Facility: **Sterile Processing Assessment** **Date:**

CRITERIA	ANSI/AAMI	COMPLIANT			COMMENTS
	Number	Y	N	N/A	
Point of Use	**6.2-6.3**				
● Gross contaminant is removed with water					
● Instruments are sorted					
♦ Sharps removed					
♦ Instruments placed back in original container					
♦ Un-used instruments placed in bottom of basket					
♦ Towel placed on top of un-used instruments					
♦ Used instruments placed on top of towel					
● Enzymatic pre-cleaner applied to used instruments					
● Water moistened towel placed over instruments					
Soiled Transport	**6.4**				
● Soiled items are contained					
● Soiled items are transported covered					
● Transportation device is labeled e.g. Soiled/Biohazard					
Decontamination					
● Environment					
♦ Temperature - 16 - 18 deg C (60 - 65 deg F)	**3.3.6.5**				
♦ Humidity - 30% - 60%	**3.3.6.6**				
♦ Air Exchanges - 10 per hour	**3.3.6.4**				
♦ Negative Air Pressure	**3.3.6.4**				
♦ Area is clean	**3.4**				
♦ Surfaces / Cabinets are non-porous	**3.3.7.1**				
♦ Lighting is sufficient	**3.3.6.7**				
♦ Temp & Humidity is checked and documented daily	**3.3.6.5-3.3.6.6**				
♦ Staff know procedure for documenting and reporting out of range readings					
♦ Soiled and Clean areas are separated physically or procedurally	**3.3.7.1**				
♦ Handwashing sink:	**3.3.6.8**				
▪ Separate from decontamination sink					
▪ Handsfree operation					
▪ Located next to exit door					
♦ Area is secure from general traffic and labeled appropriately	**3.2.4**				
● Chemistries					
♦ Water level is sufficient to submerge 1 tray	**7.5.6**				
♦ Solutions are diluted appropriately	**7.3**				
♦ Sinks are marked					
♦ Appropriate Solutions are utilized - Manual:	**7.5.3.2**				
▪ Enzymatic for pre-cleaning					
▪ Detergent for Wash					
▪ Low foaming/sudsing					
▪ Treated water for final rinse					

CRITERIA	ANSI/AAMI	COMPLIANT			COMMENTS
	Number	Y	N	N/A	
● Process Flow					
♦ Items are pre-cleaned	**7.3**				
♦ Appropriate items are submerged and cleaned under water to prevent aerosolization	**7.6.3.2**				
♦ Appropriate brushes are available and in good condition	**7.5.6**				
♦ Reusable brushes are cleaned on a routine basis - staff can articulate how & when	**7.5.6**				
♦ Disposable brushes are not reused	**N.2.2.7**				
♦ Lumens are brushed and irrigated	**7.5.3.2**				
♦ Instruments are disassembled per manufacturer's recommendations	**7.2.2**				
♦ Containers are cleaned per manufacturer's recommendations	**7.5.9**				
♦ Manufacturer's cleaning instructions are available for all items	**7.5.6**				
● Verification of cleaning process is performed	**7.5.5**				
● Safety					
♦ Approved eyewash station is available and in working condition	**3.3.8**				
♦ If eyewash station is attached to a sink hot water is disabled					
♦ Eyewash station is tested weekly and documented					
♦ Eyewash station is located in decontamination or within 10 seconds of chemicals					
♦ Staff know what MSDS is and where to find them	**4.2.2**				
♦ All chemicals have an MSDS on file					
♦ Staff know facility procedures for:	**4.2.2**				
▪ Handwashing					
▪ Bloodborne Pathogens Exposure					
♦ Staff are wearing appropriate PPE:	**4.5.2**				
▪ Waterproof Gown with sleeves					
▪ Decontamination Gloves (not procedural)					
▪ Disposable Cap					
▪ Faceshield/Goggles					
▪ Mask					
▪ Shoe Covers					
Assembly - Prep & Pack					
● Environment					
♦ Temperature - 20 - 23 deg C (68 - 73 deg F)	**3.3.6.5**				
♦ Humidity - 30% - 60%	**3.3.6.6**				
♦ Air Exchanges - 4 per hour	**3.3.6.4**				
♦ Positive Air Pressure	**3.3.6.4**				
♦ Area is clean	**3.4**				
♦ Surfaces are non-porous and easy to clean	**3.3.7.2**				
♦ Lighting is sufficient	**3.3.6.7**				
♦ Temp & Humidity is checked and documented daily	**3.3.6.5-3.3.6.6**				
♦ Staff know procedure for documenting and reporting out of range readings					
● Work Area					

CRITERIA	ANSI/AAMI	COMPLIANT			COMMENTS
	Number	Y	N	N/A	
♦ Is clean and organized	**3.4**				
♦ Contain appropriate supplies to reduce time away from assembly area e.g.:	**3.3.7.2**				
▪ Indicators/Integrators					
▪ Tray Liners					
▪ Tip Protectors					
▪ Packaging Supplies e.g. locks/arrows, data cards, filters					
▪ Sharpness Testing Material					
● Set Assembly					
♦ There is a computer tracking system in place and is used appropriately					
♦ Set sheets are accurate, organized and easy to read					
♦ Containers/Baskets are labeled to match set sheets					
♦ All instruments are inspected for:	**8.4.3**				
▪ Sharpness					
▪ Functionality					
▪ Insulation Integrity					
▪ Cleanliness esp. lumens, bone instruments					
▪ Dryness					
♦ Instruments are disassembled/assembled per manufacturer's recommendations	**8.4.1**				
♦ Lumens are flushed with sterile or distilled water	**8.3.8**				
♦ Peel pouches are not placed in instrument sets	**8.3.4**				
♦ Indicator/Integrator is placed in challenging location and all levels of multi-level trays	**10.5.2.2.2**				
● Packaging					
♦ Containers/Baskets are inspected for:	**8.4.3**				
▪ Functionality					
▪ Cleanliness					
▪ Sharp Edges					
♦ Sets are wrapped appropriately	**8.3.1**				
♦ Filters and locks are placed appropriately	**8.3.3**				
♦ Sets are labeled appropriately - wrapped items are labeled on tape	**8.3.2**				
♦ Peel Pouches:	**8.3.4**				
▪ Are appropriate size					
▪ Are sealed appropriately					
▪ Double peel pouches are appropriate size not folded					
▪ Peel pouches are placed plastic to plastic and paper to paper					
▪ Peel pouches are correct modality					
♦ Are labeled appropriately:					
▪ Accurate descriptions					
▪ Labeled on the plastic side not paper side					
♦ Manufacturer's Instructions for Use:					
▪ Wrap/Container/Peel Pouch IFUs available	**8.2**				

CRITERIA	ANSI/AAMI	COMPLIANT			COMMENTS
	Number	Y	N	N/A	
▪ Peel Pouch validation for double peel pouching available	**8.3.4**				
● Safety					
♦ Sets adhere to AAMI recommended weight limit of 25lbs	**8.4.2**				
♦ Work Stations are at appropriate heights	**3.3.7.1**				
♦ Staff assembling manual cleaned instruments are wearing gloves					
♦ Staff inspect sets for sharps prior to reaching into the baskets	**7.4.1**				
♦ Proper body mechanics are used when lifting sets and pushing carts	**6.5.4**				
Sterilization					
● Equipment Maintenance	**9.4**				
♦ Sterilizers are clean and in working order					
♦ Sterilizers are cleaned on a routine basis per manufacturer's recommendations					
♦ Preventative maintenance is performed per manufacturer's recommendations					
♦ Preventative maintenance is documented and available for review					
♦ Daily maintenance is performed per manufacturer's recommendations e.g.:					
▪ Steam traps are removed and checked/cleaned daily					
▪ STERRAD plate is removed and replaced/cleaned daily					
▪ STERIS System 1 is wiped down daily w/alcohol					
♦ Printers are in working order for accurate cycle verification					
● Loading Sterilizer	**8.5.1**				
♦ Items w/similar sterilization parameters are placed in the same load					
♦ Sets are positioned to facilitate air removal, steam penetration and drying					
♦ Containers are placed beneath wrapped items and peel pouches	**8.5.6**				
♦ Peel Pouches are placed plastic to plastic and paper to paper	**8.5.2**				
♦ Peel Pouches are positioned on their side not flat					
♦ If liners are used they are approved for use - manufacturer's IFUs on file	**8.5.1**				
♦ Difficult to dry sets are not placed over the drain					
♦ Sets are placed flat not on their sides	**8.5.3**				
♦ Packages are checked for:	**8.3.1**				
▪ Wrap integrity and appropriate tape application					
▪ Containers have filters, locks/arrows					
♦ Load stickers/labels "Lot Control Identifier" are applied containing:	**10.3.1**				
▪ Sterilizer Number or Code					
▪ Date					
▪ Cycle Number					
▪ Expiration Date - If Event Related - "Contents sterile unles package is opened or damaged. Please check before using"					
● Sterilizer Records	**10.3.2**				
♦ Each load documentation includes:					
▪ Load or Lot Number					
▪ Specific contents including quantity, department, and specific description					

CRITERIA	ANSI/AAMI	COMPLIANT			COMMENTS
	Number	Y	N	N/A	
▪ Minimum exposure Time and Temperature or print out is attached					
▪ Name/Initials of Operator					
▪ Results of BI or Bowie Dick if applicable					
▪ Response of CI or PCD if applicable					
● Cycle Selection	**8.6.1**				
♦ Appropriate cycles are posted near sterilization equipment					
♦ All items have manufacturer's recommendations on file					
● Cycle Verification					
♦ Physical Parameters are verified at end of cycle and tape is initialed/signed	**10.3.2**				
♦ CI, BI, PCD are opened, read, and documented prior to release of load	**10.6.1**				
● Load Removal	**8.8**				
♦ Load is placed in a low traffic area					
♦ Load is placed in an area away from vents, doors, windows, drafts					
♦ Load is not touched until items are cool					
♦ Loads are not released prior to cooling - if removed they are opened for flash					
♦ Documentation procedure is in place for early release of implants					
Sterile Storage					
● Environment					
♦ Temperature - 24 - 29 deg C (75 - 85 deg F)	**8.9.2**				
♦ Humidity - Not to exceed 70%					
♦ Air Exchanges - min 4 per hour					
♦ Positive Air Pressure					
♦ Area is clean	**3.4**				
♦ Surfaces are non-porous	**3.3.7.2**				
♦ Temp & Humidity is checked and documented daily	**3.3.6.5-3.3.6.6**				
♦ Staff know procedure for documenting and reporting out of range readings					
● Shelving / Bins					
♦ 8" - 10" from floor	**8.9.2**				
♦ 18" below ceiling or sprinkler heads					
♦ 2" from outside walls					
♦ If open shelving bottom shelf has barrier or solid shelf					
♦ Shelves and bins are free of dust					
♦ Shelves / bins are labeled with locations, set and peel pouch names					
♦ Shelves are organized to facilitate quick location of sets					
♦ There is an index for set location					
● Sets					
♦ Sets are placed to protect the integrity of packaging	**8.9.2**				
♦ Stacked sets do not compromise sterility	**8.9.2**				
♦ Items are rotated 1st in 1st out	**8.9.3**				

CRITERIA	ANSI/AAMI	COMPLIANT			COMMENTS
	Number	Y	N	N/A	
♦ Items are rotated based on packaging IFUs validated Shelf Life	**8.9.3**				
♦ If dust covered:					
▪ Dust cover is appropriate size					
▪ Dust cover is approved for use - manufacturer's recommendations on file					
▪ Dust cover is applied appropriately - immediately after cool down					
● Sterile Delivery	**8.10.1**				
♦ Items are cool prior to delivery					
♦ Package integrity is maintained during transport					
♦ Delivery Cart is clean and functional	**8.10.2**				
♦ Sterile items are covered for transport					
● Safety					
♦ Appropriate eye protection is available when handling chemicals	**4.5.2**				
♦ Appropriate Gloves are worn when handling chemicals					
♦ Proper body mechanics are used when lifting sets and pushing carts	**8.4.2**				
♦ Mittens are worn for burn protection	**8.8.1-8.8.2**				
♦ Alarms for EtO are in place and in working order					
♦ Staff are monitored on a routine basis for EtO exposure					
Sterilizer Testing					
● Bowie Dick / DART					
♦ Performed daily on sterilizers programmed with prevacuum cycle	**10.7.6.1**				
♦ Bowie Dick/Dart is placed horizontal on bottom shelf over drain	**10.7.6.3**				
♦ Procedure in place for failed tests	**10.7.6.5**				
♦ Staff know procedure for failed tests					
♦ 3 tests are performed after installation, major repairs, re-location	**10.8.1**				
● Biological Indicator - Process Challenge Device - PCD					
♦ Testing is performed minimally weekly preferrably daily	**10.5.3.2**				
♦ Each type of cycle is tested - per manufacturer's instructions	**10.5.3.2**				
♦ PCD is placed horizontal on bottom shelf over drain	**10.7.2.2**				
♦ A PCD is used for each wrapped load	**10.5.4**				
♦ BI is incubated in a timely manner	**10.7.2.3**				
♦ A control is incubated daily	**10.7.2.3**				
♦ Results are read and documented in a timely manner	**10.7.2.3**				
♦ Procedure in place for failed tests	**10.7.5**				
♦ Staff know procedure for failed tests					
♦ 3 tests are performed after installation, major repairs, re-location	**10.8**				
♦ Incubators are maintained per manufacturer's recommendations					
● Recall Policy and Procedure					
♦ Recall procedure in place for positive tests and wet loads	**10.11.2**				
♦ Staff know recall policy and procedure					

Facility: **Sterile Processing Assessment** **Date:**

CRITERIA	ANSI/AAMI	COMPLIANT			COMMENTS
	Number	Y	N	N/A	
♦ Policy and Procedure is based on AAMI Guidelines and facility IC and Risk Management requirements					
General					
● Housekeeping is performed on a routine scheduled basis	**3.4**				
● Traffic control limits entry to SPD	**3.2.4**				
● Attire is hospital approved - jewelry is kept to a minimum - no false nails etc.	**4.4-4.5.1**				
● Personal objects are not stored in SPD					
● Disposable/Single Use Devices are not reprocessed	**5.3**				
● Quality checkpoints are in place, documented, assessed and reported	**11.2.1**				
● Non-conformities are reported by the customer, documented, assessed and reported					
● Policy and Procedures are up to date and are based on Regulatory Guidelines					
● Policy and Procedures are adhered to					
● Staff know and understand Policy and Procedures					
● Documentation is complete	**10.3.2**				
● Audits are performed on Documentation to ensure logs are complete and accurate	**11.2.1**				
● Competencies are in place and performed on a routine basis	**4.3.1**				
● There is a routine training and inservice plan in place and adhered to	**4.3.1**				