Z314.23-12

Chemical sterilization of reusable medical devices in health care facilities

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Contents

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Preface

This is the first edition of CSA Z314.23, *Effective chemical sterilization in health care facilities.* It is one of a series of CSA Standards dealing with the safe and effective sterilization of medical supplies and equipment. It supersedes CAN/CSA-Z314.2, *Effective sterilization in health care facilities by the ethylene oxide process,* published in 2009, 2001, 1991, 1984, and 1977.

This Standard is a procedural and equipment guide for health care facilities using chemicals in liquid, gaseous, or vapour form to provide low-temperature sterilization. Its aims are twofold: to help achieve an adequate level of sterility assurance, and to protect from injury staff and patients who might be exposed to a sterilant or its by-products.

The Standard emphasizes a systems approach, recognizing that sterility assurance and the safety of personnel are dependent not only on reliable operation of chemical sterilizers, but also on proper pre- and post-sterilization practices.

CSA Standards are reviewed at least every five years, and based on the Technical Committee's decision a standard will be revised, reaffirmed, or withdrawn at that time. Users of this Standard are advised to ensure that they are working with the most recent published version.

This Standard was prepared by the Subcommittee on Chemical Sterilization under the jurisdiction of the Technical Committee on Sterilization and the Strategic Steering Committee on Health Care Technology. It has been formally approved by the Technical Committee.

March 2012

Notes:

(1) *Use of the singular does not exclude the plural (and vice versa) when the sense allows.*

(2) *Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.*

(3) *This publication was developed by consensus, which is defined by* CSA Policy governing standardization — Code of good practice for standardization *as "substantial agreement. Consensus implies much more than a simple majority, but not necessarily unanimity". It is consistent with this definition that a member may be included in the Technical Committee list and yet not be in full agreement with all clauses of this publication.*

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(c) wording of the proposed change; and
(d) rationale for the change.

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Chemical sterilization of reusable medical devices in health care facilities

0 Introduction

Medical devices are used in nearly every medical procedure. Patients and health care professionals expect these devices to be as safe as possible in terms of design, manufacture, and maintenance. The safety of medical devices begins with the manufacturer, and is supported and maintained by a system of national standards and government regulations that includes device licensing, construction and performance standards, and problem reporting systems.

Within this structure, a health care facility that reprocesses reusable devices plays an essential role. Unlike a medical device manufacturer, health care facilities face unique challenges in working with a wide array of items made by different companies, and these devices also arrive in the medical device reprocessing department (MDRD) in varying states of cleanliness and repair. It is the responsibility of the department to decontaminate each device, assess its condition, perform necessary maintenance, and disinfect or sterilize it using tested and validated methods. The ultimate goal is to be able to provide reprocessed medical devices, having confidence that they will do what they were originally manufactured to do and are safe to use on patients.

If a medical device has been validated using a chemical sterilization process and steam sterilization process, users of this Standard should recognize that the use of steam sterilization is preferable. Therefore, chemical sterilization is used primarily for medical devices that would be damaged by moist heat.

A chemical approved as a sterilant will only work if it is delivered in an appropriate manner and in adequate quantities to all parts of a medical device. Health Canada requires the manufacturers of critical classes of reusable medical devices to establish and maintain quality systems in accordance with international standards. Under these quality systems, manufacturers must validate and recommend reprocessing instructions through extensive testing. Health care facilities do not usually have the resources or expertise to do this type of validation in their own sterilizers. Instead, they must develop procedures to verify that the sterilizers are correctly performing the validated processes recommended by the manufacturer. Some gaseous sterilization processes can deliver sterile packaged items that can be stored for later use. Other sterilization processes can only be used on unwrapped items and are considered suitable only for items for immediate use.

This Standard is intended to form the basis of a quality system within a health care facility for the purpose of providing safe, reliable chemical sterilization of reusable medical devices. It is one of a series of Standards dealing with specific aspects of medical device reprocessing (MDR). This Standard sets out the framework in which health care facilities can establish, document, and maintain their own policies and procedures for the reprocessing of reusable medical devices to form a unique internal quality system. These policies and procedures should be based on several inputs, including government regulation, national standards, and equipment and device manufacturers' instructions for use and reprocessing, as well as the specific requirements that make up the quality system of the individual organization.

Quality systems in health care are intended to ensure that services and products will meet established standards and will result in appropriate clinical outcomes; in other words, to meet the expectations of those using the product or receiving the service. In reprocessing, a quality system helps to ensure that reusable medical devices are free of contamination and will work as intended.

Chemicals with approved sterilant claims and approved chemical processes providing sterilization are constantly evolving. Information regarding sterilant and sterilization approvals is current for Canada at the time of preparing this Standard and will be updated in subsequent editions. For additional information, please contact Health Canada's Therapeutic Products Directorate (TPD) at http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php.

1 Scope

1.1

This Standard specifies essential elements in implementing a program for using chemicals to sterilize medical devices in health care facilities. Such chemicals can be vapour, gaseous, or liquid and are delivered in validated concentrations and quantities in defined sterilizers.

The body of this Standard contains requirements that are common to all chemical sterilization processes, whereas requirements specific to a particular chemical sterilization technology are contained in Annexes A to E.

The following chemical sterilants are currently approved for use in sterilizers in Canada and are addressed in this Standard:

(a) gaseous and vapour chemicals:
  (i) ethylene oxide;
  (ii) hydrogen peroxide;
  (iii) ozone; and
  (iv) hydrogen peroxide-ozone; and
(b) liquid chemicals: peracetic acid.

Exposure to chemical sterilants can present risks to health care personnel and patients; this Standard includes measures to minimize the risk of such exposure as well as discharge to the environment of sterilizing chemicals and by-products.

1.2

This Standard includes general requirements for

(a) policies, procedures, and documentation;
(b) personnel qualifications and training;
(c) quality system;
(d) evaluation and purchase of reusable medical devices;
(e) work areas and equipment;
(f) preparation and packaging of medical devices requiring sterilization;
(g) sterilizer loading, unloading, and operation;
(h) procedures required following sterilization, to minimize sterilant residuals;
(i) storage of sterilized medical devices;
(j) sterility assurance, including process challenge device (PCD) construction and use;
(k) sterilizer maintenance and quality assurance; and
(l) occupational health and safety issues specifically related to chemical sterilization.

Note: *"Process challenge device" (PCD) has replaced the term "test pack".*

1.3

This Standard contains particular requirements for chemical sterilization and is to be used in conjunction with CSA Z314.3 and CAN/CSA-Z314.8. Where differences exist, the requirements of this Standard apply.

1.4

This Standard does not address

(a) a high-level disinfectant (e.g., glutaraldehyde) when it is used as a high-level disinfectant or sterilant;
(b) inactivation of chemically resistant parasites and protozoa;
(c) decontamination of reusable medical devices prior to sterilization;
  Note: *See CAN/CSA-Z314.8.*
(d) steam sterilization of reusable medical devices;
  Note: *See CSA Z314.3.*
(e) manufacturers' requirements for construction and performance of ethylene oxide sterilizers;
  Note: *See CSA Z314.1.*
(f) installation and ventilation of ethylene oxide sterilizers;
  Note: *See CAN/CSA-Z314.9.*