What's New in the CSA Standards:

DECONTAMINATION OF REUSABLE MEDICAL DEVICES

Z314.8-14

Presented by: Barbara Bolding RN, MBA

17 October, 2014

What's new in the Decontam standard?

- It's been reorganized

In the past	
1. Scope	Sections were duplicated in each standard i.e. Decontam, Steam sterilization, Chemical Sterilization. Now, Sections 4-7 from each standard have moved to: Z314.0 General Requirements
2. Reference publications	
3. Definitions	
4.2 Policy	
4.3 Procedures	
4.5 Quality system	
5. Evaluation & Purchase	
5.2 Instructions for use	
6. Personnel	
7. Reprocessing work areas & equipment	
8. Handling at point of use…	Beginning of Decontam specific info
New (2014) standard	
1. Scope	Different and specific for each standard so they remain as part of each
2. Reference publications	
3. Definitions	
4. Handling at point of use…	Beginning of Decontam specific info

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Presentation overview

Section 7: Decontamination

- Washer-disinfector process documentation

Section 8: Disinfection

- Disinfectant wipes
- Documentation for high level disinfection
- Thermal disinfection and A_0

Section 11: Flexible endoscopes

- Timely reprocessing
- Submicron water filtration
- Scope shelf life

Four Annexes

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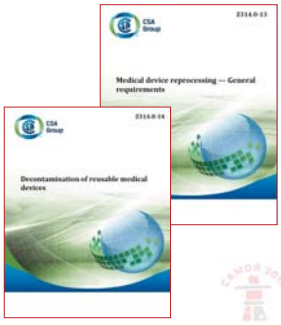
What's new in the Decontam standard?

- Lots of information has moved to "General Requirements" Z314.0-13
- Lots of Decontamination specific information has been added
  - This presentation will touch on highlights only (not every change)
- A reminder:

  The Decontam standard (Z314.08-14)
  must be **used in conjunction with**
  the General Requirements standard (Z314.0-13)



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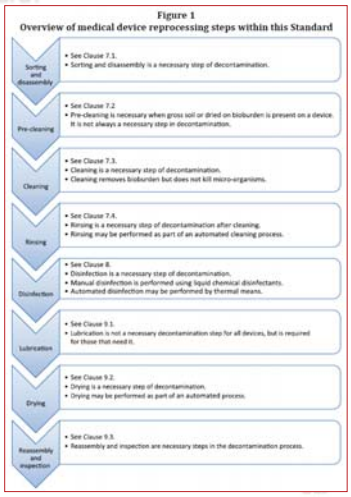
What's new in the Decontam standard?

- Section 6: Decontamination
  - 6.1 Figure 1
    - Lays out the steps of decontamination that will be covered in Sections 7—9
    - Provides a reference clause for each step
  - 6.1.3
    - Recommends the use of automated cleaning processes whenever possible
  - 6.2
    - Requires qualification testing for decontam equipment
      - i.e. IQ, OQ, PQ
      - Similar to sterilizers



What's new in the Decontam standard?

- Section 7: Sorting, disassembly, pre-cleaning, cleaning and rinsing
  - Two types of washer-disinfector process documentation
    2. Weekly verification of cleaning efficacy (7.3.5.6.2)

> Commercially available indicators or test kits shall be used at least once per week to verify cleaning efficacy. See also Clause 6.2.

What's new in the Decontam standard?

- Section 7: Sorting, disassembly, pre-cleaning, cleaning and rinsing
  - Two types of washer-disinfector process documentation…
    1. Cycle verification e.g. printout (7.3.5.6.1)

> Parameters of each washer-disinfector cycle shall be verified by printed or electronic record. This cycle record shall
> a) be accessible to the user on the prep and pack side of the washer-disinfectors for review;
> b) identify the washer-disinfector;
> c) identify the cycle number;
> d) record the cycle parameters of exposure time, temperature, or equivalent A_0 value as well as the date and time of the cycle (see Clause 8.3);
> e) indicate the reason for any parameter abnormalities (e.g., error messages, operator cancellation); and
> f) be kept in accordance with hospital policy.


CYCLE - FAST OTER
ENTER HOSPITAL NAME
ENTER DEPARTMENT
CYCLE START 01:23:45A
CYCLE DATE 5-06-13
CYCLE NUMBER 0000001
UNIT NUMBER 3684163005
MOTOR SPEED = LOW
TREATMENT TIME
TEMP RECORD STARTED AT
5-06-13 01:23:50AM
PRE-WASH1 01:23:46A
TIMER START @ 01:24:23A
TEMP= 96.1F
COMPLETE AT 01:25:23A
TEMP= 99.9F
WASH 1 01:25:53A
PUMP 3 1/2 OZ/GAL
DETERGENT
RELIANCE SV1000
Image from: http://webapi.steris.com

What's new in the Decontam standard?

- Section 8: Disinfection
  - Pre-moistened wipes for intermediate and low level disinfecting (8.2.4.3)
    - Moist enough to thoroughly wet the surface.
      - May need more than one
      - Close tightly when not in use
    - Maintain recommended contact time

What's new in the Decontam standard?

- Section 8: Disinfection
  - Documentation when high-level disinfecting
    - 8.2.6.2

The following shall be documented when manual disinfecting:
a) name of the agent;
b) dilution;
c) date and time prepared;
d) expiry date; and
e) name of employee who prepared the solution.

    - 8.2.7.2

Critical conditions specified by the manufacturer shall be documented each time that the solution is used for the high-level disinfection of a medical device. These conditions should include, but are not limited to,
a) contact time;
b) temperature during contact time;
c) concentration;
d) length of time in use (for reusable solutions) or maximum reuse period;
e) lot number of the HLD;
f) unique identifier of the medical device; and
g) unique identifier of the basin in which HLD occurred, if more than one basin is used.

What's new in the Decontam standard?

- Section 11: Flexible endoscopes
  - Send scopes to MDR for reprocessing if the reprocessing area in an endo unit cannot meet the requirements for physical space and air quality (11.5.3)
  - Timely reprocessing (11.7.3)
    - We know that delays in reprocessing can cause problems e.g. soil drying, biofilm formation
    - 3 page table identifies critical activities, time limits, problems and what to do if limits are exceeded
      - Pre-cleaning at bedside
      - Transport to decontam area
      - Initial cleaning
      - Rinsing
      - HLD contact
      - Post-processing (before drying)
      - Storage, unused

What's new in the Decontam standard?

- Section 8: Disinfection
  - Thermal disinfection introduces the concept of A_0 (8.3.1)
    - Commonly used in Europe. New to MDR in North America
    - Expression of the time / temperature relationship required to kill microorganisms to a disinfecting level (not sterilization)
    - Allows users to better compare efficacy claims
      - Various cycles of the same washer-disinfector
      - Washer-disinfectors made by different manufacturers.

A_0	Moist heat parameters	Common uses
60	1 min @ 80 ° C	Non-critical devices e.g. carts, blue ware
600	1 min @ 90 ° C	Semi-critical devices. Equivalent to pasteurization.
600	10 min @ 80 ° C	Semi-critical devices damaged by higher temperatures e.g. respiratory therapy equipment. Equivalent to pasteurization.

What's new in the Decontam standard?

- Section 11: Flexible endoscopes
  - Sub micron water filters—monitoring and maintenance (11.7.9.6.2)
    - Sub micron filtered water is only as good as it's filter
      - i.e. no debris, membrane intact, properly seated
    - Filter change frequency depends on
      - Manufacturer's instructions for use
      - Local water quality
    - Monitor and document (11.7.9.6.2.2)
      - AER fill times
        - Debris
      - Flow pressures on both sides of the filter
        - Debris, membrane compromise

Top 2 Images from: Google Images, Accessed 11 Sept 2014

What's new in the Decontam standard?

- Section 11: Flexible endoscopes
  - Endo scope shelf life
    - Scopes with lumens, that have been stored for more than 7 days shall be fully reprocessed (11.7.12.5)
      - Need a system to identify processing date or "storage expiry" date

What's new in the Decontam standard?

- Total of 7 Annexes
  - A. Characteristics that make a device difficult to clean
    - And hence to be avoided when purchasing
  - C. Sample tinfoil test (for ultrasonic)
  - E. Liquid chemical disinfectants
    - Types
    - Efficacy and typical uses
    - Interpreting product labels
    - Advantage and disadvantage of low and intermediate level disinfectants
  - G. Sample endoscope reprocessing log

What's new in the Decontam standard?

- Section 12: Ultrasound transducer probes
  - New section
  - Ultrasound probes separated from flexible scopes
    - Were combined in previous edition

RECAP: Highlights of what's new

Section 7: Decontamination
- Washer-disinfector process verification (printouts and testing)

Section 8: Disinfection
- Disinfectant wipes
- Documentation for high level disinfection, both manual and automated
- Thermal disinfection and A_0

Section 11: Flexible endoscopes
- Timely reprocessing
- Submicron water filters
- Scope shelf life

- 4 Annexes

THANKS

Barbara Bolding, RN, BSN, MBA

Consultant, Medical Device Reprocessing

bbolding@uniserve.com

General Requirements CAN/CSA Z314.0

Colleen Landers,
Registered Nurse Consultant, MDRT
October 17th , 2014

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PRESENTATION AGENDA

1. CSA Standards for reprocessing: What are they and how are they written?

2. CSA Z314.0 Medical Device Reprocessing General Requirements.
- ✓ How it relates to other standards.
- ✓ Content of Z314.0

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What are the Canadian Standards? www.csa.ca

- Best Practices in Reprocessing!
- Written in Canada, and designed for use in Canadian hospitals.
- Written to help health care providers identify the critical elements of medical device processing and infection control.
- Key elements health care facility policies and procedures.

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Z314.0 General Requirements for Reprocessing

- Overarching requirements in one standard.
- Provides Quality System, Personnel Qualifications, Manufacturer's Instructions, Evaluation and Purchase, Design, Reprocessing Principles
- Not repeated in other standards unless pertinent content but referenced.
- Need to purchase Z314.0 with all published Z314 CSA standards.

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4 Quality management system (QMS)

- Elements quality system that apply daily practice.

✓ If reprocess reusable medical devices must have a quality system.
✓ Assurance that facility's policies, processes, and procedures are in compliance with CSA Standards.
✓ Products and services provide the highest possible degree of safety and quality.

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Quality System

- Chart outlining the organizational structure of the facility.
- Requirements for management and staff qualifications.
- Customer focus.
- Communication plan.
- Performance indicators measured and monitored
- Process for change, managing adverse events and product recalls.
- Infection prevention and control.
- Occupational and environment health and safety.
- Process for regular management review.
- Each staff member is responsible for the quality of performance of his or her functions within the facility.

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Quality System Sections

- Documentation and records –quality plan and key performance indicators.
- Policies and Procedures-what required and how to maintain them.
- Senior Management responsibilities – customer focus, quality policy, planning.
- Resource management – provision for resources.
- Environmental conditions and infrastructure.
- Product realization –planning and risk .

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Manufacturer's Instructions - 5

- Procedures for evaluation and purchase of reusable medical devices and reprocessing equipment including an evaluation process.
- Devices difficult to reprocess consider single use.
- Technical data
- Device specific manufacturer's instructions.
- Written reprocessing instructions validated.
- Instructions unclear, incomplete or inadequate contact manufacturer and if not clear then do not purchase.
- If reprocessing limits specified means of tracking required.

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Personnel Qualifications - 6

- Reprocessing performed by qualified personnel
- Proper immunization
- Qualifications
- Orientation, training and continuing education
- Procedures for handling incidents
- Recertification every 5 years
- Competency assessment
- Occupational Health and Safety- communicable diseases, sharps, spills
- Infection Prevention and Control- Hand Hygiene
- Attire including Personnel Protective Equipment & Gloves

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Work Areas and Design - 7

- Separate work areas.
- Physically separate soiled, restricted access, one-way flow.
- Linens processed and folded in separate room.
- Lighting, floors, automatic/self closing doors, ceilings, walls.
- Non porous cleanable material.
- Hand Hygiene sinks and alcohol-based hand rub.
- Clean and sterile storage areas- location, shelving.
- Area cleaning schedules.
- Traffic control.

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Work Areas and Design

- Environmental controls – ventilation, temp and humidity
- Water Quality
- Design for OH&S
- Equipment automation and environmental chemical monitoring.
- Safety and security
- Reprocessing equipment – space and installation
- Maintenance and Quality assurance of equipment
- Repair and refurbishing of medical devices

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Reprocessing Principles - 8

- Apply infection prevention and control - transmission of micro-organisms.
- Routine Practices.
- Area meet requirements.
- Spaulding Classifications.
- Used medical devices consider contaminated so handle appropriately.
- Contain all liquids and vapours.
- MIFUS and standards incorporated in SOP's.

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Reprocessing Principles

- Instrument care and handling – MIFUS, handling
- Cleaning –manual and automated
- Disinfecting- if semi critical can be sterilized then performed- minimal high-level, thermal or pasteurized.
- Packaging
- Sterilization
- Storage

Process Verification, Monitoring and Adverse Events - 9

- Establish process outcomes and verify they have been achieved.
- Recalls and Alerts –
  - Circulation
  - Procedure
  - Order and
  - Report

Storage - 10

- Procedures
- Storage area –Shipping containers, cardboard & paper boxes for storage
- Inventory Management
  - Shelf Life
  - Inventory control
  - Distribution

Annex

- Annex A - Micro-organisms & infection
- Annex B - Guidance for Design MDRD
- Annex C - Additional Sterile Storage – Humidity, Temperature
- Annex D - Risk Management and Sterility Assurance
- Annex E - Water Quality
- Annex F - Sample forms and tools MDRD

Remember !

- The Canadian Standards and the Best Practices PIDAC document apply to all reprocessing no matter where it is performed not just the MDRD.
- Reprocessing effects patient and staff safety.
- All staff must be aware of the current reprocessing requirements, and receive ongoing education.
- Reprocessing is a complex process -if not performed properly it is harmful to patients/staff.

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Thank You!

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