CSA Group

Z314.0-13

Medical device reprocessing — General requirements

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Preface

This is the first edition of CSA Z314.0, *Medical device reprocessing – General requirements.* It is the core Standard 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at least every five years and, based on the Technical Committee's decision, a standard is revised, reaffirmed, or withdrawn at that time.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 Technical Committee on Sterilization under the jurisdiction of 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 periodic review, 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.*

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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.

Health Canada requires manufacturers of the more critical classes of reusable medical devices to establish and maintain Quality Management Systems (QMS) in accordance with international standards. Under QMS, manufacturers are required to validate their recommended reprocessing instructions through the use of extensive testing. Health care settings do not have the resources or expertise to do this type of validation for their own reprocessing equipment and must instead develop procedures to verify that they are correctly performing the validated processes recommended by the manufacturer. This Standard sets out requirements for health care settings to establish, document, and maintain their own policies and procedures for the reprocessing of medical devices, forming a unique internal QMS. These policies and procedures are based on several inputs, including government regulation, national standards, and the specific requirements that make up the quality system of the individual organization.

The main function of a QMS is to establish consistency and control of the required processes and documentation in order to produce quality products. A QMS for MDRDs requires management of the reprocessing area to be considered analogous to that of a manufacturing facility. The products of the MDRD are therefore decontaminated and sterilized medical devices (or any other output that would be a result of following controlled processes within the MDRD).

The MDRD referenced in this Standard refers to any reprocessing area, be it in a hospital, clinic, or anywhere within a health care setting where reprocessing occurs. The MDRD can be a simple one-person organization or a sophisticated multi-site department under a single management. As such, the complexity of the QMS varies depending on the size and complexity of the organization. This Standard also applies to all third parties that perform critical aspects of the MDRD's function.

This description of a QMS for MDRDs introduces new language and terminology (e.g., product realization, non-conformity, corrective, and preventive actions) to reprocessing. While this terminology might be

initially unfamiliar, it aligns with terminology that is in regular use within industry and is supported by many international standards.

1 Scope

1.1

This Standard is intended to form the basis of a QMS within a health care setting for the purpose of providing safe, reliable reprocessing of reusable medical devices and is designed to be used with the CSA Z314 series of Standards addressing specific aspects of medical device reprocessing.

A comprehensive QMS can be achieved when this Standard is used in combination with related subject specific standard(s) in the CSA Z314 series:

a) CSA Z314.1;
b) CSA Z314.3;
c) CAN/CSA-Z314.8;
d) CSA Z314.9;
e) CSA Z314.10.1;
f) CSA Z314.10.2;
g) CSA Z314.14;
h) CSA Z314.15;
i) CAN/CSA-Z314.22; and
j) CSA Z314.23

Note: *Some content in this Standard will be duplicated in other standards in the CSA Z314 series until future editions can be developed and redundancies removed. This Standard supersedes duplicate content of other standards in the CSA Z314 series.*

1.2

As part of a QMS, this Standard includes requirements for

a) quality management, including
    i) policies and procedures;
    ii) documentation;
    iii) roles and responsibilities;
    iv) management review;
    v) personnel qualifications and training; and
    vi) adverse event management (e.g., recalls);
b) occupational health and safety;
c) evaluation and purchase of reprocessing equipment and reusable medical devices;
d) infection prevention and control;
e) work areas and equipment;
f) environmental conditions; and
g) utilities (e.g., power supply, water, and steam quality).

1.3

This Standard applies to health care settings or providers where medical device reprocessing occurs, including but not limited to,

a) all acute care hospitals;
b) trauma centres;
c) emergency care facilities;

