

Adhering to Standards

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Canadian Standards Association (CSA) has been developing and maintaining standards in health care for more than 40 years. These standards help protect patients and workers in the health care system by setting minimum requirements for safety in medical devices, buildings, systems, and management of professional practices. They also increase efficiency in health care facilities and systems without compromising patient care.

CSA standards are developed through a consensus standards development process approved by the Standards Council of Canada. This process brings together volunteers representing varied viewpoints and interests to achieve consensus, it does not independently test, evaluate, or verify the content of standards. There are currently twelve (12) CSA 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.

CSA standards are reviewed at least every five (5) years and based on the Technical Committee's decision a standard will be revised, reaffirmed, or withdrawn at that time. Users of CSA standards are advised to ensure they are working with the most recent published version. For example, the current steam sterilization standard was revised in March, 2009 and is titled "*Effective sterilization in health care facilities by the steam process*". This is the fifth edition of CSA Z314.3, published in 2001, 1991, 1985 and 1979. This standard is intended to form the basis of a quality system within a health care facility for the purpose of providing safe, reliable steam sterilization of reusable medical devices. It is one of a series of CSA standards dealing with the safe and effective sterilization of medical supplies and equipment.

CSA sterilization standards stress that medical device reprocessing (MDR) requires a systems approach and involves more than just the parameters set on the sterilization equipment used to process items. Adhering to sterilization standards involves proper facility design which emphasizes thorough cleaning of floors, walls, work surfaces and storage areas; special attention to air flow (negative pressure in decontamination, positive pressure in clean areas), and such things as keeping pass through windows and doors closed. Adhering to sterilization standards involves personnel training with certification recommended for MDR personnel, donning clean - facility laundered attire at the facility, and frequent hand washing. Adhering to sterilization standards involves preparing and transporting soiled items properly for decontamination; cleaning, disinfecting, inspection, assembly, packaging, sterilization and careful storage of processed items. Health care professionals who purchase, use and/or reprocess medical devices have a legal and moral obligation to comply with sterilization standards for patient safety and to document they have done so.

Health care suppliers also play a critical role in adhering to standards. Health Canada requires the manufacturers of the more critical classes of reusable medical devices to establish and maintain quality systems in accordance with international standards. Under these quality systems, manufacturers must validate their recommended reprocessing instructions through the use of extensive testing. When manufacturers visit health care facilities, they should be aware of sterilization standards with regards to proper attire, hand washing, and authorized entry into restricted areas. Studies have shown that a person in street clothes can shed up to 10,000 particles per minute simply by walking. Therefore, before entering restricted areas, all staff and visitors should change into clean, hospital attire to limit contamination of these areas. Health care suppliers should encourage continuing education (CE) by creating scholarships for MDR technicians and managers who wish to get certified. These scholarships can offset some or all of the costs associated with study materials, course fees and exam costs. Lastly, health care suppliers should provide low-cost (or better yet, no-cost) CE programs directly to health care facilities that reinforce best practices as defined by CSA standards. This is a win-win situation, as knowledgeable health care workers will see the value in a supplier's product much more readily!

Keep informed on new CSA standards and services by logging on to the CSA website and registering at <http://kmi.csa.ca/>. Receive information on free sterilization CE programs and sterilization articles by logging on to the KEIR Surgical website at <http://www.keirsurgical.com/sites/en/educate/articles.html>.