New National Standard of Canada

CAN/CSA-Z314.-18

Canadian medical device reprocessing

Gale Schultz BN, RN

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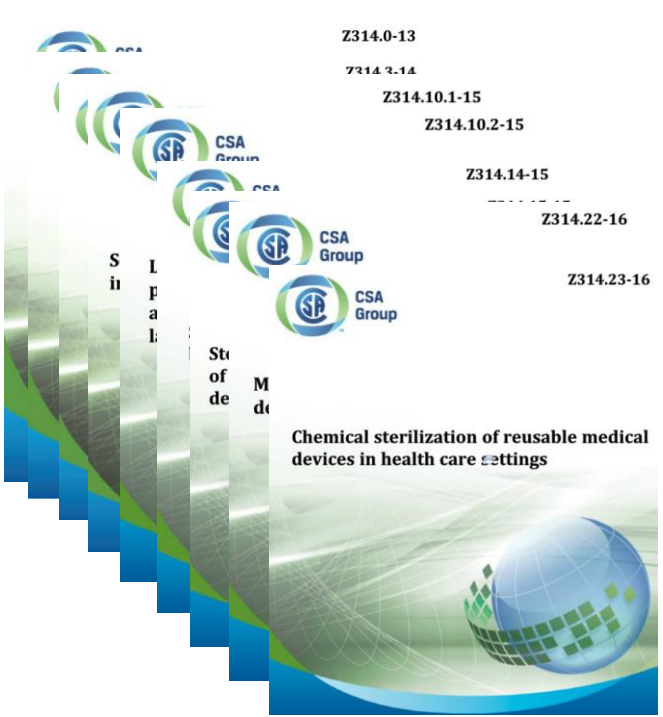
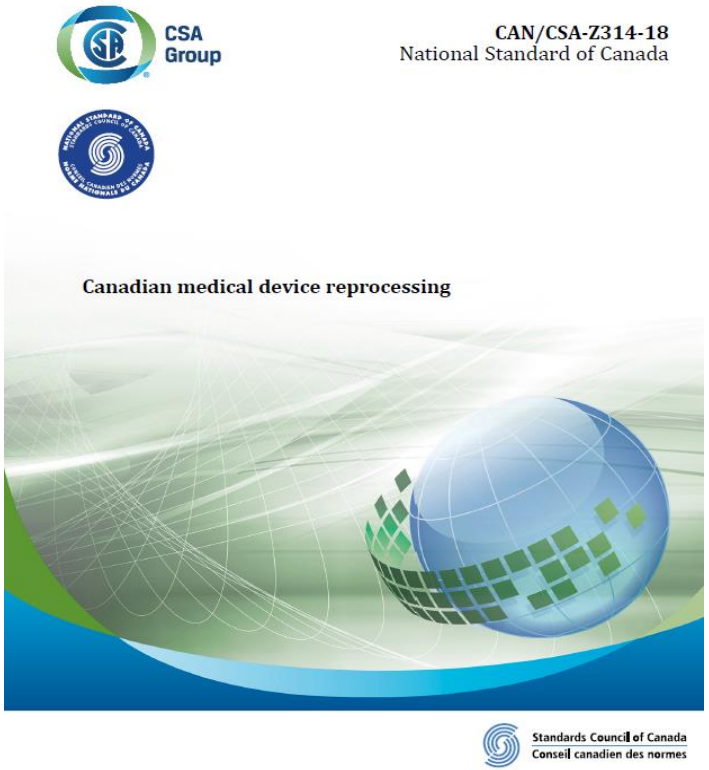
Nine CSA MDR standards now in one book!





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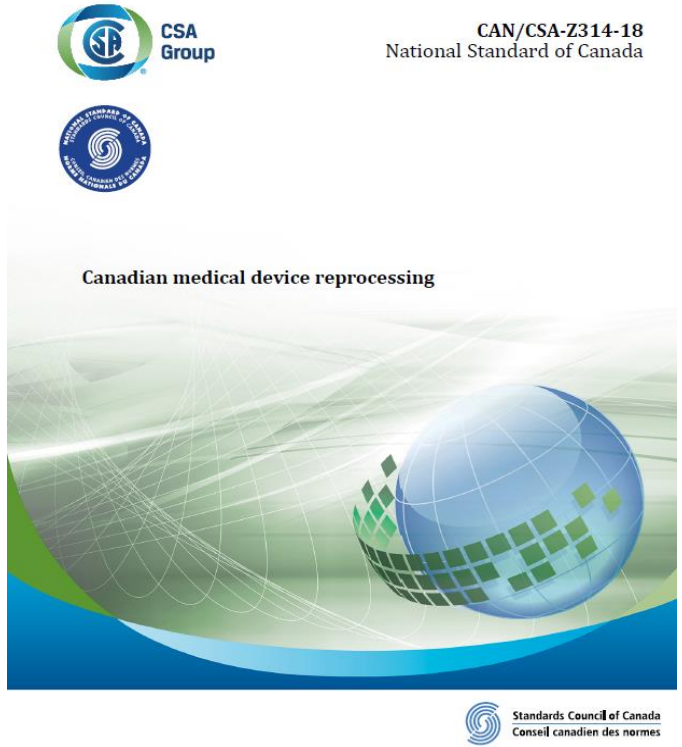
New and Improved!

- ✓ 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



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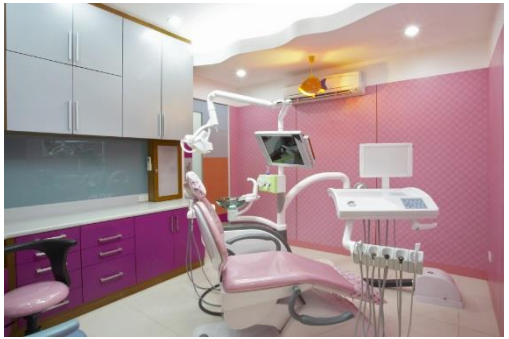
CSA Standards Development Process

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

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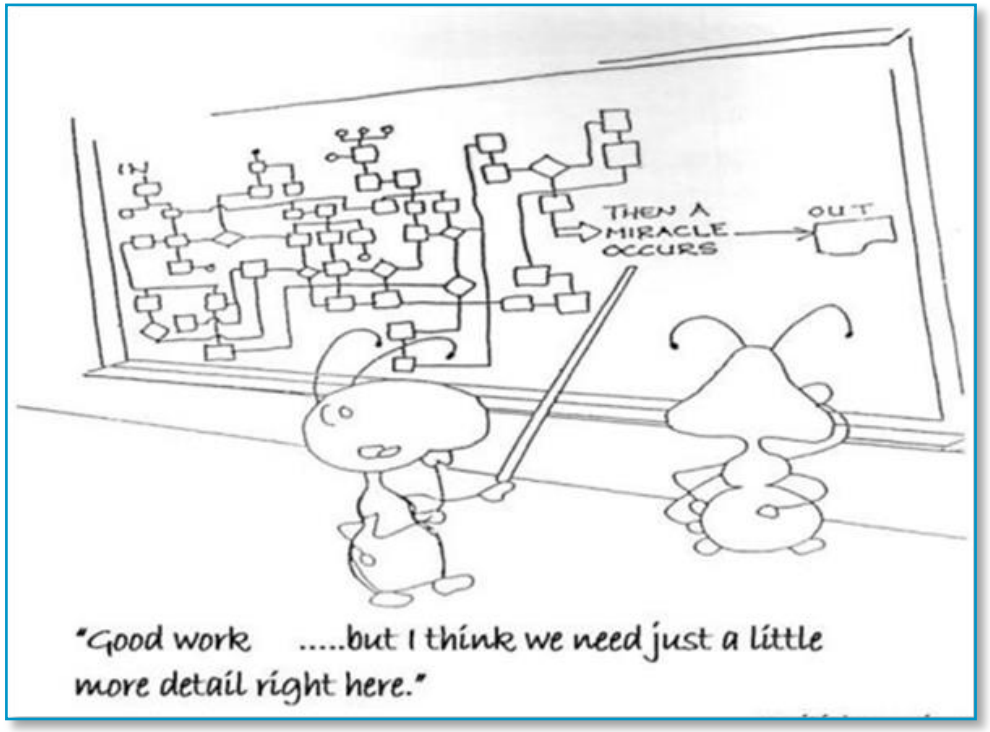

IN
THEN A MIRACLE OCCURS
OUT
"Good work .....but I think we need just a little more detail right here."

Clauses 0 – 3 - Foundation for the Standard

Preface (administrative)

0 Introduction (Informative)

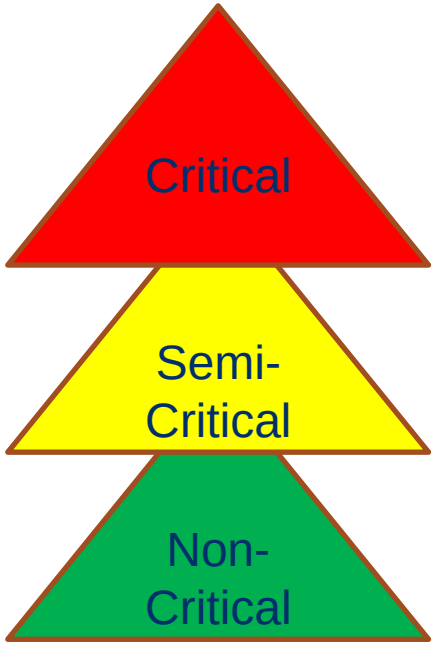
1 Scope (Informative)

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

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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

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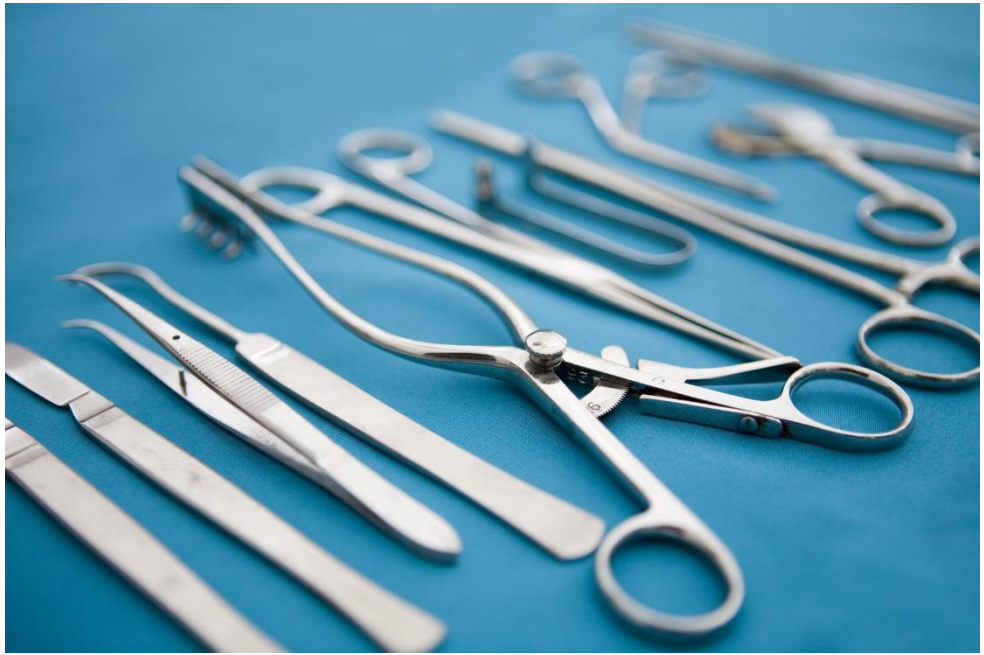
Clause 8 Evaluation and purchase

- ✓ 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

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Clause 11 Decontamination of reusable medical devices

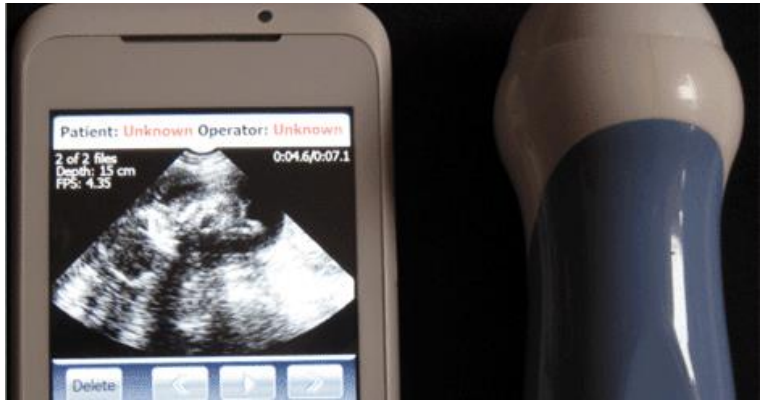
- ✓ Handling of contaminated device
- ✓ Retrieval and transport
- ✓ Sorting and disassembly
- ✓ Prep for cleaning
- ✓ Cleaning, rinsing and drying
- ✓ Disinfection
- ✓ Respiratory devices

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

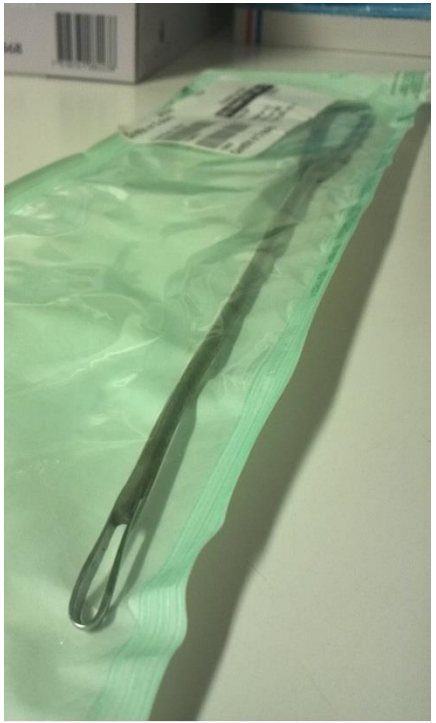


Clause 14 Preparation of medical devices for reprocessing

- ✓ 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

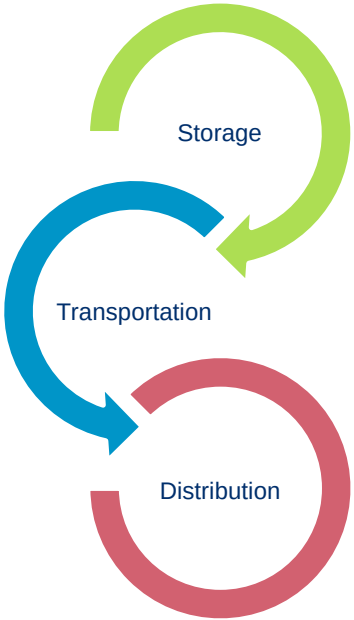
- ✓ Evaluation and purchase
- ✓ Packaging system qualifications
- ✓ Product design
- ✓ Assembly
- ✓ Labelling
- ✓ Pouches and reels
- ✓ Wrappers
- ✓ Rigid sterilization containers



Clause 16 Sterilization methods

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

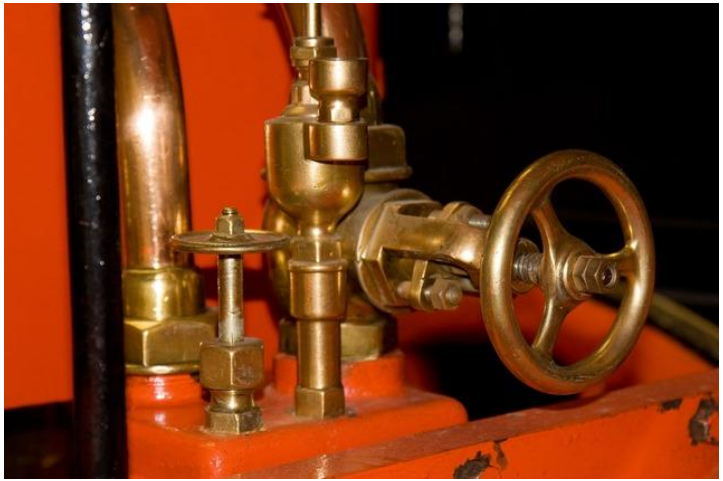
Clause 17 Storage, transportation, and distribution



- ✓ 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

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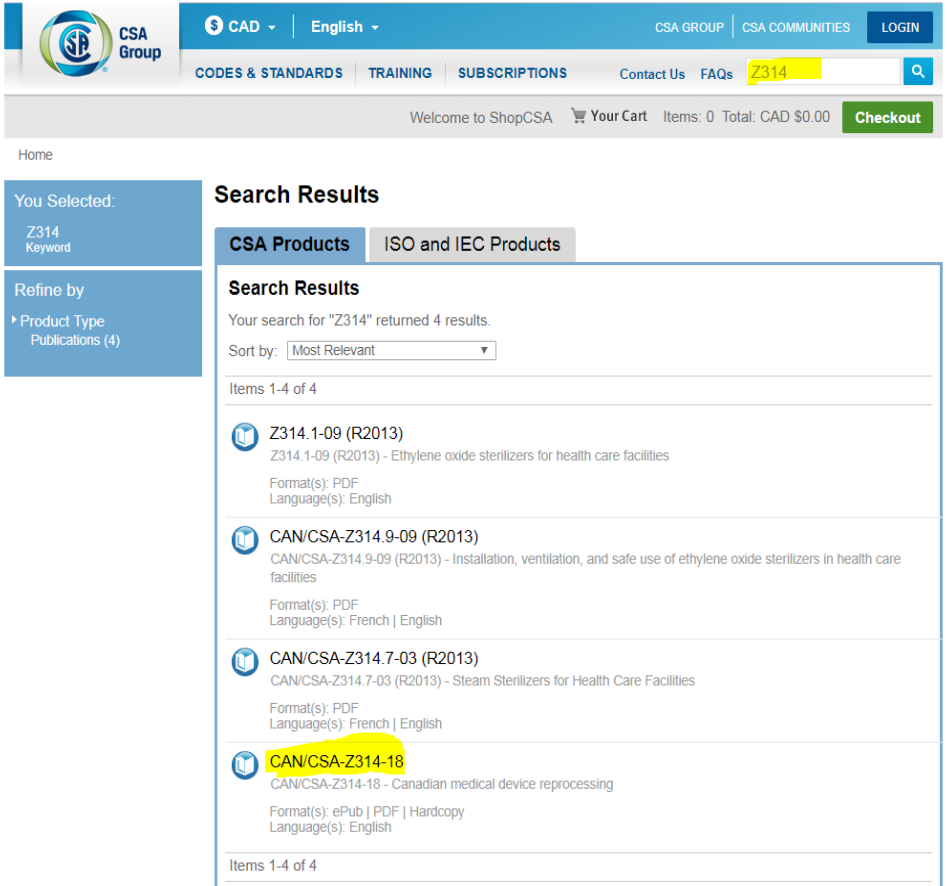
The Annexes – Supporting information

- ✓ 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 http://shop.csa.ca/
- ✓ Type Z314 in the Search field



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