AN IP VISIT TO STERILE PROCESSING: *GO WITH THE FLOW*

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Disclosures

- EDUCATIONAL CONSULTANT FOR 3M
- EDUCATIONAL CONSULTANT FOR SAGE, DIVISION OF STRYKER
- CONSULTANT, BOSTON SCIENTIFIC

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DISCLAIMER

IMPORTANT INFORMATION:

THE CONTENT OF THIS WEBINAR IS BASED ON CURRENT UNITED STATES INFORMATION INCLUDING REGULATIONS, STANDARDS, GUIDELINES, AND PRACTICES AS OF OCTOBER 27, 2022.

US GUIDANCE AND REQUIREMENTS MAY CHANGE IN THE FUTURE.

ALWAYS CONSULT PRODUCT *INSTRUCTIONS FOR USE* AND FOLLOW LOCAL LAWS AND REGULATIONS.

THIS PRESENTATION CONTAINS AN OVERVIEW OF GENERAL INFORMATION AND SHOULD NOT BE RELIED UPON, IN ISOLATION, TO MAKE SPECIFIC DECISIONS.

3

LEARNING OBJECTIVES

- Identify regulations, standards and guidelines that impact the Sterile Processing Department
- Describe the process flow in the Sterile Processing Department
- Discuss the importance of quality as it relates to the Sterile Processing Department

4

4

LEARNING OBJECTIVE 1

IDENTIFY REGULATIONS, STANDARDS AND GUIDELINES THAT IMPACT THE STERILE PROCESSING DEPARTMENT

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5

PRACTICES ARE INFLUENCED AND DICTATED BY REGULATORS

- CENTER FOR DISEASE CONTROL AND PREVENTION (CDC)
- FOOD AND DRUG ADMINISTRATION (FDA)
- CENTER FOR MEDICARE AND MEDICAID SERVICES (CMS)
- OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)
- DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)
- ENVIRONMENTAL PROTECTION AGENCY (EPA)
- OTHER LOCAL AND STATE REGULATORS

6

6

CDC HEALTH ALERT NETWORK (HAN) ALERT - 00383

THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) AND U.S. FOOD AND DRUG ADMINISTRATION (FDA) ARE ALERTING HEALTHCARE PROVIDERS AND FACILITIES ABOUT THE PUBLIC HEALTH NEED TO PROPERLY MAINTAIN, CLEAN, AND DISINFECT OR STERILIZE REUSABLE MEDICAL DEVICES.

RECENT INFECTION CONTROL LAPSES DUE TO NON-COMPLIANCE WITH RECOMMENDED REPROCESSING PROCEDURES HIGHLIGHT A CRITICAL GAP IN PATIENT SAFETY. HEALTHCARE FACILITIES (E.G., HOSPITALS, AMBULATORY SURGICAL CENTERS, CLINICS, AND DOCTORS' OFFICES) THAT UTILIZE REUSABLE MEDICAL DEVICES ARE URGED TO IMMEDIATELY REVIEW CURRENT REPROCESSING PRACTICES AT THEIR FACILITY TO ENSURE

- COMPLIANCE WITH ALL STEPS AS DIRECTED BY THE DEVICE MANUFACTURERS, AND
- HAVE IN PLACE APPROPRIATE POLICIES AND PROCEDURES THAT ARE CONSISTENT WITH CURRENT STANDARDS AND GUIDELINES.

7

CDC/FDA Health Update about the Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices. September 11, 2015. Updated October 2, 2015. https://emergency.cdc.gov/han/han00383.asp (accessed September 15, 2022)

7

CDC HEALTH ALERT NETWORK (HAN) ALERT - 00383

AUDIT AND FEEDBACK

- HEALTHCARE FACILITIES SHOULD REGULARLY AUDIT (MONITOR AND DOCUMENT) ADHERENCE TO CLEANING, DISINFECTION, STERILIZATION, AND DEVICE STORAGE PROCEDURES. AUDITS SHOULD ASSESS ALL REPROCESSING STEPS, INCLUDING:
  - ✓ PERFORMING PROMPT CLEANING AFTER USE, PRIOR TO DISINFECTION OR STERILIZATION PROCEDURES
  - ✓ USING DISINFECTANTS IN ACCORDANCE WITH MANUFACTURERS' INSTRUCTIONS (E.G., DILUTION, CONTACT TIME, STORAGE, SHELF-LIFE)
  - ✓ MONITORING STERILIZER PERFORMANCE (E.G., USE OF CHEMICAL AND BIOLOGICAL INDICATORS, READ-OUTS OF STERILIZER CYCLE PARAMETERS, APPROPRIATE RECORD KEEPING)
  - ✓ MONITORING AUTOMATED ENDOSCOPE REPROCESSOR PERFORMANCE (E.G., PRINT OUT OF FLOW RATE, TIME, AND TEMPERATURE, USE OF CHEMICAL INDICATORS FOR MONITORING HIGH-LEVEL DISINFECTANT CONCENTRATION)
- **AUDITS SHOULD BE CONDUCTED IN ALL AREAS OF THE FACILITY WHERE REPROCESSING OCCURS.**
- HEALTHCARE FACILITIES SHOULD PROVIDE FEEDBACK FROM AUDITS TO PERSONNEL REGARDING THEIR ADHERENCE TO CLEANING, DISINFECTION, AND STERILIZATION PROCEDURES.

8

CDC/FDA Health Update about the Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices. September 11, 2015. Updated October 2, 2015. https://emergency.cdc.gov/han/han00383.asp (accessed September 15, 2022)

8

CMS DOCUMENTS

- Conditions of Participation (COPs)
- State Operations Manual (SOM)
- Conditions for Coverage (CfCs)
- Hospital Infection Control Worksheet

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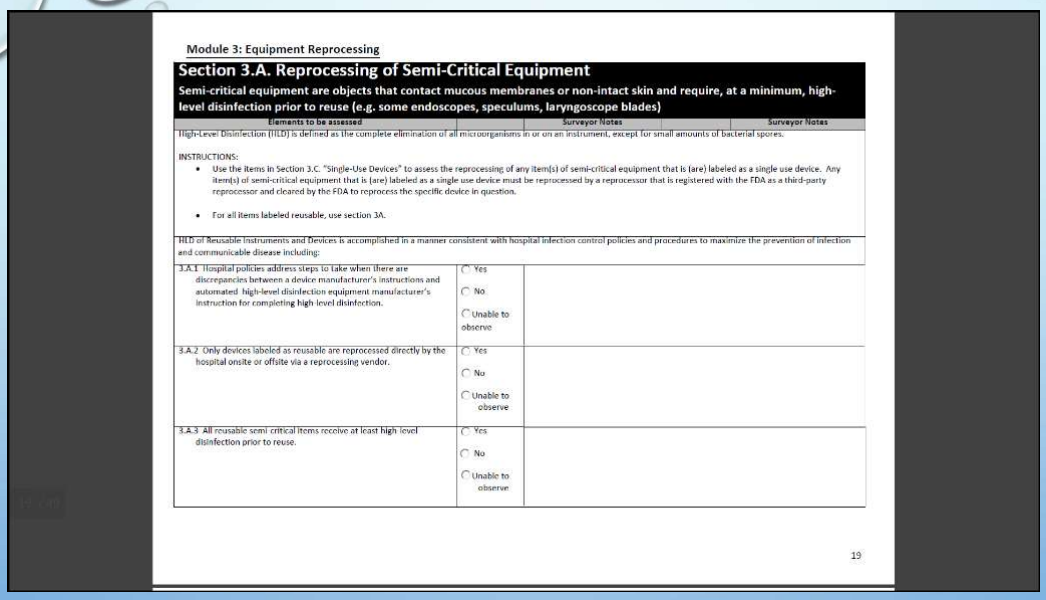

Module 3: Equipment Reprocessing

Section 3.A. Reprocessing of Semi-Critical Equipment

Semi-critical equipment are objects that contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse (e.g. some endoscopes, speculums, laryngoscope blades)

Elements to be assessed		Surveyor Notes	Surveyor Notes
High-Level Disinfection (HLD) is defined as the complete elimination of all microorganisms in or on an instrument, except for small amounts of bacterial spores.			
INSTRUCTIONS: • Use the items in Section 3.C. "Single-Use Devices" to assess the reprocessing of any item(s) of semi-critical equipment that is (are) labeled as a single use device. Any item(s) of semi-critical equipment that is (are) labeled as a single use device must be reprocessed by a reprocessor that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. • For all items labeled reusable, use section 3A.			
HLD of Reusable Instruments and Devices is accomplished in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including:			
3.A.1 Hospital policies address steps to take when there are discrepancies between a device manufacturer's instructions and automated high-level disinfection equipment manufacturer's instruction for completing high level disinfection.	○ Yes ○ No ○ Unable to observe		
3.A.2 Only devices labeled as reusable are reprocessed directly by the hospital onsite or offsite via a reprocessing vendor.	○ Yes ○ No ○ Unable to observe		
3.A.3 All reusable semi critical items receive at least high level disinfection prior to reuse.	○ Yes ○ No ○ Unable to observe		

19

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-1.pdf Accessed January 5, 2020

10

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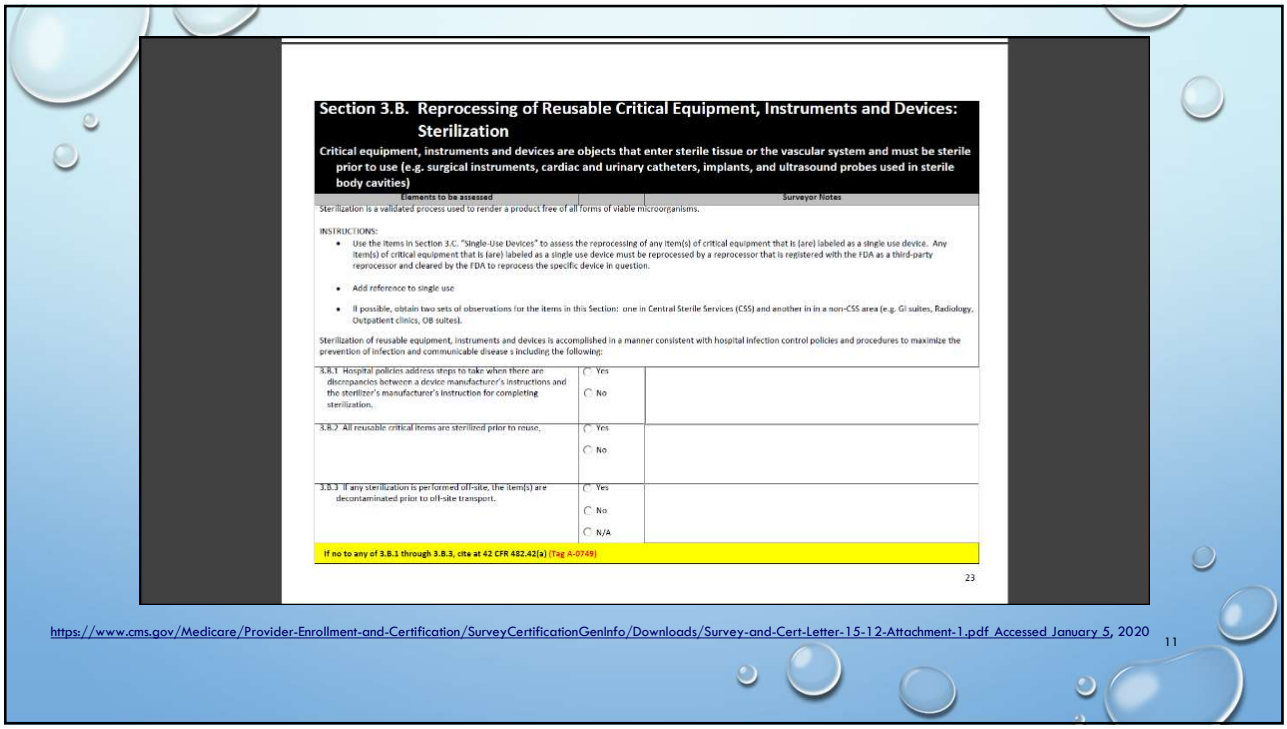


Section 3.B. Reprocessing of Reusable Critical Equipment, Instruments and Devices: Sterilization

Critical equipment, instruments and devices are objects that enter sterile tissue or the vascular system and must be sterile prior to use (e.g. surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities)

Elements to be assessed		Surveyor Notes
Sterilization is a validated process used to render a product free of all forms of viable microorganisms.		
INSTRUCTIONS: • Use the items in Section 3.C. "Single-Use Devices" to assess the reprocessing of any item(s) of critical equipment that is (are) labeled as a single use device. Any item(s) of critical equipment that is (are) labeled as a single use device must be reprocessed by a reprocessor that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. • Add reference to single use • If possible, obtain two sets of observations for the items in this Section: one in Central Sterile Services (CSS) and another in in a non-CSS area (e.g. GI suites, Radiology, Outpatient clinics, OB suites). Sterilization of reusable equipment, instruments and devices is accomplished in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease s including the following:		
3.B.1 Hospital policies address steps to take when there are discrepancies between a device manufacturer's instructions and the sterilizer's manufacturer's instruction for completing sterilization.	○ Yes ○ No	
3.B.2 All reusable critical items are sterilized prior to reuse.	○ Yes ○ No	
3.B.3 If any sterilization is performed off-site, the item(s) are decontaminated prior to off-site transport.	○ Yes ○ No ○ N/A	
If no to any of 3.B.1 through 3.B.3, cite at 42 CFR 482.42(a) (Tag A-0749)		

23

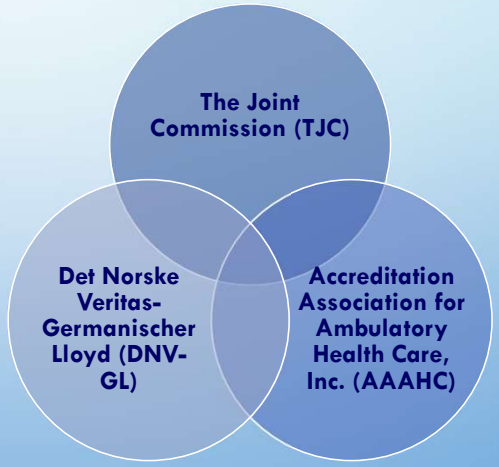
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-1.pdf Accessed January 5, 2020

11

11

STANDARDS, GUIDELINES AND PROFESSIONAL BODIES

- Association for the Advancement of Medical Instrumentation (AAMI)
- Society for Healthcare Epidemiology of America (SHEA)
- Association for Professionals in Infection Control and Epidemiology (APIC)
- Association of periOperative Registered Nurses (AORN)
- Society of Gastroenterology Nurses and Associates (SGNA)
- American Society for Gastrointestinal Endoscopy (ASGE)
- Healthcare Sterile Processing Association (HSPA)



12

12

RELEVANT STANDARDS AND GUIDELINES

Association of perioperative Registered Nurses (AORN)

- **Guidelines for Perioperative Practice**

Association for the Advancement of Medical Instrumentation (AAMI)

- **ANSI/AAMI ST79:2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities**
  - **AAMI TIR79:2018 ST&(Self Assessment for health care facilities**
- **ANSI/AAMI ST58:2013/(R)2018, Chemical sterilization and high-level disinfection in health care facilities**
  - Under review; will incorporate ST41:2008/(R)2012 Ethylene oxide sterilization in health care facilities: Safety and effectiveness
- **AAMI TIR34:2014/(R)2017 Water for the reprocessing of medical devices**
  - **Under review – elevated to a standard from a Technical Information Report. (ANSI/AAMI ST108: XX)**

13

13

Relevant AAMI Standards and Technical Information Reports

ANSI/AAMI ST90: 2017, Processing of health care products - Quality management systems for processing in health care facilities

AAMI TIR63: 2014/(R)2020 Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection

AAMI TIR67: 2018 Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities

AAMI TIR68: 2018 Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces

AAMI TIR55: 2014/(R)2017 Human factors engineering for processing of medical devices

14

(R) = Reaffirmed

14

AAMI STERILIZATION STANDARDS FOR PROTECTIVE APPAREL

ANSI/AAMI PB70:2012, *LIQUID BARRIER PERFORMANCE AND CLASSIFICATION OF PROTECTIVE APPAREL AND DRAPES INTENDED FOR USE IN HEALTH CARE FACILITIES*

- Establishes a system of classification for protective apparel and drapes used in health care facilities based on their liquid barrier performance and specifies related labeling requirements and standardized test methods for determining compliance.
  - ***By specifying a consistent basis for testing and labeling protective apparel and drapes and providing a common understanding of barrier properties (e.g., efficacy against liquid or liquid-borne microorganism penetration) based on this new classification system, the standard is intended to ultimately assist end-users in determining the type(s) of protective product most appropriate for a particular task or situation.***
- Protective apparel is worn by health care workers to help ***preserve the integrity of the sterile field and inhibit the transfer of blood, body fluids, other potentially infectious materials (OPIM), and associated microorganisms. drapes and drape accessories are also intended to inhibit the transfer of microorganisms, body fluids, and OPIM.*** Drapes and drape accessories are used as protective patient coverings to isolate a site of surgical incision from microbial and other cross-contamination.
- Surgical gowns, other protective apparel, surgical drapes, and drape accessories are devices intended to promote infection control practices and help protect patients and health care workers. this standard is based on key barrier performance tests that are used to classify the subject products into levels of performance. knowledge of these defined levels of performance will allow informed and consistent choices about the type of protective product necessary for the situation at hand.

15

ANSI/AAMI PB70:2012, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.*

15

Table B.1—Barrier performance classification of a surgical gown

Area A (Critical zone—front)	Area B (Critical zone—sleeve)	Area C (Front)	Area D (Back)		Final classification
Level 1, 2, 3, or 4	Level 1	Level 1, 2, 3, or 4	Non-protective, Level 1, 2, 3, or 4		Level 1
Level 1	Level 1, 2, 3, or 4	Level 1, 2, 3, or 4	Non-protective, Level 1, 2, 3, or 4		Level 1
Level 2, 3, or 4	Level 2	Level 1, 2, 3, or 4	Non-protective, Level 1, 2, 3, or 4		Level 2
Level 2	Level 2, 3, or 4	Level 1, 2, 3, or 4	Non-protective, Level 1, 2, 3, or 4		Level 2
Level 3 or 4	Level 3	Level 1, 2, 3, or 4	Non-protective, Level 1, 2, 3, or 4		Level 3
Level 3	Level 3 or 4	Level 1, 2, 3, or 4	Non-protective, Level 1, 2, 3, or 4		Level 3
Level 4	Level 4	Level 1, 2, 3, or 4	Non-protective, Level 1, 2, 3, or 4		Level 4

16

ANSI/AAMI PB70:2012, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

16

ASTM STANDARDS

BIOLOGICAL

- F1670/F1670M-17A STANDARD TEST METHOD FOR RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY SYNTHETIC BLOOD
- F1671/F1671M-13 STANDARD TEST METHOD FOR RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY BLOOD-BORNE PATHOGENS USING PHI-X174 BACTERIOPHAGE PENETRATION AS A TEST SYSTEM
- F1819-19 STANDARD TEST METHOD FOR RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY SYNTHETIC BLOOD USING A MECHANICAL PRESSURE TECHNIQUE
- F1862/F1862M-17 STANDARD TEST METHOD FOR RESISTANCE OF MEDICAL FACE MASKS TO PENETRATION BY SYNTHETIC BLOOD (HORIZONTAL PROJECTION OF FIXED VOLUME AT A KNOWN VELOCITY)
- F2100-21 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS
- F2101-19 STANDARD TEST METHOD FOR EVALUATING THE BACTERIAL FILTRATION EFFICIENCY (BFE) OF MEDICAL FACE MASK MATERIALS, USING A BIOLOGICAL AEROSOL OF STAPHYLOCOCCUS AUREUS

BIOLOGICAL

- F2299/F2299M-03(2017) STANDARD TEST METHOD FOR DETERMINING THE INITIAL EFFICIENCY OF MATERIALS USED IN MEDICAL FACE MASKS TO PENETRATION BY PARTICULATES USING LATEX SPHERES
- ***F2407-20 STANDARD SPECIFICATION FOR SURGICAL GOWNS INTENDED FOR USE IN HEALTHCARE FACILITIES***
- ***F3352-19 STANDARD SPECIFICATION FOR ISOLATION GOWNS INTENDED FOR USE IN HEALTHCARE FACILITIES***

RESPIRATORY

- F3387-19 STANDARD PRACTICE FOR RESPIRATORY PROTECTION
- F3407-20 STANDARD TEST METHOD FOR RESPIRATOR FIT CAPABILITY FOR NEGATIVE-PRESSURE HALF-FACEPIECE PARTICULATE RESPIRATORS

NEW: SPECIFICATION F3502-21 ON BARRIER FACE COVERINGS
- SOURCE CONTROL (PROTECT THE PUBLIC)
- OFFER PROTECTIVE CAPABILITY (PROTECT THE WEARER)

17

17

THE JOINT COMMISSION

IC.01.03.01 THE HOSPITAL IDENTIFIES RISKS FOR ACQUIRING AND TRANSMITTING INFECTIONS.

- Expectation is that a multi-disciplinary team performs a risk assessment and put in place infection control activities.
- Customized to the organization
- Risk assessment should be prioritized
  - In order of level of probability and potential for harm
  - Prioritized risk are documented (likelihood of occurrence / severity of impact)

IC.02.01.01: THE HOSPITAL IMPLEMENTS ITS INFECTION PREVENTION AND CONTROL PLAN

IC.02.02.01 THE HOSPITAL REDUCES RISK OF INFECTIONS ASSOCIATED WITH MEDICAL EQUIPMENT, DEVICES, AND SUPPLIES.

- Cleaning and performing low-level disinfection of medical equipment, devices and supplies.
- Performing intermediate and high-level and sterilization of medical equipment, devices and supplies.
- Disposing of medical equipment, devices, and supplies.
- When reprocessing single-use devices, the hospital implements infection prevention and control activities that are consistent with regulatory and professional standards.

18

The Joint Commission. Hospital Accreditation Standards. January 2022

18

THE JOINT COMMISSION

EC.02.05.01 The organization manages risks associated with its utility systems.

EC.02.04.03 The organization inspects, tests, and maintains medical equipment.

EC.02.06.05 The organization manages its space during demolition, renovation, or new construction.

HR.01.02.01 The organization defines staff qualifications

LD.04.01.07 The hospital has policies and procedures that guide and support patient care, treatment, and services.

19

The Joint Commission. Hospital Accreditation Standards. January 2022

19

THE JOINT COMMISSION HIERARCHAL APPROACH

20

20

JOINT COMMISSION – ANALYSIS OF HAZARDS

Safe Practice 4: Identification and Mitigation of Risks and Hazards

Health care organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm.

21

The Joint Commission. Improving Patient and Worker Safety: Opportunities for Synergy, Collaboration and Innovation. Oakbrook Terrace, IL: The Joint Commission, Nov 2012. https://www.jointcommission.org/improving_patient_worker_safety/ (accessed January 18, 2017)

21

IMPROPERLY STERILIZED OR HLD EQUIPMENT A GROWING PROBLEM

- The mistaken belief that the risk of passing bloodborne pathogens or bacterial agents to patients is low or nonexistent.
- Staff lack the knowledge or training required to properly sterilize or HLD equipment.
- Staff don't have access to or lack knowledge of evidence-based guidelines.
- Lack of leadership oversight.
- Sterilization or HLD of equipment becomes a low priority within the organization.
- Lack of a culture of safety that supports the reporting of safety risks.
- Processes for sterilization or HLD are not followed (i.e., staff take shortcuts).
- The time frames for proper sterilization or HLD of equipment are not followed.
- There is no dedicated staff person to oversee the proper sterilization or HLD of equipment.
- Facility design or space issues prevent proper sterilization or HLD of equipment (e.g., processing takes place in a small room that also is used for storage).
- Lack of monitoring or documentation of sterilization or HLD of equipment, which makes it difficult to track the use of equipment on a specific patient, complicating the patient notification process when an outbreak occurs.
- Equipment is spread throughout the facility and may be processed or stored in numerous locations, making it difficult to track the equipment for documentation purposes.

22

The Joint Commission Quick Safety Issue 33 May 2017 https://www.jointcommission.org/-/media/tjc/documents/newsletters/qs_33a_2017pdf.pdf

22

LEARNING OBJECTIVE 2

DESCRIBE THE PROCESS FLOW IN THE STERILE PROCESSING DEPARTMENT

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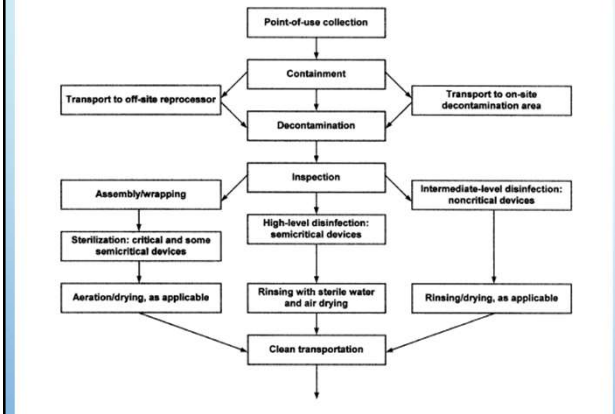
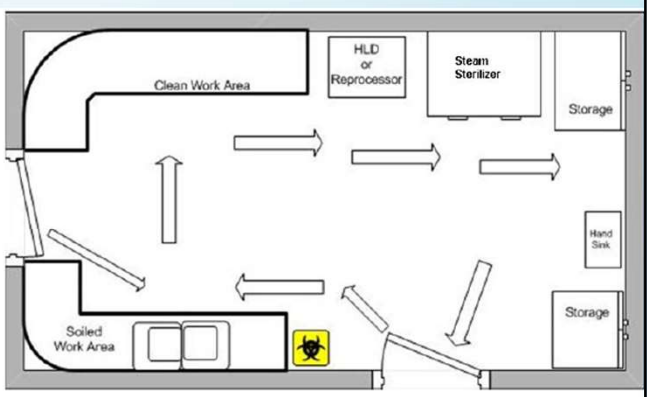


(a) Workflow in a sterile processing area
(© 2000 Canadian Standards Association)



(b) Workflow in an office-based practice

Figure 1—Workflow

24

ANSI/AAMI ST79: 2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

24

ENVIRONMENT OF CARE – FACILITY DESIGN

- CENTRALIZE AS MUCH AS POSSIBLE
- PROCESSING EQUIPMENT REQUIREMENTS
- INSTRUMENT AIR FOR DRYING
- WATER QUALITY FOR DECONTAMINATION PROCESSES AND QUALITY MONITORING SYSTEMS
- STERILANT REQUIREMENTS (E.G., STEAM, ETHYLENE OXIDE)
- SPACE CONSTRAINTS – POTENTIAL ISSUES
  - WORK TO BE DONE IN THE SPACE
  - SEPARATION OF CLEAN AND DIRTY
  - WORKFLOW – CLEAN TO DIRTY TO CLEAN
    - TRAFFIC CONTROL
  - STORAGE REQUIREMENTS – CLEAN, STERILE
  - FLOORS, WALLS, CEILINGS
  - LIGHTING – ILLUMINANCE RECOMMENDATIONS
  - EMERGENCY EYEWASH/SHOWER EQUIPMENT
- HVAC - TEMPERATURE, HUMIDITY, PRESSURE RELATIONSHIPS – POLICIES REFERENCED
  - TEMPERATURE, HUMIDITY, AIR FLOW
  - AIRFLOW PATTERNS SHOULD NOT ALLOW AIR CONTAMINATION TO ENTER CLEAN AREAS
    - PRESSURE – DIRECTION OF AIRFLOW (NEGATIVE)
  - WHEN OUT OF RANGE
    - SMALL VARIANCE, SHORT TIME – NO SIGNIFICANCE
    - LARGER, LONGER VARIANCE - CRITICAL THINKING, MULTIDISCIPLINARY TEAM DECISION
- ANY CONSTRUCTION PROJECTS ONGOING

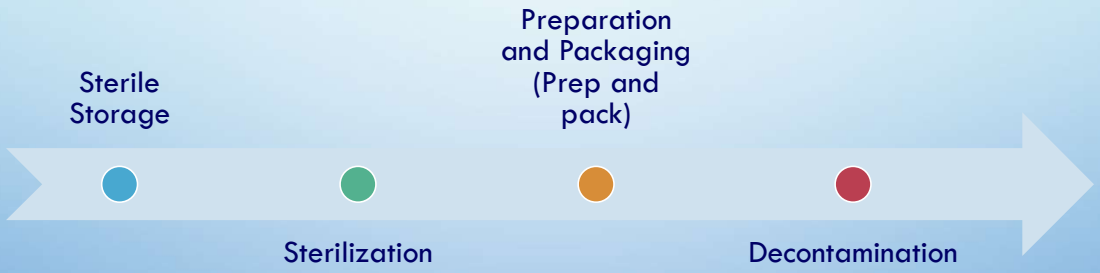
25

PERSONNEL CONSIDERATIONS

- POLICIES AND PROCEDURES
- QUALIFICATIONS
  - SUPERVISORS AND PROCESSING PERSONNEL
- EDUCATION AND TRAINING
  - INITIAL ORIENTATION, CONTINUING EDUCATION AND IN-SERVICE TRAINING
  - DOCUMENTED COMPETENCY
  - CERTIFICATION
- HEALTH AND PERSONNEL HYGIENE
  - STANDARD AND TRANSMISSION-BASED PRECAUTIONS
  - HAND HYGIENE
  - ATTIRE
  - PERSONAL PROTECTIVE EQUIPMENT
  - SAFETY DATA SHEET (SDS)
  - EYE WASH STATION (PLUMBED) / SHOWER EQUIPMENT

26

INFECTION PREVENTIONIST IN SPD WORKFLOW- CLEAN TO DIRTY



27

27

WORKFLOW

- ITEMS MOVE FROM CONTAMINATED TO BEING SAFE TO HANDLE
  - LIMITS CONTAMINATION
- WHEN STERILIZATION IS PERFORMED WITHIN THE SURGICAL SUITE A STERILE PROCESSING ROOM SHALL HAVE
  - SEPARATE CLEAN AND DECONTAMINATION AREAS, WHICH MAY BE ROOMS OR AREAS
  - DECONTAMINATION AND CLEAN SPACES THAT ARE SEPARATED BY ONE OF THREE METHODS
    - A WALL WITH A DOOR OR PASS THROUGH
    - A PARTIAL WALL OR PARTITION AT LEAST 4 FEET HIGH AND WIDTH OF THE COUNTER, OR
    - 4 FEET DISTANCE BETWEEN INSTRUMENT WASHING SINK AND AREA WHERE INSTRUMENTS ARE PREPARED FOR STERILIZATION

28

AORN Guidelines for Perioperative Practice, AORN, Denver, CO. 2022
ANSI/AAMI ST79:2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

28

STERILE STORAGE

WHAT ARE YOU LOOKING FOR?

29

29

STERILE STORAGE – BEFORE YOU ENTER

- ENSURE YOU ARE ACCOMPANIED BY THE SPD MANAGER OR DESIGNATED PERSON
- PROPER ATTIRE
  - SCRUBS OR TYVEK (BUNNY SUIT), HEADCOVER (BOUFFANT CAP) TO COVER ALL HAIR, SHOE COVER, BEARD COVER (IF FACIAL HAIR)
- PERFORM HAND HYGIENE
- ASK PERMISSION TO TAKE PICTURES
  - DO NOT TAKE PICTURES OF SPD PERSONNEL WITHOUT PERMISSION

30

30

STERILE STORAGE – WHAT TO LOOK FOR

- PERFORM A GENERAL SCAN OF THE AREA – WHAT DO YOU SEE?
  - ARE ALL PERSONNEL PROPERLY ATTIRED (ALL HAIR COVERED; BEARDS COVERED), SCRUBS CLEAN
  - PERSONNEL NOT WEARING ANY TYPE OF ARTIFICIAL NAILS
  - NAILS KEPT SHORT AND IF WEARING NAIL POLISH, IS POLISH CHIPPED OR PEELING
- CHECK DATES ON PACKAGING (INVENTORY TURNOVER)
- OPEN PACKAGES THAT ARE NOT ONE OFF (CHECK WITH SPD PERSONNEL)
- POUCHES PLACED IN CORRECT POSITION AND CRUSHED OR DAMAGED

- ENVIRONMENT OF CARE
  - HUMIDITY AND TEMPERATURE MONITORS PRESENT
  - PRESSURE DIFFERENTIAL
    - AIR FLOW FROM POSITIVE TO NEGATIVE (STERILE STORAGE TO NEXT LEVEL DOWN)
      - CHECK WITH TISSUE OR OTHER AIR FLOW MONITOR
      - DOORS NOT PROPPED OPEN
  - AREA RESTRICTED AND TRAFFIC CONTROLLED
    - PROPER SIGNS POSTED
  - NO SINKS LOCATED IN THE AREA
  - FLOORS INTACT AND MAINTAINED
    - NOT DIRTY, CHIPPED, LIFTING
  - CEILING TILES ARE SEATED AND CLEAN
  - VENTS ARE CLEAN AND SEATED
  - NO FANS IN THE AREA
  - NO CORRUGATED CARDBOARD (EXTERNAL SHIPPING CONTAINERS)
  - NO EVIDENCE OF INSECTS, ETC.
  - NO FOOD CONSUMED IN AREA

31

31

THE STERILE STORAGE AREA

- STORE STERILIZED ITEMS IN A SEPARATE AREA WITH ADEQUATE SPACE UNTIL DISTRIBUTED FOR PATIENT CARE USE
- RESTRICTED ACCESS / CONTROLLED TRAFFIC
- PROPER ENVIRONMENTAL CONDITIONS
  - TEMPERATURE, HUMIDITY AND AIR CHANGES
  - POSITIVE PRESSURE AIR FLOW (OUT)
- INVENTORY IS PROTECTED FROM CONTAMINATION
  - MINIMAL HANDLING
  - **STORE AT LEAST 8-10" FROM THE FLOOR, 18' BELOW CEILINGS AND 2" FROM OUTSIDE WALLS**
  - NO STORAGE ON FLOOR OR WINDOWSILLS
- SHELF LIFE
  - ITEMS LABELED FOR EVENT RELATED OUTDATING OR EXPIRATION

- SHOULD NOT BE STORED NEXT TO SINKS OR UNDER EXPOSED WATER OR SEWER PIPES OR IN LOCATIONS WHERE THEY MAY BECOME WET
- STORAGE ON CARTS OR SHELVES
  - CLEANLINESS STANDARDS
  - SOLID BOTTOM SHELF
- STORE SO NOT CRUSHED, BENT, COMPRESSED
- STACK CONTAINERS IF RECOMMENDED BY MDM
- STORE HEAVY INSTRUMENT TRAYS IN MIDDLE SHELVES FOR EASE OF HANDLING AND DO NOT STACK

ANSI/AAMI ST79:2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

32

32

STERILE STORAGE

PER THE JOINT COMMISSION

- STORING STERILE ITEMS IN A ROOM DESIGNATED AS A CENTRAL MEDICAL AND SURGICAL SUPPLY AREA, THE FOLLOWING WILL BE REQUIRED, PER ASHRAE STANDARD 170-2008
  - POSITIVE AIR PRESSURE RELATIONSHIP TO ADJACENT AREAS
  - MINIMUM OUTDOOR AIR EXCHANGE 2 PER HOUR
  - MINIMUM TOTAL AIR EXCHANGE 4 PER HOUR
  - MAXIMUM RELATIVE HUMIDITY 60%
  - TEMPERATURE RANGE 72° TO 78° F OR 22° TO 26° C
- REQUIRED TO FOLLOW THE MANUFACTURER'S INSTRUCTIONS FOR STORAGE AS INDICATED ON THE LABEL. IF, FOR EXAMPLE, THE MANUFACTURER OF THE STERILE SUPPLY ITEM REQUIRES A SPECIFIC TEMPERATURE AND HUMIDITY REQUIREMENT FOR STORAGE, YOUR ORGANIZATION WOULD NEED TO MEET THAT REQUIREMENT.

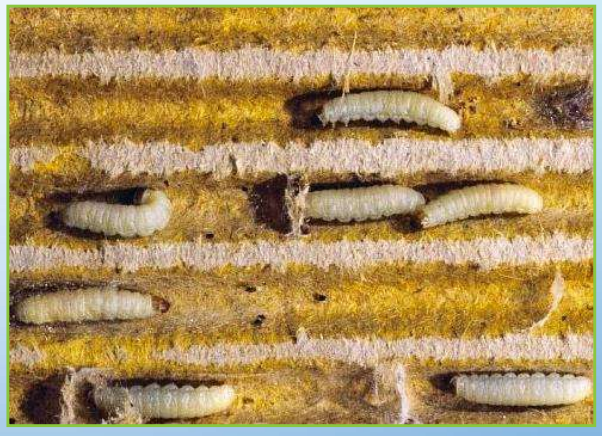
33

Managing packaged sterile supplies and devices. The Joint Commission Quick Safety. Issue 65, June 2022
ANSI/ASHRAE/ASHE Addendum h to ANSI/ASHRAE/ASHE Standard 170-2013
ANSI/ASHRAE/ASHE Standard 170-2002 Ventilation of Health Care Facilities

33

STERILE STORAGE AREA

- INVENTORY IS PROTECTED FROM CONTAMINATION
  - NO OUTSIDE SHIPPING CONTAINERS OR CORRUGATED/WEB-EDGED CARTONS



Mature Indian Meal Moth Larvae Pupating in Corrugated Cardboard

ANSI/AAMI ST79:2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Section 11.1.1
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, Photo courtesy of Department of Entomology, University of Nebraska-Lincoln. Photographer: Jim Kalisch.

34

STERILE STORAGE - SHELF LIFE

- POLICIES AND PROCEDURES FOR SHELF LIFE DETERMINATION
  - IS EVENT RELATED AND DEPENDS ON:
    - QUALITY OF PACKAGING MATERIAL
    - STORAGE CONDITIONS
    - CONDITIONS DURING TRANSPORTATION
    - AMOUNT OF HANDLING
- LABEL EACH PRODUCT
  - EXPIRATION DATE OR STATEMENT SUCH AS: "CONTENTS STERILE UNLESS PACKAGE IS OPENED OR DAMAGED. PLEASE CHECK BEFORE USING."

35

ANSI/AAMI ST79:2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Section 9.7 & 11.1.2; Section 13.3.2 and 11.1.3

35

DISTRIBUTION OF STERILE PACKAGED ITEMS

- EXCESSIVE AND IMPROPER HANDLING CAN DAMAGE THE BARRIER QUALITIES OF THE PACKAGING MATERIALS
  - AVOID DRAGGING, SLIDING, CRUSHING, BENDING, COMPRESSING, OR PUNCTURING PACKAGING AS THAT COULD COMPROMISE THE STERILITY OF THE CONTENTS
- INSPECT STERILE PACKAGES TO IDENTIFY DAMAGE TO THE INTEGRITY OF THE MATERIALS. LOOK FOR:
  - ✓TEARS, PUNCTURES, HOLES
  - ✓MOISTURE, STAINS, DUST
  - ✓EVIDENCE OF INSECTS, VERMIN

"Sterile packages that contain instrumentation and that are transported by hand should be maintained in a position parallel with the floor."

"Sterile packages to be transported from the point of processing to the point of use by means of a dedicated clean lift (i.e., one used only for clean or sterile items) should be contained in a closed bin, a closed case cart, or a plastic bag."

36

ANSI/AAMI ST79:2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

36

TRANSPORTATION OF STERILE PACKAGED ITEMS

- ITEMS MAY BE PLACED INSIDE PLASTIC OR PAPER BAGS OR BOXES
- REUSABLE COVERS AND CARTS SHOULD BE CLEANED AFTER EACH USE
- CHECK FOR LEAKS ANNUALLY OR MORE FREQUENTLY
- SECURE CARTS WITHIN VEHICLE
- ASSESS ENVIRONMENTAL CONDITIONS IN VEHICLE BOTH WHEN IN MOTION AND NOT TO SEE IF CONDENSATE IS A PROBLEM
- DECONTAMINATE

"Sterile items should be transported in a manner that will protect the items from puncture and from contamination by moisture, excessive humidity, condensation caused by exposure to temperature extremes, insects, vermin, dust and dirt, excessive air pressures, and microorganisms.."

"All clean or sterile items being transported in uncontrolled environments should be in a covered or enclosed cart with a solid bottom shelf."

"Vehicles used to transport sterile packages between health care facilities should provide for the complete separation of clean and sterile items from contaminated items."

37

ANSI/AAMI ST79:2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

37

PREPARATION AND PACKING (PREP & PACK) AND STERILIZATION AREA

WHAT ARE YOU LOOKING FOR?

38

38

PREP AND PACK AND STERILIZATION AREA BEFORE YOU ENTER

- ENSURE YOU ARE ACCOMPANIED BY THE SPD MANAGER OR DESIGNATED PERSON
- PROPER ATTIRE
  - SCRUBS OR TYVEK (BUNNY SUIT), HEADCOVER (BOUFFANT CAP) TO COVER ALL HAIR, SHOE COVER, BEARD COVER (IF FACIAL HAIR)
- PERFORM HAND HYGIENE
- ASK PERMISSION TO TAKE PICTURES
  - DO NOT TAKE PICTURES OF SPD PERSONNEL WITHOUT PERMISSION
- KNOW WHAT STERILIZATION TECHNOLOGY IS IN USE

39

39

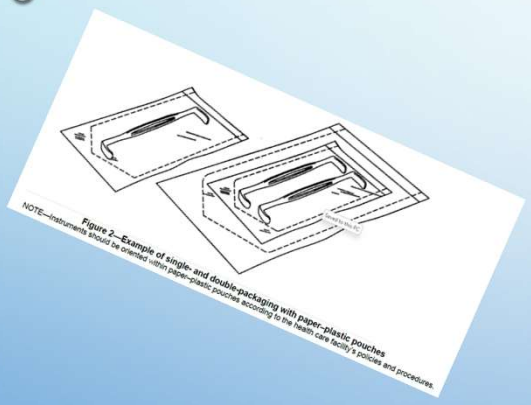
PREP AND PACK AREA - WHAT TO LOOK FOR

- PERFORM A GENERAL SCAN OF THE AREA – WHAT DO YOU SEE?
  - ARE ALL PERSONNEL PROPERLY ATTIRED (ALL HAIR COVERED; BEARDS COVERED), SCRUBS CLEAN
  - PERSONNEL NOT WEARING ANY TYPE OF ARTIFICIAL NAILS
  - NAILS KEPT SHORT AND IF WEARING NAIL POLISH, IS POLISH CHIPPED OR PEELING
- CHECK FOR ANY PEELING TAPES, RUST, ETC. USED AS MARKER ON INSTRUMENTS
- STERILIZATION PACKAGING
  - APPROPRIATE FOR THE INSTRUMENT TO BE PACKAGED
  - EXTERNAL AND INTERNAL CHEMICAL INDICATOR IN EACH PACK, POUCH AND/OR CONTAINER SYSTEMS
  - POUCHES USED ARE APPROPRIATE FOR THE TYPE OF INSTRUMENTS TO BE PACKAGED
  - PROPER LABELING OF PACKAGES (CONTENTS, SHELF LIFE)
  - SINGLE USE ITEMS ARE NOT REUSED
- ENVIRONMENT OF CARE
  - TEMPERATURE AND HUMIDITY MONITORS PRESENT
  - AIR PRESSURE DIFFERENTIAL CORRECT
    - POSITIVE TO NEGATIVE FLOW
  - ADHESIVE NOT ON SURFACES
- STERILIZATION MONITORS
  - PROPERLY STORED (PREVENT EXPOSURE TO STEAM/HEAT)
  - CHEMICAL INDICATORS IN USE IN ORIGINAL PACKAGING

40

40

PACKAGING – PAPER PLASTIC POUCHES



- USED FOR SMALL, LIGHTWEIGHT, LOW-PROFILE ITEMS
- USED, FILLED AND OPENED ACCORDING TO MIFU
- SIZE AND STRENGTH TO ACCOMMODATE ITEMS TO BE PACKAGED
- CLOSED SO ALL POUCH SEALS ARE SMOOTH (NO FOLDS, BUBBLES OR WRINKLES
- DOUBLE POUCHING SHOULD ONLY BE PERFORMED IF THE MANUFACTURER HAS VALIDATED THIS USE
- IF DOUBLE POUCHING, TWO SEQUENTIALLY SIZED POUCHES SHOULD BE USED
  - SEALED INNER POUCH SHOULD FIT INSIDE THE OTHER POUCH WITHOUT FOLDING
- POSITIONED SO THAT PLASTIC FACES PLASTIC
- SHOULD NOT BE PLACED WITHIN WRAPPED SETS OR CONTAINMENT DEVICES UNLESS VALIDATED BY THE POUCH PACKAGING MANUFACTURER AND VERIFIED BY PRODUCT TESTING IN THE HCF

41

ANSI/AAMI ST79: 2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

41

STERILIZATION AREA - WHAT TO LOOK FOR

- PERFORM A GENERAL SCAN OF THE AREA – WHAT DO YOU SEE?
  - ARE ALL PERSONNEL PROPERLY ATTIRED (ALL HAIR COVERED; BEARDS COVERED), SCRUBS CLEAN
  - PERSONNEL NOT WEARING ANY TYPE OF ARTIFICIAL NAILS
  - NAILS KEPT SHORT AND IF WEARING NAIL POLISH, IS POLISH CHIPPED OR PEELING
- INSTRUMENT COOLING
  - ARE VENTS LOCATED ABOVE WHERE COOLING OF STERILIZED ITEMS IS TAKING PLACE (ONE REASON FOR WET PACKS)
  - PROCESS INDICATOR CHANGED
  - ITEMS NOT REMOVED FROM AREA UNTIL COOLED (TEMP GUN CHECK)
  - HOT ITEMS ARE NOT BEING HANDLED
  - ISSUES WITH WET/DRY STEAM
- CHECK INTERIOR OF STERILIZER IF NOT IN USE
  - ARE DRAIN TRAPS CLEAN
  - IS THE INSIDE OF THE CHAMBER CLEAN
  - IS THERE DUST ACCUMULATINGG ON THE STERILIZER
  - CHECK BEHIND THE STERILIZER (USUALLY BEHIND DOOR NEXT TO STERILIZER
- IS IUSS USED FREQUENTLY
- IUSS USED FOR IMPLANTABLE DEVICES
- ENVIRONMENT OF CARE
  - TEMPERATURE AND HUMIDITY MONITORS PRESENT
  - PRESSURE DIFFERENTIAL
    - AIR FLOW FROM POSITIVE TO NEGATIVE (STERILE STORAGE TO NEXT LEVEL DOWN)
      - CHECK WITH TISSUE OR OTHER AIR FLOW MONITOR
      - DOORS NOT PROPPED OPEN
  - AREA RESTRICTED AND TRAFFIC CONTROLLED
    - PROPER SIGNS POSTED
  - NO SINKS LOCATED IN THE AREA
  - FLOORS INTACT AND MAINTAINED
    - NOT DIRTY, CHIPPED, LIFTING
  - CEILING TILES ARE SEATED AND CLEAN
  - VENTS ARE CLEAN AND SEATED
  - NO FANS IN THE AREA
  - NO CORRUGATED CARDBOARD (EXTERNAL SHIPPING CONTAINERS)
  - NO EVIDENCE OF INSECTS, ETC.
  - NO FOOD CONSUMED IN AREA
  - MAINTENANCE RECORDS

42

42

ANSI/AAMI ST79: 2017 A3: 2020 Modification of content pertaining to frequency of cleaning for routine care of sterilizers for sterile processing areas in health care facilities

REVISED SECTION 12.4 – ELIMINATED DAILY CLEANING RECOMMENDATION

- ROUTINE CARE
  - VISUALLY INSPECTED ACCORDING TO THE MANUFACTURER'S WRITTEN IFU.
  - DAILY CARE – E.G., RECORDING CHARTS, PRINTERS, PRINTER RIBBONS, MARKING PENS AND INK.
  - WEEKLY OR OTHER PRESCRIBED INSPECTION AND CLEANING SHOULD BE PERFORMED AS SPECIFIED IN THE MIFU AND SHOULD BE DOCUMENTED PER INTERNAL PROCEDURES.
    - EXAMPLES OF ITEMS TO BE OBSERVED ARE EXCESSIVE STAINING AND DISCOLORATION OF THE INTERNAL CHAMBER, FOLLOW THE PROCESS FOR CLEANING THE INTERNAL SURFACES OF THE STERILIZER AS OUTLINED IN THE MIFU

43

43

STERILIZATION AND HIGH-LEVEL DISINFECTION

- HEAT AND MOISTURE RESISTANT ITEMS
  - STEAM STERILIZATION
    - GRAVITY DISPLACEMENT – GRAVITY ONLY CYCLES
    - DYNAMIC AIR-REMOVAL STERILIZERS (E.G., PREVACUUM, STEAM-FLUSH PRESSURE-PULSE) – AIR IS REMOVED DYNAMICALLY BASED ON THE STERILIZER
    - SOME STERILIZERS PROVIDE BOTH GRAVITY DISPLACEMENT OR DYNAMIC AIR-REMOVAL CYCLES
    - SOME ARE LARGE CAPACITY OR TABLE-TOP MODELS
- HEAT AND MOISTURE SENSITIVE ITEMS
  - ETHYLENE OXIDE
  - HYDROGEN PEROXIDE GAS PLASMA
  - OZONE AND HYDROGEN PEROXIDE
  - VAPORIZED HYDROGEN PEROXIDE
- HIGH-LEVEL DISINFECTION
  - AUTOMATED ENDOSCOPE REPROCESSOR
  - MANUAL

44

44

STERILIZATION PROCESS

- EFFECTIVE CLEANING
- APPROPRIATE PACKAGING MATERIALS AND WRAPPING TECHNIQUES
- CORRECTLY PACKAGED DEVICES
- PROPER LOADING OF STERILIZER
- CORRECT STERILANT QUALITY AND QUANTITY
- PROPER FUNCTIONING OF THE STERILIZER
- CORRECT CHOICE OF STERILIZATION CYCLE
- FOLLOW MANUFACTURER'S INSTRUCTION

- STERILIZATION PARAMETERS
  - STEAM STERILIZATION
    - TIME
    - TEMPERATURE
    - SATURATED STEAM
  - HYDROGEN PEROXIDE GAS STERILIZATION
    - TIME
    - TEMPERATURE
    - STERILANT GAS CONCENTRATION

45

45

STERILIZATION PROCESS

OPERATIONAL DEFINITION

TOTAL OPERATION WHICH KILLS OR REMOVES ALL FORMS OF MICROORGANISMS

PRACTICAL DEFINITION

PROBABILITY OF THE ABSENCE OF ALL LIVING ORGANISMS

46

46

IMMEDIATE USE STEAM STERILIZATION (IUSS)

47

47

IMMEDIATE USE STEAM STERILIZATION (IUSS)

- USED FOR URGENT / EMERGENT NEEDS
  - SITUATIONS OUTLINED IN POLICIES AND PROCEDURES AVAILABLE
- EFFORTS TO REDUCE IUSS
  - NOT FOR CONVENIENCE
  - NOT ROUTINE OR FREQUENT PRACTICE
  - NOT USED DUE TO LACK OF INSTRUMENTATION
  - NOT USED FOR LACK OF TIME
  - DOCUMENTATION
  - NOT PERFORMED ON IMPLANTS
  - NOT PERFORMED ON PATIENTS SUSPECTED TO HAVE CREUTZFELDT-JAKOB DISEASE (CJD)
- DEVICE IFU PROVIDE IUSS INSTRUCTIONS
- INSTRUMENTS DECONTAMINATED AS FOR ITEMS THAT WILL UNDERGO TERMINAL STERILIZATION
- PLACED IN A RIGID STERILIZATION CONTAINER SYSTEM THAT IS INTENDED FOR THE CYCLE PARAMETERS TO BE USED TO FACILITATE ASEPTIC TRANSFER TO THE POINT OF USE
- USED IMMEDIATELY AND NOT STORED FOR FUTURE USE OR HELD FROM ON PROCEDURE TO THE NEXT
- PROCESS MONITORING
  - PHYSICAL
  - BIOLOGICAL INDICATOR
  - CHEMICAL INDICATOR

ANSI/AAMI ST79: 2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

48

48

WHAT IS AN IMPLANT?

ACCORDING TO FDA, "DEVICE THAT IS PLACED INTO A SURGICALLY OR NATURALLY FORMED CAVITY OF THE HUMAN BODY IF IT IS INTENDED TO REMAIN THERE FOR A PERIOD OF 30 DAYS OR MORE. FDA MAY, IN ORDER TO PROTECT PUBLIC HEALTH, DETERMINE THAT DEVICES PLACED IN SUBJECTS FOR SHORTER PERIODS ARE ALSO 'IMPLANTS.' "

21 CFR 812.3(D)

Immediate use steam sterilization (IUSS) should not be used for implantable devices except in cases of emergency when no other option is available.

49

49

DECONTAMINATION AREA

What are you looking for?

50

50

DECONTAMINATION AREA - WHAT TO LOOK FOR

- PERFORM A GENERAL SCAN OF THE AREA – WHAT DO YOU SEE?
  - ARE ALL PERSONNEL PROPERLY ATTIRED (ALL HAIR COVERED; BEARDS COVERED), SCRUBS CLEAN; FACE SHIELD AND MASKS WORN
  - PERSONNEL NOT WEARING ANY TYPE OF ARTIFICIAL NAILS
  - NAILS KEPT SHORT AND IF WEARING NAIL POLISH, IS POLISH CHIPPED OR PEELING
- EYEWASH STATION PLUMBED, CLEANED AND CHECKED WEEKLY
- HANDWASHING SINKS NOT USED TO CLEAN CONTAMINATED INSTRUMENTS
- CHECKS CARTS AND TRAYS TO SEE IF SPRAYED TO KEEP MOIST AT THE POINT OF USE
- DETERGENTS DILUTED ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS FOR USE
- SPILL KITS
- MAINTENANCE RECORDS
- ULTRASOUND WASHER CLEAN
  - IS THE PROPER DETERGENT USED
  - IS THE WASHER MONITORED
  - USED FOR CLEANING FINE INSTRUMENTS
- CHECK INTERIOR OF WASHER-DISINFECTOR (W-D)
  - ARE DRAIN TRAPS CLEAN
  - IS THE INSIDE OF THE CHAMBER CLEAN
  - IS THERE DUST ACCUMULATINGG ON THE W-D
  - IS THE W-D MONITORED
- MANUAL CLEANING
  - APPROPRIATE NUMBER OF SINKS AVAILABLE
  - PROPER WATER QUALITY AVAILABLE (E.G., SOFTENED)
  - BRUSHES USED APPROPRIATE FOR CLEANING

51

51

DECONTAMINATION AREA - WHAT TO LOOK FOR

- ENVIRONMENT OF CARE
  - PRESSURE DIFFERENTIAL
    - AIR FLOW FROM POSITIVE TO NEGATIVE (STERILE STORAGE TO NEXT LEVEL DOWN)
      - CHECK WITH TISSUE OR OTHER AIR FLOW MONITOR
      - DOORS NOT PROPPED OPEN
  - AREA RESTRICTED AND TRAFFIC CONTROLLED
    - PROPER SIGNS POSTED
  - NO SINKS LOCATED IN THE AREA
  - FLOORS INTACT AND MAINTAINED
    - NOT DIRTY, CHIPPED, LIFTING
  - CEILING TILES ARE SEATED AND CLEAN
  - VENTS ARE CLEAN AND SEATED
  - NO PORTABLE FANS USED IN THE AREA
  - NO CORRUGATED CARDBOARD (EXTERNAL SHIPPING CONTAINERS)
  - NO EVIDENCE OF INSECTS, ETC.
  - NO FOOD CONSUMED IN AREA
  - SHARPS CONTAINERS AND TRASH CANS AVAILABLE
  - NO DUST/GRIME UNDER ANTI-FATIGUE MATS

52

52

HANDLING, COLLECTION, AND TRANSPORT OF CONTAMINATED ITEMS

- REUSABLE ITEMS SHOULD BE SEPARATED FROM WASTE AT THE POINT OF USE. CONTAMINATED DISPOSABLE ITEMS SHOULD BE DISCARDED INTO AN APPROPRIATE CONTAINER; PUNCTURE-RESISTANT CONTAINERS MUST BE USED FOR SHARPS.
- ALL ITEMS CONTAMINATED WITH BLOOD, BODY FLUIDS, AND TISSUE MUST BE PLACED IN A LEAKPROOF CONTAINER BEFORE TRANSPORT.
- CONTAMINATED REUSABLE ITEMS SHOULD BE CONTAINED IN SUCH A WAY THAT THE CONTENTS OF THE CONTAINERS ARE READILY IDENTIFIABLE AS CONTAMINATED BY EVERYONE WHO SUBSEQUENTLY HANDLES THE ITEMS.
- THE PROCEDURES FOR PACKAGING AND TRANSPORTING CONTAMINATED ITEMS OFF-SITE FOR PROCESSING MUST COMPLY WITH APPLICABLE DEPARTMENT OF TRANSPORTATION (DOT) AND STATE REGULATIONS.

53

53

MANUFACTURER'S INSTRUCTIONS

- MANUFACTURER'S WRITTEN INSTRUCTIONS FOR USE (MIFU) ARE AN INTEGRAL PART OF INSTRUMENT AND DEVICE PROCESSING
  - SHOULD BE AVAILABLE FOR CLEANING AGENTS, DISINFECTING AGENTS, PACKAGING, INSTRUMENT, DEVICES AND EQUIPMENT (AERS, STERILIZERS, ETC.)
  - SHOULD BE UP TO DATE / MOST RECENT
  - EASILY ACCESSIBLE TO PROCESSING STAFF
  - SHOULD BE FOLLOWED TO ALLOW FOR CONSISTENT PROCESSING OF THE SAME DEVICE/INSTRUMENT EVERY TIME
  - MULTI-DISCIPLINARY TEAM SHOULD DEVELOP INSTRUCTIONS FOR CLEANING, DISINFECTION AND/OR STERILIZATION SHOULD THERE NOT BE ONE AVAILABLE FROM THE MANUFACTURER
  - IFUS SHOULD BE REVIEWED PRIOR TO PURCHASE OF INSTRUMENT, DEVICES AND EQUIPMENT TO ENSURE THEY ARE CLEAR AND EASY TO FOLLOW
  - AVAILABLE IN HARD COPY OR ELECTRONIC

54

54

PERSONAL PROTECTIVE EQUIPMENT (PPE)

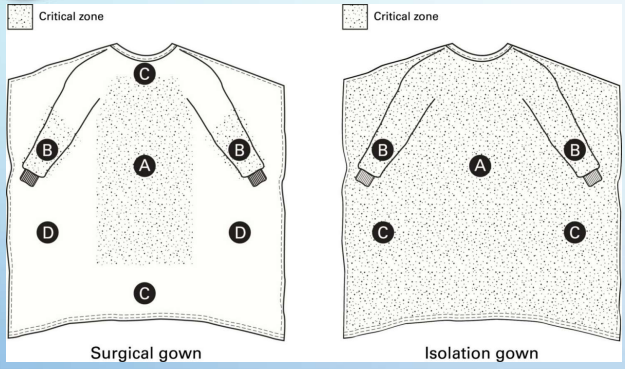
- ✓LIQUID-RESISTANT COVERING WITH SLEEVES
- ✓HEAVY-DUTY LATEX FREE OR PLASTIC GLOVES
- ✓SURGICAL FACE MASK (IMPERVIOUS TO FLUID AND HIGH FILTRATION)
- ✓SAFETY GLASSES THAT WRAP AROUND THE EYE OR FACE SHIELD
- ✓DISPOSABLE HAIR COVERING
- ✓PROPER FOOTWEAR

ANSI/AAMI ST79:2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

OSHA 29 CFR 1910.1030

55

ANSI/AAMI PB70 CRITICAL ZONES FOR GOWNS



Ofstead et al in a pilot project found that routine reprocessing activities generated substantial splashing, with droplet dispersal of up to 5 feet away from decontamination sinks. Currently recommended PPE did not adequately protect SPD personnel from exposure to clean water and cleaning solution during simulated activities, which would be presumed to be highly contaminated during normal daily activities.

56

ANSI/AAMI PB70:2012, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.
Ofstead, CL et. al. Droplet dispersal in decontamination areas of instrument reprocessing suites. American Journal of Infection Control 50 (2022) 126-132

56

ANSI/AAMI ST79: 2017 A1: 2020 ENVIRONMENTAL SERVICES/FANS/FOOD AND DRINK

REVISIONS- CLAUSES 3.2.1.1; 3.4

- POLICY AND PROCEDURE – RESTRICT FOOD AND BEVERAGE IN **ALL** STERILE PROCESSING AREAS; PROVIDE ALTERNATE LOCATIONS
- ENVIRONMENTAL CLEANING PROCEDURES - IN **ALL** STERILE PROCESSING AREAS (I.E., DECONTAMINATION, PREPARATION, PACKAGING, STERILIZATION, STERILE STORAGE)
  - WORKFLOW FROM CLEAN AREAS (E.G., STERILE STORAGE, PACKAGING, STERILIZATION) TO SOILED AREAS (E.G., DECONTAMINATION AREA).
  - ALL EQUIPMENT AND SUPPLIES USED FOR ENVIRONMENTAL CLEANING OF THE DECONTAMINATION AREA SHOULD NOT BE UTILIZED IN ANY OTHER AREA OF THE FACILITY
- CLEANING SCHEDULE DAILY WEEKLY
- CLEANING VERIFICATION

REVISION (3.3.5.5.) - HEATING, VENTILATION, AND AIR CONDITIONING (HVAC) OPERATING PARAMETERS

- ADDED A NEW 2ND PARAGRAPH AND ADDITIONAL CONTENT FOR THE RATIONALE
  - NEITHER FIXED NOR PORTABLE FANS SHOULD BE PERMITTED IN ANY AREA OF STERILE PROCESSING.
  - ALL WINDOWS AND DOORS THAT AFFECT THE VENTILATION AND AIRFLOW (POSITIVE TO NEGATIVE) SHOULD BE KEPT CLOSED WHEN NOT IN USE.
    - CREATE TURBULENT AIR
    - DISTURBANCE OF DUST AND MICROORGANISMS FROM FLOOR AND WORK SURFACES
    - INTERFERE WITH AIR FLOW BALANCE

57

ANSI/AAMI ST79: 2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

57

ANSI/AAMI ST79: 2017 A2: 2020 INSPECTION OF INSULATED INSTRUMENTS

ADDITION OF NEW SECTIONS – 8.2; 8.2.1

INSTRUMENT INSPECTION (SEE TABLE 1)

- VISUALLY INSPECTED FOR CLEANLINESS AND INTEGRITY
  - ENHANCED INSPECTION WITH MAGNIFICATION, BORESCOPES [INTERNAL LUMENS], OR OTHER INSPECTION METHODS
  - FOLLOW MANUFACTURER'S WRITTEN INSTRUCTIONS (INSTRUMENT AND VISUALIZATION TOOL)
  - REPEATED CLEANING AND DECONTAMINATION UNTIL CLEAN
  - REMOVE DAMAGED INSTRUMENTS FROM SERVICE

INSTRUMENTS INTENDED TO BE USED WITH ELECTRIC CURRENT

- TESTED FOR INTEGRITY EACH TIME IT IS PROCESSED IN ACCORDANCE WITH THE INSTRUMENT MANUFACTURER'S WRITTEN IFUS FOR INSPECTION.
- VISUAL INSPECTION WITH LIGHTED MAGNIFICATION FOR DEFECTS AS DEFINED BY THE MIFU
- INSULATION TESTING PER INSTRUMENT MIFU
- CABLES/CORDS - INSPECT AND CHECK FOR INTEGRITY AND CONTINUITY
- FOLLOW INSULATION TESTER WRITTEN MIFU

58

ANSI/AAMI ST79: 2017 Amendments A1:2020, A2:2020, A3:2020 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

58

CLEANING

59

59

BASIC DEFINITIONS

Cleaning	High-Level Disinfection (HLD)	Sterilization
Removal of organic soil	Microbial kill under defined conditions	Kills all living organisms including spores
Microbes and soil can still be present	Spores are not killed	Effectiveness dependent on meticulous cleaning
Device can still be infectious	Effectiveness dependent on meticulous cleaning	

60

60

SPAULDING CLASSIFICATION

CRITICAL: Medical/surgical devices which enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

SEMICRITICAL: Medical devices that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL: Medical devices/environmental surfaces that touch only intact skin require low-level disinfection

61

61

CLEANING, DISINFECTION (MICROBICIDAL PROCESSES), AND OTHER DECONTAMINATION STEPS

- POLICIES AND PROCEDURES
- THE HEALTH CARE ORGANIZATION SHOULD ESTABLISH POLICIES AND PROCEDURES FOR ALL METHODS OF CLEANING AND DECONTAMINATION OF REUSABLE ITEMS.
- PROCESS AUDITS TO MONITOR COMPLIANCE WITH THE VARIOUS POLICIES AND PROCEDURES SHOULD BE PERFORMED ON A SCHEDULED BASIS, WITH APPROPRIATE FOLLOW-UP TO ADDRESS PROBLEMS.
- MAINTAINS CONSISTENCY AND EFFECTIVENESS OF THE CLEANING AND DECONTAMINATION PROCESSES CONSISTENT WITH APPLICABLE STANDARDS AND RECOMMENDED PRACTICES.
- AUDITS OF THE PROCESS CAN HELP TO IDENTIFY GAPS SO METHODS CAN BE IDENTIFIED TO IMPROVE THE PROCESS.
- IN ALL CASES, ALWAYS FOLLOW THE MANUFACTURER'S WRITTEN INSTRUCTIONS.
- THE HEALTH CARE ORGANIZATION, INCLUDING REPRESENTATIVES OF STERILE PROCESSING AND OF INFECTION PREVENTION AND CONTROL, SHOULD **PURCHASE ONLY THOSE DEVICES THAT CAN BE DECONTAMINATED APPROPRIATELY BY A METHOD AVAILABLE IN THE HEALTH CARE FACILITY.**
- PERSONNEL PERFORMING DECONTAMINATION AND CLEANING TASKS MUST WEAR PPE AND BE TRAINED TO SAFELY PERFORM DECONTAMINATION-RELATED TASKS. (SEE 29 CFR 1910.1030.)
- TO BE RENDERED SAFE TO HANDLE, SOME MEDICAL DEVICES REQUIRE ONLY THOROUGH CLEANING; OTHERS, BECAUSE OF OCCUPATIONAL EXPOSURE CONSIDERATIONS (SUCH AS POTENTIAL EXPOSURE TO EBOLA OR CLOSTRIDIUM DIFFICILE), SHOULD BE CLEANED AND SUBJECTED TO A MICROBICIDAL PROCESS.

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62

62

POINT OF USE (POU) TREATMENT

- WIPING AND FLUSHING OF INSTRUMENTATION USED DURING A CASE IN THE OR / PROCEDURE ROOM
- KEEPING INSTRUMENTS MOIST BASED ON MANUFACTURER'S INSTRUCTIONS AND FACILITY POLICY AND PROCEDURE UNTIL THEY REACH PROCESSING AREA
- MULTI-PART INSTRUMENTS SHOULD BE OPENED AND DISASSEMBLED ACCORDING TO MANUFACTURER'S INSTRUCTION FOR USE
- TRANSPORTATION FROM POU TO PROCESSING AREAS
  - PRE-APPROVED TRANSPORTATION ROUTES
  - SHARPS TRANSPORT VIOLATES OSHA REQUIREMENTS
- CLEANING OF EQUIPMENT PRIOR TO REMOVAL

63

63

WATER QUALITY

IN WINE THERE IS WISDOM, IN BEER THERE IS FREEDOM, IN WATER THERE IS BACTERIA.

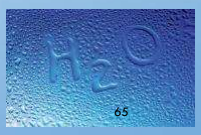
BENJAMIN FRANKLIN

64

64

WATER, WATER, EVERYWHERE BUT CAN'T USE A DROP!

- WATER QUALITY IS EXTREMELY IMPORTANT FOR ALL STAGES OF INSTRUMENT AND DEVICE PROCESSING
  - ASSESS, TREAT AND MONITOR
- SELECTION OF WATER OF THE APPROPRIATE QUALITY IS IMPORTANT FOR:
  - CLEANING CONTAMINATED MEDICAL DEVICES
    - MANUAL AND WASHER-DISINFECTORS
    - ULTRASONIC CLEANERS
    - CART WASHERS
  - DILUTING DETERGENTS AND HIGH-LEVEL DISINFECTANTS
    - AUTOMATED ENDOSCOPE REPROCESSORS (AER)
- RINSING DEVICES SUCH AS ITEMS THAT WILL BE STERILIZED OR HIGH-LEVEL DISINFECTED
- WATER NEEDS TO BE FREE OF CONTAMINANTS SUCH AS:
  - WATERBORNE PATHOGENS (*PSEUDOMONAS* AERUGINOSA/NONTUBERCULOUS MYCOBACTERIA/*STENOTROPHOMONAS MALTOPHILIA, LEGIONELLA SPP.,* ETC.)
  - ENDOTOXIN / BIOFILM



65

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65

WATER QUALITY

- PHYSICAL, CHEMICAL AND MICROBIOLOGICAL QUALITY SHOULD BE MONITORED
- EC.02.05.02: THE HOSPITAL HAS A WATER MANAGEMENT PROGRAM THAT ADDRESSES LEGIONELLA AND OTHER WATERBORNE PATHOGENS. NOTE: THE WATER MANAGEMENT PROGRAM IS IN ACCORDANCE WITH LAW AND REGULATION
  - EP 2 WATER RISK MANAGEMENT PLAN; MONITORING PROTOCOLS; ETC.

66

The Joint Commission. 2022 Hospital Accreditation Standards

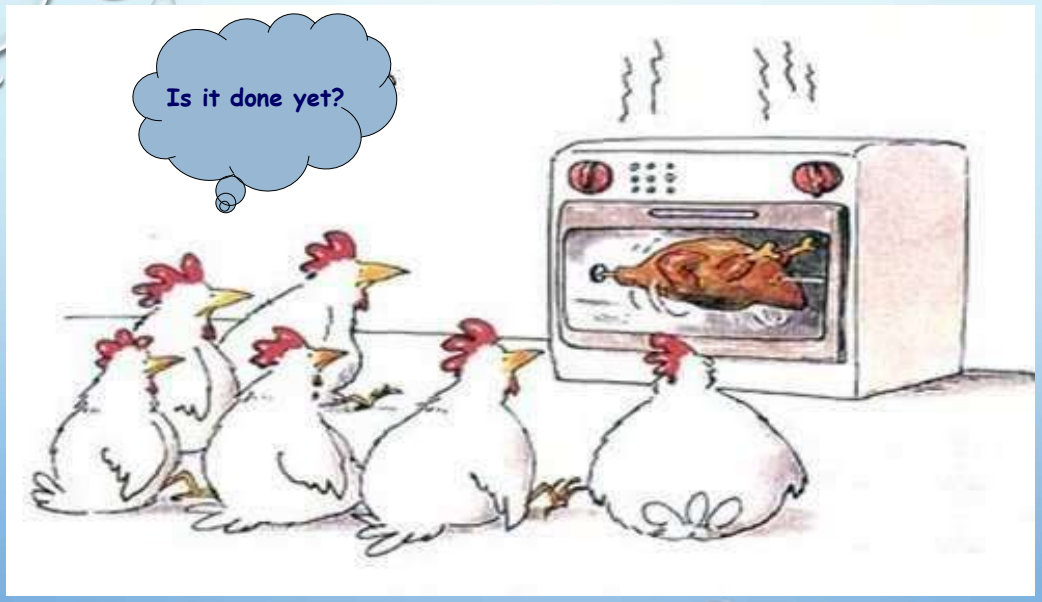
66

LEARNING OBJECTIVE 3

DISCUSS THE IMPORTANCE OF QUALITY AS IT RELATES TO THE STERILE PROCESSING DEPARTMENT

67

67



68

68

QUALITY CONTROL

- QC IS CRITICAL TO SUCCESSFUL PROCESSING AND IMPROVE PERFORMANCE
- ALL FACILITIES SHOULD HAVE A COMPREHENSIVE QC PROGRAM
  - PRODUCT IDENTIFICATION AND TRACEABILITY TO THE PATIENT (EACH ITEM, PACKAGE LABELED WITH DETAILED CONTENT LIST; IMPLANTS CRITICAL)
  - DOCUMENTATION AND RECORD-KEEPING (EPIDEMIOLOGICAL TRACKING AND ASSESSMENT OF RELIABILITY)
  - VERIFICATION AND MONITORING OF THE CLEANING PROCESS (DEVICES AND EQUIPMENT)
  - MONITORING OF HIGH-LEVEL DISINFECTION AND STERILIZATION PROCESSES
  - PRODUCT RECALLS
  - QUALITY PROCESS IMPROVEMENT

69

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69

QUALITY CONTROL

- VERIFICATION TESTING SHOULD BE PERFORMED ON ALL MECHANICAL CLEANING EQUIPMENT EACH DAY AS PART OF THE OVERALL QUALITY ASSURANCE PROGRAM
  - TESTED EACH DAY IT IS USED AND RECORD RESULTS
  - REQUEST TEST PROCEDURES FROM DEVICE MANUFACTURERS THAT CAN BE EASILY REPLICATED AND THAT CAN ASSIST USERS IN RECOGNIZING WHETHER CLEANING WAS EFFECTIVE FOR ALL DEVICE AREAS
  - METHODS OF VERIFICATION INCLUDE:
  - ✓ DIRECTLY TESTING INDIVIDUAL INSTRUMENTS FOR RESIDUAL SOILS (E.G., ADENOSINE TRIPHOSPHATE [ATP], PROTEIN, HEMOGLOBIN);
  - ✓ EMPLOYING A TEST DEVICE THAT IS A CONSISTENT AND REPEATABLE CHALLENGE TO THE CLEANING EFFECTIVENESS OF THE EQUIPMENT; AND
  - ✓ MONITORING CRITICAL PARAMETERS TO EVALUATE THE PERFORMANCE OF THE MECHANICAL CLEANING EQUIPMENT
- IMPORTANT FOR DEVICES WITH COMPONENTS THAT CANNOT BE READILY INSPECTED FOR CLEANLINESS (E.G., SPRING HINGES, LUMENS, POROUS MATERIAL, CREVICES)
  - VISUAL INSPECTION
  - HAND-HELD MAGNIFICATION
  - LIGHTED MAGNIFICATION
  - TABLETOP/SWIVEL ARM MAGNIFICATION
  - USB/COMPUTER SUPPORTED MAGNIFICATION
  - BORESCOPE FOR LUMENED DEVICES/INSTRUMENTS

70

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70

MONITORING WASHER-DISINFECTOR

71

MONITORING ULTRASONIC CLEANERS

Ultrasonic cleaning equipment should be cleaned every day that it is used according to the manufacturer's written IFU.

In addition to following the manufacturer's written IFU, the following actions should be taken:

- Request performance verification test methods from the ultrasonic equipment manufacturer.
- Perform cavitation testing daily whenever the equipment is in use.
- Prior to using it, degas the solution in accordance with the ultrasonic equipment manufacturer's IFU.
- Avoid placing plastics and soft metal (e.g., lead hands) in the ultrasonic cleaner.
- Keep the lid closed when the ultrasonic cleaner is in use unless otherwise directed by the device manufacturer's written IFU.

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72

72

QUALITY CONTROL

- STERILIZATION PROCESS MONITORING
  - MONITORING OF EVERY PACKAGE AND STERILIZATION LOAD
  - ROUTINE MONITORING OF STERILIZER EFFICACY
  - QUALIFICATION TESTING OF THE STERILIZER AFTER INSTALLATION, RELOCATION, STERILIZER MALFUNCTION, MAJOR REPAIRS, AND STERILIZATION PROCESS FAILURES
  - PERIODIC PRODUCT QUALITY ASSURANCE TESTING

73

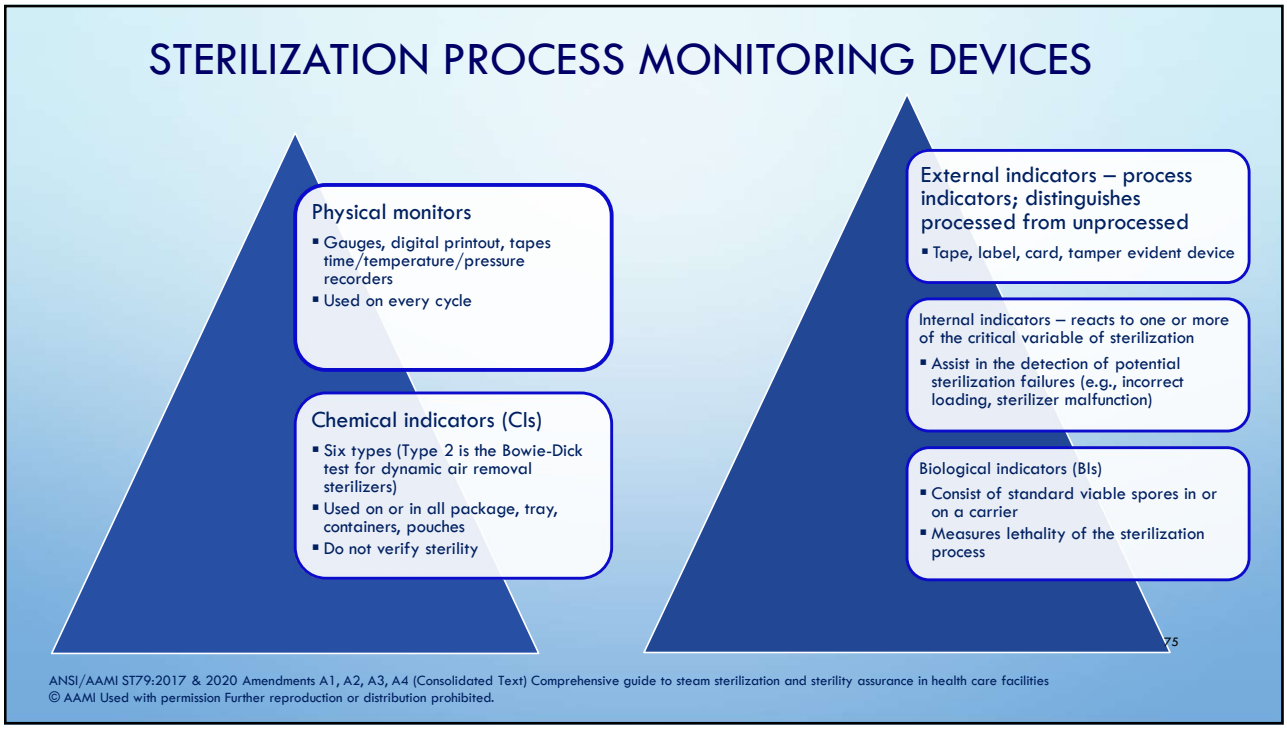
73

REASONS FOR MONITORING THE STERILIZATION PROCESS

- ✓ENSURE PROBABILITY OF STERILITY OF PROCESSED MEDICAL DEVICES
- ✓DETECT STERILIZATION FAILURE ASAP: QUARANTINE MEDICAL DEVICES UNTIL FINAL BI RESULT KNOWN
- ✓VERIFY A CORRECTED FAILURE ASAP…… GET STERILIZER BACK INTO SERVICE
- ✓CONTROL COSTS
- ✓REMOVE MEDICAL DEVICES INVOLVED IN FAILURES BEFORE PATIENT USE
- ✓HELPS DETERMINE IF EVENTS DURING STERILIZATION PROCESS MET PARAMETERS
- ✓PROVIDES VERIFICATION OF ADHERENCE TO POLICIES/PROCEDURES
- ✓PROMOTE PATIENT SAFETY AND IMPROVE OUTCOMES

74

74


STERILIZATION PROCESS MONITORING DEVICES
Physical monitors
Gauges, digital printout, tapes time/temperature/pressure recorders
Used on every cycle
Chemical indicators (CIs)
Six types (Type 2 is the Bowie-Dick test for dynamic air removal sterilizers)
Used on or in all package, tray, containers, pouches
Do not verify sterility
External indicators – process indicators; distinguishes processed from unprocessed
Tape, label, card, tamper evident device
Internal indicators – reacts to one or more of the critical variable of sterilization
Assist in the detection of potential sterilization failures (e.g., incorrect loading, sterilizer malfunction)
Biological indicators (BIs)
Consist of standard viable spores in or on a carrier
Measures lethality of the sterilization process
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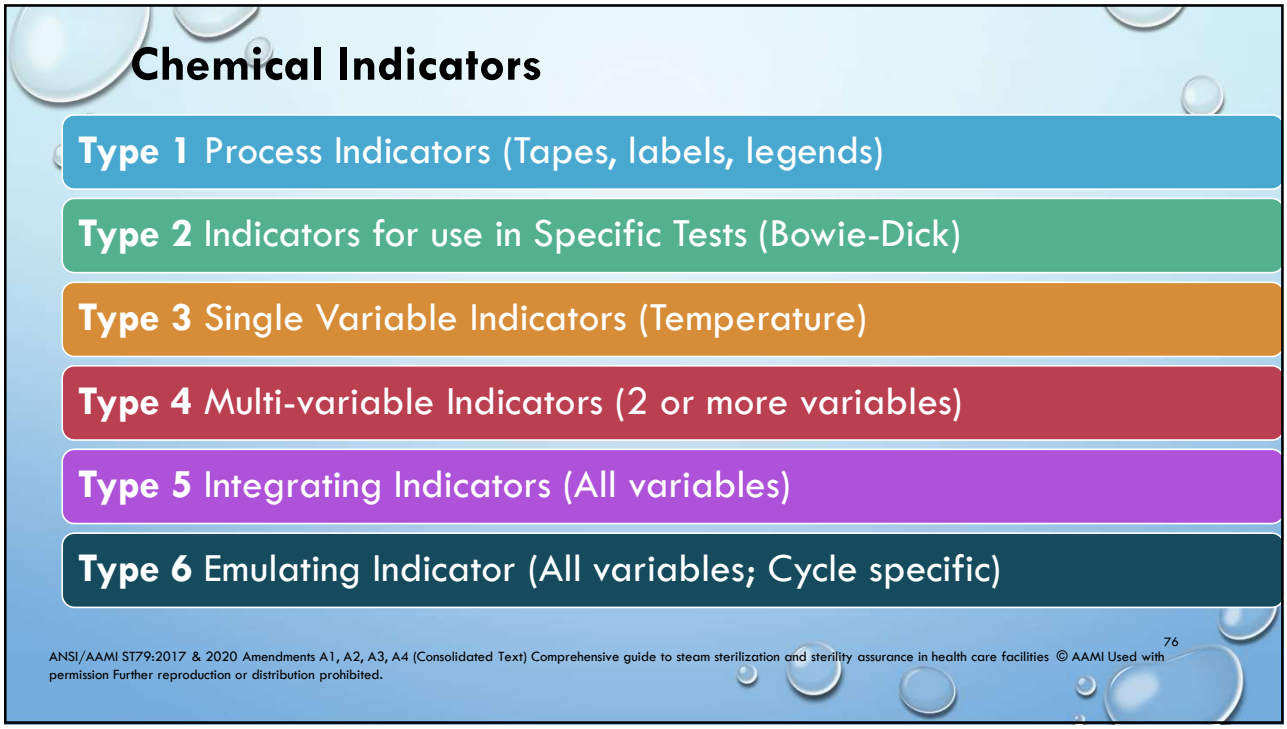
Chemical Indicators
Type 1 Process Indicators (Tapes, labels, legends)
Type 2 Indicators for use in Specific Tests (Bowie-Dick)
Type 3 Single Variable Indicators (Temperature)
Type 4 Multi-variable Indicators (2 or more variables)
Type 5 Integrating Indicators (All variables)
Type 6 Emulating Indicator (All variables; Cycle specific)
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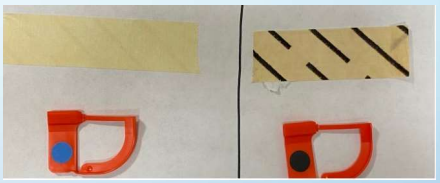
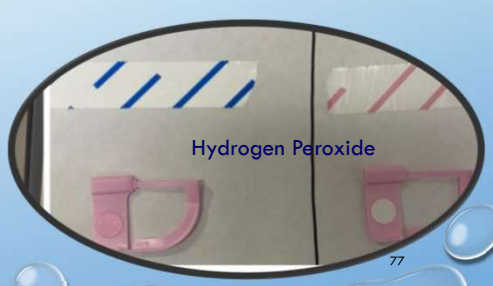
TYPE 1 PROCESS INDICATOR





77

77

TYPE 2: INDICATORS FOR SPECIFIC TESTS

- EQUIPMENT CONTROL
- TESTING STERILIZER PERFORMANCE
  - BOWIE-DICK TEST MONITORS EFFICACY OF AIR REMOVAL AND STEAM PENETRATION IN 132-135ºC (270-275°F) DYNAMIC-AIR REMOVAL STERILIZERS (I.E., VACUUM ASSISTED STERILIZERS)
    - UNIFORM COLOR CHANGE – USE
    - NOT UNIFORM COLOR CHANGE – RETEST
    - IF NOT UNIFORM, SHUT DOWN AND CALL REPAIR PERSON
    - RE-QUALIFY IF MAJOR REPAIR

78

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78

TYPE 4 AND TYPE 5 CHEMICAL INDICATOR

Type 5 Integrating Indicators (All Variables)

Before **After**

Steam Chemical Indicator

Type 4 Multivariable Indicators (2 or more)

Before **After**

Hydrogen Peroxide Chemical Indicator

79

79

BIOLOGICAL INDICATOR MONITORING

BIOLOGICAL INDICATORS (BACTERIAL SPORES) PROVIDE THE ONLY DIRECT MEASURE OF THE LETHALITY OF THE STERILIZATION PROCESS.

80

80

CDC GUIDELINES

GUIDELINE FOR DISINFECTION AND STERILIZATION IN HEALTHCARE FACILITIES, 2008

- *"BIOLOGICAL INDICATORS ARE RECOGNIZED BY MOST AUTHORITIES AS BEING **CLOSEST TO THE IDEAL MONITORS OF THE STERILIZATION PROCESS BECAUSE THEY MEASURE THE STERILIZATION PROCESS DIRECTLY BY USING THE MOST RESISTANT ORGANISMS (I.E., BACILLUS SPORES)** AND NOT BY MERELY TESTING THE PHYSICAL AND CHEMICAL CONDITIONS NECESSARY FOR STERILIZATION."*

Ref: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf , page 76 Updated May 2019

81

81

STERILIZATION ASSURANCE

- PROBABILITY
- ASSURANCE LEVEL OF 10^{-6}
- INDIVIDUAL STERILIZATION MONITORS DOES NOT INDICATE STERILITY
- NEED THE COMBINATION OF ALL MONITORS TO GIVE AN ASSURANCE OF STERILITY

Physical + Chemical + Biological = Probability of sterility (1 in a million chance that an item is not sterile)

82

82

ROUTINE STERILIZER EFFICACY MONITORING

- BIOLOGICAL INDICATOR
  - STEAM/VH2O2 – *GEOBACILLUS STEAROTHERMOPHILUS*
  - *EO – BACILLUS ATROPHAEUS*
  - USED WITHIN A PROCESS CHALLENGE DEVICE
- PROCESS CHALLENGE DEVICE (PCD)
  - DESIGNED TO SIMULATE THE PRODUCT TO BE STERILIZED
  - MAY CONTAIN BI AND/OR CI (TYPE 5 OR TYPE 6)
  - CONSTITUTES A DEFINED RESISTANCE TO A STERILIZATION PROCESS AND USED TO ASSESS EFFECTIVE PERFORMANCE OF THE PROCESS
  - PLACED IN THE MOST CHALLENGING AREA IN THE STERILIZER FOR STERILANT PENETRATION
  - COMMERCIALLY AVAILABLE, DISPOSABLE, PREASSEMBLED CHALLENGE PACK
  - USER-ASSEMBLED CHALLENGE TEST PACK OR TEST TRAY
- BD PCD FOR DYNAMIC AIR REMOVAL STERILIZER
  - DAILY
- ROUTINE LOAD RELEASE OF NON-IMPLANTABLE DEVICES
  - PCD CONTAINING BI; OR PCD CONTAINING BI AND TYPE 5 CI; OR PCD CONTAINING TYPE 5 OR TYPE 6 CI
  - STEAM STERILIZER TESTED WEEKLY, PREFERABLY EVERY DAY THE STERILIZER IS USED.
  - VH2O2 STERILIZERS – EACH CYCLE TYPE TESTED AT LEAST DAILY, PREFERABLY EVERY LOAD
  - EO STERILIZATION – EVERY LOAD
- ROUTINE LOAD RELEASE OF IMPLANTABLE DEVICES
  - PCD CONTAINING A BI AND TYPE 5 CI IN EVERY LOAD
  - LOAD NOT RELEASED UNTIL THE RESULTS OF THE BI IS KNOWN

83

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83

ROUTINE STERILIZER EFFICACY MONITORING

- IMMEDIATE USE STEAM STERILIZER (IUSS)
  - BI PCD REPRESENTATIVE OF TRAY ROUTINELY PROCESSED
  - EACH TYPE OF TRAY CONFIGURATION IN ROUTINE USE SHOULD BE TESTED SEPARATELY
    - PERFORATED, MESH BOTTOM, OPEN SURGICAL TRAY
    - RIGID STERILIZATION CONTAINER SYSTEM
    - PROTECTIVE ORGANIZING CASE
    - SINGLE-WRAPPED SURGICAL TRAY
    - EMPTY LOAD ON BOTTOM SHELF OVER DRAIN
  - BD PCD IF DYNAMIC-AIR-REMOVAL
    - DAILY
- TABLE-TOP STERILIZERS
  - BI PCD REPRESENTATIVE OF PACKAGE OR TRAY ROUTINELY PROCESSED AND MOST DIFFICULT TO STERILIZE
  - BI PCD SHOULD CONTAIN ITEMS NORMALLY PRESENT DURING ROUTINE STERILIZATION
  - FULL LOAD IN COLD POINT (CHECK WITH STERILIZER MANUFACTURER)

84

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84

OTHER REQUIRED TESTING

- TESTING SHOULD BE PERFORMED
  - AT THE TIME THE STEAM STERILIZER IS INSTALLED, RELOCATED, OR REPAIRED AND THE TIME IT IS RELEASED FOR USE IN THE HEALTH CARE FACILITY.
  - FOR BOTH GRAVITY-DISPLACEMENT AND DYNAMIC-AIR-REMOVAL STERILIZERS
  - THREE CONSECUTIVE CYCLES SHOULD BE RUN, ONE RIGHT AFTER THE OTHER, WITH A PCD
- DYNAMIC-AIR REMOVAL STERILIZERS
  - THREE CONSECUTIVE CYCLES SHOULD BE RUN, ONE RIGHT AFTER THE OTHER, WITH THE BOWIE-DICK TEST PACK
  - EACH TEST RESULT DEMONSTRATING SUFFICIENT AIR REMOVAL
  - EMPTY CHAMBER SHOULD BE USED FOR THE TESTS.
- TABLE-TOP STERILIZERS
  - BI PCD REPRESENTATIVE OF PACKAGE OR TRAY ROUTINELY PROCESSED AND MOST DIFFICULT TO STERILIZE
  - BI PCD SHOULD CONTAIN ITEMS NORMALLY PRESENT DURING ROUTINE STERILIZATION
  - FULL LOAD IN COLD POINT (CHECK WITH STERILIZER MANUFACTURER)
  - THREE CONSECUTIVE CYCLES

85

85

RECORDKEEPING – STERILIZER RECORDS

- RECORDING CHART, PRINTER, TAPE SHOULD BE REVIEWED, SIGNED, AND DATED BY OPERATOR AFTER EACH CYCLE INDICATING AN ACCEPTABLE
- EACH CYCLE
  - LOAD NUMBER
  - CONTENTS OF THE LOT OR LOAD IF NOT ON STERILIZER RECORD
  - OPERATOR IDENTIFICATION
  - BI / CI/ BD TEST RESULTS, IF APPLICABLE
  - RESPONSE OF CI IN PCD IF APPLICABLE
  - ANY REPORTS OF INCONCLUSIVE OR NONRESPONSIVE CI FOUND LATER IN THE PROCESSED DEVICES
- DOCUMENT LOT NUMBERS AND RESULTS OF BIOLOGICAL INDICATOR(BI) TESTING
  - TEST BI(S) AND CONTROL BI(S), IF APPLICABLE
- RETAIN RECORDS ACCORDING TO FACILITY POLICIES BASED ON LOCAL, STATE, FEDERAL AND ACCREDITING AGENCY REQUIREMENTS

86

86

ANSI/AAMI STANDARDS – PRODUCT RECALLS

WRITTEN POLICIES AND PROCEDURES FOR THE RECALL OF ITEMS THAT HAVE BEEN PROCESSED AND ISSUED OR STORED FOR LATER USE.

- **RECALL PROCEDURE**
  - IN WRITING
  - CIRCUMSTANCE FOR ISSUING RECALL ORDER
  - INCLUDE QUARANTINE AND RETRIEVAL OF ITEMS BACK TO LAST NEGATIVE BI
  - COMMUNICATED TO THE AFFECTED DEPARTMENTS AND ACTIONS NEEDED
  - STERILIZATION OF LOT NUMBER OF ITEMS TO BE RECALLED
  - IDENTIFY PRODUCTS TO RECALL, PEOPLE/DEPARTMENTS TO NOTIFY
  - PEOPLE/PERSONS AUTHORIZED TO GIVE RECALL ORDER
  - PERSON/PEOPLE DESIGNATED AS RESPONSIBLE FOR EXECUTING THE RECALL ORDER

- **RECALL REPORT**
  - CIRCUMSTANCES THAT PROMPTED THE ORDER
  - DOCUMENTATION OF MICROBIOLOGICAL TEST RESULTS WHEN POSITIVE BI INITIATED THE RECALL
  - CORRECTIVE ACTION TAKEN TO PREVENT A RECURRENCE
  - PRODUCTS INTENDED FOR RECALL AND ACTUALLY LOCATED IN THE RECALL
  - VERIFY THAT THE RECALLED ITEMS WERE REPROCESSED OR DESTROYED, AS APPROPRIATE

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87

87

CONTINUOUS QUALITY IMPROVEMENT

- ENCOMPASSES THE ENTIRE STERILIZATION AND / OR HIGH-LEVEL DISINFECTION PROCESS
- CONDUCTING REGULAR QUALITY AUDITS/TRACERS AND THE INFECTION PREVENTION AND CONTROL RISK ASSESSMENT
  - ASSESS ALL COMPONENTS OF THE STERILIZATION PROCESS FOR THE ONGOING ABILITY TO ACHIEVE THE DESIRED OUTCOME OF CONSISTENTLY DELIVERING A STERILE PRODUCT TO THE USER
  - USE TRENDED DATA – E.G., # BI TESTS / BI FAILURES FOR EACH STERILIZER, EDUCATION COMPLIANCE (PERCENT ATTENDING OR PERCENT PASSING TESTS OR COMPETENCY MEASURES), TIME AND COMPLETENESS OF STERILIZER PREVENTIVE MAINTENANCE, ABILITY TO LOCATE ALL ITEMS DURING RECALLS, AND COMPLETENESS OF TEST RECORDS
- STAFF SHOULD UNDERSTAND DEPARTMENT GOALS AND PI ACTIVITIES
- NO SINGLE "RIGHT WAY" TO IMPLEMENT CQI
- CROSS-FUNCTIONAL TEAM APPROACH

88

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88

PRODUCT TESTING

- VERIFIES INFORMATION PROVIDED BY THE MANUFACTURER
- PERFORMED BEFORE ITEMS ARE PLACED INTO ROUTINE USE
- PLACE MULTIPLE BIs AND CIs INTO AREA OF PACKAGES DETERMINED TO BE THE GREATEST CHALLENGE
  - CORNERS
  - DIFFERENT LAYERS
  - NEXT TO THE HEAT SINK (METAL MASS)
- LABEL AS PRODUCT TESTING
- PLACE IN FULL LOAD
- RUN THE APPROPRIATE CYCLE
- DOCUMENT
- DATE TESTING PERFORMED
- NAME OF SET, TRAY OR ITEM
- PLACEMENT OF ALL BIS AND CIS (PHOTO)
- TEST RESULTS
- RESULTS DETERMINE ROUTINE PLACEMENT OF BI AND CI
- EXAMINE FOR EVIDENCE OF EXCESS MOISTURE

89

89

ANSI/AAMI ST91 Risk Analysis

Risk analysis = risk assessment + risk management + risk communication

"THE PROCESSING RISK ANALYSIS SHOULD BE PART OF THE HEALTH CARE FACILITY'S OVERALL INFECTION PREVENTION AND CONTROL RISK ANALYSIS IN ACCORDANCE WITH ACCREDITATION AGENCY REQUIREMENTS."

- RISK ASSESSMENT
  - IDENTIFYING THE SOURCE OF THE FAILURE; ESTIMATING THE LIKELIHOOD OF FAILURE OCCURRING, ASSESSING THE CONSEQUENCES OF IF FAILURE OCCURS; AND PREPAREDNESS TO MANAGE THE FAILURE.
- RISK MANAGEMENT
  - INCLUDES DETERMINING WHICH OF THE FAILURES IDENTIFIED IN THE RISK ASSESSMENT PROCESS REQUIRE MANAGEMENT AND SELECTING AND IMPLEMENTING PLANS AND CORRECTIVE ACTION.
- RISK COMMUNICATION
  - INCLUDE AN INTERACTIVE DIALOGUE BETWEEN SPD, USER AREAS, INFECTION PREVENTIONIST AND RISK MANAGEMENT PERSONNEL.

"IT SHOULD BE PERFORMED AT LEAST ANNUALLY AND SHOULD BE RE-EVALUATED WHENEVER SIGNIFICANT CHANGES OCCUR."

90

90

SUMMARY

- BE FAMILIAR WITH THE REGULATORY, STANDARDS, GUIDELINES, RECOMMENDED BEST PRACTICES TO BE ABLE TO SPEAK TO COMPLIANCE
- ACCREDITATION AGENCIES AND CMS CONDITIONS OF PARTICIPATION EXPECTS THAT PATIENT WILL BE TREATED WITH INSTRUMENTS AND DEVICES THAT MEET STANDARDS AND GUIDELINES FOR SAFE PATIENT CARE
- STAFF ARE TRAINED AND COMPETENCY DOCUMENTED TO PERFORM STERILIZATION / HIGH-LEVEL DISINFECTION
- POLICIES AND PROCEDURES ARE UP TO DATE, BASED ON THE MOST RECENT STANDARDS / GUIDELINES AND APPROPRIATELY REFERENCED
- MANUFACTURERS INSTRUCTIONS SHOULD BE UP TO DATE AND FOLLOWED CONSISTENTLY TO ENSURE POSITIVE OUTCOMES
- QUALITY CONTROL INCLUDES MONITORING OF THE STERILIZATION AND HIGH-LEVEL DISINFECTION PROCESSES AND ARE NECESSARY TO BE ASSURED STERILITY OF INSTRUMENTS AND DEVICES
- PAY CLOSE ATTENTION TO STORAGE, DISTRIBUTION AND TRANSPORT OF STERILIZED ITEMS
- CONTINUOUS QUALITY IMPROVEMENT PROCESS SHOULD BE IN PLACE ADDRESSING ALL STEPS IN THE STERILIZATION PROCESS
- CONDUCT ONGOING TRACERS / AUDITS / ASSESSMENTS AND RISK ASSESSMENT TO ENSURE EXPECTED OUTCOMES

91

91

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92

92

93