



HEALTH CARE

The New CAN/CSA Z314-18 Canadian Medical Device Reprocessing

A Clause by Clause Summary of Changes

OVERVIEW

Medical devices are used in some way in nearly every medical procedure – devices that are expected to be both functionally and microbiologically safe. Safety depends upon a detailed process that begins with the manufacturer and ends with correctly reprocessed medical devices. Medical device reprocessing is supported and maintained by a system of national standards and government regulations that includes medical device licensing, construction and performance standards, troubleshooting, and reporting.

With this in mind, CSA Group recently published a new national standard of Canada that replaces nine standards from the CSA Z314 Medical Device Reprocessing series: Z314.0, Z314.3, Z314.8, Z314.10.1, Z314.10.2, Z314.14, Z314.15, Z314.22, and Z314.23. This new standard serves as a valuable resource for all health care settings where reusable medical devices are utilized and require reprocessing – from private offices such as dentists, podiatry and surgery clinics

to large hospitals and acute/long-term care facilities. It was developed to streamline content – a 375 page document versus the 633 pages of the standards separately – as well as remove redundancies, improve readability and flow, update technical content where needed, and to better align with the medical device reprocessing workflow.

To help clarify the changes in this new standard, changes by Clause are summarized here.

Clause 4 General Requirements

- Mandates cleaning before further reprocessing

Clause 5 Quality Management Systems

- Simpler clause with supporting examples given in Annex A
- New 'operations' section

Clause 6 Personnel

- Better addresses personal protective equipment (PPE) for the decontamination area and blood and body fluid spills

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Clause 8 Evaluation and Purchase

- Added new sections on validation and MIFUs, performance characteristics of container systems, and mandate to reprocess newly purchased reusable medical devices before use

Clause 10 Work Areas and Design

- Criteria for location of reprocessing equipment
- Strong recommendation to use automated reprocessing equipment
- Requirements for protecting clean and sterile medical devices and supplies stored in treatment rooms or operating rooms

Clause 11 Decontamination of Reusable Medical Devices

- Revised figure 11.1 on decontamination steps
- Performance testing to ensure cleanliness is now required for each day that an automated cleaning system is used
- Need to remove visible soil from the medical device before ultrasonic cleaning is performed
- Requirement to test sonication performance of an ultrasonic cleaner at least weekly, or preferably each day it is used
- Drying requirements now include medical devices meant to be further disinfected or chemically sterilized
- Now covers testing for the MEC of a reusable HLD
- Requirement to test the washer disinfector daily for cleaning and weekly for temperature

NEW Clause 12 Flexible Endoscopes

- Requirement to visually inspect endoscopes for cleanliness and damage following cleaning and rinsing

NEW Clause 13 Ultrasound Transducer Probes

- Must take precautions not to mix two different chemicals in the same reprocessing space

NEW Clause 14 Preparation of Medical Devices for Reprocessing

- Must verify cleanliness and functionality of all medical devices by visual inspection
- Lighting and magnification requirements
- New table 14.1 on work area lighting
- Must disassemble devices to their simplest component parts before inspecting for cleanliness
 - Need to follow the chemical sterilizer MIFUs regarding the lumen lengths and inside diameters, and number of lumens per device

Clause 15 Selection and Use of Sterile Barrier Systems

- Requirement to package reprocessed reusable medical devices using validated sterile barrier systems
- Requirement to confirm packaging system qualifications (IQ, OQ, PQ) by visual inspection
- Manufacturers need to demonstrate that reusable packaging material performance is maintained through multiple uses
- Requirement to re-evaluate sterile barrier system integrity if a protective cover is removed but the packaged item is not used
- Requirement for the installation qualification to establish that the MDRD work area can accommodate the pouch packaging system
- Requirements for operational qualification (OQ) of sealed sample test packages

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- Need to determine the appropriate number of sample packages to be included in a batch to perform quality testing
- Added OQ samples acceptance criteria
- Pouching requirements expanded and double pouching covered

Clause 16 Sterilization Methods

- Combines steam and chemical sterilization
- Added PCD validation requirement to OQ test methods
- Requirement to discard single-use items from test sets
- Requirement to create PQ test loads and to quarantine test load packages until all indicators pass
- Changed external and internal indicators to Type 1, 2, 3, 4, 5 or 6 to align with ISO
- Manufacturers need to validate implants for the type of sterilization being used
- Conduct routine biological indicator testing following the sterilizer and PCD MIFUs
- Removed option to use in-house PCDs
- When to check external chemical indicators
- IUSS personnel requirements and need for at least one IUSS to be on emergency power system
- Adds IUSS sterility assurance
- Adds section on table-top steam sterilization

Clause 18 Equipment Maintenance and Quality Assurance

- Added new section
- Includes utilities
- Clarification for testing in response to events – normal preventive maintenance isn't considered an event

Clause 19 Selection and Use of Gowns and Drapes

- Need to reprocess newly purchased reusable wrappers, gowns, and drapes before initial use unless packaged and sterilized by the manufacturer

Clause 20 Laundering, Maintenance, and Preparation of Reusable Gowns, Drapes, and Wrappers

- Added explanation that folding of linen in a separate room is meant to minimize lint infiltration

Annexes

- Annexes from older Z314 series revised and updated for Z314-18
- New Annex A on applying CAN/CSA-ISO 9001 QMS requirements to medical device reprocessing



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