipment/device. Those performing this inspection must be provided with education that includes:

- a) validating results of chemical tape and internal monitors, if present;
- b) visually inspecting the equipment/device for discolouration or soil; if present, the item is removed from service and reprocessed;
- c) checking for defective equipment/devices and removing them from use;
- d) checking for dampness or wetness (e.g., high humidity); if present, reprocessing may be required;
- e) reassembly of equipment/device if required.

➤ Refer to Appendix B, 'Recommendations for Physical Space for Reprocessing'

Recommendations:

90. Sterility of sterile items must be maintained until used.

- 91. Reprocessed medical equipment/devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage.**
- 92. 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.**

Summary of Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings

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

	Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
1. Purchasing and Assessing Medical Equipment/Devices and/or Products for Disinfection or Sterilization Processes						
1.	Do not purchase medical equipment/devices that cannot be cleaned and reprocessed according to the recommended standards.					
2.	When purchasing reprocessing equipment or chemical products for reprocessing, consideration must be given to Occupational Health requirements, client/patient/resident safety and environmental safety issues.					
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) must meet established quality reprocessing parameters. Such equipment should not be purchased or used until this process is established.					

	Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
4.	Manufacturers' 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.					
5.	Newly purchased, non-sterile critical and semicritical medical equipment/devices shall first be inspected and reprocessed according to their intended use.					
6.	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.					
7.	Because of the risks associated with Creutzfeldt-Jakob disease (CJD), surgical instruments that are used on <u>high risk neurological and eye tissue from clients/patients/residents at high risk for CJD</u> 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".					
2. Environmental Requirements for Reprocessing Areas						
8.	There must be a centralized area for reprocessing medical equipment/devices.					

Recommendation		Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
9.	<i>The decontamination work area shall be physically separated from clean areas by walls or partitions.</i>					
10.	<i>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.</i>					
11.	<i>Wherever chemical disinfection/sterilization is performed, air quality must be monitored when using products that produce toxic vapours and mists.</i>					
12.	<i>There must be a regular schedule for environmental cleaning in the Sterile Processing Department that includes written procedures and clearly defined responsibilities.</i>					
3. Policies and Procedures						
13.	<i>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.</i>					

Recommendation		Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
14.	<i>All policies and procedures for reprocessing medical equipment/devices require review by an individual with infection prevention and control expertise.</i>					
15.	<i>A procedure shall be established for the recall of improperly reprocessed medical equipment/devices.</i>					
4. Education and Training						
16.	<i>The policies of the health care setting shall specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical equipment/devices.</i>					
17.	<i>All aspects of reprocessing shall be supervised and shall be performed by knowledgeable, trained personnel.</i>					
18.	<i>Managers, supervisors and staff involved in reprocessing shall have completed a recognized qualification/certification course in reprocessing practices.</i>					
19.	<i>A plan must be in place for each person involved in reprocessing to obtain certification qualification.</i>					

	Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
5. Occupational Health and Safety for Reprocessing						
20.	Occupational Health and Safety for the health care setting will review all protocols for reprocessing medical equipment/devices to verify that worker safety measures and procedures to eliminate or minimize the risk of exposure are followed and are in compliance with the Occupational Health and Safety Act, R.S.O. 1990, c.O.1 and its Regulation including the Health Care and Residential Facilities - O. Reg. 67/93 amended to O. Reg. 631/05.					
21.	There is a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics or lip balm and handling contact lenses in the reprocessing area.					
22.	Appropriate personal protective equipment (PPE) shall be worn for all reprocessing activities.					
23.	All staff working in reprocessing shall be offered Hepatitis B immunization unless they have documented immunity to Hepatitis B.					
24.	Measures and procedures shall be written to prevent and manage injuries from sharp objects.					

Recommendation		Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
25.	Measures and procedures shall be in place for immediate response to worker exposure to blood and body fluids.					
6. Transportation and Handling of Contaminated Medical Equipment/Devices						
26.	Disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point-of-use, prior to transportation.					
27.	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.					
28.	A process shall 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).					
29.	Contaminated equipment/devices shall not be transported through areas designated for storage of clean or sterile supplies, client/patient/resident care areas or high-traffic areas.					
30.	Sterile and soiled equipment/devices shall not be transported together.					

	Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
7. Factors Affecting the Efficacy of the Reprocessing Procedure						
31.	<i>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.</i>					
8. Disassembly, Inspection and Cleaning of Reusable Medical Equipment/Devices						
32.	<i>Reusable medical equipment/devices must be thoroughly cleaned before disinfection or sterilization.</i>					
33.	<i>If cleaning cannot be done immediately, the medical equipment/device must be submerged in tepid water and detergent or enzymatic cleaner to prevent organic matter from drying on it.</i>					
34.	<i>Factors that affect the ability to effectively clean medical equipment/devices must be considered prior to cleaning.</i>					

	Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
35.	<i>The process for cleaning should include written protocols for disassembly, sorting, soaking, physical removal of organic material, rinsing, drying, physical inspection, lubrication and wrapping.</i>					
36.	<i>Audits of the cleaning process must be done on a regular basis.</i>					
9. Selection of Product/Process for Reprocessing						
37.	<i>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.</i>					
38.	<i>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.</i>					
39.	<i>Products used for decontamination must be appropriate to the level of reprocessing that is required for the use of the medical equipment/device.</i>					

Recommendation		Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
40.	<i>The process and products used for cleaning, disinfection and/or sterilization of medical equipment/devices must be compatible with the equipment/devices.</i>					
41.	<i>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.</i>					
10. Disinfection of Reusable Medical Equipment/Devices						
42.	<i>Noncritical medical equipment/devices are to be decontaminated using a low-level disinfectant.</i>					
43.	<i>Semicritical medical equipment/devices must be decontaminated using, at a minimum, high-level disinfection. Sterilization is the <u>preferred</u> method of decontamination.</i>					
44.	<i>Noncritical and semicritical medical equipment/devices that are owned by the client and re-used by a single client in their home do not require disinfection between uses, provided that they are adequately cleaned prior to reuse.</i>					

	Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
45.	All disinfectants must have a Drug Identification Number (DIN) from Health Canada.					
46.	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.					
47.	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.					
48.	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.					
49.	Manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated.					
50.	A preventive maintenance program for pasteurizing equipment must be implemented and documented.					

Recommendation		Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
51.	<i>Following the pasteurizing cycle, medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and that is used exclusively for the drying of pasteurized equipment/devices.</i>					
52.	<i>A log of contents, temperature and time is to be maintained for each pasteurizer cycle.</i>					
11. Reprocessing Endoscopy Equipment/Devices						
53.	<i>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 and annual competency testing.</i>					
54.	<i>Each health care setting in which endoscopic procedures are performed shall have written detailed procedures for the cleaning and handling of endoscopes.</i>					
55.	<i>Ventilation shall be such as to remove toxic vapours generated by, or emitted from, cleaning or disinfecting agents.</i>					
56.	<i>Endoscopic cleaning shall commence immediately following completion of the clinical procedure.</i>					

	Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
57.	<i>Patency and integrity of the endoscope sheath should be verified through leak testing, performed after each use.</i>					
58.	<i>Endoscopic equipment/devices shall be rinsed and dried prior to disinfection or sterilization.</i>					
59.	<i>Critical endoscopes shall be sterilized.</i>					
60.	<i>Semicritical endoscopes and accessories (excluding biopsy forceps and brushes) must receive at least high-level disinfection after each use.</i>					
61.	<i>Endoscopic accessories (e.g., biopsy forceps and brushes) that break the mucosal barrier must be disposable or sterilized after each use.</i>					
62.	<i>If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components are compatible with the AER.</i>					
63.	<i>Final drying of semicritical endoscopes shall be facilitated by flushing all channels with 70% isopropyl alcohol, followed by forced air purging of the channels.</i>					

Recommendation		Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
64.	<i>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.</i>					
65.	<i>The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during the procedure, should receive high-level disinfection or sterilization at least daily.</i>					
66.	<i>A preventive maintenance program for automated endoscope reprocessor (AER) must be implemented and documented.</i>					
67.	<i>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 clients/patients/residents that includes recording the endoscope number in the client/patient/resident record.</i>					
12. Sterilization of Reusable Medical Equipment/Devices						
68.	<i>Critical medical equipment/devices must be sterilized.</i>					

	Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
69.	<i>All sterilization processes must ensure that they follow the manufacturer's instructions for installation, operation and preventive maintenance of the equipment.</i>					
70.	<i>The sterilization process must be validated and documented with written policies and procedures.</i>					
71.	<i>The sterilization process requires testing, monitoring with results recorded and auditing.</i>					
72.	<i>A biological indicator shall be used to test the sterilizer each day and for each type of cycle that it is used; in every load subjected to ethylene oxide sterilization; and in every load containing implantable devices.</i>					
73.	<i>Input from a professional with infection prevention and control expertise must be obtained prior to the purchase of a new sterilizer.</i>					
74.	<i>Sterilizers must be subjected to rigorous testing and monitoring on installation and following disruptions to their normal activity.</i>					

	Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
13. Flash Sterilization						
75.	<i>Flash sterilization shall only be used in emergency situations and must never be used for implantable equipment/devices.</i>					
14. Unacceptable Methods of Disinfection/Sterilization						
76.	<i>Boiling is not an acceptable method of sterilization.</i>					
77.	<i>The use of ultraviolet light is not an acceptable method of disinfection/sterilization.</i>					
78.	<i>Glass bead sterilization is not an acceptable method of sterilization.</i>					
79.	<i>The use of a chemiclave for sterilization poses an environmental risk and must be closely monitored.</i>					
80.	<i>The use of microwave ovens for sterilization is not acceptable.</i>					
15. Continued Monitoring and System Failures						
81.	<i>If a failed chemical indicator is found, the contents of the package shall be reprocessed before use.</i>					

	Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
82.	<i>A procedure must be established for the recall of improperly reprocessed medical equipment/devices.</i>					
83.	<i>The recall procedure should include assessment of client/patient/resident risk and a procedure for subsequent notification of physicians, clients/patients/residents, other facilities and/or regulatory bodies if indicated.</i>					
84.	<i>Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.</i>					
16. Single-Use Medical Equipment/Devices						
85.	<i>The health care setting must have written policies regarding single-use medical equipment/devices.</i>					
86.	<i>Critical and semi-critical medical equipment/devices labelled as single-use must not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor.</i>					
87.	<i>Needles must be single-use and must not be reprocessed.</i>					

Recommendation		Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
CLEANING, DISINFECTION AND STERILIZATION OF MEDICAL EQUIPMENT/DEVICES IN ALL HEALTH CARE SETTINGS						
88.	<i>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 re-used, even if designated as reusable by the manufacturer.</i>					
89.	<i>Home health care agencies may consider re-using single-use semicritical medical equipment/devices for a single client in their home when reuse is safe and the cost of replacing the equipment/device is prohibitive for the client.</i>					
17. Storage and Use of Reprocessed Medical Equipment/Devices						
90.	<i>Sterility of sterile items must be maintained until used.</i>					
91.	<i>Reprocessed medical equipment/devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage.</i>					
92.	<i>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.</i>					

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**
<u>Cleaning</u> 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.	All reusable equipment/devices	▪ All reusable equipment/devices ▪ Oxygen tanks and cylinders	** concentration and contact time are dependant on manufacturer's instructions ▪ Quaternary ammonium compounds (QUATs) ▪ Enzymatic cleaners ▪ Soap and water ▪ Detergents ▪ 0.5% Accelerated hydrogen peroxide
<u>Low-Level Disinfection</u> 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.	Noncritical equipment/devices	▪ Environmental surfaces touched by staff during procedures involving parenteral or mucous membrane contact (e.g. dental lamps, dialysis machines) ▪ Bedpans, urinals, commodes ▪ Stethoscopes ▪ Blood pressure cuffs ▪ Oximeters ▪ Glucose meters ▪ Electronic thermometers ▪ Hydrotherapy tanks ▪ Client/patient/resident lift slings ▪ ECG machines/leads/cups etc. ▪ Sonography (ultrasound) equipment/probes that only contact intact skin ▪ Bladder scanners ▪ Baby scales ▪ Cardiopulmonary training mannequins ▪ Environmental surfaces (e.g. IV poles, wheelchairs, beds, call bells) ▪ Fingernail care equipment that is single-client/patient/resident use	** concentration and contact time are dependant on manufacturer's instructions ▪ 3% Hydrogen peroxide (10 minutes) ▪ 60-95% Alcohol (10 minutes) ▪ Hypochlorite (1000 ppm) ▪ 0.5% Accelerated hydrogen peroxide (5 minutes) ▪ Quaternary ammonium compounds (QUATs) (10 minutes) ▪ Iodophors ▪ Phenolics ** (should not be used in nurseries)

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED			
Level of Processing/Reprocessing	Classification of Equipment/Device	Examples of Equipment/Devices	Products**
<u>High-Level Disinfection</u> 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.	Semicritical equipment/devices	▪ Flexible endoscopes that do not enter sterile cavities or tissues ▪ Laryngoscopes ▪ Bronchoscopes, cystoscopes (sterilization is preferred) ▪ Respiratory therapy equipment ▪ Nebulizer cups ▪ Anaesthesia equipment ▪ Endotracheal tubes ▪ Specula (nasal, anal, vaginal – disposable equipment is strongly recommended) ▪ 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	** concentration and contact time are dependant on manufacturer's instructions ▪ 2% Glutaraldehyde (20 minutes at 20°C) ▪ 6% Hydrogen peroxide (30 minutes) ▪ 0.55% Ortho-phthalaldehyde (OPA) (10 minutes at 20°C) ▪ Pasteurization (30 minutes at 71°C) ▪ 7% Accelerated hydrogen peroxide (20 minutes) ▪ 0.2% Peracetic acid (30-45 minutes)
<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.	Critical equipment/devices	▪ Surgical instruments ▪ Foot care equipment ▪ Implantable equipment/devices ▪ Endoscopes that enter sterile cavities and spaces (e.g., arthroscopes, laparoscopes) ▪ Bronchoscopes, cystoscopes (sterilization preferred) ▪ Biopsy forceps, brushes and biopsy equipment associated with endoscopy (disposable equipment is strongly recommended)	** concentration and contact time are dependant on manufacturer's instructions ▪ Steam autoclave ▪ 100% Ethylene oxide ▪ Dry heat ▪ Hydrogen peroxide gas plasma (75 minutes at 50°C)

MANUFACTURERS' RECOMMENDATIONS FOR PRODUCT, CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED			
Level of Processing/Reprocessing	Classification of Equipment/Device	Examples of Equipment/Devices	Products**
		▪ Colposcopy equipment ▪ Electrocautery tips ▪ Endocervical curettes ▪ Fish hook cutters ▪ Transfer forceps ▪ Eye equipment, including soft contact lenses ▪ Dental equipment including high speed dental hand pieces	▪ 2.5-3.5% Glutaraldehyde (10 hours at 20°C) ▪ 0.2% Peracetic acid (12 minutes at 50-56°C) ▪ 6-25% Hydrogen peroxide liquid (6 hours) ▪ 7% Accelerated hydrogen peroxide (6 hours at 20°C)

Adapted from:

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

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

Appendix B: Recommendations for Physical Space for Reprocessing

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.
3. Storage of food, drink, or personal effects in decontamination areas shall be prohibited.

Space Recommendations:

1. **There must be clear separations between soiled and clean areas¹⁶:**
 - a) decontamination work areas should be physically separated from clean and other work areas by walls or partitions to control traffic flow and to contain contaminants generated during the stages of decontamination;
 - b) soiled work areas must be physically separated from all other areas of the space;
 - c) walls or partitions should be constructed of materials capable of withstanding frequent cleaning with the cleaning and disinfecting products used in the health care setting;
 - d) doors to all work areas should be kept closed at all times; self-closing doors are recommended to restrict access and optimize ventilation control; and
 - e) in healthcare facilities, doors should be pass-through, to ensure one-way movement by staff from contaminated areas to clean areas.
2. **There must be adequate space provided for decontamination equipment and materials used for cleaning and reprocessing¹⁶:**
 - a) work surfaces and surrounding areas should be designed to minimize crowding of work space;
 - b) work surfaces shall be flat, cut-resistant, seamless and composed of a non-porous material so they can be cleaned, disinfected and dried; stainless steel surfaces are recommended;
 - c) counter tops should be waterproof and have a backsplash;
 - d) there should be at least two adjacent decontamination sinks; if only one or two sinks are available, precautions should be taken to avoid recontaminating equipment/devices;
 - e) decontamination sinks should:
 - i) be at a height that allows staff to use them without bending or straining;
 - ii) be deep enough to immerse items to be cleaned;
 - iii) be large enough to accommodate trays or baskets of instruments;
 - iv) not have an overflow; and
 - v) be equipped with water ports for the flushing of instruments with lumens, if appropriate.
3. **There must be an area for donning or removing Personal Protective Equipment (PPE):**

If staff interchange is required between clean and contaminated areas, PPE shall be carefully removed and hands thoroughly washed.

4. **There must be easy access to hand hygiene facilities¹⁶:**
 - a) dedicated hand washing sinks must be provided;
 - b) hand washing sinks should be conveniently located in or near all decontamination and preparation areas and at all entrances to and exits from the decontamination area;
 - c) hand washing facilities should also be located in all personnel support areas (e.g., change rooms);
 - d) “hands-free” operating sinks are recommended;
 - e) hand washing sinks must not be used for other purposes; and
 - f) accessible, adequately supplied and properly functioning soap dispensers, towel dispensers and alcohol-based hand rub, shall be made available.
5. **There must be easy access to emergency supplies¹⁶:**
 - a) eye-wash stations, deluge showers and spill equipment should be provided as necessary;
 - b) consult jurisdictional occupational health and safety statutes/regulations.
18. **The reprocessing area is regularly and adequately cleaned^{9, 16}:**
 - a) There is an area for storage of dedicated housekeeping equipment and supplies;
 - b) wet-vacuuming or hand-mopping with a clean mop head and clean, fresh water should be done at least daily;
 - c) spills are cleaned up immediately; and
 - d) there is an area for waste.

Medical equipment/device reprocessing areas require a ‘Hospital Clean’ regimen that includes:

- a) In sterile processing areas:
 - i) clean and disinfect all countertops, work areas, sinks and equipment surfaces at least daily;
 - ii) clean and disinfect sinks each shift at a minimum and more frequently as necessary;
 - iii) clean floors at least daily;
 - iv) clean shelves daily in sterilization areas, preparation and packing areas and decontamination areas;
 - v) clean shelves every three months in sterile storage areas;
 - vi) clean case carts after every use;
 - vii) clean walls every six months; and
 - viii) clean light fixtures, sprinkler heads and other fixtures every six months.
- b) In user units, clinics, endoscopy suites and other sterile storage areas:
 - i) clean and disinfect countertops, work areas and equipment surfaces at least daily;
 - ii) clean and disinfect sinks between each use;
 - iii) clean floors daily;
 - iv) clean shelves monthly;
 - v) clean walls every six months; and
 - vi) clean light fixtures, sprinkler heads and other fixtures every six months.

- For more information about ‘Hospital Clean’, see the MOHLTC’s ‘Best Practices for Environmental Cleaning in All Health Care Settings’.⁹

7. There is adequate storage space:

- a) there is an area for transportation equipment (e.g., carts, trolleys); and
- b) clean supplies and PPE must be stored in a separate area from soiled items and cleaning processes.

Environment Recommendations**1. In healthcare facilities ventilation, temperature and humidity of the Sterile Processing Department meets or exceeds CSA standards^{16, 49}:****a) CSA requirements for ventilation:**

- i) minimum 8 air changes per hour for soiled areas, 10 air changes per hour for clean areas
- ii) minimum 2 outdoor air changes per hour for soiled areas, three outdoor air changes per hour for clean areas
- iii) soiled areas: negative pressure
- iv) clean areas: positive pressure
- v) exhaust air vented outdoors and not recirculated
- vi) portable fans must not be used in any area of the sterile processing department

b) CSA recommendations for temperature and humidity:

- i) room temperature of all decontamination work areas should be between 18-20°C and between 20-23°C for clean areas
- ii) relative humidity should be maintained between 30-60% (preferably 40-50%) and be monitored daily
- iii) an independent humidity monitor that is calibrated regularly should be used in each sterile storage area
- iv) if humidity increases such that sterile packages become damp or wet (e.g., > 70%), the integrity of the package may be compromised¹:
 - immediately notify facility management and ensure that remedial action is taken
 - remove as much inventory as possible from the affected area; consider moving off-site if feasible
 - if items are visibly damp or damaged, they must be repackaged and reprocessed; if single-use, the item must be discarded
 - if there is no visible effect of moisture, the items may be used
 - if humidity reading after 24 hours is still >70%, a risk assessment must be performed to determine which items can be used, reprocessed or discarded

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

[Refer to Annex F in the Canadian Standards Association's 'Decontamination of Reusable Medical Devices' CAN/CSA-Z314.8-08]

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.

Water should appear colourless, clean and without sediment. Limiting values of water contaminants¹⁶:

- pH: 6.5 to 8
 - Evaporation residue: ≤ 15 mg/L
 - Conductivity: ≤ 50 $\mu\text{S}/\text{cm}$
 - Hardness: ≤ 0.1 mmol/L
 - Cadmium: ≤ 0.005 mg/L
 - Chloride: ≤ 3 mg/L
 - Iron: ≤ 0.2 mg/L
 - Lead: ≤ 0.05 mg/L
 - Phosphate: ≤ 0.5 mg/L
 - Silica: ≤ 2 mg/L
 - Other heavy metals: ≤ 0.1 mg/L
-

Adapted from:

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

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

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

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

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

NOTE: This sample checklist 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 are to be reprocessed in accordance with both the Ministry of Health and Long Term Care's "*Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings*", Public Health Agency of Canada infection control guidelines and current CSA standards. **Audits should be carried out on a regular basis** (e.g., annually).

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 are being reprocessed according to the MOHLTC's '*Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings*'. Audit results should be reviewed by the sterile processing department and the reprocessing committee.

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				
Cleaning				
Equipment/devices are cleaned using an enzymatic cleaner prior to reprocessing				
Cleaning is done in a separate area from where the instrument will be used (i.e., <i>designated dirty area</i>)				
Personal protective equipment is worn for cleaning and decontamination (<i>eye protection, mask, gown and gloves</i>)				
High-Level Disinfection				
Equipment/devices are subjected to high-level disinfection according to manufacturer's instructions, using an approved high-level disinfectant				
High-level disinfectant concentration is checked daily				
High-level disinfectant is not kept for more than 2 weeks, even if test strips indicate concentration is effective				
Quality Control on test strips is carried out as per manufacturer's instructions				
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				

Item	Yes	No	Partial	Comments
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				
Sterilization				
Equipment/devices are sterilized by an approved sterilization process				
Bowie Dick for high-vacuum sterilizer is done daily				
Sterilizer physical parameters are reviewed after each run				
Log is kept of physical parameters				
Sterilizer is monitored with biological indicator daily (<i>each type of cycle i.e., flash, long loads</i>)				
Log is kept of biological indicator results				
If biological indicator is positive, loads are recalled and the positive test is investigated				
Sterilizer has a preventive maintenance program				
Log is kept of preventive maintenance				
Log is kept of all maintenance associated with a positive biologic monitor				
Indicator tape is used on outside each wrapped package				
A chemical indicator is used inside each wrapped package				
Log is kept of each load and items in load				
Chemical indicators are checked before equipment/devices are used				
If flash sterilization is used, a log is kept of flash sterilizer use				
Flash sterilized equipment/devices are noted in the client/patient/resident's chart along with rationale for use				
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				
There a process in place that clearly identifies a non-reprocessed instrument from one that has been reprocessed				
Purchasing & Reprocessing Instructions				
Manager/purchaser is aware of purchasing policy for all medical equipment/devices requiring reprocessing				
There are explicit written reprocessing instructions from the manufacturer for each equipment/device to be reprocessed				
There are written policies and procedures for reprocessing that are compatible with current published reprocessing standards and guidelines.				
Education & Core Competency				
Manager and staff are educated on how to reprocess medical equipment/devices when: - First employed - Minimum of annually - Following any authorized change in process				

Item	Yes	No	Partial	Comments
○ When new reprocessing equipment is purchased ○ When new medical equipment/devices are purchased				
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 departments and Infection Prevention and Control are notified when follow up is required.				
There is 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: _____

Adapted from: Sunnybrook Health Sciences Centre

Appendix D: Sample Program Audit Tool for Endoscope Reprocessing

NOTE: This audit tool provides the program elements required for reprocessing endoscopes, to assist health care settings to develop their own audit tools and task lists for endoscope reprocessing procedures.

	Program Element	Specific Procedure	Yes / No/ Or N.A.	M.R.P.	Comment / Strategy for Improvement
1.	Comply with endoscope manufacturer's recommendations for cleaning	A. Endoscope is wiped and flushed immediately following procedure			
		B. Debris collected in the endoscope is removed (e.g., brushing)			
		C. Debris collected on the endoscope is removed (surface cleaning)			
		D. A leak test is performed			
		E. The endoscope is visually inspected to verify effective operation			
2.	Verify that endoscope can be reprocessed in site's automated endoscope reprocessor (AER)	A. There is documentation from endoscope manufacturer confirming compatibility of each scope with AER.			
		B. There is documentation from AER manufacturer confirming testing of individual endoscope in the facility's system.			
		C. Specific steps in reprocessing have been verified with the endoscope manufacturer before reprocessing endoscope in AER.			

	Program Element	Specific Procedure	Yes / No/ Or N.A.	M.R.P.	Comment / Strategy for Improvement
3.	Compare manufacturers' instructions and resolve conflicts.	A. Conflicts between the reprocessing instructions provided by the AER manufacturer and those provided by the endoscope manufacturer are 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 are in place for endoscopes not compatible with the AER.			
		B. There is compliance with the endoscope manufacturer's recommendations for hospital-approved chemical disinfectant.			
5.	Reprocessing protocol incorporates a final drying step.	A. All channels of reprocessed endoscopes are flushed with alcohol followed by purging with air.			
		B. Endoscopes are stored in a manner that minimized the likelihood of contamination or collection / retention of moisture.			
6.	Staff adhere to facility's procedures for preparing endoscope for client/patient/resident.	A. There is written confirmation that the AER's processes are applicable to each specific endoscope model.			
		B. Endoscope-specific reprocessing instructions from the AER manufacturer are correctly implemented.			
		C. Written, device-specific reprocessing instructions for every endoscope model are available to reprocessing staff.			
		D. Written policies and procedures for the 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 in all procedures.			
		B. Competency is maintained by periodic (annual) hands on training with every endoscope model and AER used in the facility.			

	Program Element	Specific Procedure	Yes / No/ Or N.A.	M.R.P.	Comment / Strategy for Improvement
		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. There is additional training with documented competency for new endoscope or AER models .			
8.	A comprehensive quality control program is in place.	A. There are periodic visual inspections (e.g., monthly) of the cleaning and disinfecting procedures.			
		B. There is a scheduled and documented endoscope preventive maintenance program.			
		C. There is a documented preventive maintenance program for AERs.			
		D. There is a documented preventive maintenance program for all reprocessing system filters.			
		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 endoscopes leaving the endoscope reprocessing area (e.g., repairs, loaners, O.R.)			
		I. There is a surveillance system that detects clusters of infections /pseudoinfections associated with endoscopic procedures.			

	Program Element	Specific Procedure	Yes / No/ Or N.A.	M.R.P.	Comment / Strategy for Improvement
9.	Staff adhere to Routine Practices.	A. Correct hand hygiene technique is demonstrated.			
		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 endoscope cleaning and reprocessing.			
		E. Heavily soiled and wet linen is placed into a waterproof 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 <i>Occupational Health and Safety Act</i> , R.S.O. 1990, c.O.1 and associated Regulations including the <i>Health Care and Residential Facilities</i> - 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 <i>Occupational Health and Safety Act</i> , R.S.O. 1990, c.O.1 and associated Regulations including the <i>Health Care and Residential Facilities</i> - O. Reg. 67/93 Amended to O. Reg. 631/05.			

Adapted from:

Kingston General Hospital, Kingston, Ontario (Infection Control Manual)

Appendix E: Sample Observational Audit Tool/ User Task List for Cleaning, Disinfection and/or Sterilization of Flexible Endoscopes

NOTE: This tool is a sample designed for competency verification of endoscope reprocessing staff through observation and is provided to assist health care settings in developing their own audit tools. It may also be used as a task check list by reprocessing staff.

Leak Testing	√	Comments
Wear appropriate personal protective equipment (PPE).		
Discard disposable valves.		
Place reusable valves and irrigation ports and removable parts into enzymatic cleaner.		
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.		

Manual Cleaning	√	Comments
Prepare enzymatic cleaner as per manufacturer's instructions with regard to dilution rate, temperature and time.		
Completely immerse the entire endoscope in freshly prepared enzymatic cleaner in basin 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 cleaner each time brush is passed through channel.		
Brush suction valve housing and instrument channel port with channel opening brush until all debris is removed.		
Attach a 30ml. syringe to the adapter and send enzymatic cleaner into the channels at least three times.		
Soak the endoscope in the enzymatic cleaner 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.		

Manual Disinfection	√	Comments
Test the HLD dilution as per facility protocol.		
Immerse the entire endoscope, valves, cleaning brush and 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 and 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 client/patient/resident record and logbook with date.		
Manipulate angulation knobs to test scope flexibility. Ensure optical clarity of telescope.		
Dry for ETO sterilization where required.		
Send accessories, e.g., biopsy brushes, for steam sterilization.		

Automated Disinfection	√	Comments
If applicable, test the HLD dilution as per facility protocol.		
Properly place the endoscope, valves, cleaning brush and 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 client/patient/resident record. Record endoscope number in AER logbook with date.		
Manipulate angulation knobs to test scope flexibility. Ensure optical clarity of telescope.		
Dry for ETO sterilization where required.		
Send accessories, e.g., biopsy brushes, for steam sterilization.		

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

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: _____

Adapted from:

Sunnybrook Health Sciences Centre and from the Carsen Medical Imaging Group

Appendix F: Advantages and Disadvantages of Currently Available Reprocessing Options

STERILIZATION

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	Dental equipment Sterilization is achieved after 20 minutes exposure. It is highly recommended that steam sterilization be used in place of chemiclaves.	- Mechanical – each cycle/load - Chemical – each pack - Biological – daily (<i>Geobacillus stearothermophilus</i> spores)		Toxic chemicals used (chemicals may be considered hazardous waste in some jurisdictions)
Dry Heat Gravity convection Mechanical convection	- Anhydrous oil - Powders, creams - Glass - Foot care equipment - Heat tolerant equipment/devices <u>Temperatures – time</u> 171°C – 60 min 160°C – 120 min 149°C – 150 min 141°C – 180 min 121°C – 12 hours	- Mechanical – each cycle/load - Chemical – each pack - Biological – daily (<i>Bacillus atrophaeus</i> spores)	- No corrosive or rusting effect on instruments - Reaches surfaces of instruments that cannot be disassembled - Inexpensive	- 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

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	- Heat sensitive equipment/devices - Lensed instruments that require sterilization EtO concentration based on manufacturer's instructions Temperature – variable Humidity – 50% Time – extended processing time (several hours)	- Mechanical – each cycle/load - Chemical – each pack - Biologic al– each cycle/load (<i>Bacillus atrophaeus</i> spores) Routine testing shall include a biological indicator placed in the centre of each load to be sterilized, and a chemical indicator in each pack. A rapid readout biologic al indicator is available (4 hours)	Not harmful to heat-sensitive and lensed instruments	- Expensive - Toxic to humans - Requires monitoring of residual gas levels in environment - Requires aeration of sterilized products prior to use - 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	- 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	- Mechanical – each cycle/load - Chemical – each pack - Biological – daily (<i>G. stearothermophilus</i> spores) Testing should include each type of cycle and load configuration (e.g., open tray, rigid container, single wrapper) to be used that day. One biological indicator 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	- 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/residents, 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	- Limited use as a chemosterilant - Sometimes used to reprocess hemodialyzers - Gaseous form used to decontaminate laboratory safety cabinets	- Biologic al indicators are not available - Concentration must be monitored	Active in the presence of organic materials	- Toxic - Carcinogenic - Strong irritant - Pungent odour - Cannot be monitored for sterility
Glass bead sterilizers	Not acceptable	None	Not acceptable	
Glutaraldehyde (2.5%-3.5%)	- May be used on metals, plastics, rubber, equipment/devices with lens cement - May use on heat sensitive equipment/devices 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. Sterilized equipment/devices must be rinsed with sterile water to remove all residual chemical. Sterilized equipment/devices must be handled in a manner that prevents contamination from process through storage to use	- Exposure time and temperature must be maintained - Monitors are available for pH and dilution concentration - Biological indicators are not available Concentration is monitored using test strips provided by the product manufacturer. Testing must be done at least daily. 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.	- Heat sensitive equipment/devices - Does not coagulate protein	- 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	
Hydrogen Peroxide , Accelerated (7%)	Heat sensitive equipment/devices Sterility is achieved after 6 hours of undiluted solution at 20°C. (refer to product label for time and temperature).	- Biological indicators are not available - Chemical – test kits to monitor the concentration are available from the manufacturer and must be used for each load	- Safe for environment - Non-toxic - Rapid - Inexpensive - Active in the presence of organic materials	- Contraindicated for use on copper, brass, carbon-tipped devices and anodised aluminum - Cannot monitor for sterility
Hydrogen peroxide gas plasma	Heat sensitive equipment/devices Sterility is achieved after 75 minutes at 50°C	Follow manufacturer's instructions - Chemical – each pack - Biological – daily (<i>Bacillus stearothermophilus</i> spores)	- 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	- 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%)	- Heat sensitive equipment/devices (e.g. eye equipment) - Costly equipment/devices that may be lost in transit Sterility is achieved after 6 hours.	- Biological indicators are not available - Concentration must be monitored	- Less toxic than other chemical sterilants - Safe for environment - Rapid	- 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	Critical equipment/devices Some semicritical equipment/devices	Effective sterilization must be monitored	Completely kills all forms of microbial life including spores	
Peracetic acid (0.2%)	Heat sensitive immersible equipment/devices (e.g. endoscopes, dental and surgical instruments) 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).	- 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 - Biological – daily (G. <i>stearothermophilus</i> spores)	- Rapid - Automated - Leaves no residue - Effective in presence of organic matter - Sporicidal at low temperatures - Safe for environment	- Monitoring of efficacy of sterilization cycle with spore strips is questionable - Can be used for immersible instruments only - Corrosive - Incompatibility with some materials (e.g., aluminum) - Unstable, particularly when diluted In vapour form, PAA is volatile, has a pungent odour, is toxic and is a fire and explosion hazard.
Steam Sterilization Small table top sterilizers Gravity displacement sterilizers High-speed vacuum sterilizers	First choice for critical equipment/devices - Heat tolerant instruments and accessories - Linen - Liquids - Foot care equipment Raised pressure (preset by manufacturer) to increase temperature to 121°C. Time varies with temperature, type of material and whether the instrument is wrapped or not. Steam must be saturated (narrow lumen equipment/devices may require prehumidification)	- 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 - Biological – daily and on every type of cycle to be used; and with each load of implantable equipment/devices; Place biological indicator near the drain in a fully loaded sterilizer (G. <i>stearothermophilus</i> spores). Loads containing implantable devices shall be quarantined until the results of the biological indicator testing are available.	- Inexpensive - Rapid - Efficient - Non-toxic - Good penetration	- 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

HIGH-LEVEL DISINFECTION

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%)	- 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 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.	- 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). 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.	- Noncorrosive to metal, plastic, rubber, lens cements - Active in presence of organic material	- 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%)	- Heat sensitive equipment/devices - Delicate equipment/devices Achieves high-level disinfection with undiluted 7% solution after at least 20 minutes at 20°C (refer to product label for time and temperature).	Test kits to monitor the concentration are available from the manufacturer and must be used with each load.	- Safe for environment - Non-toxic - Active in the presence of organic materials - Rapid - Inexpensive	Contraindicated for use on copper, brass, carbon-tipped devices and anodised 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.
Hydrogen peroxide (6%)	- Semicritical equipment used for home health care - Disinfection of soft contact lenses Achieves high-level disinfection after at least 30 minutes.	Not currently available	- Strong oxidant - Rapid action - Safe for the environment - Low cost	- Must be stored in cool place, protect from light - Contraindicated for use on copper, brass, carbon-tipped devices and aluminum
Ortho-phthalaldehyde (OPA) (0.55%)	- Endoscopy equipment/devices (contraindicated for cystoscopes) - Heat sensitive equipment/devices Achieves high-level disinfection after at least 10 minutes at 20°C.	Test strips for concentration are available from the manufacturer and must be used at least daily (preferably with each load).	- Superior penetration - Rapid activity - Active in presence of organic materials - Non-irritating vapour - Does not require activation or dilution	- Stains protein, including hands, requiring gloves and gown for use - Expensive - Contraindicated for cystoscopes due to risk of sensitization and anaphylaxis⁵⁰
Pasteurization	- Respiratory therapy equipment - Anaesthesia equipment Achieves high-level disinfection at 71°C for 30 min.	- 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 instructions	- Rapid, simple, moderate cost - Alternative to chemicals - Non-toxic - Can be used for some plastics	- Dry well & store carefully to prevent contamination - Difficult to monitor efficacy of the process - Preventive maintenance required

LOW-LEVEL DISINFECTION

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
Alcohols (60-95%)	- External surfaces of some equipment (e.g. stethoscopes) - Noncritical equipment used for home health care - Used as a skin antiseptic Disinfection is achieved after 10 minutes of contact. Observe fire code restrictions for storage of alcohol.	Monitoring not required	- Non-toxic - Low cost - Rapid action - Non-staining - No residue - Effective on clean equipment/devices that can be immersed	- 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 - Contraindicated in the Operating Room
Chlorines	- Hydrotherapy tanks, exterior surfaces of dialysis equipment, cardiopulmonary training manikins, environmental surfaces - Noncritical equipment used for home health care - Blood spills	Monitoring not required	- Low cost - Rapid action - Readily available in non hospital settings	- 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

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.	<u>Dilution of Household Bleach</u> [REF: Health Canada/PHAC: "<i>Hand Washing, Cleaning, disinfection and Sterilization in Health Care</i>". Table 7, page 17] <u>Undiluted</u>: 5.25% sodium hypochlorite, 50,000 ppm available chlorine <u>Blood spill – major</u>: dilute 1:10 with tap water to achieve 0.5% or 5,000 ppm chlorine <u>Blood spill – minor</u>: dilute 1:100 with tap water to achieve 0.05% or 500 ppm chlorine <u>Surface cleaning, soaking of items</u>: dilute 1:50 with tap water to achieve 0.1% or 1,000 ppm chlorine			▪ Must be stored in closed containers away from ultraviolet light & heat to prevent deterioration ▪ Stains clothing and carpets
Accelerated Hydrogen Peroxide 0.5% (7% solution diluted 1:16)	▪ Isolation room surfaces ▪ Clinic and procedure room surfaces Low-level disinfection is achieved after 5 minutes of contact at 20°C.	Monitoring not required, however test kits are available from the manufacturer	▪ 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	▪ Contraindicated for use on copper, brass, carbon-tipped devices and anodised aluminum

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
Hydrogen peroxide 3%	- Noncritical equipment used for home health care - Floors, walls, furnishings Disinfection is achieved with a 3% solution after 10 minutes of contact.	Monitoring not required	- Low cost - Rapid action - Safe for the environment	- Contraindicated for use on copper, zinc, brass, aluminum - Store in cool place, protect from light
Iodophors (Non-antiseptic formulations)	- Hydrotherapy tanks - Thermometers - Hard surfaces and equipment that do not touch mucous membranes (e.g. IV poles, wheelchairs, beds, call bells) DO NOT use antiseptic iodophors as hard surface disinfectants	Monitoring not required	- Rapid action - Non-toxic	- Corrosive to metal unless combined with inhibitors - Inactivated by organic materials - May stain fabrics and synthetic materials
Phenolics	- Floors, walls and furnishings - Hard surfaces and equipment that do not touch mucous membranes (e.g. IV poles, wheelchairs, beds, call bells) DO NOT use phenolics in nurseries	Monitoring not required	- 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	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

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
Quaternary ammonium compounds (QUATs)	- Floors, walls and furnishings - Blood spills prior to disinfection DO NOT use QUATs to disinfect instruments	Monitoring not required	- Non corrosive, non-toxic, low irritant - Good cleaning ability, usually have detergent properties - Rinsing not required - May be used on food surfaces	- 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)

Adapted from:

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

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

Appendix G: Resources for Education and Training

Resources for Infection Prevention and Control

1. Organizations and Publications

Canadian Standards Association (CSA)

Source for national standards in sterilization and sterilizing equipment.

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

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.pidac.ca/>

Public Health Agency of Canada (PHAC)

Public Health Agency of Canada. Guidelines – Infectious Diseases. Infection Control Guidelines – Hand

Washing, Cleaning, Disinfection and Sterilization in Health Care. Canada Communicable Disease Report. 1998; 27(Suppl 8): i-xi, 1-55.

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

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

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

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

Infection Control Guidelines.

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

PubMed

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

<http://www.pubmed.com>

2. Professional Associations

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

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

<http://www.chica.org>

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

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

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

The College of Physicians and Surgeons of Ontario

Infection Control in Physician's Office, 2004.

<http://www.cpso.on.ca/policies/guidelines/default.aspx?id=1766>

Resources for Training in 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.csao.net/education/index.php>

Algonquin College (Ottawa)

Offers course on Sterile Supply Processing.

<http://xweb.algonquincollege.com/courseDetail.aspx?id=HLT0151>

Centennial College (Toronto)

Offers certificate course in processing:

Introduction to Sterile Supply: <http://www.centennialcollege.ca/cgi-bin/FM.cgi?cecrs=SSPP-110>

Sterile Supply Processing: <http://www.centennialcollege.ca/cgi-bin/FM.cgi?cecert=7920>

Fanshawe College (London)

Offers Sterile Processing Technician certificate course.

<http://www.fanshawec.ca/EN/ce/ce/9512/health.html>

Ontario Hospitals Association (OHA)

Offers courses for CSAO workers.

<http://www.oha.com>

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