# Sterilization Audit Checklist

Date: _____ Auditor: _____

Facility: _____

Contacts: _____

## Decontamination Area

| | Yes (compliant) | No (non-compliant) |
|---|---|---|
| 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-compliant) |
|---|---|---|
| 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




UPrevent
U have the power to prevent infections

Contact your McKesson Medical-Surgical Account Executive for more information or call us at **866.McK.ANSWer (866.625.2679)**.


2016-0105