

Reusable & Single-Use Medical Devices Standards

Standards for the reprocessing of reusable medical devices and for the use of single-use medical devices, in all health care facilities and settings

Alberta Health, Government of Alberta

September 2019

Reusable & Single-Use Medical Devices Standards: Standards for the reprocessing of reusable medical devices and for the use of single-use medical devices in all health care facilities and settings

ISBN 978-1-4601-4547-0

Reader Information

The *Reusable & Single-Use Medical Devices Standards* (“Standards”) have been developed with input from experts in infection prevention and control, infectious diseases, medical device reprocessing, and environmental public health, representing Alberta Health, Alberta Health Services, and Covenant Health. Alberta Health also consulted with Alberta’s health profession regulatory colleges in the development of these Standards. The Canadian Standards Association (CSA) Z314-18 standards for Canadian medical device reprocessing are the key reference material for these Standards. Information from sources including Accreditation Canada, Health Canada, the Canadian Agency for Drug Technologies in Health (CADTH), Infection Prevention and Control Canada (IPAC), the Public Health Agency of Canada (PHAC), the World Health Organization (WHO), the US Centers for Disease Control and Prevention (CDC), and the US Food and Drug Administration (FDA) has also been considered.

Applicability

These Standards apply to Alberta Health Services and its contracted service providers. Alberta Health recommends that these Standards be applied in all health care facilities or settings where health services are provided.

Documents Updated/Replaced

These Standards update and replace the *Standards for Cleaning, Disinfection and Sterilization of Reusable Medical Devices for Health Care Facilities and Settings*, June 2012 and the *Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices*, February 2011.

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Introduction

The *Reusable & Single-Use Medical Devices Standards: Standards for the reprocessing of reusable medical devices and for the use of single-use medical devices in all health care facilities and settings* (“Standards”) establish minimum requirements for the use of single-use medical devices and the cleaning, disinfection, and sterilization (“reprocessing”) of reusable medical devices between client use.

The goals of these Standards are to:

- control and prevent the transmission of microorganisms to clients, personnel, the public, and the environment;
- minimize the risk of harm to clients and personnel;
- promote the safe use of single-use medical devices; and
- support health profession regulatory colleges, health care professionals, and other personnel who use or reprocess medical devices.

These Standards are organized into three parts. Part A addresses minimum requirements related to the use of single-use medical devices. Part B covers minimum requirements related to reprocessing reusable medical devices, including associated environmental and structural requirements for medical device reprocessing (MDR) areas, standards for procurement, and education and training requirements. Part C establishes the minimum requirements for a quality management system that applies to both single-use and reusable medical devices.

Compliance with these Standards is mandatory for Alberta Health Services (AHS) as the Standards are delivered by Directive, issued under s.8 of the [Regional Health Authorities Act](#). Additionally, AHS is required to impose these Standards on their contracted service providers.

Alberta Health recommends the Standards be applied in any facility or setting where health services are provided and where a single-use or reusable medical device may be used or reprocessed. This includes privately operated community-based health care settings, home-based businesses, and private clinics.

Under the [Health Professions Act](#) 3(1)(c), health profession regulatory colleges must establish, maintain, and enforce standards of continuing competence and standards of practice appropriate to the regulated profession. Regulatory colleges are encouraged to use these Standards in order to meet this obligation.

The standards set out in this document were developed using the [CSA Z314-18: Canadian medical device reprocessing](#) standards prepared by the Canadian Standards Association (CSA). These Standards are consistent with recommendations and guidelines from Health Canada, the Public Health Agency of Canada (PHAC), and the Spaulding classification system.

Additional standards and guidelines established by Health Canada and the CSA that are not referenced in these Standards may also be applicable. Organizations must also comply with relevant legislation including but not limited to Alberta's [Occupational Health and Safety Act](#), OHS Regulation and OHS Code, and [Dangerous Goods Transportation and Handling Act](#) and its pursuant regulation.

If an organization is unable to meet these minimum standards for reprocessing, it can choose to outsource its MDR or use single-use medical devices instead of reusable devices.

These Standards are based on current information. Best practices in MDR will evolve as evidence and technology change. It is the organization's responsibility to ensure it has current infection prevention and control and reprocessing practices in place.

The Spaulding Classification System

Spaulding, E.H. 1971. The role of chemical disinfection in the prevention of nosocomial infections in *Proceedings of the International Conference on Nosocomial Infections*, 1970. Eds. Brachman, P.S. and Eickoff, T.C. Chicago: American Hospital Association: 254–274.

The Spaulding classification system divides medical devices into three categories based on the potential risk of infection: critical medical devices, semi-critical medical devices, and non-critical medical devices.

The Spaulding classification system establishes the minimum level of reprocessing needed to ensure medical devices are safe for use between clients.

STERILIZATION	HIGH LEVEL DISINFECTION	INTERMEDIATE OR LOW LEVEL DISINFECTION
<i>Devices below must be cleaned, and then sterilized</i>	<i>As a minimum, devices below must be cleaned, and then high level disinfected²</i>	
<p>Critical medical devices I.e., devices that enter sterile tissues, including the vascular system.</p> <p>Examples of critical medical devices include but are not limited to:</p> <ul style="list-style-type: none"> • surgical medical devices (CSA Z314-18, 16.1.2.1) • biopsy forceps and brushes (CSA Z314-18, 12.7.1.2 and 16.1.2.1) • endoscopes and accessories that enter sterile cavities and spaces (CSA Z314-18, 16.1.2.1), including arthroscopes (CSA Z314-18, 16.2.4.4.4), bronchoscopes (CSA Z314-18, 12.1.5 and 16.2.4.4.4), and cystoscopes (CSA Z314-18, 12.1.5) 	<p>Semi-critical medical devices I.e., devices that make contact with intact mucous membrane or non-intact skin.</p> <p>Examples of semi-critical medical devices include but are not limited to:</p> <ul style="list-style-type: none"> • respiratory equipment (CSA Z314-18, 11.8 and Annex C, C.6, 2.2) • vaginal specula • ultrasound transducer probes that come into contact with mucous membrane (e.g., vaginal probes, transesophageal echocardiogram probes) (CSA Z314-18, 13.1.2) • pessary and diaphragm fitting rings 	<p>Non-critical medical devices and equipment I.e., devices and equipment that make contact with intact skin or do not make direct contact.</p> <p>Examples of non-critical medical devices include but are not limited to:</p> <ul style="list-style-type: none"> • stethoscopes • blood pressure cuffs
<p>Dental medical devices¹ Including semi-critical dental medical devices that are compatible with heat and moisture, and critical dental medical devices (CSA Z314-18, 16.1.2.1).</p>		
<p>Foot care devices¹ I.e., foot care equipment that is reused between clients (CSA Z314-18, 16.1.2.1).</p> <p>Examples of foot care devices may include but are not limited to nail nippers, files, rasps or nail probes.</p>		

¹ Even though some dental medical devices and foot care devices may be classified as semi-critical medical devices, sterilization of these devices between client use is the appropriate reprocessing method due to the possibility that dental and foot care procedures can become invasive.

² If a semi-critical medical device can be safely sterilized in accordance with the MIFU, the preferred final reprocessing step for a semi-critical medical device is sterilization.

Definitions

A₀	<p>A theoretical measurement of microbiological lethality delivered by a moist heat disinfection process expressed in terms of the equivalent time in seconds and temperature.</p> <p>Reference: CSA Z314-18, p. 22.</p>
Biological indicator (BI)	<p>A test system containing viable bacterial spores providing a defined resistance to a specified sterilization process.</p> <p>Reference: CSA Z314-18, p. 23.</p>
Chemical indicator (CI)	<p>A test 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.</p> <p>Reference: CSA Z314-18, p. 24.</p>
Cleaning	<p>The removal of contamination from an item to render it visually free of soil and quantified as below specified levels of the substance to be measured.</p> <p>Reference: CSA Z314-18, p. 24.</p>
Client	<p>The recipient of health care services. May also be called a patient, consumer, individual, or resident.</p> <p>Reference: Accreditation Canada: <i>Reprocessing of Reusable Medical Devices</i> (2018), p. 3.</p>
Commercial reprocessor	<p>A company that reprocesses medical devices and offers its activities and products as a service in compliance with the Food and Drugs Act and the Medical Devices Regulations and the corresponding requirements to meet appropriate standards for safety, effectiveness, and labelling.</p> <p>Reference: Adapted from Health Canada: <i>Update: Notice to Stakeholders - Health Canada's Regulatory Approach to Commercial Reprocessing of Medical Devices Originally Labelled for Single Use.</i> (Accessed July 22, 2019.)</p>
Competent	<p>In relation to a person, means adequately qualified, suitably trained, and with sufficient experience to safely perform work without supervision or with only a minimal degree of supervision.</p> <p>Reference: Government of Alberta, <i>Occupational Health and Safety Act</i> (2018).</p>

Critical medical device	A medical device that enters sterile tissues, including the vascular system. Reference: CSA Z314-18, p. 31.
Decontamination/ decontaminated	The process of cleaning, by use of physical and/or chemical means, to remove, inactivate, or destroy pathogenic micro-organisms, in order to render an object safe for handling. Reference: Adapted from CSA Z314-18, p. 24.
Disinfectant	Chemical(s) used for disinfection, including high-level disinfectant (HLD), intermediate-level disinfectant (ILD), and low-level disinfectant (LLD). Reference: CSA Z314-18, p. 24.
Disinfection/ disinfect/ disinfected	The process to inactivate viable micro-organisms to a level previously specified as being appropriate for a defined purpose. (See definitions for high-level disinfection, intermediate-level disinfection, and low-level disinfection). Reference: CSA Z314-18, p. 25.
Drug identification number (DIN)	A drug identification number (DIN) is an eight (8) digit numerical code assigned to each drug product marketed under the Food and Drugs Act and Regulations . A DIN identifies the following product characteristics: <ul style="list-style-type: none"> • manufacturer; • brand name; • medicinal ingredient(s); • strength of medicinal ingredient(s); • pharmaceutical form; and • route of administration. Reference: Adapted from Health Canada: <i>Guideline on Preparation of DIN Submissions</i> (1995). (Accessed July 22, 2019.)
Hand hygiene	Hand washing, hand antisepsis or other actions taken to maintain healthy hands and fingernails. Reference: Adapted from CSA Z314-18, p. 26.

Health care facility or setting

A facility or setting in which a client receives health services including, but not limited to, the following:

- hospitals;
- ambulatory care clinics;
- urgent care services;
- non-hospital surgical facilities;
- mobile treatment centres;
- public health clinics;
- hospices;
- addiction and mental health clinics and facilities;
- private clinics delivering health services in community settings;
- settings where dental and dental hygiene services are provided;
- diagnostic imaging centres;
- laboratories;
- supportive living facilities (including but not limited to designated-supportive living);
- long-term care facilities (nursing homes and auxiliary hospitals);
- educational institutions;
- correctional centres; and
- private dwellings, when health services are provided in the client's home or another private dwelling such as a home-based business.

High efficiency particulate air (HEPA) filter

An air filter with an efficiency of 99.97% in the removal of airborne particles 0.3µm or larger in diameter.

[Reference: CSA Z317.13, *Infection Control during Construction or Renovation of Health Care Facilities*, p. 17.](#)

High level disinfection

A process capable of killing vegetative bacteria, mycobacteria (including *Mycobacterium tuberculosis*), fungi, and lipid and nonlipid viruses, as well as some, but not necessarily high numbers of, bacterial spores.

[Reference: CSA Z314-18, p. 26.](#)

Immediate-use steam sterilization (IUSS)

A steam sterilization process designed and used for the sterilization of surgical devices when routine sterilization processes cannot be used.

[Reference: Adapted from Accreditation Canada: *Reprocessing of Reusable Medical Devices* \(2018\), p. 6.](#)

Infection prevention and control (IPC)	The discipline concerned with preventing health care associated infection. Reference: Infection Prevention and Control Canada (IPAC) Program Standard , December 2016. (Accessed July 23, 2019.)
Intermediate level disinfection	A process capable of killing vegetative bacteria, mycobacteria (including <i>Mycobacterium tuberculosis</i>), fungi, and lipid and nonlipid viruses. Reference: CSA Z314-18, p. 27.
Installation qualification (IQ)	The process of obtaining and documenting evidence that equipment has been provided and installed according to its specification. Reference: CSA Z314-18, p. 27.
In-use life	The maximum number of days or use cycles that a product can be used. Reference: CSA Z314-18, 11.7.2.3.1.
Low level disinfection	A process capable of killing most vegetative bacteria and some fungi, as well as enveloped (lipid) viruses (e.g., influenza, hepatitis B and C, and HIV). Low level disinfection does not kill mycobacteria, non-enveloped viruses, or bacterial spores. Reference: CSA Z314-18, p. 28.

Manufacturer

A person (including a partnership, firm or association) who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person and with respect to the medical device, is responsible for the following:

- designing;
- manufacturing;
- assembling;
- processing
- labelling;
- packaging;
- refurbishing;
- modifying;
- assigning the medical device an intended purpose; or
- depending upon the class of the medical device, providing validated MIFU for reprocessing;

whether those tasks are performed by that person or on their behalf.

A manufacturer may also be a person or department who develops or modifies a medical device for use within the organization (but not for resale).

References: Adapted from CSA Z17664, 2.5 and Health Canada's [Medical Devices Regulations](#), and Health Canada's [Guidance Document: Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices](#) (June 2011). (Accessed July 23, 2019.)

Manufacturer's instructions for use (MIFU)

The validated, written directions provided by the manufacturer or distributor of a medical device or product, that contains the necessary information for the safe and effective use of the medical device or product.

Reference: CSA Z314-18, p. 28.

Note: The term MIFU may also be used to refer to written instructions for use developed internally or by a commercial reprocessor, that have been validated by an approved laboratory.

Medical device

Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for a human being for any of the following purposes:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap;
- investigation, replacement, or modification of the anatomy, or of a physiologic process; or
- control of conception,

and that does not achieve its principal intended purpose in or on the human body by pharmacological, immunological, or metabolic means, but that can be assisted in its function by such means.

Notes:

1. For the purpose of clarity and in alignment with the definitions of (medical) devices in the federal [Food and Drugs Act](#) and the [Medical Devices Regulations](#), dental devices are considered medical devices.
2. For the purposes of these Standards, foot care devices are considered medical devices.
3. Under the [Medical Devices Regulations](#), Health Canada licenses high-level disinfectants and sterilants used in the reprocessing of medical devices as medical devices. However, in the context of these Standards, the term “medical device” does not include high-level disinfectants and sterilants.

References: Adapted from CSA Z314-18, p. 28 and Health Canada’s [Medical Devices Regulations](#).

Medical device licence (MDL)

A licence issued to a manufacturer by Health Canada, for a specific medical device.

Medical device reprocessing (MDR) area

An area where the reprocessing of reusable critical and semi-critical medical devices occurs. This includes centralized MDR departments, or any area where reprocessing of reusable critical and semi-critical medical devices takes place.

Reference: Adaptation of definition for “medical device reprocessing department” in CSA Z314-18, p. 28.

Minimum effective concentration (MEC)	The lowest concentration of a liquid chemical sterilant or disinfectant that achieves the claimed microbial activity. Reference: CSA Z314-18, p. 28.
Non-critical medical device	A medical device, which either touches only intact skin but not mucous membranes, or does not touch the client. Reference: CSA Z314-18, p. 31.
Occupational health and safety (OHS)	A cross-disciplinary field that is concerned with protecting the physical, psychological, and social health and safety of people at work, preventing worker injury and illness, and considers both the worker and the work environment. Reference: Adapted from Government of Alberta, <u>Occupational Health and Safety Act</u> (2018).
One-way workflow	The practice of ensuring that reprocessing work flows in one direction from the dirtiest to the cleanest. Reference: CSA Z314-18, p. 29.
Operational qualification (OQ)	The process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures. Reference: CSA Z314-18, p. 29.
Organization	An entity responsible for the management of a health care facility or setting.
Packaging	(verb) — A step in the sterilization process in which a medical device is enclosed in materials or a container designed to <ul style="list-style-type: none"> a) allow the penetration and removal of the sterilant during sterilization; and b) protect the medical device from contamination and other damage following sterilization and until the time of use. Reference: CSA Z314-18, p. 29.
Performance qualification (PQ)	The process of obtaining and documenting evidence that the equipment, as installed and operated according to operational procedures, consistently performs according to predetermined criteria and thereby yields product meeting its specification. Reference: CSA Z314-18, p. 30.

Personal protective equipment (PPE)	Equipment or clothing worn by a person for protection from health or safety hazards associated with conditions at a work site. Reference: Government of Alberta, <u>Occupational Health and Safety Code (2018)</u> .
Policy	A document outlining an organization's plan or course of action. Reference: Adapted from Accreditation Canada: <i>Infection Prevention and Control Standards (2017)</i>, p. 5.
Process challenge device (PCD)	An item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process. Reference: CSA Z314-18, p. 30.
Reposable medical device	A medical device designated for a specific and limited number of uses by the manufacturer. Reference: Adapted from CSA Z314-18, 7.2 and 7.7.
Reprocessing/ reprocess/ reprocessed	The cleaning, disinfection, and/or sterilization of a potentially contaminated medical device so that it is safe and effective for use on a client. Reference: Adapted from Accreditation Canada, <i>Reprocessing of Reusable Medical Devices (2018)</i>, p. 6.
Reusable medical device	A device that has been designed by the manufacturer, through the selection of materials and/or components, to be reprocessed and reused. Reference: CSA Z314-18, p. 30.
Routine practices	The approach to infection control used to minimize or prevent exposure to microorganisms in health care facilities and settings, i.e., blood and body fluid, secretions, and excretions from all clients. Examples of routine practices include hand hygiene, point of care risk assessment, use of personal protective equipment, environmental cleaning, and waste and sharps handling. References: CSA Z314-18, p. 31 and <u>Alberta Health Services: IPC Routine Practices</u>. (Accessed July 23, 2019.)
Semi-critical medical device	A medical device that comes into contact with mucous membranes or non-intact skin, but does not penetrate them. Reference: CSA Z314-18, p. 31.


Sharps

Needles, knives, scalpels, blades, scissors, and other items that can cut or puncture a person, that may also be contaminated with a biohazardous material.

Reference: Government of Alberta, [Occupational Health and Safety Code \(2018\)](#).

Single-use medical device

Critical and semi-critical medical devices labelled by their manufacturers to be used only once. The manufacturer may use terms, including but not limited to the following, to designate a device for single-use only:

- disposable;
- consumable;
- not for re-use or do not re-use;
- discard after single-use;
- do not use twice; or
- a symbol such as: 

References: ISO 7000, Registration number 1051; ISO 15223-1:2016, 5.4.2; and Health Canada, [Update: Notice to Stakeholders - Health Canada's Regulatory Approach to Commercial Reprocessing of Medical Devices Originally Labelled for Single Use](#) (May 2016). (Accessed July 23, 2019.)

Standard operating procedure (SOP)

A thorough, step-by-step documentation of a procedure.

Note:

The objectives of an SOP are to

- define the system of information and control;*
- minimize the risk of misinterpretation and error inherent in oral or casually written communication;*
- provide unambiguous procedures to be followed and the order in which they should be performed; and*
- provide confirmation that process parameters have been achieved.*

Reference: CSA Z314-18, p. 31.

Sterilization/sterilize/sterilized

The validated process used to render a product free from viable microorganisms.

Reference: CSA Z314-18, p. 32.

Thermal disinfection

Moist heat that is applied at or above a specified temperature, to all parts of the item, for a specified time, to achieve the required level of disinfection.

Reference: Adapted from CSA Z314-18, p. 33.

Thermal high level disinfection

Thermal disinfection that achieves high level disinfection.

Thermal high level disinfection must, at a minimum, meet parameters that are equivalent to pasteurization. An A_0 value of 600 is equivalent to pasteurization using hot water immersion at 71°C (160°F) for a minimum contact time of 30 minutes.

References: CSA Z314-18, 11.8.1, 11.8.4.1.1, 11.8.4.2.3, and Table 11.1.

Validation/ validated

A confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Notes:

1. The objective evidence needed for validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.
2. The term “validated” is used to designate the corresponding status.
3. The use conditions for validation can be real or simulated.

Reference: CSA Z314-18, p. 33.

PART A: SINGLE-USE MEDICAL DEVICES

1. Single-Use Medical Devices

- 1.1 Single-use medical devices shall only be used on a single client for a single procedure and then must be discarded.

References: ISO 15223-1:2016, 5.4.2 and CADTH: [Reprocessing Single-Use Medical Devices](#). (Accessed July 22, 2019.)

- 1.2 A single-use medical device shall not be used beyond the expiry date specified by the manufacturer.

References: [Medical Devices Regulations](#), 21(1)(g) and ISO 11607-1:2006, 3.5

- 1.3 A sterile critical single-use medical device shall be maintained as sterile until point of use.

- 1.4 Opened but unused single-use medical devices must be discarded, unless the manufacturer provides validated manufacturer's instructions for use (MIFU) for reprocessing (e.g., orthopaedic plates and screws).

Reference: CSA Z314-18, 14.5.1.3

- 1.5 Prior to using a single-use medical device that was purchased in a non-sterile state, that single-use medical device shall be inspected and processed according to the validated MIFU (e.g., dental burs, endodontic files, and orthopedic plates and screws).

Reference: Morrison, A. & Conrod, S. (2009). Dental Burs and Endodontic Files: Are Routine Sterilization Procedures Effective? *Journal of the Canadian Dental Association*, 75(1), p. 39. Retrieved from <https://cda-adc.ca/jcda/vol-75/issue-1/39.pdf>. (Accessed June 6, 2018.)

Commercial Reprocessing of Single-Use Medical Devices

- 1.6 Notwithstanding clauses 1.1-1.5, single-use medical devices may be reprocessed for reuse, if reprocessed by a commercial reprocessor operating in accordance with Health Canada's requirements for reprocessing and distribution of medical devices originally authorized and labelled as single-use medical devices.

Note: Under the authority of the [Food and Drugs Act](#) and [Medical Devices Regulations](#), Health Canada holds commercial reproducers, which are companies that reprocess and redistribute medical devices originally authorized and labelled for single use to Canadian health care facilities, to the same requirements as manufacturers of new devices. This means that commercial reproducers must meet requirements for licensing, quality system management, labelling, investigating and handling complaints, maintaining distribution records, conducting recalls, reporting incidents, and informing Health Canada of any changes to the information in their licence application.

Reference: Health Canada: [Update: Notice to Stakeholders - Health Canada's Regulatory Approach to Commercial Reprocessing of Medical Devices Originally Labelled for Single Use](#). (Accessed July 22, 2019.)

PART B: REPROCESSING OF REUSABLE MEDICAL DEVICES

2. Environmental and Structural Requirements for an MDR Area

- 2.1 The MDR area shall be a designated area, separate from client care areas, and activity in the area shall be restricted to the reprocessing of reusable medical devices.

References: CSA Z314-18, Definition (p. 28), 10.1, and 11.7.2.4.1

- 2.2 All MDR areas shall:

- 2.2.1 have physical separation of clean and dirty areas;

Reference: CSA Z314-18, 10.1

- 2.2.1.1 In existing health care facilities and settings where physical separation (i.e., with walls or partitions) of reprocessing areas is not possible, spatial separation and a one-way work flow pattern must be established to limit cross-contamination.

Note: *If your organization requires support in identifying an adequate degree of spatial separation, you are encouraged to contact a public health inspector or an infection control professional (ICP) for advice.*

- 2.2.2 have at least two adjacent sinks, large enough to immerse the largest piece of equipment, to clean and rinse soiled items;

Reference: CSA Z8000-18, 10.7.3.2

- 2.2.2.1 Notwithstanding 2.2.2, in existing smaller community-based health care facilities or settings where two adjacent sinks dedicated for equipment cleaning and rinsing are not possible, a dedicated basin for rinsing equipment after cleaning in a dedicated sink is an acceptable alternative. The dedicated basin must be large enough to fully submerge the item being rinsed.

Note: *It is understood that many MDR areas in smaller community-based health care facilities and settings have only a one-compartment sink. In any new construction, future renovation or relocation of a community-based health care facility or setting, the MDR area should comply with these Standards.*

2.2.3 have hand hygiene stations (either hand hygiene sinks or alcohol-based hand rub (ABHR) dispensers with products that have a Health Canada DIN or Natural Product Number (NPN), and contain 60% to 90% alcohol) at all entrances to, and exits from, the MDR area and readily available within the MDR area;

2.2.3.1 Designated hand hygiene sinks shall have properly functioning soap dispensers and paper towel dispensers.

2.2.3.2 Designated hand hygiene sinks shall be used for the purpose of hand hygiene only.

Note: *It is recommended that newly built or renovated health care facilities and settings are designed to include hand hygiene sinks with hands free controls at all entrances to, and exits from, the MDR area and readily available within the MDR area.*

[Reference: CSA Z314-18, 10.2.3](#)

2.2.4 have surfaces that can be cleaned;

2.2.4.1 All work surfaces and surrounding area shall be intact, cut-resistant, and seamless, and shall be composed of non-porous, non-shedding material capable of withstanding frequent cleaning.

[References: CSA Z314-18, 10.2.1.4 and 10.2.1.5](#)

2.2.5 restrict access to areas where reprocessing occurs;

[Reference: CSA Z314-18, 10.2.1.1](#)

2.2.5.1 In existing smaller community-based health care facilities or settings, where MDR areas may also be used for other purposes, access shall be restricted during reprocessing activities and until the area has been appropriately cleaned.

Notes:

1. *To determine whether or not this is an appropriate option for your organization, contact a public health inspector or an infection control professional (ICP) for advice.*
2. *In any new construction, future renovation or relocation of a community-based health care facility or setting, the MDR area should comply with these Standards.*

- 2.2.6 be designed to facilitate one-way workflow;
[Reference: CSA Z314-18, 10.1](#)
- 2.2.7 have adequate lighting for the tasks being performed in all work locations; and
[References: CSA Z314-18, 10.2.2.3.1, CSA Z8000-18, 7.6.4.4, and CSA Z317.5-17, 4.5.2](#)
- 2.2.8 use a water source which meets the equipment manufacturer's specifications for water and steam quality.
[References: CSA Z314-18, 16.8.3.2, 18.6, and Annex G](#)
- 2.3 Areas where clean, disinfected, and sterile medical devices are stored shall:
- 2.3.1 be dedicated to the storage of clean, disinfected, and sterile items;
[Reference: CSA Z314-18, 10.2.5.1](#)
- 2.3.2 be designed to have adequate space to prevent crushing or damage to packaging;
[References: CSA Z314-18, 10.2.5.1 and 17.1.1](#)
- 2.3.3 have sufficient lighting to allow easy reading of labels and to determine the condition of packaging; and
[Reference: CSA Z314-18, 10.2.5.7](#)
- 2.3.4 be cleaned following an established schedule.
[Reference: CSA Z314-18, 10.2.5.12](#)

3. Procurement of Reusable Medical Devices and Reprocessing Equipment and Supplies

The decision to purchase a reusable medical device requires many considerations including the capacity of the organization's MDR resources to safely reprocess the medical device for re-use. Some reusable medical devices are constructed with components or characteristics such as narrow lumens, valves, or crevices that can make reprocessing difficult. If it will be difficult for an organization to reprocess a reusable medical device, the organization should consider using a single-use medical device instead.

Reference: CSA Z314-18, 8.1.5

3.1 The decision to purchase or trial reusable medical devices, reprocessing equipment and supplies, or reusable surgical textiles shall involve representatives from the departments in the organization that will use, reprocess, and maintain the items.

3.1.1 This decision shall include consultation with appropriate MDR and IPC personnel, as applicable for the organization.

References: CSA Z314-18, 8.1.2 and 8.1.5

3.2 Prior to purchasing or trialing a medical device, including medical device reprocessing equipment, the organization shall confirm that the device has a valid medical device licence issued under the Government of Canada's [Medical Devices Regulations](#).

Note: *The Medical Devices Active Licence Listing (MDALL) contains product-specific information on all medical devices that are currently licensed for sale in Canada, or have been licensed in the past. This system has been designed to help health care workers who are contemplating the purchase of a Class II, III, or IV medical device to verify that the manufacturer has an active medical device licence. Since medical device licences can be suspended by Health Canada, cancelled during the annual renewal of licences by Health Canada, or discontinued by the manufacturer, it is important to conduct this verification each time the purchase of a medical device is considered. The MDALL can be accessed on Health Canada's website at <https://health-products.canada.ca/mdall-limh/index-eng.jsp>.*

References: CSA Z314-18, 8.2.3 and Health Canada: [Purchase of Licensed Medical Devices for Use in Health Care](#). (Accessed July 22, 2019.)

3.2.1 The organization shall not purchase or trial a reusable medical device that does not have a valid medical device licence.

3.3 Non-critical medical devices intended for use between clients shall be purchased with validated MIFU for reprocessing when available, and when not available, a standard operating procedure (SOP) shall be developed in consultation with IPC and MDR personnel.

Note: *Some health care facilities and settings may need to go outside their organization to find the appropriate IPC and MDR expertise to develop reprocessing SOP for non-critical medical devices.*

Reference: CSA Z314-18, 11.6.2.1

3.4 Reusable foot care devices intended for use between clients shall be purchased with validated MIFU for reprocessing when available, and when not available, an SOP shall be developed in consultation with IPC and MDR personnel.

Note: *Some health care facilities and settings may need to go outside their organization to find the appropriate IPC and MDR expertise to develop reprocessing SOP for foot care devices.*

3.5 Prior to purchasing or trialing a reusable critical or semi-critical medical device, the organization shall confirm that there is written confirmation that the MIFU for reprocessing have been validated according to Health Canada's requirements.

Note: *Additional information about MIFU and the requirements Health Canada expects manufacturers to meet with respect to validation of MIFU can be found in Health Canada's "Guidance Document: Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices". The document is available on the Health Canada website at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-information-manufacturers-sterilization-reusable-medical-devices.html>.*

References: CSA Z314-18, 8.1.3 and 8.1.4

3.5.1 The organization shall not purchase or trial a reusable critical or semi-critical medical device if there is no written confirmation that the MIFU for reprocessing have been validated.

Reference: CSA Z314-18, 8.1.3

- 3.6 Prior to purchasing or trialing a reusable critical or semi-critical medical device, personnel accountable for MDR shall review the written, validated MIFU to determine:
- 3.6.1 that the recommended reprocessing procedures are specific to the medical device and the instructions are clear, complete, adequate, and in accordance with the level of reprocessing required for the medical device's intended use;
 - 3.6.2 that there are instructions for disassembly, cleaning, type of sterilization or level of disinfection required, cycle parameters, and maintenance;
 - 3.6.3 if there is a limit to the number of times the medical device can be reprocessed (i.e., if the medical device is a reusable device) or if reprocessing will contribute to degradation of the medical device; and
 - 3.6.4 that the recommended reprocessing procedures can be achieved, given the organization's reprocessing resources.

References: CSA Z314-18, 7.1 and 7.2 and CSA Z17664, 3.1

- 3.7 In the event that the MIFU does not contain the information required in 3.6.1, 3.6.2, and 3.6.3, the organization shall contact the manufacturer for clarification or additional information.

Note: Health care facilities and settings that are not able to obtain the relevant information should report this to Health Canada at:

- a) 1-800-267-9675;
- b) mdpr@hc-sc.gc.ca; or
- c) http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2011-devices-materiaux/index-eng.php.

Reference: CSA Z314-18, 7.5

- 3.8 Before purchasing reprocessing equipment, the organization shall:
- 3.8.1 obtain technical and safety data, specifications, and other information specific to the equipment for required utilities and connections (e.g., electrical, steam, water, plumbing, air supply, and ventilation); and
 - 3.8.2 ensure the minimum service space requirements set out by the manufacturer can be met.

References: CSA Z314-18, 10.2.4.1.3, 18.1, and 20.1.2.2

4. General Reprocessing Requirements

- 4.1 Reusable medical devices that have been used shall be reprocessed.
 - 4.1.1 Contaminated reusable medical devices that have not undergone reprocessing shall be clearly identified.
[Reference: CSA Z314-18, 11.3.2.3](#)
- 4.2 Reusable medical devices that come from an opened or compromised package shall be reprocessed prior to use.
[Reference: CSA Z314-18, 17.5.3.1](#)
- 4.3 Newly purchased reusable critical and semi-critical medical devices shall be reprocessed before initial use unless they are packaged and sterilized by the manufacturer.
[Reference: CSA Z314-18, 8.1.6](#)

Cleaning Accessories

- 4.4 Cleaning accessories shall be inspected before use to ensure they are not damaged. Damaged cleaning accessories shall not be used.
[Reference: CSA Z314-18, 11.6.4.4](#)
- 4.5 Reusable cleaning accessories shall be reprocessed after use in accordance with the MIFU, inspected for damage, and stored in a clean, dry place.
[Reference: CSA Z314-18, 11.6.4.4](#)
- 4.6 Single-use cleaning accessories shall be discarded following use.
[References: CSA Z314-18, 11.6.4.4 and 12.7.1.6](#)

5. Pre-Cleaning and Transportation of Contaminated Reusable Medical Devices

- 5.1 Personnel shall pre-clean used reusable medical devices immediately after use and prior to transportation and further manual or automated cleaning.

Reference: [CSA Z314-18, 11.2.1](#)

- 5.1.1 At the point of use, single-use sharps shall be removed from reusable medical devices and disposed of in a puncture-resistant sharps container.

Reference: [CSA Z314-18, 11.2.3](#)

- 5.1.2 Organic matter shall not be allowed to dry on reusable medical devices. Reusable medical devices shall be kept moist by using foam, spray, or gel specifically intended for this use, or by using a towel moistened with water, and in accordance with the MIFU.

References: [CSA Z314-18, 11.2.1](#) and [11.3.2.1](#)

- 5.2 Contaminated items shall be transported in covered, fully-enclosed, leak-proof containers or closed carts that are designed to prevent the spill of liquids, protect reusable medical devices from damage, and allow for effective decontamination after each use.

- 5.2.1 Sterile or clean reusable medical devices and soiled reusable medical devices shall be transported in a manner that prevents cross-contamination (i.e., in separate containers and carts).

- 5.2.2 All containers and carts containing contaminated medical devices shall be so identified.

References: [CSA Z314-18, 11.3.1.3](#) and [11.3.2.3](#)

- 5.3 Contaminated reusable medical devices shall be transported to the MDR area in such a way so as not to contaminate the surrounding environment.
 - 5.3.1 Contaminated reusable medical devices shall follow designated routes to avoid high-traffic and client-care areas, and areas designated for storage of clean or sterile medical devices and supplies.
 - 5.3.1.1 In smaller community-based health care facilities and settings, the designated transportation route shall minimize exposure to high-traffic and client-care areas and avoid areas designated for the storage of clean or sterile medical devices and supplies.

Reference: [CSA Z314-18, 11.3.2.2](#)

6. Preparation and Cleaning of Reusable Medical Devices

Sorting and Disassembly

- 6.1 All contaminated medical devices shall be inspected and sorted before reprocessing to ensure that the appropriate cleaning agents and procedures are applied to the correct devices.

References: CSA Z314-18, 11.2.2 and 11.4.1

- 6.2 All medical devices consisting of multiple components (e.g., minimally invasive surgical medical devices) shall be disassembled in accordance with the MIFU.

Reference: CSA Z314-18, 11.4.1

Cleaning

- 6.3 Each medical device shall be thoroughly cleaned prior to disinfection or sterilization.

Reference: CSA Z314-18, 11.6.1.1

- 6.4 Cleaning methods shall be consistent with the medical device's MIFU and appropriate for the type of medical device and the amount of soil to be removed.

Reference: CSA Z314-18, 11.6.1.2

- 6.5 While cleaning may be done by either a manual or automated process, critical and semi-critical medical devices shall be cleaned using an automated process whenever possible.

Reference: CSA Z314-18, 11.1.2

Manual Cleaning

- 6.6 If manual cleaning is required, the medical device's MIFU for reprocessing shall be followed, including any specifications for detergent type, water type, or water temperature and cleaning methods.

Reference: CSA Z314-18, 11.6.4.1

- 6.7 Immersible medical devices shall be completely submerged during cleaning to prevent the generation of aerosols and non-immersible medical devices shall be cleaned according to the MIFU.

Reference: CSA Z314-18, 11.6.4.2

Automated Cleaning

Automated washers are available in several designs and configurations, including but not limited to washer-disinfectors, washer-pasteurizers, and ultrasonic cleaners. Some automated washers may also be used for terminal disinfection of medical devices, which will be addressed in section seven.

Reference: CSA Z314-18, 11.6.5.1.1

- 6.8 Automated washers and ultrasonic cleaners used for cleaning shall be used in accordance with the MIFU.
- Reference: CSA Z314-18, 11.6.5.1.1
- 6.8.1 The performance of the automated cleaning system (e.g., automated washers) shall be tested each day that it is in use, using commercially available indicators or test kits.
- Reference: CSA Z314-18, 11.6.5.3.5
- 6.8.2 Ultrasonic cleaners shall be tested for sonication performance (e.g., commercial methods or the foil test) at least weekly.
- Reference: CSA Z314-18, 11.6.6.6
- 6.8.3 The ultrasonic detergent solution shall be changed at least daily or more frequently when visibly soiled or if the ultrasonic cleaner or solution MIFU specifies more frequent changes (e.g., with every cycle).
- Reference: CSA Z314-18, 11.6.6.5
- 6.9 The medical device's MIFU shall be followed to ensure medical devices are compatible with the automated washer's process conditions (e.g., moisture, temperature, chemicals, water quality, and pressure).
- Reference: CSA Z314-18, 11.6.5.2.1

Rinsing and Drying

- 6.10 Chemical residues and loosened soil shall be completely rinsed from the medical device prior to disinfection or sterilization. Rinsing may be included as a final step in an automated cleaning process. If not, the medical device shall be rinsed manually.

Reference: [CSA Z314-18, 11.6.7.1](#)

- 6.11 Reusable medical devices shall be dried prior to disinfection or sterilization, as directed by the MIFU.

Reference: [CSA Z314-18, 11.6.8.1](#)

- 6.11.1 Unless dried using an automated process, the exterior surfaces of medical devices shall be manually dried with a clean, lint-free, or low-lint soft-absorbent towel.

Note: *Drying of non-critical devices may be done by air-drying, or in accordance with the MIFU.*

Reference: [CSA Z314-18, 11.6.8.3](#)

Reassembly

- 6.12 Decontaminated medical devices shall be reassembled according to the MIFU. Reassembly shall take place in a clean and dry area.

Reference: [CSA Z314-18, 14.3.3](#)

Inspection

- 6.13 Medical devices shall be visually inspected for cleanliness, damage, integrity, and functionality prior to disinfection, sterilization, or subsequent use.

References: [CSA Z314-18, 11.4.2 and 14.3.3](#)

- 6.13.1 Cleaned medical devices that are visibly soiled shall be cleaned again.

Reference: [CSA Z314-18, 11.1.1.1](#)

- 6.13.2 Medical devices that are damaged or in poor working condition shall be removed from service, labelled, and segregated from usable medical devices. Such medical devices shall either be repaired or disposed of in accordance with the documented SOPs.

Reference: [CSA Z314-18, 14.3.3](#)

7. Disinfection of Reusable Medical Devices

Disinfection is the final reprocessing step before a semi-critical or non-critical medical device can be considered safe for reuse between clients. The disinfection process may be a manual or automated process, and medical devices may be disinfected using chemicals (chemical disinfection) or heat (thermal disinfection), depending on the MIFU for reprocessing specific to the device and the device's Spaulding classification.

There are four levels of disinfectant activity: 1) low-level disinfectants; 2) intermediate-level disinfectants; 3) high-level disinfectants; or 4) sterilants. Low level and intermediate level disinfection are suitable for non-critical medical devices and high level disinfection is the minimum level of reprocessing required for semi-critical medical devices. Sterilants may be used in the sterilization of medical devices, and will be addressed in section eight.

High level disinfection can be achieved using liquid chemical high-level disinfectants, thermal high level disinfection or pasteurization. (The method used will be device specific and may change as new technologies emerge and are approved by Health Canada.)

Reference: Health Canada: [Guidance Document: Disinfectant Drugs](#) (2018). (Accessed July 23, 2019.)

Note: *When a semi-critical medical device can be safely sterilized in accordance with the MIFU, the recommended final reprocessing step for a semi-critical medical device is sterilization. Sterilization is addressed in section eight.*

- 7.1 Disinfection of reusable medical devices shall take place in accordance with the MIFU of the device and shall also follow the MIFU for the disinfection process, equipment, and products.

Reference: CSA Z314-18, 11.7.1.2

- 7.2 Only chemical disinfectants that have a Health Canada drug identification number (DIN) or a medical device licence (MDL) issued by Health Canada, shall be used in health care facilities and settings for the disinfection of reusable medical devices.

Notes:

1. *Since March 16, 2018, high-level disinfectants and sterilant solutions intended for use on medical devices have been classified as Class II medical devices by Health Canada, and they are subject to the requirements of the [Medical Devices Regulations](#). Additionally, Health Canada has announced its intention to pursue an amendment to the Regulations that reclassifies these products as Class III medical devices, in order to better align the device risk classification with the nature and intended use of the products.*
2. *The Medical Devices Active Licence Listing (MDALL) contains product-specific information on all medical devices, including high-level disinfectants, that are currently licensed for sale in Canada, or have been licensed in the past. This system has been designed to help health care workers who are contemplating the purchase of a Class II, III, or IV medical device to verify that the manufacturer has an active medical device licence. Since MDLs can be suspended by Health Canada, cancelled during the annual renewal of licences by Health Canada, or discontinued by the manufacturer, it is important to conduct this verification each time the purchase of a high-level disinfectant is considered. The MDALL can be accessed on Health Canada's website at <https://health-products.canada.ca/mdall-limh/index-eng.jsp>.*

References: CSA Z314-18, 11.7.2.1.2 and Health Canada: [Notice: Classification and Licensing of High-Level Disinfectants and Sterilants as Medical Devices \(Archived\)](#) (accessed October 21, 2019), [Guidance Document – Safety and effectiveness requirements for high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices](#) (accessed October 21, 2019), and [Purchase of Licensed Medical Devices for Use in Health Care](#) (accessed July 22, 2019).

- 7.3 A liquid chemical disinfectant shall not be used beyond its:
- a) expiry date; and
 - b) in-use life.

References: CSA Z314-18, 11.7.2.3.4 and 11.7.2.5.2

- 7.4 Reusable liquid chemical disinfectant solutions shall:

- 7.4.1 be clearly identified and include the expiry date;

Reference: CSA Z314-18, 11.6.2.4

- 7.4.2 be stored in containers that are cleaned, disinfected, and dried prior to changing the solution; and
- 7.4.3 be kept covered with a tight-fitting lid, except when introducing or removing a medical device to or from the solution.

Reference: CSA Z314-18, 11.7.2.3.5

Non-Critical Devices

Note: *In most cases, non-critical reusable medical devices can be disinfected at the point of use.*

- 7.5 Non-critical reusable medical devices shall be disinfected between client use using an intermediate-level disinfectant (ILD) or low-level disinfectant (LLD).

Reference: CSA Z314-18, 11.6.2.3

- 7.5.1 ILD or LLD wipes shall be moist enough to thoroughly wet the surface for the indicated contact time and a new wipe shall be used if the area to be disinfected cannot be completely wetted with a single wipe.

Reference: CSA Z314-18, 11.6.2.3

Semi-Critical Medical Devices

- 7.6 If a reusable semi-critical device cannot be sterilized, then it shall, at a minimum, be high level disinfected between client use.

Reference: CSA Z314-18, 11.7.2.1.1

Liquid Chemical High Level Disinfection

- 7.7 The minimum effective concentration (MEC) of a reusable high-level disinfectant (HLD) shall be tested and recorded, according to the MIFU of the disinfectant.

References: CSA Z314-18, 11.7.2.4.2 and 12.9.2.1

- 7.7.1 MEC testing shall be performed at the beginning of each day that the solution is used for manual high level disinfection (or more frequently if specified in the MIFU of the HLD) and in each cycle for automated high level disinfection.

- 7.7.2 Quality assurance testing of test strips used to test MEC shall be followed in accordance with test strip MIFU.

Reference: CSA Z314-18, 11.7.2.4.2

- 7.7.3 Test strips used to test MEC shall not be used beyond the test strip's expiry date or the manufacturer's in-use shelf life.

Reference: CSA Z314-18, 11.7.2.4.2

- 7.7.4 An HLD shall not be used beyond a failed MEC test.
[Reference: CSA Z314-18, 11.7.2.3.4](#)
- 7.8 When performing manual disinfection of a semi-critical medical device:
- 7.8.1 All parts of the medical device shall be in complete contact with the HLD, and all air bubbles shall be removed.
[Reference: CSA Z314-18, 11.7.2.5.1](#)
- 7.8.2 The contact time and temperature shall be measured from the point at which the semi-critical medical device achieves complete contact with the HLD and there are no trapped air bubbles.
[Reference: CSA Z314-18, 11.7.2.4.3](#)
- 7.9 If an automated disinfection system is used, the contact time and temperature shall be monitored as specified in the MIFU and the disinfectant maintained within the manufacturer's recommended ranges for temperature and concentration throughout the contact time.
[Reference: CSA Z314-18, 11.7.2.4.3](#)
- 7.10 Automated disinfection systems shall provide a record that critical cycle parameters (e.g., disinfectant temperature, concentration, contact time) have been met.
[References: CSA Z314-18, 12.9.2.3 and 13.3.11.1](#)
- 7.11 Following chemical high level disinfection, each semi-critical medical device shall be thoroughly rinsed with sterile or bacteria-free water (e.g., achieved by submicron filtration).
[Reference: CSA Z314-18, 11.7.2.6.1](#)
- 7.11.1 If rinsing is done manually, it shall include at least three separate rinses unless otherwise specified by the HLD manufacturer.
[Reference: CSA Z314-18, 11.7.2.6.2](#)
- 7.12 After high level disinfection and rinsing, the semi-critical medical device shall be dried in accordance with the MIFU.
[Reference: CSA Z314-18, 11.7.2.6.1](#)

- 7.13 At a minimum, the organization shall document and maintain records on:
- 7.13.1 HLD solution (including product name, lot number, expiry date, date of solution change, and initials of staff preparing the solution and documenting the process);
[Reference: CSA Z314-18, 11.7.2.5.2](#)
 - 7.13.2 high level disinfection test strips (including name of test strip, lot number, expiry date, quality control test results for each time a new test strip bottle is opened, and the initials of staff doing the testing and documentation);
[Reference: CSA Z314-18, 11.7.2.5.2](#)
 - 7.13.3 results of MEC testing;
[References: CSA Z314-18, 11.7.2.4.2 and 11.7.2.5.2](#)
 - 7.13.4 contact time and temperature during high level disinfection;
[References: CSA Z314-18, 11.7.2.4.3 and 11.7.2.5.2](#)
 - 7.13.5 cycle parameters; and
[References: CSA Z314-18, 11.7.2.5.2 and 11.8.4.2.4](#)
 - 7.13.6 medical device name or type documentation.
[Reference: CSA Z314-18, 11.7.2.5.2](#)

Thermal Disinfection/Pasteurization

- 7.14 If a washer-disinfector or washer-pasteurizer is intended to provide thermal high level disinfection, the organization shall obtain documentation from the washer-disinfector or washer-pasteurizer manufacturer or a third party to confirm that it has been validated for thermal high level disinfection.
[Reference: CSA Z314-18, 11.8.4.1.6](#)
- 7.15 If a washer-disinfector or pasteurizer is used for thermal disinfection, it shall be equipped with sensors and a recording device for time and temperature and/or equivalent A_0 value.
[References: CSA Z314-18, 11.6.5.3.6, 11.8.4.1.2, and 11.8.4.1.7](#)
- 7.15.1 The accuracy of the recording device shall be periodically confirmed with an independent calibration device, and the frequency and method of testing shall be in accordance with the MIFU.
[Reference: CSA Z314-18, 11.8.4.1.7](#)

- 7.15.2 When a washer-disinfector is used for the thermal high level disinfection of semi-critical medical devices (e.g., respiratory devices), the washer-disinfector shall provide a record of attaining A_0 600 through either printed or electronic means.
[Reference: CSA Z314-18, 11.8.4.1.2](#)
- 7.16 The organization shall ensure the washer-disinfector or pasteurizer and the selected cycle are appropriate to the medical device being reprocessed and its intended use.
[Reference: CSA Z314-18, 11.8.4.1.1](#)
- 7.17 The washer-disinfector or pasteurizer MIFUs for loading configurations and cleaning agents shall be followed.
[Reference: CSA Z314-18, 11.8.4.1.3](#)
- 7.18 Validated manifolds and attachments shall be used to facilitate optimal circulation of water through the reusable medical devices being reprocessed.
[Reference: CSA Z314-18, 11.8.4.1.1](#)
- 7.19 Pasteurizers shall reach a minimum temperature of 71°C for a minimum contact time of 30 minutes, unless a higher temperature is specified in the MIFU for the medical device.
[Reference: CSA Z314-18, 11.8.4.2.3](#)
- 7.19.1 Air pockets shall be displaced from the load before pasteurization via manipulation of the load by the washer-pasteurizer in accordance with the equipment MIFU and all devices shall be completely submerged in a water bath during the pasteurization cycle.
[Reference: CSA Z314-18, 11.8.4.2.3](#)
- 7.20 Following thermal disinfection in a washer-disinfector or pasteurizer, reusable medical devices shall be handled in a manner that minimizes contamination.
[References: CSA Z314-18, 11.8.4.1.5 and 11.8.4.2.2](#)
- 7.20.1 Following the disinfection cycle, respiratory devices shall be dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and is used only for the drying of disinfected medical devices.
[Reference: CSA Z314-18, 11.8.4.1.8](#)

8. Sterilization of Reusable Medical Devices

Sterilization is the final reprocessing step for reusable critical medical devices, and for many reusable semi-critical medical devices. For heat tolerant medical devices, steam sterilization is used and for non-heat tolerant medical devices, chemical sterilization is used. The correct method of sterilization is identified in the MIFU for each medical device. Proper packaging is essential to maintain sterility by providing a barrier to contamination.

Note: *the following processes or equipment are not acceptable equipment or processes to achieve sterilization: boiling, ultraviolet light, glass bead sterilization, and the use of microwave ovens, conventional ovens, or dishwashers.*

- 8.1 A reusable critical medical device shall be sterilized between client use.
[Reference: CSA Z314-18, 16.1.2.1](#)
- 8.2 Reusable foot care devices shall be sterilized between client use.
[Reference: CSA Z314-18, 16.1.2.1](#)
- 8.3 Semi-critical dental medical devices that are compatible with heat and moisture shall be steam sterilized between client use.
[Reference: CSA Z314-18, 16.1.2.1](#)
- 8.4 Sterilization of reusable medical devices shall take place in accordance with:
 - 8.4.1 the MIFU of the device; and
[Reference: CSA Z314-18, 7.4](#)
 - 8.4.2 the MIFU for the sterilization process, equipment, and products.
[References: CSA Z314-18, 11.7.2.2.2, 15.1.2, and 16.2.4.1](#)

Qualification and Requalification

- 8.5 Installation qualification of sterilization equipment (including large chamber and table top steam sterilizers and chemical sterilizers) shall be performed and documented according to the manufacturer's specifications.
[References: CSA Z314-18, 16.5.2.1, 16.5.2.2, and 16.5.2.3](#)

8.6 Operational qualification of sterilization equipment (including large chamber and table top steam sterilizers and chemical sterilizers) shall be performed at installation.

References: [CSA Z314-18, 16.5.3.1 and 16.5.3.3.2](#)

8.7 Operational requalification shall take place at least annually and following a major sterilizer repair, sterilizer relocation, an unexplained sterility failure, and, for steam sterilizers, following any disruption to steam supply or change to steam pressures.

References: [CSA Z314-18, 16.5.3.2.1 and 16.8.3.3](#)

8.8 Operational qualification and requalification testing shall include a verification of each cycle used by the health care facility or setting, according to the MIFU for testing.

References: [CSA Z314-18, 16.5.3.1 and 16.5.3.2.3](#)

8.9 Operational qualification and requalification testing shall be conducted by:

8.9.1 Running three consecutive cycles in an empty chamber using PCDs with biological indicators. For table-top steam sterilizers, testing will take place in a fully loaded chamber.

References: [CSA Z314-18, 16.5.3.2.3 and 16.8.3.3](#)

8.9.2 Additionally, in dynamic air removal sterilizers that use pre-vacuum cycles, ensuring that the sterilizer:

- a) meets the requirements of an air removal test and leak-rate test; and
- b) is tested with three consecutive air removal tests (e.g., Bowie-Dick) in an otherwise empty sterilizer.

Reference: [CSA Z314-18, 16.5.3.2.5](#)

8.10 Performance qualification shall be performed to ensure setting-specific packages and loads can be sterilized with the equipment and processes used in the health care facility or setting.

Reference: [CSA Z314-18, 16.5.4.1.2](#)

8.10.1 Performance qualification shall use products (e.g., instrument sets) and sterilizer loads used by the health care facility or setting. The products and loads shall:

- a) be assembled according to the sterilizer MIFU; and
- b) adhere to any limitations of validated medical devices, materials, weights, lumen diameters, and lumen lengths.

Reference: [CSA Z314-18, 16.5.4.1.1](#)

8.10.2 In addition, performance qualification shall be performed when there are new materials, processes, or conditions that could affect sterilization.

Reference: CSA Z314-18, 16.5.4.1.3

Chemical Sterilants

8.11 The organization shall ensure a chemical sterilant has a Health Canada drug identification number (DIN) or a medical device licence (MDL) issued by Health Canada.

Notes:

1. *Since March 16, 2018, high-level disinfectants and sterilant solutions intended for use on medical devices have been classified as Class II medical devices by Health Canada, and they are subject to the requirements of the [Medical Devices Regulations](#). Additionally, Health Canada has announced its intention to pursue an amendment to the Regulations that reclassifies these products as Class III medical devices, in order to better align the device risk classification with the nature and intended use of the products.*
2. *The Medical Devices Active Licence Listing (MDALL) contains product-specific information on all medical devices, including sterilant solutions, that are currently licensed for sale in Canada, or have been licensed in the past. This system has been designed to help health care workers who are contemplating the purchase of a Class II, III, or IV medical device to verify that the manufacturer has an active medical device licence. Since MDLs can be suspended by Health Canada, cancelled during the annual renewal of licences by Health Canada, or discontinued by the manufacturer, it is important to conduct this verification each time the purchase of a sterilant solution is considered. The MDALL can be accessed on Health Canada's website at <https://health-products.canada.ca/mdall-limh/index-eng.jsp>.*

References: CSA Z314-18, 16.2.4.3.1 and Health Canada: [Notice: Classification and Licensing of High-Level Disinfectants and Sterilants as Medical Devices \(Archived\)](#) (accessed October 21, 2019), [Guidance Document – Safety and effectiveness requirements for high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices](#) (accessed October 21, 2019), and [Purchase of Licensed Medical Devices for Use in Health Care](#) (accessed July 22, 2019).

8.12 A chemical sterilant shall be labelled with an expiry date and shall not be used beyond the expiry date or the in-use life limit, whichever comes first.

Reference: CSA Z314-18, 16.2.4.3.2

Packages and Labels

- 8.13 Packaging of reusable medical devices for sterilization shall take place in accordance with the MIFU of the device, the sterilization equipment, and the sterilization packaging manufacturer, and when packaging is required, it shall be done using a validated sterile barrier system (e.g., pouches, wrappers, or rigid sterilization container systems).

References: [CSA Z314-18, 7.4, 15.1.1, 15.1.2, 15.7.1, 15.8, and 15.9](#)

- 8.14 Packages shall be labelled with sterilizer load identification information, including the sterilizer number, the load number in that sterilizer, and the sterilization date.

References: [CSA Z314-18, 15.6.3.1 and 15.6.3.2](#)

- 8.14.1 Labelling systems shall be validated for the sterilization process.

Reference: [CSA Z314-18, 15.6.1](#)

- 8.14.2 For pouches, a label shall be placed on the transparent portion of the packaging.

Reference: [CSA Z314-18, 15.6.2](#)

- 8.14.3 For wrapped packages, writing shall be on the closure tape, not directly on the wrappers.

Reference: [CSA Z314-18, 15.6.2](#)

Loading and Unloading

- 8.15 Packages shall be placed in the sterilizer chamber in a manner that facilitates air removal, sterilizing agent penetration, sterilant evacuation, and, in the case of steam sterilization, drying.

- 8.15.1 Wrapped items shall not contact the interior walls of the sterilizer chamber, as contact can damage the wrapper.

- 8.15.2 Pouches and wrapped packages shall not be stacked or compressed.

- 8.15.3 Between packages there shall be adequate space to ensure effective sterilizing agent penetration, evacuation, and drying.

Reference: [CSA Z314-18, 16.2.2.1.3](#)

- 8.16 Sterile packages shall be cooled to room temperature before handling.

Reference: [CSA Z314-18, 16.2.5.6](#)

- 8.17 For vapour systems, care shall be taken to ensure that there is no moisture or droplets in the chamber or on packages. Any visible moisture shall be considered to be chemical sterilant.

[Reference: CSA Z314-18, 16.2.5.5](#)

- 8.18 During unloading, packages shall be inspected for:

- a) package integrity;
- b) dryness;
- c) presence of a label;
- d) the correct change in an external chemical indicator;
- e) an intact seal, if used; and
- f) evidence of potential contamination.

If a package does not meet the inspection criteria, the contents shall not be used.

[Reference: CSA Z314-18, 16.2.5.2](#)

Sterility Assurance

- 8.19 Sterilization indicators shall be used only for the sterilizer type and sterilization cycle for which they were designed and validated and shall be used according to the sterilizer and indicator MIFUs.

[Reference: CSA Z314-18, 16.6.2.2](#)

- 8.19.1 Sterilization indicators shall not be used beyond their expiry date and shall be stored according to the MIFU.

[Reference: CSA Z314-18, 16.6.2.4](#)

Chemical Indicators

- 8.19.2 Both internal and external chemical indicators shall be included with each package prepared for sterilization.

[References: CSA Z314-18, 16.6.5 and 16.6.6](#)

- 8.19.2.1 The internal chemical indicator shall be placed in the area of the package that is least susceptible to sterilizing agent penetration. If a multi-layer container is being used, chemical indicators shall be placed at each level.

[Reference: CSA Z314-18, 15.5.2.2](#)

8.19.2.2 Notwithstanding 8.19.2, if an internal chemical indicator is clearly visible from the outside of a package (e.g., through a plastic wrapper), an external chemical indicator is not required.

References: [CSA Z314-18, 16.6.1 and 16.6.5](#)

Air Removal Test (i.e., Bowie-Dick/Dart)

8.19.3 For dynamic air removal-type sterilizers (pre-vacuum cycles), an air removal test shall be performed every day the sterilizer is used.

Reference: [CSA Z314-18, 16.6.7.1](#)

Biological Indicators

8.19.4 A biological indicator contained within a PCD shall be used to test the sterilizer for each type of cycle used (e.g., dynamic air removal, gravity) and at the shortest exposure time, within a full load. This test shall be done at least daily when the sterilizer is in use.

***Note:** A PCD should present a challenge to the process that is equal to or greater than the challenge posed by the most difficult item that is routinely sterilized. A biological test pack is an example of a PCD. A PCD can be commercially manufactured or prepared in-house following the PCD manufacturer's instructions.*

References: [CSA Z314-18, 16.6.8.1 and Annex I: Informative, I.1](#)

8.19.4.1 If a steam sterilizer will be used for multiple types of cycles, each type of cycle used shall be tested daily.

8.19.4.2 If a chemical sterilizer is used, routine testing shall be performed on the cycles identified for monitoring by the manufacturer of the chemical sterilizer.

Reference: [CSA Z314-18, 16.6.8.1](#)

8.19.5 Every load containing implantable medical devices shall be monitored using a biological indicator PCD.

Reference: [CSA Z314-18, 16.6.8.2](#)

8.19.5.1 Implantable medical devices shall be quarantined until the results of the biological indicator test are available.

Reference: [CSA Z314-18, 16.6.11.1](#)

8.19.5.2 Early release of implants shall not be used to compensate for inventory shortages or scheduling problems.

Reference: CSA Z314-18, 16.6.11.1

8.19.5.3 Early release of implants shall only be done in situations where there is an urgent, unplanned need (e.g., trauma-related devices) and if an implant must be released before the biological indicator test results are available, the following shall apply:

- a) Evaluation of a Type 5 or Type 6 chemical indicator in the biological indicator PCD, the specific cycle physical parameters, and any visible chemical indicators shall be assessed and the results documented.
- b) Information identifying the implant and the client it was used on shall be documented.
- c) A report shall be prepared, reviewed, and maintained according to the organization's risk management policy and shall contain the:
 - i. client's identifier;
 - ii. implant identification number;
 - iii. surgeon's name;
 - iv. time and date of the procedure;
 - v. results of any physical or chemical indicators used in the sterilization process; and
 - vi. results of the biological indicator once they are known.
- d) For steam sterilization, if a Type 5 or 6 chemical indicator is also used to monitor an implant load, the results shall be interpreted before a load is released.

Reference: CSA Z314-18, 16.6.11.1

8.20 At the conclusion of a sterilization cycle and before the load is removed, the operator shall confirm that the required parameters and all phases of the sterilization cycle including aeration (if required) have been met.

Reference: CSA Z314-18, 16.2.5.4

8.21 Routine monitoring shall include assessment of:

- a) physical parameters of each sterilizer cycle (e.g., sterilization time, temperature, pressure, sterilant concentration), which shall be verified by examination of the sterilizer printout or electronic record on completion of each cycle before the load is released;

References: CSA Z314-18, 16.6.1, 16.6.3.1, and 16.8.3.1

- b) chemical indicators; and
- c) biological indicators, when present.

Reference: CSA Z314-18, 16.6.1

8.22 If a package is released based on monitored physical parameters and internal chemical indicator results, the internal chemical indicator shall be Type 5 or Type 6.

Note: *Type 5 and Type 6 internal chemical indicators measure all critical parameters for steam sterilization and provide additional quality assurance for monitoring medical devices. Other types of internal chemical indicators might not be designed to measure all critical parameters, so deviations in critical variables might go undetected.*

Reference: CSA Z314-18, 16.6.6

8.23 All sterilizers used in Alberta health care facilities and settings must come equipped with a printer or electronic record that records cycle parameters within three years of these Standards coming into force.

Note: *CSA Z314-18, 16.8.3.1 indicates that the cycle documentation provided by a printer is now considered essential quality assurance information.*

8.23.1 In the period before the transition required by 8.23 is completed, if a health care facility or setting is using a sterilizer that does not come equipped with a printer, personnel shall:

- a) check the sterilizer's displays and manually record the sterilization time and temperature at intervals during each cycle; and
- b) use a Type 5 chemical indicator in each package.

Note: *A Type 5 indicator, sometimes called an "integrator", is a particular type of chemical indicator that will respond to all of the critical parameters of steam sterilization. This means that its appearance will change when the correct time, temperature, and steam quality have been achieved during a cycle. The results of a Type 5 integrator are closely correlated (matched) to the results of a*

biological indicator. This means that both the chemical indicator and the biological indicator will show similar pass or fail results.

Reference: CSA Z314-18, 16.8.3.1

- 8.24 Documentation of sterility assurance shall include a printout or electronic cycle parameter record, a load control label, a load contents record, and associated chemical or biological indicator test results for each cycle.

Reference: CSA Z314-18, 16.6.10

- 8.25 In the event of a failed indicator test or any other issue noted upon inspection, the organization shall have processes in place to recall and reprocess the affected medical devices.

References: CSA Z314-18, 16.6.13.1, 16.6.13.2, and 16.6.13.3

Immediate-Use Steam Sterilization

- 8.26 Immediate-use steam sterilization (IUSS) shall be used only for situations where there is an urgent, unplanned need, with no other options available, or the medical device can only be sterilized with an immediate-use cycle (e.g., battery packs charged just before surgery).

8.26.1 Further to 8.26, IUSS shall not be used for reasons of convenience, to save time, to compensate for inventory shortages, or to address scheduling problems.

Note: *Practical measures that should be taken by the organization to avoid the need for IUSS include:*

- a) *maintaining adequate inventories of medical devices;*
- b) *coordinating medical device reprocessing with surgical schedules so that properly reprocessed devices are available when needed;*
- c) *making provisions to prevent the override of computerized booking systems where such an override will place pressure on medical device supplies; and*
- d) *articulating clearly defined responsibilities between the departments involved (e.g., the MDR area, operating room nursing staff, materials management, infection prevention and control) to coordinate scheduling decisions and make available conflict resolution in the event of scheduling problems.*

References: CSA Z314-18, 16.7.1.2 and 6.7.1.3

8.27 Other than for the unavoidable, emergency situations described in 8.26, IUSS shall not be used to sterilize:

- a) implants; or
- b) organic materials (e.g., cranial bone flaps).

Reference: CSA Z314-18, 16.7.1.4

8.28 Medical devices that have been sterilized using IUSS shall be used immediately and shall not be stored.

Reference: CSA Z314-18, 16.7.6

***Note:** It is important that critical medical devices are maintained as sterile until point of use. Prior to and upon opening a package containing a critical medical device at the point of use, the user should inspect the integrity of the packaging (including reviewing the results of the internal and external chemical indicators) and the reprocessed medical device itself, to ensure no obvious contamination or damage exists.*

References: CSA Z314-18, 15.3.4, 15.7.1, and 17.5.3.2.1

9. Storage

- 9.1 Reprocessed critical and semi-critical medical devices shall be protected from contamination by:
- a) rotating stock via first-in, first-out;
 - b) keeping items clean, dry, and protected;
 - c) keeping items well-separated from soiled items and soiled areas via barriers and/or distance; and
 - d) distributing items using clearly labelled, clean, enclosed transportation carts, bins, totes, or plastic bags;
 - e) ensuring they are not stored on the floor or a window sill, under sinks or near water sources, in open corridors or client rooms, or in the same area as hazardous materials.

References: CSA Z314-18, 10.2.5.3, 10.2.5.4, 12.5.4, 13.3.14, 17.1.2, 17.6.1.1, and 17.6.4.1

10. Education and Training

10.1 The organization shall ensure all personnel involved in the reprocessing of critical and semi-critical medical devices are appropriately educated and trained for the reprocessing duties/tasks that they perform.

References: [CSA Z314-18, 6.2, 6.4, and 6.5](#)

10.1.1 Reprocessing of critical and semi-critical medical devices in centralized MDR departments and endoscopy reprocessing areas shall be performed by personnel employed as MDR technicians.

Reference: [CSA Z314-18, 6.5](#)

10.1.1.1 Personnel employed as medical device reprocessing technicians in these settings shall be certified, and maintain certification, in one of the following recognized programs:

- CSA Certification for Certified Medical Device Reprocessing Technicians; or
- International Association of Healthcare Central Service Material Management Certification for Certified Registered Central Service Technicians.

10.1.1.2 Personnel in these settings who are in a developmental role and are not yet certified must be directly supervised by an individual who is certified in one of the recognized certification programs.

10.1.2 Any reprocessing of critical and semi-critical medical devices performed in areas outside of centralized MDR departments and endoscopy reprocessing areas shall be reviewed by the organization.

10.1.2.1 The organization shall assess and determine the appropriate level of education and training required for the reprocessing duties/tasks being performed.

Reference: [CSA Z314-18, 6.6.1](#)

10.1.2.2 Personnel who reprocess critical and semi-critical medical devices, but are not employed as medical device reprocessing technicians, shall receive training in a formal medical device reprocessing training program recognized by the organization, or comprehensive in-house training, and shall successfully complete competency testing.

Reference: [CSA Z314-18, 6.5](#)

10.1.2.2.1 Comprehensive in-house training shall, at a minimum, set out principles that align with these Standards.

10.1.2.2.2 Personnel who have not been fully trained and/or competency tested shall not reprocess critical and semi-critical medical devices unless under the direct supervision of fully trained and/or competency tested personnel.

References: [CSA Z314-18, 6.2 and 6.6.1](#)

10.1.3 The organization shall establish and document requirements for, and frequency of, education, training, orientation, and competency assessment for new and existing personnel, as appropriate for the MDR duties/tasks performed.

Reference: [CSA Z314-18, 6.6.1](#)

10.1.4 The organization shall document and maintain records of education, training, orientation, and competency assessments of personnel who reprocess critical and semi-critical medical devices.

Reference: [CSA Z314-18, 6.6.2](#)

PART C: QUALITY MANAGEMENT SYSTEMS

11. Quality Management Systems

A quality management system (QMS) is a formalized system that documents policies, processes, standard operating procedures (SOPs), and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet or exceed appropriate provincial and national standards, provide assurance and quality control, and support client safety.

Adapted from the American Society for Quality (ASQ), "What is a Quality Management System?": <https://asq.org/quality-resources/quality-management-system>. (Accessed: October 21, 2019).

- 11.1 The organization shall have clear accountability and lines of responsibility for:
- 11.1.1 all aspects of MDR, wherever MDR takes place in the organization; and
 - 11.1.2 the appropriate use of single-use medical devices.
- References: CSA Z314-18, 5.1.1, 5.1.2, 5.3.1, 5.3.5, 5.3.6, and 5.3.7
- 11.2 The organization shall have written policies and SOPs in place that meet or exceed appropriate provincial and national standards and guide the organization through all aspects of MDR.
- References: CSA Z314-18, 5.7.2.1, 5.7.2.2, and 5.7.2.3
- 11.2.1 The organization's medical device reprocessing policies and/or SOPs shall include (but not be limited to):
- 11.2.1.1 all steps in the reprocessing of reusable medical devices, based on MIFU;
- References include but are not limited to CSA Z314-18, 11.1.3, 11.7.1.2, 11.7.2.3.1, 15.1.2, 15.2.1, 16.2.2.1.1, 16.2.2.1.2, 16.7.1.5, and 16.7.5.3

- 11.2.1.2 specific, detailed SOPs for medical devices that present unique and complex challenges for reprocessing, such as flexible endoscopes, based on MIFU;
[Reference: CSA Z314-18, 8.1.5](#)
 - 11.2.1.3 the installation, operational, and performance qualification and requalification requirements of reprocessing equipment and products, based on MIFU;
[References: CSA Z314-18, 15.2.4, 16.5.4.2, 16.5.4.2.1, and 16.8.3.2](#)
 - 11.2.1.4 regular inspection and preventative maintenance requirements for reusable medical devices and equipment, based on MIFU;
[References: CSA Z314-18, 18.5.1 and 18.5.2](#)
 - 11.2.1.5 actions to be taken following a failed sterility indicator or unexplained parameter change, based on MIFU;
[Reference: CSA Z314-18, 16.6.13.1](#)
 - 11.2.1.6 management of limited use (reposable) devices, if used, based on MIFU;
[Reference: CSA Z314-18, 7.7](#)
 - 11.2.1.7 recall procedures; and
[References: CSA Z314-18, 5.7.7.1.1 and 16.6.13.4](#)
 - 11.2.1.8 management of loaned, reusable medical devices, if applicable.
[References: CSA Z314-18, 9.1.6, 9.1.7, and additional CSA standards in Section 9 “Loaned, reusable medical devices”](#)
- 11.3 The organization shall have a written policy regarding single-use medical devices that is consistent with section 1 of these standards.
- 11.3.1 The organization shall make sure that its policies related to single-use medical devices are available to all users, and shall provide awareness training as required.

11.4 The organization shall have policies and/or SOPs in place that include but are not limited to:

11.4.1 the required occupational health and safety activities, including use of appropriate personal protective equipment when performing MDR and when using single-use medical devices;

References: CSA Z314-18, 6.2 and 6.7.1.1

11.4.2 IPC routine practices;

Reference: CSA Z314-18, 6.7.1.2

11.4.3 the storage (including environmental conditions and requirements related to identification and labelling), transportation, and distribution of single-use and reusable devices and products;

References: CSA Z314-18, 12.5.4, 13.3.14, and 17.3.3.1

11.4.4 the practices and procedures required to maintain the sterility of packages and sterile medical devices, over time and until point of use, based on MIFU;

References: CSA Z314-18, 15.2.4 and 17.5.3.2.1

11.4.5 the requirement to use a clean or sterile sheath on ultrasound transducer probes that will come into contact with mucous membranes (in addition to the requirement that these probes shall, at a minimum, be cleaned and undergo high level disinfection according to the MIFUs); and

Reference: CSA Z314-18, 13.1.2

11.4.6 contingency plans for emergency situations that include but are not limited to:

- a) loss of staff;
- b) loss of or decrease in supply chain or inventory;
- c) loss of utilities including potable water;
- d) loss of reprocessing equipment;
- e) loss of or damage to sterile storage and/or laundry areas; and
- f) spills of hazardous substances.

References: Health Canada's "Emergency Preparedness" page at <https://www.getprepared.gc.ca/index-eng.aspx> (accessed July 22, 2019); CSA Z314-18, 6.7.4.1.6, 6.7.4.3.2, 6.7.4.3.3, 10.2.4.1.2, 16.7.2.4, 17.7, 18.1.1, 18.6.4.5, and 20.6.1.2; and CSA Z1600-17

- 11.5 The organization shall conduct a regularly scheduled review of all written policies and SOPs.

References: CSA Z314-18, 5.3.7 and 5.7.1

- 11.5.1 The organization shall review and revise policies and SOPs related to improvements or corrective actions as required (e.g., following a review of an accident, error, or event related to the function).

References: CSA Z314-18, 5.7.4 and 5.7.5

- 11.5.2 The development and subsequent review and update of policies and SOPs shall be performed by an individual experienced in medical device reprocessing who has the authority to make the necessary changes to ensure conformance with current or new requirements and/or changes in practice.

Reference: CSA Z314-18, 5.7.2.4

Documentation

Documentation, including clear record retention policies, is a key pillar of a quality management system. Specific documentation requirements for disinfection, sterilization, and education and training processes are included in sections seven, eight, and ten of these standards, respectively.

- 11.6 The organization shall retain records of reprocessing according to the health care facility or setting's policy and applicable legislation. These records shall include, but not be limited to, the following:

References: CSA Z314-18, 5.7.1 and 12.9.2.1

Note: *Applicable legislation may vary depending on the organization and provider. Additionally, health profession regulatory colleges may have policies for their members that define the period of time for which their members may be required to keep clinical records.*

- 11.6.1 preventative maintenance of reusable medical devices and equipment;

Reference: CSA Z314-18, 18.1.3

- 11.6.2 results of installation, operational, performance qualification and requalification, and routine testing of reprocessing equipment and products;

References: CSA Z314-18, 16.5.2.2 and 16.5.3.2.4

- 11.6.3 management and handling of loaned, shared, and leased medical devices; and
[References: CSA Z314-18, 9.1.5.1 and 9.1.5.3](#)
- 11.6.4 documentation of unique identifiers that link a specific endoscope to a specific client, and the critical reprocessing parameters of that endoscope.
[Reference: CSA Z314-18, 12.9.2.3](#)
- 11.7 The MIFU for medical devices, equipment, and supplies shall be received and maintained in printed form (e.g., in binders, manuals, or monographs) or in electronic format and be readily accessible to those needing access and shall be updated as required.
[Reference: CSA Z314-18, 7.1](#)
- 11.8 If reprocessing of reusable medical devices is being performed by an external or internal subcontractor, the subcontractor shall comply with these Standards.
[Reference: CSA Z314-18, 5.7.2.6](#)
- 11.9 Organizations that provide services involving contact with high-risk tissues from clients suspected or known to have Creutzfeldt-Jakob Disease or prion-related disease shall develop policies to manage medical devices in accordance with Health Canada and the Public Health Agency of Canada's [Infection Control Guidelines: Classic Creutzfeldt-Jakob Disease in Canada — Quick Reference Guide](#).
- 11.10 The organization shall review and monitor personnel compliance with these standards in accordance with its written policy on monitoring and reporting, and results of such monitoring shall be documented.
- 11.11 The organization shall have a process for assessing risk when a breach or lack of compliance with these standards occurs and shall report as appropriate.

Note: Reporting will vary depending on setting. Within AHS and third parties contracted by AHS, non-compliance shall be reported as set out in the Alberta Health Standards for IPC – Accountability and Reporting and the corresponding directive. In other settings, it may be appropriate to report to a Medical Officer of Health, AHS Environmental Public Health and/or the corresponding health profession regulatory college.