Z314.22-10

Management of loaned, reusable medical devices

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Preface

This is the second edition of CSA Z314.22, *Management of loaned, reusable medical devices*. It supersedes the previous edition, published in 2004 under the title *Management of loaned, shared, and leased medical devices*. It is intended to be used with the CSA Z314 series of Standards pertaining to the reprocessing of medical devices.

This Standard was prepared by the Subcommittee on Loaned, Reusable Medical Devices, 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. It will be submitted to the Standards Council of Canada for approval as a National Standard of Canada.

October 2010

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) where possible, phrase the request in such a way that a specific "yes" or "no" answer will address the issue.
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(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

Health care facilities use loaned, reusable medical devices for a number of reasons. Apart from the potential cost savings of not keeping expensive medical devices in inventory, loaned, reusable medical devices allow health care facilities to save on maintenance costs as well as to keep up with changing technology.

Nevertheless, these devices can create difficulties for a health care facility if they arrive at the facility without notice, incomplete, unclean, or too late for reprocessing. Manufacturers and distributors can likewise be affected if devices are returned contaminated or incomplete.

As a way of addressing these problems, this Standard specifies common requirements for health care facilities, manufacturers, distributors, and other parties involved with loaned, reusable medical devices. The goal of this Standard is to help protect patients, health care professionals, manufacturers, and distributors from the hazards and costs associated with contaminated medical devices, damaged or missing parts, scheduling issues, and malfunctions.

1 Scope

1.1

This Standard specifies requirements for the lending of

(a) critical and semi-critical reusable medical devices; and
(b) single-use medical devices, such as implants, that accompany and are intended to be used with the loaned, reusable device.

This Standard applies to all health care facilities and vendors that provide, use, transport, or maintain loaned, reusable medical devices.

1.2

This Standard specifies requirements for

(a) policies and procedures related to the lending and trial of medical devices;
(b) accountabilities and responsibilities;
(c) staff qualifications, orientation, education, training, and other personnel considerations;
(d) transportation between organizations;
(e) quality assurance;
(f) emergency procedures; and
(g) required documentation.

Note: *Examples of the types of transactions covered by this Standard include*
(a) health care facility to health care facility; and
(b) vendor to health care facility and health care facility to vendor.

1.3

The following areas are not addressed in this Standard:

(a) decontamination of reusable medical devices (see CAN/CSA-Z314.8);
(b) maintenance;
(c) sterilization of medical devices (see CSA Z314.2 and CSA Z314.3); and