Sterilization Audit Checklist

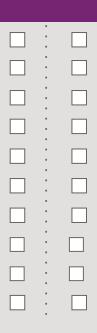
Date:	Auditor:
Facility:	
Contacts:	

Decontamination Area	Yes (compliant)	No (non-complia
Is the area restricted to authorized personnel only?		:
Are doors and pass-through windows kept closed when not being used?		
Is the area clean and free of improper items, e.g. debris, shipping boxes, fans, food, drinks?		
Are floors, walls, ceiling and work surfaces made of material that can withstand frequent cleaning?		
Is the temperature and humidity controlled properly and recorded daily?		
Do all personnel donn (put on) and doff (remove) appropriate PPE properly?		
Are soiled items transported properly, i.e. gross soil removed, pre-soak solution added, biohazard ID?		
Are all loaner trays delivered to Decontamination with written IFU within time policy time frame?		
Are instruments soaked and cleaned per their written IFU, i.e. brushes, chemicals and cleaning steps?		· □
Are mechanical washers loaded properly and tested daily for washing effectiveness?		



Packaging, Sterilization and Storage Areas

Are personnel properly dressed, i.e. hair completely covered, no jewellery or artificial nails?
Are work surfaces, shelves, floors, walls and ceilings made of proper materials and routinely cleaned?
Are instruments dried, inspected for cleanliness/function and sorted prior to packaging?
Are wrapped trays and/or rigid containers assembled without peel pouches or count sheets inside?
Are appropriate internal Chemical Indicators/Integrators being used with all packages?
Are disposable filters used with rigid container systems validated by the rigid container manufacturer?
Are packages loaded properly in sterilizer with pouches on edge and trays not exceeding 25 lbs?
Are sterilizer cycles set according to the sterilizer, packaging and device MFR's written instructions?
Are processed loads allowed to cool to room temperature (75°F) before distributed or stored?
Are sterile packages stored on clean storage shelves and are "wrapped" trays not stacked?



₹)	Quality Control And Record Keeping	Yes (compliant)	No (non-complian
	Are sterilizer printouts observed, initialled and maintained for each sterilization cycle?		
	Are steam pre-vacuum sterilizers tested daily for proper air removal (Bowie-Dick test)?		
	Are sterilizers tested with a BI inside a PCD (Steam and VH2O2 daily, EO gas every load)?		:
	Are all implant loads monitored with a BI and a Class 5 chemical indicator within a PCD?		
	Is the STERRAD CycleSure BI incubated within 5 minutes of cycle completion?		
	Are Control (unprocessed) BIs used daily for each incubator and from the same lot as the Test BI?		
	Are incubators routinely checked for proper temperature and for full incubation of each BI?		
	Are sterilizers retested (all modes, 3 consecutive times) after installation, major repairs or failures?		
	Have all loaner and/or purchased instrument trays been verified for standard sterilization cycles?		
	Is there a formal, written RECALL POLICY in place in case of sterilization failure?		

Comments

ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST58 Chemical sterilization and high-level disinfection in health care facilities. AORN Guidelines For Perioperative Practice. ASP, STERRAD Model NX, 100S, 100NX and 200 Educational Manual

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