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Z314.3-14

Effective sterilization in health care settings by the steam process



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Preface

This is the sixth edition of CSA Z314.3, *Effective sterilization in health care settings by the steam process*. It supersedes the previous editions, published in 2009, 2001, 1991, 1985, and 1979. It is designed to be used with CSA Z314.0 *Medical device reprocessing — General requirements* and others in a series of CSA Group Standards dealing with the safe and effective sterilization of medical supplies and equipment.

CSA Group 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at least every five years, and based on the Technical Committee's decision, a standard will be revised, reaffirmed, or withdrawn at that time.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 Moist Heat Sterilization under the jurisdiction of the Technical Committee on Sterilization and the Strategic Steering Committee on Health Care Technology.

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 after date of publication, and 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; and*
 - d) *rationale for the change.*

Z314.3-14

Effective sterilization in health care settings by the steam process

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 disinfect or sterilize 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, *Medical device reprocessing — General requirements*, which provides a framework to establish, document, and maintain requirements for the reprocessing of medical devices as part of a quality management system.

CSA Z314.3 is intended to provide requirements for the safe and reliable steam sterilization of reusable medical devices, water and steam quality, and extended steam sterilization cycles.

1 Scope

1.1

This Standard specifies essential elements for using steam 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.

Notes:

- 1) *The term “health care setting” includes, but is not limited to, hospitals, nursing homes, extended-care facilities, clinics, medical and dental offices, and health units in industry. See CSA Z314.0 for a more comprehensive definition.*
- 2) *Comprehensive guidance for small, community health care settings can be found in CSA SPE-1112.*

1.2

This Standard includes requirements for

- a) sterilization equipment including tabletop sterilizers;
- b) preparation and packaging of medical devices requiring sterilization;
- c) sterilizer loading and operation;