Is Your Sterile Processing Department Ready for Survey?

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Objective:

- **Identify regulatory requirements essential to a successful survey.**
  - Personnel Considerations
    - Design Considerations
      - Receiving
        - Transport & Decontamination
          - Preparation & Packaging
            - Sterilization
              - Sterile Storage
                - Quality Assurance

2

Staff Competency and Education

Leadership

- Certification as a Sterile Processing Technician
- Certification in Sterile Processing Leadership
- Certification as a GI Technical Specialist
- Well versed in state and federal regulations
  - **NJ* (AAMI is LAW)** ①
- Active member Patient Safety Committee
- Quality Improvement (IP monitors)
- Safety, Quality and Product evaluations

Operational Staff/Technicians

- Certification **within 2 years** ① of hire
  - **NJ* Mandatory**
- Orientation Checklist
- Training Competency
- Routine Competency
- Documented in-services
  - 12 pts. Per year IAHCSMM (1 year. Cert). CRCST
  - 10 pts. Per year Sterile University (5 year Cert.) CBSPD

3

Dress Code ② ③ ④

Attire

- Facility Laundered Scrubs
- All Facial Hair Covered (Except eye brows)
- All arm hair covered; **warm up jackets** ② ③
- No nail polish, artificial, nails clean & trimmed
- No jewelry, watches
- Closed toe comfortable shoes

PPE - Decontamination

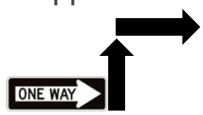
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION
12/2016

- Heavy duty/longer gloves – should go over the cuff of the impervious gown (neck to knees)
- Fluid resistant mask / face shield
- Disposable Impervious Knee High Shoe Covers
- Hands are washed after PPE removed

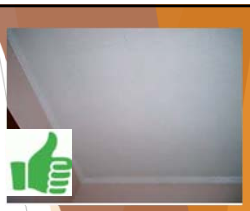
4

Design Consideration ④

- Department signage posted
- Ceiling tiles, solid surfaces, *NO* shedding, stained or porous materials
- Temperature, humidity
- Air Exchanges, Ventilation and Exhaust
- Appropriate supplies to do each task as assigned
- Lighting
- Workflow



  - Decontamination – soiled to clean
  - Sterilization
    - clean instrument inspection – (lighted magnifier)
    - packaging and labeling
    - sterilization
    - sterile storage



5

Receiving ② ③ ④

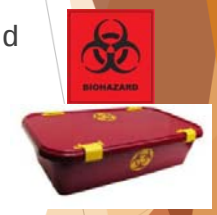
- Break out area
- Sterile supplies / instruments
  - Remove supplies from cardboard box / tote
  - Place on a clean cart
  - Move to sterile processing and/or storage
- Cardboard Boxes – NO corrugated cardboard, anywhere!!

- Soiled linen and trash should be separated from receipt of clean supplies / instruments

6

Pre-Cleaning & Transport ③ ④ ⑦

- **Soiled Transport**
  - Separate disposable waste, reusable items and remove all sharps at point of use (*Sharps Safety*)
  - **Pre-cleaning** instruments / medical devices point of use w/enzymatic foam wipe / spray
    - Instruments should **NOT** be transported in containers full of liquid
  - Transport in sealed biohazard containers or closed transport system
- Soiled instruments *must be kept moist* and not in queue for excessive periods time (IFU of enzymatic foam).



- **Loaner Instruments**
  - *ALL* new and loaner instrumentation MUST be decontaminated and reprocessed before use!
  - Follow all manufacturer's *written* **I**nstructions **F**or **U**se (IFU) ✸
  - Loaners policy & procedures (Do you have CJD Prion Cycles?)

7

Decontamination ④ ⑤ ⑦

- Workflow – soiled to clean
- Proper PPE
- Temperature, humidity, air exchanges, ventilation, exhaust
- Safety Data Sheets (SDS), Manufacturer's Instructions for Use (IFU), Equipment Manuals and preventative maintenance schedules.
- Solutions and cleaning agents: Must be validated for surgical instrumentation!
  - Proper dilution rates: measuring cups or detergent management systems
  - Water fill line indicated in soaking / cleaning sink(s)
  - Expiration dates
  - Solution containers labeled when opened
- Eye wash stations located with in *10 seconds* of travel time – (located on a hand washing sink *NOT* on the decontamination instrument cleaning sink)
- Patient Care Equipment (i.e. IV poles, hyperthermia units, etc.)
  - Medical Equipment cleaning validated by the IFU
  - Cleaning policy & procedure is followed

8

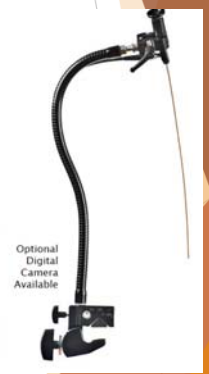
Decontamination ④ ⑤ ⑦

- Disassembly of complex/multi-part instruments
- Do *NOT* use saline on instrumentation
- Three basin sinks (36"x 8-10" deep) – sufficient counter space
  1. Pre-soaking
  2. Cleaning - Under the water line
     - Correct cleaning tools are available - Instrument cleaning brushes as per device manufacturer IFU (reusable vs. disposable)
     - Cleaning is *NOT* performed in hand washing sinks
     - Sharp and delicate instruments are separated from heavy
  3. Rinsing
     - Water quality (TIR34) ⑤ Distilled/ Deionized/ Reverse Osmosis
- Manual cleaning & proper rinsing of instrumentation
- Mechanical washers

9

Preparation & Packaging ③ ④ ⑥

- Workflow: Clean to Sterile Storage
- Weight Limits (25lbs. max) (Scale – routine calibration)
- **Instrument Inspection**
  - Functionality - Sharpness test kits
  - Instrument Damage / Cleanliness
    - Lighted magnifier
    - Microscopes – suctions and shavers✷
- Insulation testing
- Instrument marking tape
- Instrument discoloration *HOT TOPIC*



10

Preparation & Packaging ③ ④ ⑥

- **Packaging materials** (steam & low temperature sterilization)
  - Rigid containers
  - Wraps
  - Peel Pouches

    - Light weight instruments only (no more than **2** in a pouch)
    - Tip protectors – protect sharps

    - Instrument(s) must be in the *open* position
    - Refrain from double pouching unless validated by IFU
- Single use devices *cannot* be reprocessed *unless* validated by IFU

Sterilization ④ ⑥

- Preventive maintenance agreement for each sterilizer
- Bowie Dick Tests - Daily (PreVac ONLY)
- Routine Biological Indicator (BI) testing – Weekly, Daily preferred, *Every load – Best Practice*
- Implants are monitored with a Biological Indicators/ Process challenge device (PCD)
  - Implant loads are not released until the BI results **are read negative** ①
  - Implants are traceable to the patient
- Current manufacturer **i**nstructions **f**or **u**se (IFU) for every instrument – *MUST* be available
- PreVac & Gravity are used according to the IFU
- Extended Cycles are run per IFU

- **Documentation** for each load
  - Sterilizer ID #
  - Sterilizer Cycle
  - Lot # of the PCD pack
  - Load contents traceable to patients
  - Critical parameters for specific sterilization method
  - Operator's name
  - Results of the sterilization CI & BI
  - Sterilization records should be retained according to policy
  - Cooling Packages
  - Recall Process

12

Immediate Use Sterilization

Steam ③ ④

- Items are cleaned in a decontamination sink (*NOT* hand washing sink)
- Use of validated IUSS rigid containers
- Manufacturer IFU support IUSS
  - Gravity vs. PreVac
- Cycles are documented and patient traceable
- Transport techniques to prevent contamination
- Implants (only when defined as loss of life or limb)
  - BI on the load
  - Release when BI **is read negative** ①
- *Cannot IUSS* due to *insufficient instrument inventory*

Chemical ⑥

- Diagnostic tests are performed daily
- CI is used on every cycle
- Routine Staff competencies are performed and documented
- Point of use *ONLY*. Cannot be stored as a sterile item.
- Emergency eyewash within *10 seconds* of machine/ chemical
- All items processed are documented and patient traceable
- Verification that the chemical is properly emptied

13

Sterile Storage ③ ④

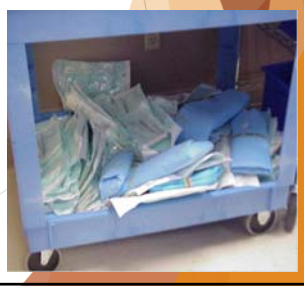
- Storage should *NOT* be located near water or splash possibility
- Wipeable surfaces and routine cleaning - logs available
- Bottom shelves are solid and 8-10" above the floor
- 18" below the sprinkler head or ceiling
- 2-3" from the outside walls

- Temperature & Humidity monitored and recorded *daily*
- Air Exchanges
- Appropriate signage – Restricted Area
- *NO* corrugated boxes

14

Sterile Storage ③ ④

- Sterile items must be separated from clean items; cannot be on the same shelf
- Stacking is limited or prohibited; wrapped trays, no more than 2 high is *highly preferred*
- Peel pouches
  - Labeled on plastic side (validated marker that is non-toxic and can withstand intense heat up to 500°F)
  - Neatly positioned /not overcrowded
- Shelf Life
  - Time vs. Event – Follow the manufacturer's IFU



15

Quality Assurance

- Routine Tracers & Audits – documented
- Process Improvement plans "What are you working on this year?"
- Documentation accuracy
- Verification Testing of Equipment & Instruments
  - Mechanical Washers
  - Cart Washers
  - Ultra Sonic Irrigators
  - Steam Sterilizers
  - Low Temperature Sterilizers
  - Point of Use Sterilizers (Immediate Use Sterilizers)
  - Insulation Testers
  - Microscopes; lumens & shavers
  - Lighted magnification
  - Endoscope Check

16

Flexible Endoscopes – *Major Focus* ⑥ ⑦

- Design Considerations
- Transport practices – Soiled / Clean
- Leak Testing
- Decontamination
  - Manufacturer's instructions for use (IFU)
- Cleaning verification/ Gram Negative testing
- Lighted magnification / Microscopes
- High Level Disinfection practices
  - Scope processing
  - Chemicals / Supplies
  - Alcohol Flushes
- Water Quality ⑤ ⑦
- Storage cabinets – hanging vertical, hang-time, cleaning (log)
- Documentation – traceable back to the patient

17

Flexible Endoscopes – *Major Focus* ⑥ ⑦

- Filter Changes
- Preventative maintenance
  - Scopes
  - Equipment
- Auditing and Surveillance
- Routine Documented Competencies
- Instrument grade air – drying scopes
- Cleaning brushes – Reusable or disposable?
- Detergents/Chemicals
  - Use of measuring cups
- Use of timers
- HLD Processors or Manual – following the IFU
- Documentation *traceable to the patient* ✸

Instrument (Medical) Air YELLOW

18

HOT TOPICS

- Flexible Endoscopes
- Manufacturer's **I**nstructions **F**or **U**se otherwise known as **IFU**
- Discolored, broken & closed instruments inside of a sterile tray or package
- Laryngoscope blades & handles
- Immediate Use Sterilization practices
- TASS Precautions – follow instrument manufacturer IFU – *RINSE, RINSE, RINSE*
- CJD Policy and Procedures
- Temperature & Humidity
- Transport of trays from point of use to decontamination: *NO DRY INSTRUMENTS!!*
- Verification methods for cleaning, sterilization, and equipment. PM schedule.
- Documentation
- Biological monitoring
- Tracking implants/instruments to patients
- *Hand Hygiene, Hand Hygiene, Hand Hygiene!*

- *All above can be found in the following references:* ① ② ③ ④ ⑤ ⑥ ⑦ ⑧

19

Acronyms / Glossary:

- AER – Automatic Endoscope Reprocessor - *A unit for mechanical cleaning, disinfecting, and rinsing of flexible endoscopes.*
- BD – Bowie Dick Test (Type 2) *for prevac sterilizers only. Daily to test vacuum pump*
- BI – Biological Indicator - *provide the only direct measure of the lethality of the sterilization process.* Use weekly, preferably daily but *ALWAYS* with *implants* ④
- CI – Chemical Indicator/Integrator - Each package
  - **External** (Type 1 – sterilization tape)- *The external CI should visually denote that the package has been exposed to physical conditions present in the steam sterilizer.*
  - **Internal** –*ONLY* Type 5-Integrating - Steam (preferred) Type 3 – Liquid Chemical Sterilization
- DI - Deionized water
-  - Expiration Date

20

Acronyms / Glossary:

- HLD – High Level Disinfection –
- IFU – **I**nstructions **F**or **U**se✱
- LLD – Low Level Disinfection
-  - Manufactured Date
- MEC – Minimum Effective Concentration
- MRC – Minimum Recommended Concentration
- PCD – Process Challenge Device
- PM – Preventive Maintenance
- RO – Reverse Osmosis
-  - Single Use *ONLY*

21

References

① NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES — N.J.A.C. Title 8 Chapter 43G Hospital Licensing Standards (ASC included)

②  International Association Healthcare Central Service Material Management, Technical Manual 8th Edition

③  2017 Guidelines for Perioperative Practice

④ NEW  AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

22

References

⑤ 

AAMI TIR34: Water for Reprocessing of Medical Devices

⑥ 

AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities

⑦ 

AAMI ST91:2015 Flexible and semi-rigid endoscope processing in health care facilities

⑧ 

Sterile Processing in Healthcare Facilities Preparing for Accreditation Surveys

http://www.seaveyhealthcareconsulting.com/sitebuilderconten t/sitebuilderfiles/sterileprocessingauditchecksheetfebruary201 3.pdf

23

Patient Safety is the #1 focus of *every* healthcare facility

Thank You