CSA Group

Z314.15-15

Storage, transportation, and distribution of single use and reusable medical devices

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CSA Group

Standards Update Service

Z314.15-15
August 2015

Title: *Storage, transportation, and distribution of single use and reusable medical devices*

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Z314.15-15

Storage, transportation, and distribution of single use and reusable medical devices

Published in August 2015 by CSA Group
A not-for-profit private sector organization
178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3

*To purchase standards and related publications, visit our Online Store at **shop.csa.ca***
or call toll-free 1-800-463-6727 or 416-747-4044.

ISBN 978-1-4883-0030-1

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Preface

This is the third edition of CSA Z314.15, *Storage, transportation and distribution of single use and reusable medical devices.* It supersedes the previous edition published in 2010. It is one of the CSA Z314 series of Standards dealing with decontamination, disinfection, sterilization and handling of sterile medical devices.

This Standard specifies requirements for the storage, handling, transportation, and distribution of single use and reusable medical devices in facilities where open-inventory (split-case) storage and handling services are provided.

This Standard is intended to assist health care settings and other storage facilities in establishing safe and effective storage and handling practices to ensure that medical devices are protected from microbial contamination and other damage. This Standard specifies a systems approach, recognizing the trend in health care to use shared, centralized storage solutions that can be located on and/or off site and introduces classification categories (tiers) for storage facilities.

This Standard has been revised to work in tandem with applicable requirements of CSA Z314.0, *Medical device reprocessing – General requirements,* and other standards in the CSA Z314 series.

CSA group would like to acknowledge the contributions of Andrée Pelletier, Johanne Dionne, Diane Pinsonnault, and Anne Marie Rancourt towards the development of this Standard.

This Standard was prepared by the Subcommittee on Warehousing of Medical Supplies, under the jurisdiction of the Technical Committee on Sterilization and the Strategic Steering Committee on Health Care Technology Systems.

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 change.*

Z314.15-15
Storage, transportation, and distribution of single use and reusable medical devices

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.

Safe storage of single use and reusable medical devices is necessary to protect these devices from damage. Traditionally single use and reusable medical devices have been stored in sterile storage areas associated with operating room medical device reprocessing, and storage areas within the health care setting.

In recent years, with the regionalization of health care services and the increased use of contract services as well as the purchase of single use sterile medical devices, health care settings have begun to use centralized facilities such as warehouses or on-site storerooms for the storage of single use and reusable medical devices. In these facilities, shipping containers of medical devices are opened or unpacked, and medical devices are stored in open inventory (split-case), bins, or totes until needed. These facilities also pick medical devices and repack them into bins, totes, or case carts for transportation to the point of use. Off-site storage is also provided by some contract reprocessing and laundry services. These trends have resulted in the need to address warehouses that store and distribute open inventory.

This Standard provides a common set of specifications for health care settings, storage facilities, off-site reprocessors, and warehouses that do open inventory (both third party and health care setting owned), and materials management consultants to use when contracting for, arranging, and managing the storage of medical devices.

This Standard should 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, as well as other requirements for personnel, infection, prevention and control, occupational health and safety, area design, etc.

1 Scope

1.1

This Standard specifies requirements and recommended practices for the storage, handling, transportation, and distribution of single use and reusable medical devices in facilities where open-inventory (split-case) storage and handling services are provided.

1.2

This Standard covers

a) physical and functional requirements for storerooms, and other storage facilities that provide open-inventory (split-case) storage of single use and reusable single use or reusable medical devices;

   Note: *See CSA Z314.0 for additional requirements for sterile storage areas for reprocessed products.*

b) environmental conditions for storage and transportation;
c) staff qualifications, orientation, and education; occupational health and safety; and other personnel considerations;
d) storage and handling of single use and reusable medical devices;
e) management of case cart systems;
f) onsite distribution; and
g) emergency procedures.

1.3

The storage facilities covered by this Standard include the following:

a) sterile storage areas associated with operating room and medical device reprocessing areas including third party/off site reprocessors (tier 1) (i.e., single use opened case products and reprocessed medical devices);
b) storage areas outside of the sterile core within the health care setting that store both clean and sterile inventory (tier 2) (i.e., single use opened case products and reprocessed medical device); and
c) storage areas that distribute and/or transport open single use inventory clearly separated from storage areas that distribute and/or transport closed cases (tier 3).

Note: *Tier 3 can include onsite and offsite warehouse storage locations.*

1.4

This Standard does not apply to

a) the reprocessing of reusable medical devices that have become contaminated through accident or mishandling during storage, transportation, or on-site distribution;

   Note: *See CSA Z314.8.*

b) the storage of medical devices at the point of manufacturing;
c) transportation between the point of manufacturing and the warehouse or storage area; and
d) warehousing that does not include low unit of measure (opened case product) distribution (e.g., vendor warehouse with bulk storage).

1.5

In this Standard, “shall” is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard; “should” is used to express a recommendation or that which is advised but not required; and “may” is used to express an option or that which is permissible within the limits of the Standard.

Notes accompanying clauses do not include requirements or alternative requirements; the purpose of a note accompanying a clause is to separate from the text explanatory or informative material.

Notes to tables and figures are considered part of the table or figure and may be written as requirements.

Annexes are designated normative (mandatory) or informative (non-mandatory) to define their application.

1.6

The values given in SI units are the units of record for the purposes of this Standard. The values given in parentheses are for information and comparison only.

2 Reference publications

This Standard refers to the following publications, and where such reference is made, it shall be to the edition listed below:

CSA Group

Z314.0-13
Medical device reprocessing — General requirements

Z314.3-14
Effective sterilization in health care settings by the steam process

Z314.8-14
Decontamination of reusable medical devices

Z314.23-12
Chemical sterilization of reusable medical devices in health care settings

CAN/CSA-Z317.2-10
Special requirements for heating, ventilation, and air-conditioning (HVAC) systems in health care settings

Z317.5-98 (R2013)
Illumination systems in health care settings

CAN/CSA-Z317.13-12
Infection control during construction, renovation, and maintenance of health care settings

ASHRAE (American Society of Heating, Refrigerating and Air-Conditioning Engineers)

ANSI/ASHRAE 52.2-2007
Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size

Government of Canada—Health Canada

Guidance Document: Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices
http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_reprocessing_im_ld_retraitement-eng.php

Government of Canada—Public Health Agency of Canada

Hand hygiene practices in healthcare settings, 2013. See the Government of Canada publications website at the following link:
http://www.publications.gc.ca/site/eng/home.html