

Exception Submission for 149.3 or 567.53(1) - Offsite Sterile Processing

§ 149.3. Facilities - The hospital shall have a central supply service physically separated from other areas. Central supply service shall be provided with facilities to process, sterilize, store, and dispense supplies and equipment.

OR

§ 567.53 Sterilization Control – There shall be written policies to establish the following:

(1) A method of control to assure sterilization of supplies and water.

- Narrative that clearly states where each of the following functions will occur and what modifications will be made if they are not all occurring in one facility:
 - **Processing**
 - Testing Procedures (if using reprocessed scopes)
 - Communication with the remote processing team prior to purchase of new equipment
 - High Level Disinfection & Decontamination of Surgical Instrumentation Prior to Transport
 - **Sterilizing**
 - Provision for Emergency Sterilization Utilizing the “One-Tray Method”
 - **Storing**
 - Length of time dirty items will be stored before processing
 - Location and security of clean item storage
 - **Dispensing**
 - Labeling and Tracking of Equipment & Trays including the ability to trace the source and cause of an SSI outbreak
 - Location, Plan and Extent of Case Cart Picking to include monitoring and staging of pre-picked carts
 - Transport method (distance, time, climate control, training of drivers for loading/unloading biohazard & sterilized supplies, efforts to prevent cross contamination, notification of delay/cancelation of delivery, etc.)
 - Transportation in Compliance with DOT & OSHA regulatory requirements
 - Risk Mitigation of Environmental Hazards (humidity/temp)
 - Adherence to and incorporate AAMI, AORN, APIC, CDC, WHO, SGNA and other recognized organizations as applicable
- Building Plans showing the Path of Travel along with a descriptive narrative
- List which supplies/supply types will be included in this new process
- Policies & Procedures to Include:
 - Provision for Maintaining Staff Competencies and access to IFUs
 - Standardized Auditing Process for all sites involved to include distributions of audit results
 - Process for assuring adequate equipment/supplies are available for capacity increases, turn-around-time, failures upon opening/unusable packs, etc.