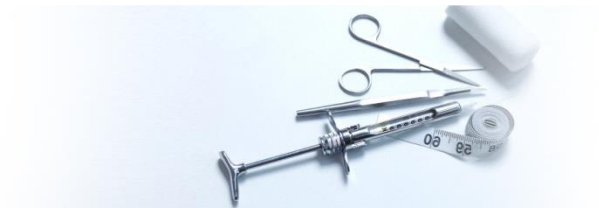
# CSA Z314 Series Standards

## Understanding the Standards

*September 10,2013*

Ian Pequegnat



Annual Conference
September 8-10, 2013

CENTRAL SERVICE ASSOCIATION OF ONTARIO

# Where do standards come from?

## What influences their development

The International Organization for Standardization (ISO)

- Global consensus standard through ISO/TC 198, Sterilization of Healthcare Products.
- adopted by countries worldwide

The European Committee for Standardization (CEN)

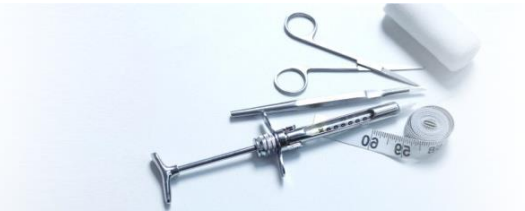
- develops sterilization standards through CEN/TC 204, Sterilization of Medical Devices
- Have formal regulatory role for European Union countries as mandated by the European Medical Devices Directive

The Association for the Advancement of Medical Instrumentation (AAMI)

- Develops consensus standards, recommended practices, and technical information reports (TIRs) for the U.S. medical industry.
- The American National Standards
- Numerous AAMI sterilization documents have been included on FDA's list of recognized consensus standards

Canadian Standards Association (CSA)

- Develops consensus standards, recommended practices for the Canadian medical industry
- Accredited by the Standards Council of Canada
- Standards are not legislated
- Medical Devices and facilities licenced through Health Canada



# Some examples of applicable Standards – Industry and Facilities

***Z314 Series***

Z314.0-13 *Medical device reprocessing — General requirements* Committee

Z314.8-08 *Decontamination of reusable medical devices*

Z314.3-09 *Effective sterilization in health care facilities by the steam process*

*Z314.23-12 Chemical sterilization of reusable medical devices in health care facilities*

***CAN/ISO Series***

CAN/CSA-Z15883-1-09 *Washer-disinfectors — Part 1 through Part 5*

CAN/CSA-Z11140-1-07 *Sterilization of health care products — Chemical indicators: General requirements*

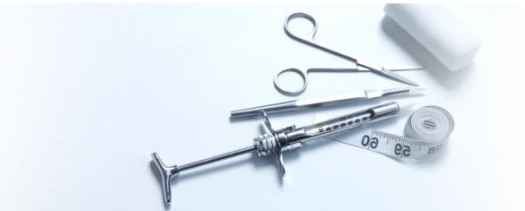
CAN/CSA-Z11138-1-07 *Sterilization of health care products — Biological indicators*

**ISO Series**

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 9001:2000, *Quality management systems — Requirements*

ISO 17664 Sterilization of medical devices — *Information to be provided by the manufacturer for the processing of resterilizable medical devices CAN/CSA-Z17664-06*



# Who develops standards?

## Is government consulted or informed of changes to the standards?

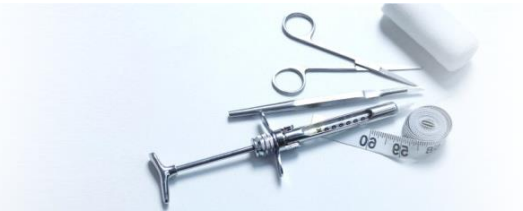
- **General Interest**
- Not associated with production, distribution, direct use, or regulation of the subject product(s),
- Demonstrated relevant expertise or credentials.
- May include representatives of professional associations, consumer interests, or representatives of the academic, scientific, and consulting interests.

- **Government/Regulatory Authority**
- Regulators of the subject product(s), material(s), or service(s);

- **Producer Interest**
- Producers (manufacturing goods), promotion, retailing, or distribution of the subject product(s), material(s), or service(s);

- **User Interest**
- End users outside of an institutional setting
- Not associated with production and/or distribution of the product(s),
- Third-party reprocessers, laundries, etc.

- **User Institutional**
- End users within an institutional setting (usually a health care facility)
- Not associated with production and/or distribution of the product(s)



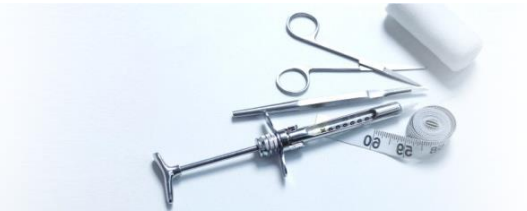
# Input to development - who, what, and why

**Technical Committee**

- Voting members representing several balanced groups of stakeholders – currently 32
- Associate members – non voting
- Project Manager

- **Subcommittees for Z314.xx**
- Advise the TC on specific changes or additions necessary to the standards
    - Members
    - Stakeholders from industry, government , Healthcare settings

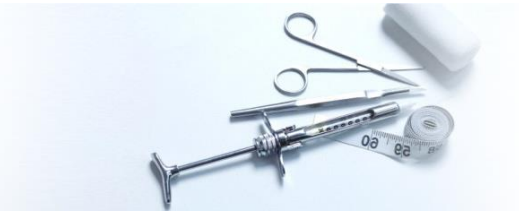
- **Public Review**
- Any stakeholder from at large
- Posted on CSA website
- Stakeholder groups such as CSAO and CHICA notified



# How can I have input into the standards development?

- CSA encourages input from stakeholders during public review
- Documents posted for comment and review
- inquiries@csagroup.org
  - "Proposal for change"
  - "Request for interpretation"

- Current development of Communities of Interest for Healthcare
- Live chat rooms
- Provide better awareness to the standards development process
- Better involvement for Public review



# Why should I follow these standards? What is the risk to the hospital if departments are not following the standards?

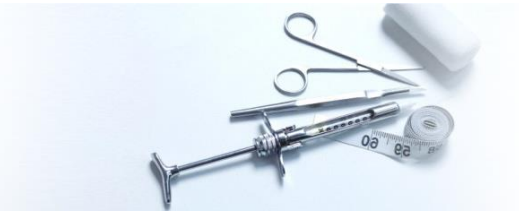
- A standard is an established norm.
- CSA Standards are not legislated

  - Standardized
  - Evidence based
  - Quality system
  - Best practices
  - Repeatability
  - Tractability
  - Help to ensuring safe patient outcomes
  - Employee safety

- **Accreditation Canada**
- Standards developed in response to Healthcare organizations, regulators and government
- CSA Standards are incorporated into many elements
- Accreditation Canada audit tools

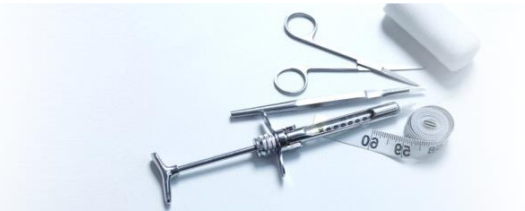
- Provincial Standards

- Facility or setting policies



# How do standards influence my department policies and procedures?

- Developed from inputs including government regulation, national standards, and the setting requirements
  - Each setting will have different processing equipment, organizational structure, Customer requirements etc.
- Ensure the consistency of each product, process, and/or service provided.
- These policies and procedures will be followed as part of the overall QMS



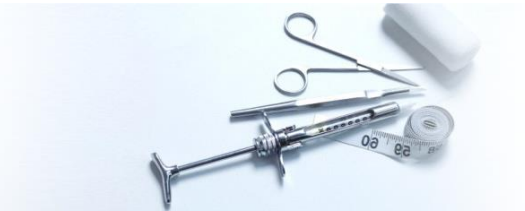
# Single use items which are very costly and yet no additional funding is awarded to hospitals to implement such changes

- Z314 series do not apply to single use devices
  - ***Information concerning safety, technology, cost/benefit, and legal issues involving the reuse publications***
    - *The Canadian Healthcare Association (1996), ECRI Institute (1997)*
    - *The Canadian Agency for Drugs and Technologies in Health (CADTH 2011).*

- Z314 series are driving for repeatable and effective processes

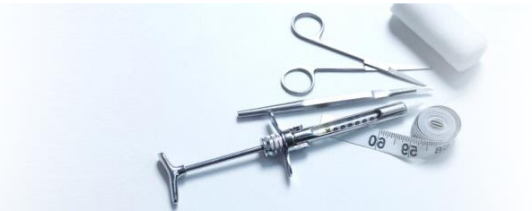
- Where it is not possible to acquire reusable equipment and supplies, or to safely implement processes required for adequate reprocessing (e.g., remote health care settings without dedicated, trained reprocessing personnel), single-use devices may be considered

- This may influence facility assessments:
  - Purchasing and
  - Provincial on transportation policies on the safe transport of goods



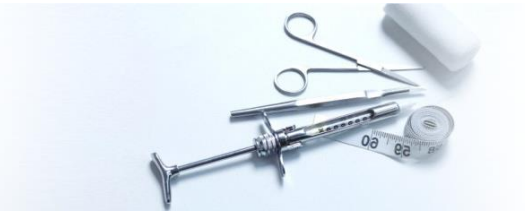
# What if a new standard is introduced which obsoletes my equipment or department?

- Standards are designed to give assistance with development and redevelopment of MDRD's
  - •One way work flow
  - •Ventilation and lighting
  - •Transportation of devices
- •Equipment has a lifecycle
  - •Evaluation criteria to determine risk or benefit of newer technologies
- •Work within policies and procedures which align with current practice and available processes



# Why do standards change?

- CSA standards are generally on a 5 year life cycle
  - Revision
  - Reaffirmation
- Can issue amendment during this period
- Challenge is to remain current
  - Changing technologies
  - Changing international standards
  - Best practices – new methods
  - Clinical studies
  - New laws
  - New insights from real world experience



# What are some of the key updates?

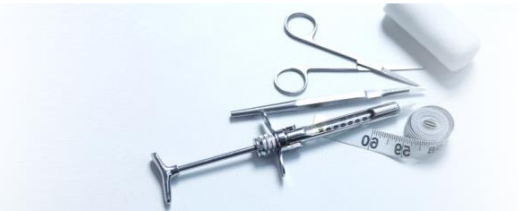
## Z314.0-12 Medical device Reprocessing — General requirements

- **Rational for Change**

- Simplify

- Eliminate complexity and duplication in each document i.e. Definitions
    - Documents revised on different schedules making changes which superseded older documents
        - Confusion
        - Difficult to manage
        - Time consuming for each revision

- Incorporate new elements for a Quality Management System including documented procedures for routine practices, reporting, education and sterility assurance
    - Adverse events and the employment of corrective actions as part of the risk assessments
        - Common to all Standards

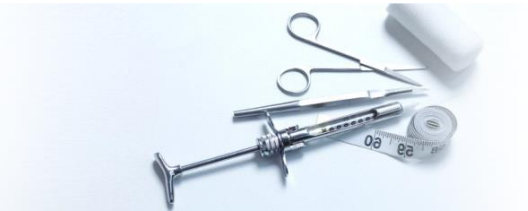


# Reprocessing of Medical Devices
## The need for a QMS

**Manufacturers** validate that an instrument can be reliably cleaned and sterilized / disinfected and is appropriate for reuse – with repeatable outcomes

**MDRDs** verify that cleaning / sterilization equipment is functional and that in-hospital cleaning / sterilization methods are consistently performed using device manufacturer validated methodologies.

The goal is to provide medical devices that perform as intended by the manufacturer and are safe for reuse.



# Z314.0-12 Medical device Reprocessing — General requirements

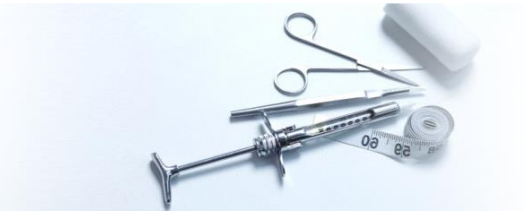
**Scope - expanded**

- The MDRD refers to any reprocessing area, be it in a hospital, clinic or anywhere within a health care setting where reprocessing occurs

- Can be a large department or single person processing

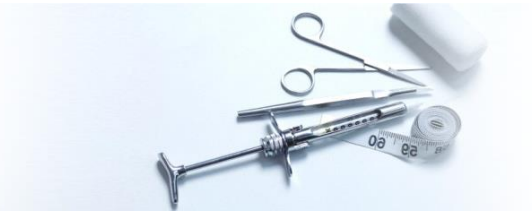
- These differences will be addressed in the QMS

- Z314.0-13 is designed to be used with the Z314 series of Standards



# Z314.0-13 Medical device Reprocessing — General requirements

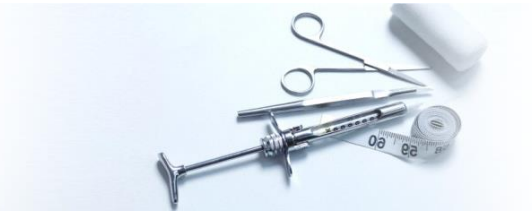
- This document will also focus on requirements for
  - Quality management
  - Occupational health and safety;
  - Evaluation and purchase of reprocessing equipment and reusable medical devices;
  - Infection prevention, and control;
  - Work areas and equipment;
  - Environmental conditions;
  - Utilities (e.g., power supply, water, and steam quality).



# Z314.23 - Chemical sterilization of reusable medical devices in health care facilities

**Released in 2012**

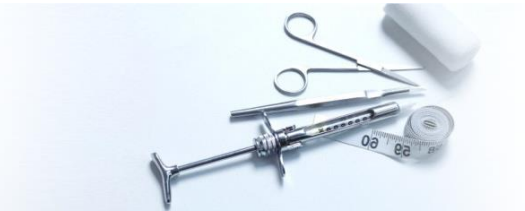
- Supersedes CAN/CSA-Z314.2, *Effective sterilization in health care facilities by the ethylene oxide process*
- Developed health care facilities using chemical sterilization process of traditional and non traditional systems
- Gaseous, Vapour and Liquid chemicals:
    - Ethylene oxide;
    - Hydrogen peroxide;
    - Ozone;
    - Hydrogen peroxide-ozone;
    - Liquid chemicals: peracetic acid.



# Z314.23 - Chemical sterilization of reusable medical devices in health care facilities

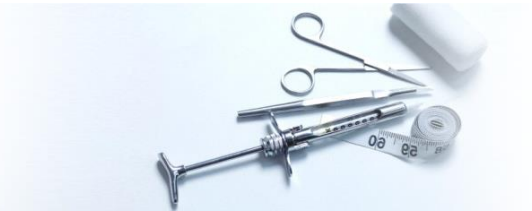
**Focus**

- Chemical sterilizers utilize dedicated sterilants validated as part of a system
  - Achieve an adequate level of sterility assurance,
  - To protect from injury staff and patients who might be exposed to a sterilant or its by-products
    - Measures to minimize the risk of such exposure as well as discharge to the environment of sterilizing chemicals and by-products.
  - Validation of devices, and accessories such as packaging and container systems



# Z314.23 - Chemical sterilization of reusable medical devices in health care facilities

- Emphasis on
  - Reliable operation of chemical sterilizers
  - Proper pre- and post-sterilization practices.
  - Procedures required following sterilization to minimize sterilant residuals
  - Use of appropriate PPE and environmental requirements



# Future Revisions

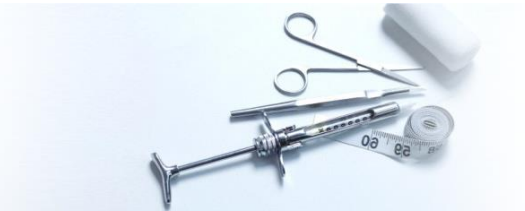
## Z314.8 Decontamination of reusable medical devices

- Prerequisite for all sterilization methods

- Document will be simplified through introduction of Z314.0
  - Provide better clarity to required steps for decontamination
  - To be used in conjunction with Z314.0

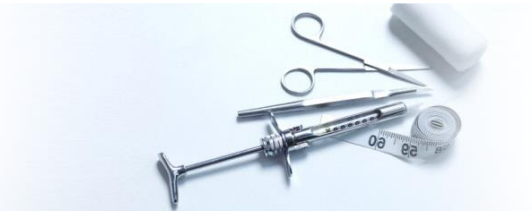
- Influence of international standards-CAN/CSA-Z15883-1-09
  - Expansion of Ao concept for thermal disinfection
  - Use of cleaning indicators as a means to establish baseline in installation and routine testing

- Outline decontamination processes
  - Manual
  - Automated
    - Thermal vs. Pasteurization
    - Chemical
      - Expanded sections on use of ILD and LLD and HLD (Manual and Automated)



# Z314.8 Decontamination of reusable medical devices

- Specific guidance for processing
  - Anesthesia products
    - Thermal
    - Pasteurization
  - Flexible Endoscopes and accessories - locations and timeliness
    - Manual
    - AER
  - Ultrasound Transducer Probes
  - Electronic and powered devices
  - Non-critical medical devices



# Future Revisions

## Z314.3 Effective sterilization in health care facilities by the steam process

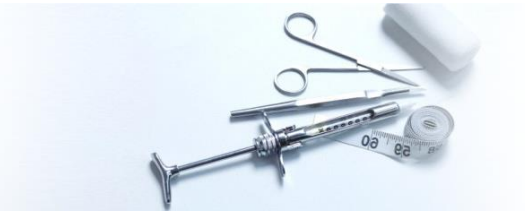
- Subcommittees currently completing sectional reviews
  - Focus review of:
    - Loading/unloading operations
    - Water quality/ steam quality
    - Extended cycles
    - Sterility Assurance
      - IQ/OQ/PQ
    - Immediate use sterilization

- Process to go back to committee for review

- Release for public review

- Committee to evaluate public review and revise

- Vote and release for publication



# Standards Application

## Certified Medical Device Reprocessing Technician (CMDRT)

- Certification developed by CSA and CSA America in conjunction with industry stakeholders
  - Provide assurance that an individual possesses the competencies deemed necessary to perform the job function MDRT.

- Standardized testing
  - The candidate possesses the knowledge, skills and decision-making abilities necessary to practice the proper techniques for cleaning, disinfection and sterilization of medical instruments and devices.

- National in scope

- Materials include Z314 series standards, Accreditation Canada Standards, Provincial standards such as PIDAC

- Certification linked to practical experience and recognized medical device reprocessing educational program. (CSAO or college)