Canadian Standards for Decontamination, Sterilization and Infection Control in Health Care Facilities

The Canadian Standards Association (CSA) currently offers twelve standards dealing with decontamination, sterilization, and infection prevention and control in health care facilities. Most of these are National Standards of Canada, meaning they meet the requirements set out and enforced by the Standards Council of Canada.

Written in Canada, and designed for use in Canadian hospitals, the standards are intended to help health care providers identify the critical elements of medical device processing and infection control, and to make sure these elements are part of health care facility procedures.

Committees of experts that include manufacturers, health care professionals, scientists and regulators developed each of these standards. The standards represent their consensus on best practices with respect to policies and procedures, personnel and facility management, and routine practices. As such they provide essential guidance to health care facility administration and personnel, as well as to outside services such as offsite reprocessors and laundries.

The CSA standards for health care facilities provide a comprehensive set of requirements aimed at protecting the health of patients and staff. They should be in all processing departments, and they should be part of any facility policies and procedures related to medical device reprocessing and infection control. These standards can be ordered online at www.csa.ca; by mail or fax using the attached form; or by speaking with a customer service representative at 1-800-463-6727.

Standards for all Health Care Facilities

CAN/CSA-Z314.8-Decontamination of Reusable Medical Devices
This Standard contains general requirements (including those for policies, procedures, training and facilities) for decontamination of reusable diagnostic and therapeutic medical devices. It also has specific sections dealing with reusable respiratory/anesthesia devices, flexible fibre optic endoscopes, and electronic patient-applied devices.

CAN/CSA-Z314.10 Selection, Use, Maintenance & Laundry of Reusable Textile Wrappers, Surgical Gowns and Drapes for Health Care Facilities
Z314.10 defines essential elements in the selection, use, maintenance, continued serviceability, and laundering of reusable textile wrappers, surgical gowns, and drapes for use in health care facilities. It includes minimum construction and performance requirements for reusable textiles to help health care facilities choose products with barrier qualities that are appropriate for their intended use. It may also be useful to health care facilities in evaluating contract services connected with the reprocessing of reusable surgical textiles.

Z314.14 Selection and Use of Rigid Sterilization Containers
This Standard covers the selection, proper use and maintenance of all types of sterilization containers, from wrapped organizing trays to stand-alone container systems. The selection information looks at rigid containers in terms of the total needs and capabilities of the health care facility, and includes minimum testing, construction and performance requirements to help health care facilities choose products that are appropriate for their intended use. The use and maintenance requirements cover handling, disassembly, processing and preparation for sterilization, and aseptic presentation for use.

Z314.15 Warehousing, Storage and Transportation of Clean and Sterile Medical Devices
Traditionally, health care facilities have stored clean and sterile medical devices in their sterile storage areas, where they are protected from microbial contamination and other damage. In recent years, with the regionalization of health care services and the increased use of contract services, health care facilities have begun to use centralized facilities such as warehouses or on-site storerooms for the storage of clean and sterile medical devices. This Standard provides a common set of specifications for health care facilities, storage facilities, off-site reprocessors, and materials management consultants to use when contracting for, arranging, and managing the storage and transportation of medical devices.

Z314.22 Management of Loaned, Shared and Leased Medical Devices
This Standard provides common requirements for health care facilities, manufacturers, distributors, and other parties involved with the lending, sharing, and leasing of medical devices. The goal of the Standard is to help protect patients, health care professionals, and manufacturers or distributors from the hazards and costs associated with contaminated medical devices, damaged or missing parts, scheduling issues, or malfunctions.
Plus 1112 Infection Prevention and Control in Office-Based Health Care and Allied Services
This is a handbook for smaller, non-hospital-based health care facilities, such as doctors’ and dentists’ offices. Although it is consistent with the CSA standards for decontamination and sterilization in health care facilities, it provides additional information on infection control, and sets out its information in a clear, easy-to-understand format.

Z317.13 Infection Control During Construction or Renovation of Health Care Facilities
The first edition of CSA Standard Z317.13, Infection Control During Construction or Renovation of Health Care Facilities is part of a series of standards related to health care facility engineering. The intent of this standard is to provide guidance on preventing construction-related health care facility acquired infections and to present preventive measures intended to protect patients, health care facility staff, and visitors from disease transmission or other conditions such as allergic reactions during the construction or renovation of the health care facility.

Standards for facilities that perform Steam Sterilization

Z314.3 Effective Sterilization in Health Care Facilities by the Steam Process
This is the core standard for steam sterilization in health care facilities. It includes requirements for policies and procedures, personnel, sterilization areas, wrapping, sterilization and storage. Its aim is to help facilities to achieve an adequate level of sterility assurance. It emphasizes a systems approach, recognizing that sterility assurance depends not only on reliable sterilizer operation but also on proper pre- and post-sterilization practices.

Z314.7 Steam Sterilizers for Health Care Facilities
Z314.7 is primarily a manufacturing standards for steam sterilizers, but it should be in the hospital engineering department of any facility that uses these devices. It specifies minimum construction and performance requirements for steam sterilizers, to ensure their proper operation, and to protect the safety of personnel.

Z314.13 Recommended Standard Practices for Emergency (Flash) Sterilization
This Standard is intended to assist health care personnel in the proper application of emergency sterilization. The Standard includes functional and physical design criteria for areas of hospitals where emergency sterilization is carried out; staff qualifications and other personnel considerations; sterilization processing procedures; and quality assurance.

Standards for facilities that perform EtO Sterilization

Z314.1 Ethylene Oxide Sterilizers for Health Care Facilities
This is a manufacturer’s standard for EtO sterilizers, but it should be in the hospital engineering department of any facility that uses these devices. It specifies minimum construction and performance requirements for EtO sterilizers, to ensure their proper operation, and to protect the safety of personnel.

Z314.2 Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process
Z314.2 is the core standard for EtO sterilization in health care facilities. It includes requirements for policies and procedures, personnel, sterilization areas, wrapping, sterilization and storage. Its aim is to help facilities to achieve an adequate level of sterility assurance, and to protect from injury staff and patients who may be exposed to ethylene oxide gas or its byproducts. Like Z314.2 it emphasizes a systems approach, recognizing that sterility assurance depends not only on reliable sterilizer operation but also on proper pre- and post-sterilization practices.

Z314.9 Installation and Ventilation of Ethylene Oxide Sterilizers in Health Care Facilities
This Standard is for any health care facility using EtO as a sterilant, installing new ethylene oxide sterilization equipment, or modifying existing equipment. The Standard’s aim is to help ensure the safety of personnel and patients, and to meet government regulations on exposure and worker safety respecting the use of ethylene oxide gas.