New National Standard of Canada

CAN/CSA-Z314-18

Canadian medical device reprocessing

Colleen Landers R.N.; MDRT

CSA Group

Value of Standards

Standards play an important role in safety, security, the environment and the global economy, by fostering wider acceptance of emerging technologies and helping to manage risk.

Members Drive Standards for Social Good

- +9,000 Engaged and Dedicated Volunteer Members
- +1,300 Standards Technical Committees

CSA Group

Standards & Codes Drive Trust and Safety

Electrical and Gas

Healthcare

Power Generation and Delivery

Construction and Infrastructure

Over **3,000** standards, codes & related products in **50+** technology areas

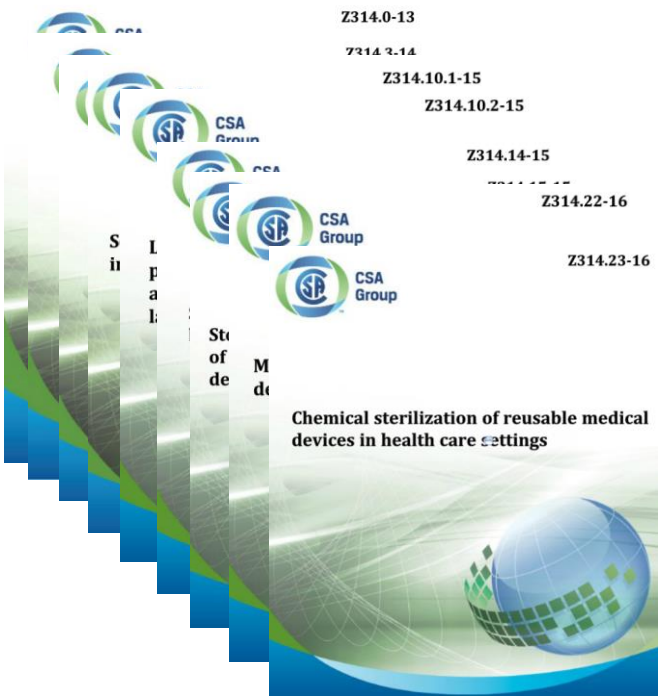
Public and Workplace Safety

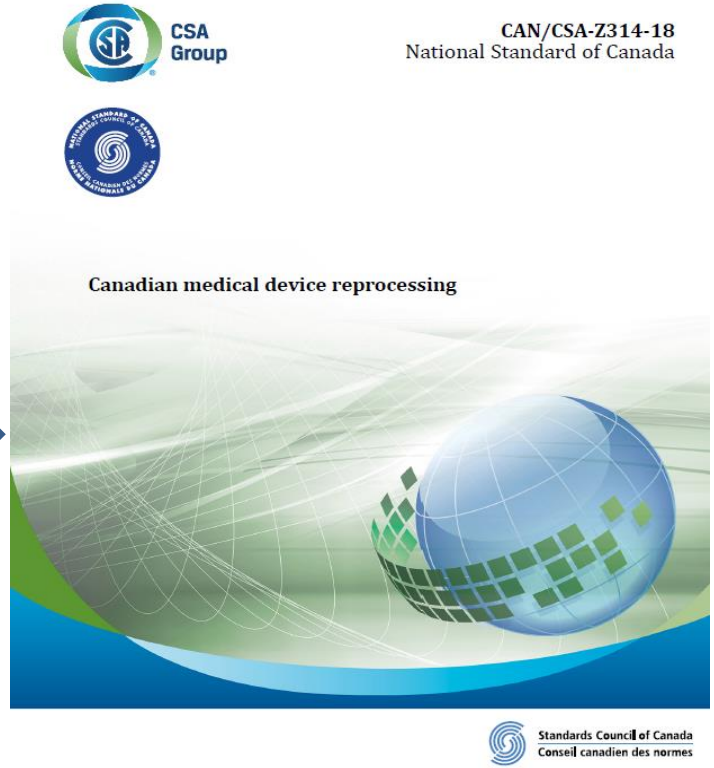
Petroleum and Natural Gas

Environment

Business Excellence

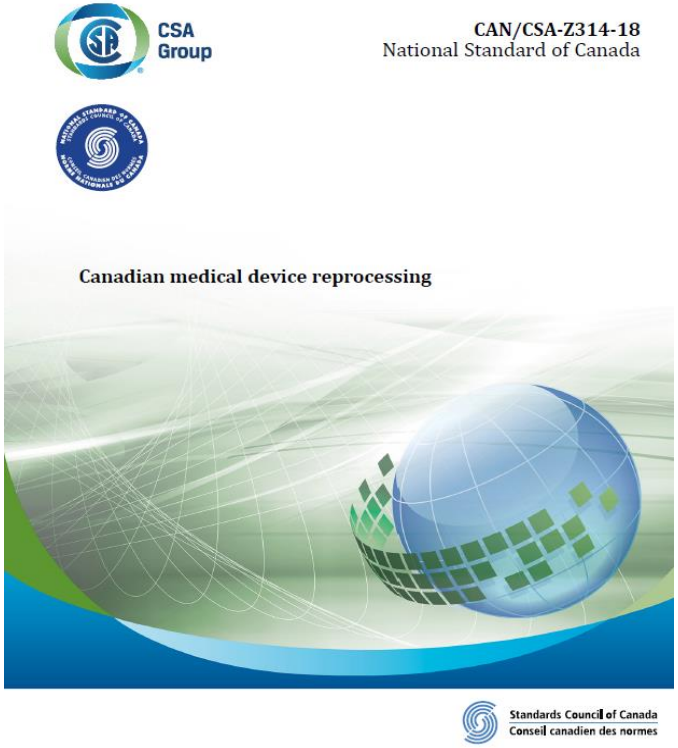
Nine CSA MDR standards now in one book!





New and Improved!

- ✓ Streamlines content (633 → 375 pages)
- ✓ Removes redundancies
- ✓ Improves readability and flow
- ✓ Updates technical content where needed
- ✓ New content on preparation and maintenance
- ✓ Better aligns with the MDRD workflow
- ✓ Annexes streamlined and updated



CSA Standards Development Process

Who needs this standard?

- ✓ Everyone who reprocesses reusable medical devices (hospitals, dental offices, foot care, ophthalmology offices, etc.)
- ✓ Search the Z314 pdf to “find” sections specific to your needs

Clauses 0 – 3 - Foundation for the Standard

Preface (administrative)

0 Introduction (Informative)

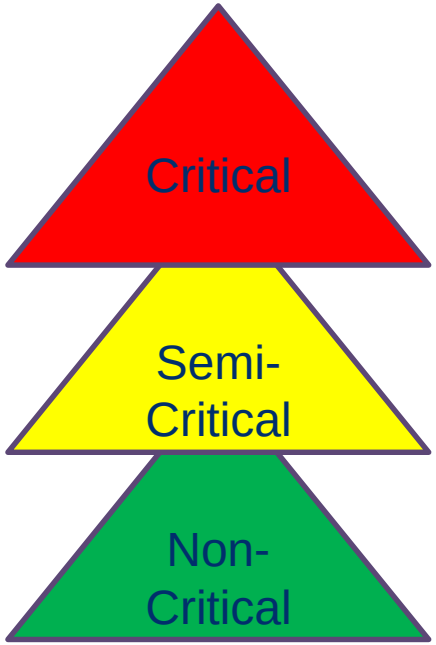
1 Scope (Informative)

2 Reference publications (Informative)

3 Definitions (Normative)

Clause 4 General requirements

- ✓ Start of technical requirements
- ✓ Spaulding's criteria
- ✓ (New) All devices shall be cleaned before further reprocessing (disinfection or sterilization).
- ✓ Made risk assessment normative



Clause 5 Quality management system (QMS)

- ✓ Key performance indicators
- ✓ Leadership and planning
- ✓ Process and service quality
- ✓ Provision of resources
- ✓ Human Resources
- ✓ Operations (New)
- ✓ Environmental conditions and infrastructure

Clause 6 Personnel

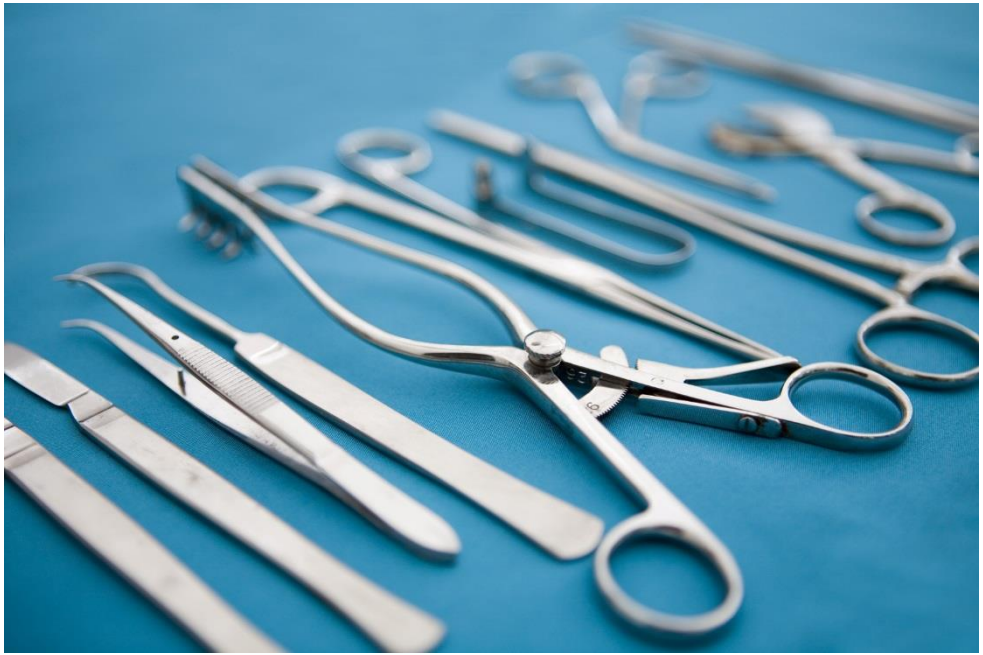
- ✓ Staff and manager qualifications
- ✓ Occupational health and safety
- ✓ Infection prevention and control
- ✓ Personal protective equipment

Clause 7 Manufacturer's instructions for use (MIFUs)

- ✓ Medical devices need clear, validated MIFUs
- ✓ Ensuring ability to perform reprocessing
- ✓ Information supplied with sterilization containers

Clause 8 Evaluation and purchase

- ✓ Reusable medical devices
- ✓ Reprocessing equipment
- ✓ Sterile barrier systems
- ✓ Consumables



Clause 9 Loaned, reusable medical devices

- ✓ Prohibits user modification
- ✓ Must use licensed devices
- ✓ Documentation
- ✓ Requirements for coordination and timing

Clause 10 Work areas and design

- ✓ Physical space and location of reprocessing equipment
- ✓ Lighting (new)
- ✓ Environmental cleaning
- ✓ Clean and sterile storage
- ✓ Case cart management
- ✓ Traffic and environment controls
- ✓ Environmental cleaning

Clause 11 Decontamination of reusable medical devices

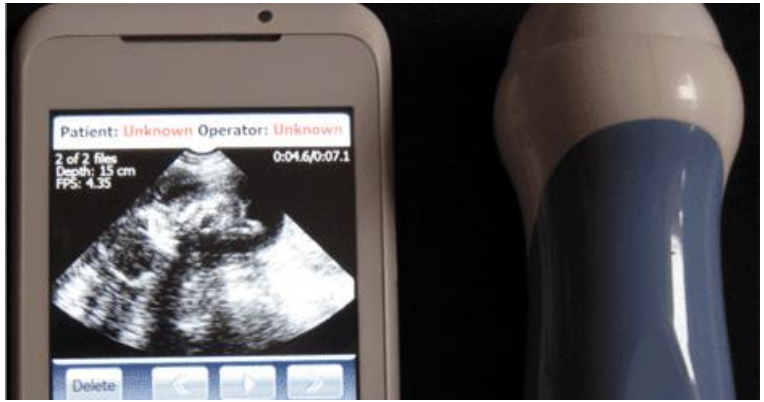
- ✓ Handling of contaminated device
- ✓ Retrieval and transport
- ✓ Sorting and disassembly
- ✓ Prep for cleaning
- ✓ Cleaning, rinsing and drying
- ✓ Disinfection
- ✓ Respiratory devices

Clause 12 Flexible endoscopes

- ✓ Reprocessing area
- ✓ External providers
- ✓ Reprocessing endoscopes
- ✓ Storage
- ✓ Sterilization
- ✓ Accessories
- ✓ Damaged devices
- ✓ Quality assurance and records

Clause 13 Ultrasound transducer probes

- ✓ Reprocessing area
- ✓ Reprocessing ultrasound transducer probes
- ✓ Quality assurance and record-keeping

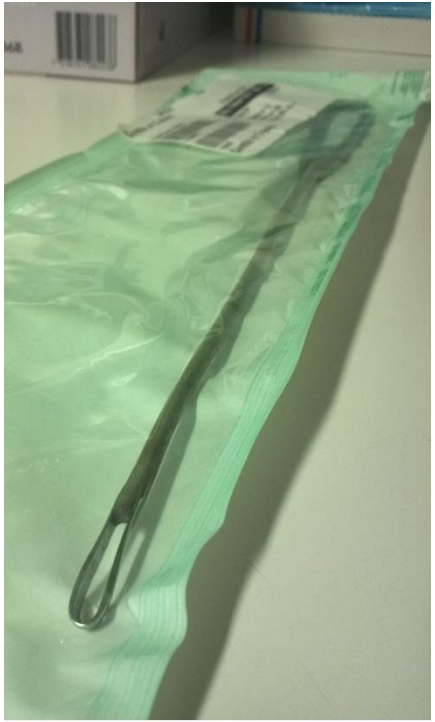


Clause 14 Preparation of medical devices for reprocessing

- ✓ Instrument care and handling
- ✓ Drying
- ✓ Verification of cleanliness and functionality
- ✓ Lubrication
- ✓ Additional preparation requirements for steam and chemical sterilization

Clause 15 Selection and use of sterile barrier systems

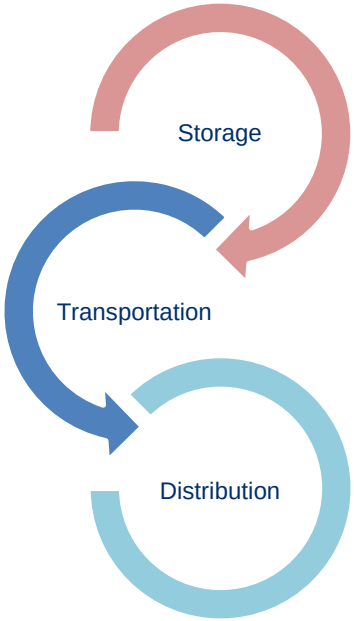
- ✓ Evaluation and purchase
- ✓ Packaging system qualifications
- ✓ Product design
- ✓ Assembly
- ✓ Labelling
- ✓ Pouches and reels
- ✓ Wrappers
- ✓ Rigid sterilization containers



Clause 16 Sterilization methods

- ✓ Covers steam and chemical
- ✓ Dust covers
- ✓ Sterility assurance
- ✓ Routine monitoring
- ✓ IUSS
- ✓ Table-top steam sterilization

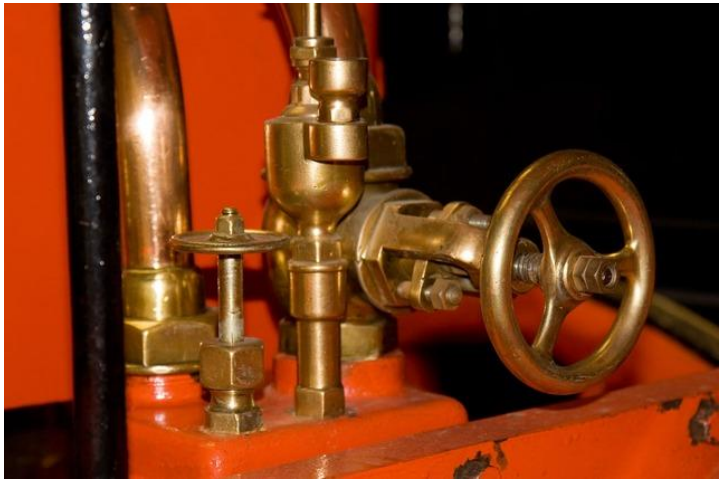
Clause 17 Storage, transportation, and distribution



- ✓ Sterile storage area
- ✓ Physical and functional requirements
- ✓ Environmental cleaning
- ✓ Handling
- ✓ Transportation and distribution
- ✓ Emergencies

Clause 18 Equipment maintenance and quality assurance

- ✓ Table-top sterilizers
- ✓ Ethylene oxide
- ✓ Submicron water filters
- ✓ Repair or refurbishing
- ✓ Utilities (steam, feed water)



Clause 19 Selection and use of gowns and drapes

- ✓ Evaluation and purchase of reusable gowns and drapes
- ✓ Selection of gowns and drapes
- ✓ Use of gowns and drapes
- ✓ Containment and handling of soiled gowns and drapes at the point of use

Clause 20 Laundering, maintenance, and preparation of reusable gowns, drapes, and wrappers

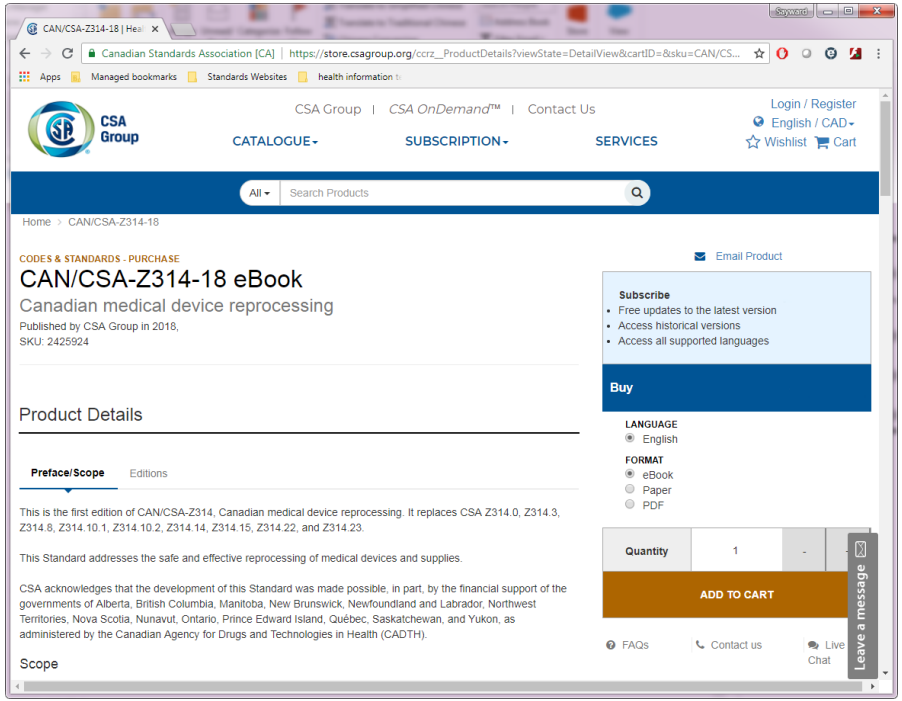
- ✓ Laundry equipment and personnel
- ✓ Work areas and equipment
- ✓ Prevention of stains and other damage
- ✓ Maintenance
- ✓ Handling, transport, receiving, and storage of soiled and clean textiles
- ✓ Laundering
- ✓ Preparation and packaging

The Annexes – Supporting information

- ✓ 19 annexes
- ✓ 18 provide guidance for implementation of mandatory content
- ✓ 1 (Annex E) is mandatory covering information to be supplied by the manufacturer

Thank you!

- ✓ CAN/CSA Z314-18 can be purchased at https://store.csagroup.org/
- ✓ Type Z314 in the Search field



CSA Group

CSA Group