SEAVEY HEALTHCARE CONSULTING®
STERILE PROCESSING SURGICAL SERVICES
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Established in 2003

Sterile Processing Best Practices Audit Check Sheet

INTRODUCTION

The 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. 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 standards and recommendations from The Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Nurses (AORN) and the Centers for Disease Control (CDC).

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Sterile Processing Best Practices Audit Tool

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Date:	**Audit conducted by:**
Reference	* AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012
Design Considerations Section 3*	□ Workflow dirty to clean – physical separation by walls or partitions ○ Traffic control – policy and procedure, signs posted, red lines ○ Restricted to authorized personnel only ○ Cardboard boxes removed before items are brought to clean areas □ Space proportioned to expected volume □ Compressed air, nitrogen, vacuum system and source of distilled or DI water □ Steam quality, purity and quantity - monitored □ Equipment maintenance records maintained □ Floors and walls level and can withstand frequent cleaning □ Ceilings flush surface, no shedding materials with recessed and enclosed pipes □ Doors and windows (pass throughs) kept closed □ Ventilation ○ Soiled area, negative - 10 air exchanges per hour ○ Clean/sterile area, positive - 10 air exchanges per hour □ Temperature and humidity levels monitored and recorded daily, ○ Temperature ▪ 68-73^0 F clean areas ▪ 60-65^0 F decontamination areas ○ Humidity ▪ 30-60% in work areas ▪ Not over 70% in sterile storage areas □ Adequate lighting □ Hand hygiene facilities conveniently located in clean and decontamination areas □ Appropriate storage of PPE and cleaning supplies, □ Ergonomic factors adjustable work stations and sinks, adjustable chairs, stools □ Three sinks of 36 X 8-10” deep – sufficient counterpace □ Eye wash stations located within 10 seconds travel time – 15 minute flush, tepid water □ Water quality matches manufactures recommendations □ Distilled, deionized or reverse osmosis water use for final rinse on instruments □ Housekeeping procedures ○ All areas cleaned daily (should be the same as in OR)

	○ Separate cleaning equipment for decontamination
Personnel considerations Section 4*	□ Supervisors ○ Certified in Sterile Processing Management ○ Demonstrate comprehensive understanding of ▪ Relevant state and federal regulations ▪ Occupational Safety and Health Administration (OSHA) blood borne pathogens exposure control plan ▪ Engineering and work-practice controls ○ Actively participate in committees such as: ▪ Infection Prevention and Control ▪ Quality improvement (sterilization reports sent to IP) ▪ Safety, and ▪ Product Evaluation and standardization □ Staff certified within 2 years □ Orientation and education performed and documented ○ Demonstrated knowledge of and documented competence ○ 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 ○ Facility laundered scrub attire donned at hospital ○ All facial hair covered (except for eyebrows) □ Manufacturers' written instructions for use (IFU) available and followed ○ Devices ○ Chemicals ○ Sterilizers □ Appropriate PPE available and routinely used ○ Heavy duty/longer gloves ○ Fluid resistant face mask ○ Hands are washed after removing PPE
Receiving , handling, collection, and transport of contaminated items. Section 5 and 6*	□ Policy and procedure for loaners □ Items removed from External shipping containers □ Newly purchased and repaired items decontaminated before use □ Manufacturers' written instructions for use (IFU) available and followed ○ Equipment ○ Instruments ○ Chemicals □ Separation of waste and reusable items at point of use □ Sharps segregated inside the container □ Soiled items immediately contained and transported ○ Containers, devices or carts marked as biohazard ○ Items not transported in liquid
Cleaning and	□ Manufacturers' written instructions for use (IFU) available and followed

other decontamination processes
 	
Section 7*
	□ Appropriate cleaning and decontamination solutions
	  ○ Dilution – measuring cups, lines or dispensing units for acurate measuring
	  ○ Expiration dates
	  ○ 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
	□ Water quality meets manufacturers requirements
	□ Disinfectant concentration is tested per manufacturer's recommendations

Packaging, preparation, and sterilization
 	
Section 8*
	□ Correct selection and use of packaging materials and their accessories
	□ Labeling on indicator tape, patient record cards or plastic side of peel packs
	□ Instrument set weights not over 25 pounds - scale available
	□ 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
	  ○ On all levels
	□ 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 refurbishing plan
	□ Instrument tape (if used) is in good condition
	□ Tip protectors are validated for use
	□ Any single use devices reprocessed (needs to be FDA cleared)
	□ Instrument tracking system available
	□ 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
	  ○ Extended cycles run per manufacture's IFU
	□ Use of prevaccum unless IFU indicates gravity only

	□ Implants ○ monitored with a biological indicator (BI) and a class 5 CI ○ not released until results of BI available ○ Traceable to the patient □ Documentation for each load ○ Sterilizer identification ○ Type of sterilizer and cycle used ○ Lot control number ○ Load contents, specifics in order to trace to patient ○ Critical parameters for specific sterilization method ○ Operator's name, and ○ Results of the sterilization process monitors (physical, CI, BI) □ Sterilization Monitors ○ BI - run daily in steam ○ 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 □ Unloading sterilizer - all items are cool to room temperature before handling ○ Infrared temperature guns available □ IUSS practices ○ Items are appropriately cleaned ○ Use of closed validated flash containers ○ All parameters documented and traceable to the patient ○ Aseptic transportation to point of use ○ Implants (only in defined emergency situations) ▪ BI and Class 5 CI run with all implants ▪ Not released until results of BI are available ○ Not used as a substitute for sufficient instrument inventory □ Storage conditions ○ Cleanable surfaces ○ Bottom shelves are solid and 8-10" above the floor ○ 18" below the ceiling (or level of sprinkler head) ○ 2" for outside walls □ Sterile items separate from clean items □ Heavy wrapped trays are not stacked □ Shelf life/event related – stock rotation □ Controlled area (appropriately attired persons only) signs posted □ Handwashing facilities readily available No web-edged or corrugated boxes, or external shipping containers
Quality control Section 10*	□ Monitoring of mechanical cleaning equipment ○ Tested upon installation, weekly (preferable daily) and after major repair ○ Monitoring and verifying of cleaning process documented ○ Each sterile product labeled with a lot control identifier ○ Sterilization records for each cycle complete

	□ Sterilizer process monitoring ○ Every package and sterilization load ○ Routine monitoring of sterilizer efficacy ○ Qualification testing ○ Periodic product quality assurance testing ○ Correct PCD used for each cycle ○ Bowie Dick test daily □ Sterilization process failures (Figure 12 and Table 8 in ST79) ○ Action taken when BI, CI or physical monitor indicates failure □ Recall process in place and reported to Infection Prevention and Control
Quality process improvement Section 11*	□ Measurements of process performance ○ Ongoing process for verifying compliance ○ Audits conducted on a regular basis □ Risk Analysis ○ Part of facilities overall infection prevention and control risk analysis ○ Performed at least annually ○ When significant changes occur □ 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 12*	□ 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
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 ○ 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	