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Z314.23-16

Chemical sterilization of reusable medical devices in health care settings

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Z314.23-16
April 2016

Title: *Chemical sterilization of reusable medical devices in health care settings*

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Z314.23-16

Chemical sterilization of reusable medical devices in health care settings

Published in April 2016 by CSA Group
A not-for-profit private sector organization
178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3

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or call toll-free 1-800-463-6727 or 416-747-4044.

ISBN 978-1-4883-0373-9

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Preface

This is the second edition of CSA Z314.23, *Effective chemical sterilization in health care facilities.* It supersedes the previous edition published in 2012. It is one of a series of CSA Group Standards dealing with the safe and effective sterilization of medical supplies and equipment.

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.

This new edition has been revised to align with CSA Z314.0.

This 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 Group acknowledges that the development of this Standard was made possible, in part, by the financial support of the governments of Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nova Scotia, Nunavut, Ontario, Prince Edward Island, Québec, Saskatchewan, and Yukon, as administered by CADTH.

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, and has been formally approved by the Technical Committee.

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 Standard 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 Standard.*

4) *To submit a request for interpretation of this Standard, please send the following information to inquiries@csagroup.org and include "Request for interpretation" in the subject line:*

a) *define the problem, making reference to the specific clause, and, where appropriate, include an illustrative sketch;*
b) *provide an explanation of circumstances surrounding the actual field condition; and*
c) *where possible, phrase the request in such a way that a specific "yes" or "no" answer will address the issue.*

Committee interpretations are processed in accordance with the CSA Directives and guidelines governing standardization and are available on the Current Standards Activities page at standardsactivities.csa.ca.

5) *This Standard is subject to review five years from the date of publication. Suggestions for its improvement will be referred to the appropriate committee. To submit a proposal for change, please send the following information to inquiries@csagroup.org and include "Proposal for change" in the subject line:*

a) *Standard designation (number);*
b) *relevant clause, table, and/or figure number;*
c) *wording of the proposed change;*
d) *rationale for the change.*

Z314.23-16
Chemical sterilization of reusable medical devices in health care settings

0 Introduction

Medical devices are used in nearly every medical procedure. Patients and health care professionals expect these medical devices to be functionally and microbiologically safe. 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 medical device licensing, construction and performance standards, and problem reporting systems.

Within this structure, areas or departments that reprocess medical devices within or for a health care setting play an essential role and face unique challenges. Unlike a medical device manufacturer, medical device reprocessing personnel work with a wide array of medical devices manufactured by different companies, received in varying states of cleanliness and repair. It is the responsibility of the medical device reprocessing department (MDRD) to decontaminate, inspect, perform necessary maintenance, and sterilize or disinfect each medical device using the device manufacturer validated methodologies.

The goal is to provide medical devices that perform as intended by the manufacturer and are safe for reuse.

This Standard is one of a series of standards to be used in conjunction with CSA Z314.0, which provides a framework to establish, document, and maintain requirements for the reprocessing of medical devices as part of a quality management system. This Standard is intended to provide requirements for the safe and reliable chemical sterilization of reusable medical devices for those devices that are sensitive to heat.

Chemical sterilization is used primarily for medical devices that would be damaged by moist heat. Chemical sterilization processes kill microorganisms via alkylation (ethylene oxide) or oxidation (hydrogen peroxide vapour with or without gas plasma or ozone, and peracetic acid sterilization systems).

A chemical approved as a sterilant will only work if it is delivered according to the manufacturers written instructions with the correct contact time and temperature, and in adequate quantities to expose 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 settings 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.

Chemical sterilization processes are 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 for using chemical processes to sterilize medical devices in health care settings, with the object of achieving an adequate level of sterility assurance and minimizing the risk of injury to health care setting personnel and patients.

Note: *The term "health care setting" includes, but is not limited to, hospitals, free standing surgical centres, nursing homes, extended-care facilities, clinics, medical and dental offices, and health units in industry. See CSA Z314.0 for a more comprehensive definition.*

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

a) gaseous and vapourized chemicals:
   i) ethylene oxide;
   ii) hydrogen peroxide;
   iii) hydrogen peroxide-ozone; and
b) liquid chemicals:
   i) 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 any harmful sterilizing chemicals and by-products.

1.2

This Standard includes chemical sterilization specific requirements for

a) work areas and equipment;
b) preparation and packaging of medical devices;
c) sterilizer loading, unloading, and operation;
d) procedures that might be required following sterilization, to minimize sterilant residuals;
e) sterility assurance, including process challenge device (PCD) and use;
f) sterilizer maintenance and quality assurance; and
g) occupational health and safety (OHS) issues specifically related to chemical sterilization systems.

1.3

This Standard contains particular requirements for chemical sterilization and is to be used in conjunction with CSA Z314.0, CSA Z314.3, CSA Z314.8, CSA Z314.14, CSA Z314.15, CSA Z314.10.1, CSA Z314.10.2, and CAN/CSA-Z314.22.

1.4

This Standard does not address

a) general requirements applicable to all sterilization methods;
   Note: *See CSA Z314.0.*
b) decontamination of reusable medical devices;
   Note: *See CSA-Z314.8.*
c) the manual use of liquid chemical sterilants;
   Note: *See CSA Z314.8.*
d) automated use of high level disinfectants;
   Note: *See CSA Z314.8.*

