SEAVEY HEALTHCARE CONSULTING®

STERILE PROCESSING SURGICAL SERVICES

303-467-0868 office/fax

www.seaveyhealthcareconsulting.com

Established in 2003

Sterile Processing Best Practices Audit Check Sheet

INTRODUCTION

Sterile Processing plays a major role in patient safety and its importance cannot be overestimated. This role takes knowledgeable, responsible people and a workplace that facilitates effective and efficient processing to properly perform these tasks. Thus, it is essential that Perioperative Nurses, Infection Preventionists (IP) and Risk Management understand and support the roles and responsibilities of SPD for the sake of safe patient care.

Clinical practices and infection control guidelines continue to be developed as we gain understanding of the risk factors and strategies for prevention of infections. Technology is changing the way procedures are performed as well as how instruments, equipment, and supplies are reprocessed. Current published professional recommendations for cleaning, disinfecting, sterilizing, sterile storage, environmental cleaning, and facility design, and personnel considerations should be strictly followed with adherence to policies and procedures closely monitored.

The efficacy of any sterilization process depends on four phases:

- a consistent system for lowering and limiting bioburden before sterilization,
- properly preparing items for sterilization,
- selecting the appropriate sterilization parameters, and
- establishing and implementing controls to maintain the sterility of sterilized items until they are used.

These steps are critically interdependent, and each must be accomplished effectively and efficiently to produce and maintain a sterile product.

The delivery of sterile healthcare products for use in patient care depends not only on the efficacy of the sterilization process itself but also on the following five factors:

a) efficient facility design,
b) proper training of personnel,
c) good infection prevention and control practices designed to prevent health-care-associated infections,
d) effective quality controls and process improvement systems that encompass all aspects of device reprocessing from point of use through sterilization to reuse, and
e) appropriate documentation and reporting practices that enable traceability to the patient.

PERFORMING AUDITS

Critical aspects of infection prevention include proper reprocessing procedures and sterility maintenance. Facilities should perform routine audits for all reprocessing and sterilization areas. These audits should be conducted by the reprocessing manager and the IP.

The following is a list of important issues to monitor based on ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilites. Some monitoring issues are based on AORN guidelines.

SEAVEY HEALTHCARE CONSULTING®
STERILE PROCESSING SURGICAL SERVICES .
303-467-0868 office/fax
www.seaveyhealtcareconsulting.com
Established in 2003

Sterile Processing Best Practices Audit Tool

Rose Seavey MBA, BS, RN, CNOR, CRCST, CSPDT

Date:	**Multidisciplinary audit conducted by:**
References	* ANSI/AAMI ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* AORN *Guideline for environmental cleaning*. In: AORN Guidelines for periOperative Practice, 2017. AORN Guideline for Surgical Attire. In: AORN *Guidelines for periOperative Practice*, 2017. ANSI/ASHRAE/ASHE Standard 170-2013, *Ventilation of health care facilities.*
Design Considerations Section 3*	□ Workflow dirty to clean – physical separation by walls or partitions ○ Traffic control – policy and procedure, signs posted, red lines ○ SPD restricted to authorized personnel only ○ External shipping containers and web-edged corrugated cardboard boxes removed before items are brought to clean areas ▪ Break out area/room (3.3.6.5) □ Space proportioned to expected volume □ Instrument air with valve; vacuum system; and source of critical water for final rinse □ Steam quality, purity and quantity routinely monitored □ Equipment maintenance records maintained and readily available □ All surfaces (e.g., floors, walls, ceilings, cabinets) are durable, smooth, and cleanable. □ Ceilings flush surface, no shedding materials with recessed and enclosed fixtures □ Doors and windows (pass throughs) kept closed □ Compliance with ASHRAE 170 (the health care facility should identify which version of ASHRAE170 will be used based on when the HVAC system was initially installed or last upgraded). □ Adequate lighting in all areas– lighted magnifier □ Hand washing station (sinks and waterless alcohol-based hand rub dispensers) conveniently located in clean and decontamination areas ○ Not in decontam sink □ Appropriate storage of PPE and cleaning supplies, □ Ergonomic factors adjustable work stations and sinks, adjustable chairs, stools □ Three sinks of 36 inches wide x 8-10 inches deep; sufficient counterpace attached □ Instrument air with valve adjustment available □ Eye wash stations located within 10 seconds travel time – 15 minute flush; tepid water □ Source of critical water for final rinsing □ Critical water for all final rinse and creation of steam □ Housekeeping procedures

	○ All areas cleaned daily (should be the same as in OR) (AORN Guideline for Environmental Cleaning) ○ Clean work areas are cleaned before dirty work areas (AORN Guideline for Environmental Cleaning)
Personnel considerations Section 4*	□ Supervisors/Managers ○ Prepared for this responsibility by education, training, and experience. ○ Minimum recommended qualifications ▪ Certification in Sterile Processing Management ▪ Participate in continuing education programs and courses ▪ Demonstration of current knowledge of pertinent state and federal regulations, such as OSHA blood-borne pathogen exposure control plan to include engineering and work-practice controls ▪ Comprehensive knowledge of pertinent state and federal regulations, such as OSHA blood borne pathogens exposure control plan to include engineering and work-practice controls ○ Actively participate in committees such as: ▪ Infection Prevention and Control ▪ Risk management ▪ Hazardous materials ▪ Quality improvement ▪ Safety ▪ Product Evaluation and standardization □ Staff ○ Certification within 2 years of hire ○ Orientation and education performed and documented ○ Demonstrated knowledge of and documented competence verified by a subject matter expert ○ Continuing education at regular intervals ○ Training for all new instrumentation, devices, and equipment. □ Training manual with documented competencies for all staff □ Consistently adhering to dress code ○ Clean surgical attire provided by and donned at the facility ○ All head and facial hair covered (except for eyebrows and eyelashes) ○ No jewelry on hands or wrists ○ Arms and ears covered when assembling items (AORN Guideline for Surgical Attire) □ Manufacturers' written instructions for use (IFU) available and followed ○ Devices ○ Chemicals ○ Equipment □ Appropriate PPE available and routinely used ○ Heavy duty/longer utility gloves fitted at the wrists ○ Liquid-resistant coverings with sleeves ○ Liquid-resistant shoe covers if potential for exposure ○ Fluid- resistant face mask ○ Eye protection ○ Hands are washed after removing PPE

Receiving , Section 5*	□ Formalized program and policy for loaned or borrowed instruments □ Items removed from external shipping containers (Breakout area) □ Newly purchased and repaired items decontaminated before use □ Disposable items □ Disposition of sterile items issued but not used □ Manufacturers' written instructions for use (IFU) available and followed o Equipment o Instruments o Chemicals
Handling, collection, and transport of contaminated items **Section 6***	□ Separate waste and sharps at point of use □ Throughout surgical or invasive procedure: o Wipe instruments with sterile moistened sponge to remove gross soil o Irrigate lumens with sterile water □ After pre-cleaning at point of use o Place instruments into respective containers o Identify instruments needing repair o Protect delicate instruments o Segregate reusable sharp instruments o Place heavy instrument on bottom □ OSHA requirements o Transport devices be marked with a biohazard label, a red bag, or other means of identifying contamination o Puncture-resistant, leak-proof on the sides and bottom, closable, and labeled o Items not transported in liquid □ Transport between buildings and off-site (6.5.6, 6.5.7)
Cleaning, disinfection (microbicidal processes) and other decontamination steps Section 7*	□ Manufacturers' written instructions for use (IFU) available and followed □ Appropriate cleaning and decontamination solutions o Dilution – measuring cups, lines or dispensing units for accurate measuring or dosers used o Expiration dates o Solution containers labeled □ Presoaking □ Disassembly of multiple part instruments and rigid containers □ Sharps and delicates separate □ No use of saline on instruments □ Cleaning happens as soon as possible (point of use) □ Instruments kept moist until they are cleaned □ Not cleaned in hand sinks or scrub sinks □ Brushing occurs under water - □ Brushes appropriate sized and disposable or decontaminated at least daily □ Nonlinting cloths or sponges used □ Water quality meets manufacturers requirements o Critical water for final rinse □ Disinfectant concentration is tested per manufacturer's recommendations □ Cleaning verification tools routinely used

	○ Mechanical equipment ○ Manual cleaning □ Brushes disposable or frequently cleaned and disinfected □ Mechanical cleaning equipment loaded per IFU
Preparation, and assembly of instruments Section 8*	□ Follows IFU for placement □ Instrument set weights not over 25 pounds - scale available □ Ratcheted instrument unlatched □ Instruments are in good condition □ Stylets and plugs removed from lumens □ Manufacturers' written IFU for assembly followed □ Multipart instruments disassembled for sterilization, unless IFU indicates otherwise □ Instrument tape (if used) is in good condition (competencies on application) □ Sharps protected with validated tip protectors □ Tray liners designed and intended for sterilization □ Any single use devices reprocessed (needs to be FDA cleared) □ Instrument tracking system available
Packaging Section 9*	□ Labeling before sterilization with non-toxic ink □ Label on non porous side of pouch or indicator tape or patient record cards □ Peel packs proper size/type ○ No double peel packs unless validated by manufacture ▪ Not folded □ Internal and external chemical indicators (CI) used for all packages ○ Geometric center of wrapped packages ○ Rigid containers – follow manufacturers IFU
Sterilization Section 10*	□ Loading the sterilizer ○ Peel packs and lighter items on top shelf ○ Peel packs and linen packs are set on edge (not horizontal) ○ No stacking of pans (without manufactures' recommendations) □ Peel pouches and textile packs stand on edge □ Current manufacture IFU for sterilization parameters readily available and followed □ Use of dynamic-air-removal cycle unless IFU indicates gravity-displacement only □ Unloading sterilizer - all items are cool to room temperature before handling ○ Load released and signed by qualified person ○ Infrared temperature guns available □ IUSS practices ○ Not used for convenience or a substitute for sufficient inventory ○ Items are appropriately cleaned per IFU ○ Use of rigid sterilization container system ○ Used immediately and not stored for later use ○ Identified as IUSS ○ BI and Type 5 CI run with all implants ▪ Not released until results of BI are available □ A sterilizer cart or carriage and/or validated transport tray should be used □ After cooling and prior to load release, all sterile packs are inspected for:

	○ Holes, package integrity or presence moisture
Storage and transportation Section 11*	□ Storage conditions ○ Cleanable surfaces ○ Bottom shelves are solid and 8-10 inches above the floor ○ 18 inches below the ceiling (or level of sprinkler head) ○ 2 inches for outside walls □ Closed or covered cabinets – especially in high traffic areas □ Sterile items not stored on floors or windowsills □ Sterile items separate from clean items □ No external or web-edged shipping containers □ Avoid dragging, sliding, crushing or puncturing packages □ Shelf life/event related – stock rotation in place – labeled correctly □ Dedicated lifts - maintained □ Off-site transportation (11.3.5)
Instillation, care, and maintenance of sterilizers Section 12*	□ Instruction manuals readily available □ Sterilizers inspected and cleaned daily according to manufacturers' IFU □ Preventative maintenance and repair records readily available □ Maintenance and repair records readily available (electronic or paper) □ Maintenance performed by a qualified service provider □ Controls, indicators, and recording devices periodically calibrated as specified in manufacturers' IFU
Process monitoring, testing and quality control Section 13*	□ Monitoring of mechanical cleaning equipment ○ Tested upon installation, weekly (preferable daily) and after major repair ○ Product identification and traceability to patient ○ Package labeling and expiration dating – lot control □ Sterilizer process monitoring ○ Every package and sterilization load ▪ Correct PCD used for each load ○ Routine monitoring of sterilizer efficacy ○ Qualification testing ○ Periodic product quality assurance testing ○ Bowie Dick test daily ○ Each sterile product labeled with a lot control identifier ▪ Sterilizer identification ▪ Type of sterilizer and cycle used ▪ Lot control number ▪ Load contents, specifics in order to trace to patient ○ Sterilization records for each cycle complete ○ Product identification and traceability to the patient □ Sterilization monitors ○ BI – at least weekly/daily – best practice, every load ○ BI - run in every load for ethylene oxide, hydrogen peroxide, or ozone ○ Same lot number for control and the processed BI – both documented

	□ Sterilization records storage follows the facilities record retention policy
	□ Implants
	  ○ monitored with a biological indicator (BI) and a type 5 CI
	  ○ not released until results of BI available
	  ○ Traceable to the patient
	  ○ Critical parameters for specific sterilization method
	  ○ Operator's name, and
	  ○ Results of the sterilization process monitors (physical, CI, BI)
	□ Sterilization process failures (Figure 10 Decision Tree - ST79)
	□ Potential causes for sterilization process failures (Table 4 ST79)
	□ Recall process in place and reported to Infection Prevention and Control

Quality process improvement
 	
Section 14*
	□ Performance measures and process monitors
	□ Quality system model
	□ Risk analysis completed for all aspects of sterilization to identify risks (CQI program)
	  ○ CMS, state and local requirements followed
	  ○ Performed at least annually
	  ○ Re-evaluated with significant changes
	□ Sterilization procedures based on current standards
	  ○ Performance measures for problem investigation
	  ○ Planned, systematic and ongoing process for verifying compliance
	  ○ Audits conducted on a regular basis
	  ▪ Decontam practices
	  ▪ Personnel competencies
	  ▪ Handling contaminated items
	  ▪ Packaging
	  ▪ Labeling
	  ▪ Sterilization
	  ▪ Repair records
	□ Risk analysis routine preformed – multidisciplinary
	  ○ Part of facilities overall infection prevention and control risk analysis
	□ Monitoring and documentation of cleaning verification
	  ○ Both mechanical and manual cleaning (See Annex D)
	□ CQI program
	  ○ Assess all components of reprocessing
	  ○ Consistency and standardization across the facility
	  ○ Employee involvement

New product evaluation Section 15*	□ Sterile processing is part of the multidisciplinary product evaluation committee □ Manufacturer's IFU for reusable devices are reviewed prior to purchase to ensure it can be properly reprocessed at the facility □ Multidisciplinary committee representation from all affected by new product

Policies and procedures	□ Policies are updated according to current best practices
	□ All sterilization and reprocessing policies and procedures readily available for staff
	  ○ Dress code followed (no artificial nails or polish)
	  ○ Care and handling of instruments and powered equipment
	  ○ Packaging systems - selection and use

	○ Sterilization recall ○ Sterile storage ○ Chemical disinfectant (including high-level disinfecting) ○ Shelf Life (event related) ○ Preventive Maintenance for equipment ○ Steam shutdown ○ Sterilization - steam and low temp ○ High-level disinfection ○ Endoscopes – cleaning and processing ○ Environmental cleaning ○ Creutzfeldt-Jakob disease (CJD) ○ Toxic Anterior Segment Syndrome (TASS) ○ Management of Loaner Instrumentation ○ Single Use Devices □ Up-to-date and referenced □ Followed and monitored
Comments	