

NJ Dept of Health Central Service Standards
SUBCHAPTER 8. CENTRAL SERVICE

8:43G-8.1 Central service policies and procedures

(a) The hospital's central service shall have written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and implemented. These policies and procedures shall be approved by the hospital's infection control committee.

(b) Policies and procedures for central service shall include at least decontamination and sterilization activities, including receiving, decontamination, storage, cleaning, packaging, disinfection, sterilization, and distribution of reusable items.

(c) All equipment and instruments in the hospital shall be processed according to central service cleaning and sterilization policies and procedures.

(d) Manufacturers' written recommendations for equipment use, testing, and cleaning shall be readily available in central service and in the department where the equipment is used.

(e) Methods for processing reusable medical devices shall conform with the following or revised or later editions, if in effect, incorporated herein by reference:

1. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Good Hospital Practice: Steam Sterilization and Sterility Assurance." ST 46;
2. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use." ST 37;

3. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Safe Use and Handling of Glutaraldehyde-based Products in Health Care Facilities." ST 58;

4. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Guidelines for the Selection and use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities." ST 33;

5. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Steam Sterilization and Sterility Assurance Using Table Top Sterilizers in Office-Based, Ambulatory Care, Medical, Surgical and Dental Facilities," January 1998, ST 42R;

6. Society of Gastroenterology Nurses and Associates, Inc., "Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes" (2000);

7. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Nonclinical Settings," ST 35; and

8. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness," October 1998, ST 41R.

(f) The documents referenced in (e) above are reviewed and/or revised every five years or more frequently as needed; the most current document is to be used. The AAMI requirements can be obtained from: The Association for the Advancement of Medical Instrumentation, 3330 Washington Building, Suite 400, Arlington, VA 22209 or at the AAMI website at www.aami.org. SGNA's Standards and Guidelines are available from the Society of Gastroenterology Nurses and Associates, Inc., 401 North Michigan Ave., Chicago, IL 60611-4267, or at www.sgna.org.

8:43G-8.2 Central service staff qualifications

- (a) There shall be a full-time director or supervisor of central service.
- (b) The director or supervisor of central services shall have two years of supervisory experience and shall be certified through a national sterile processing program recognized by the New Jersey Department of Health and Senior Services.
- (c) All personnel involved in sterile processing shall be certified through a national sterile processing program recognized by the New Jersey Department of Health and Senior Services within three years of employment and by August 2, 2009.
- (d) Personnel involved in the use of ethylene oxide shall have the appropriate licensure from the New Jersey Department of Environmental Protection.

8:43G-8.3 Central service staff education and training

- (a) Requirements for the central service education program shall be as provided in N.J.A.C. 8:43G-5.9.
- (b) All new central service employees shall receive on-the-job training on practices and equipment unique to the hospital.
- (c) Competency for processing tasks shall be documented annually by the employee's supervisor or by the Director of Central Services

8:43G-8.4 Central service patient services

- (a) Entrance to the central service processing and decontamination area shall be restricted to persons attired in hospital-laundered or protective attire, in relation to the purpose and scope of their duties.
 - 1. All personnel performing decontamination, preparation, and assembly shall be provided hospital laundered scrubs.
- (b) All reusable patient care items shall be reprocessed according to manufacturers' written recommendations.
- (c) There shall be a preventive maintenance program for all patient care equipment processed by central service that includes performance verification records. Preventive maintenance shall be documented and records shall be available for inspection.
- (d) Sterile supplies which bear an expiration date shall not exceed the shelf life date as recommended by the manufacturer of the packaging and/or of the device contained.
 - 1. Muslin blends shall not exceed a shelf life of 30 days.
 - 2. A policy and procedure to retrieve and reprocess outdates shall be established and enforced.

(e) If the facility is using an Event Related Sterility program, the process shall:

1. Be approved by the Hospital Infection Control Committee;
2. Have a continuous process improvement plan with monthly audits and documentation of facility compliance including:
3. Proper transportation of sterile product;
 - ii. Proper storage conditions of sterile product;
 - iii. Proper rotation of sterile product; and
 - iv. Maintenance of sterile pack integrity; and
4. Include annual inservice education as part of mandatory Infection Control inservicing.

8:43G-8.5 Single use medical devices and outsourcing

(a) Single use patient care items shall not be reprocessed except under the following conditions:

1. The manufacturer provides written instruction for cleaning and sterilization of the item and the facility has the resources to meet those specifications; and/or
2. Methods for processing single use patient care items conform with the following Food and Drug Administration regulations:
 - i. Premarket notification, registration and listing shall comply with Title 21 CFR, Part 807, incorporated herein by reference, as amended and supplemented; and
 - ii. Quality system regulations shall be as specified in 21 CFR Part 807, incorporated herein by reference, as amended and supplemented; and
3. A quality control program shall be established to ensure the delivery of a safe product as specified in the contract with the third party processor.

(b) Policies and procedures shall be established following OSHA's Blood Borne Pathogens regulation, 29 CFR § 1910.1030, incorporated herein by reference, as amended and supplemented, for the transport of contaminated equipment to off site reprocessing facilities.

(c) Shared reprocessing by multi-hospital reprocessing centers shall meet the following standards:

1. Policies and procedures for all processing protocols shall be approved by all facilities in the network in conjunction with infection control and all sterile processing managers.
2. Instruments and devices transported off site for processing shall be inventoried and precleaned prior to transportation.

3 All decontamination, assembly and sterilization shall be performed according to the device manufacturer's written recommendations.

4. The following records shall be maintained at the processing facility:

- i. Sterilization logs shall be maintained for all items sterilized; and
- ii. Biological monitoring as specified in N.J.A.C. 8:43G-8.8(a).

(1) Immediate notification shall be made to the receiving hospital upon a positive biological result.

5. Transport of sterile product shall be performed using disinfected, impervious containers that are either locked or sealed in covered carts.

8:43G-8.6 Central service space and environment

(a) Each sterilizer processing area shall have exhaust ventilation to remove heat, moisture and odors

without recirculating the exhaust to other areas of the hospital.

(b) Exterior shipment cartons shall not be brought into sterile supply storage or processing areas.

(c) Soiled or contaminated supplies shall be physically separated from those that are clean or sterile.

(d) All work surfaces in central supply shall be cleaned with germicidal disinfectant at the end of each work shift and more frequently as necessary.

(e) An area shall be designated for central supply employees to change their clothing and store personal items.

8:43G-8.7 Use and sterilization of patient care items

(a) Patient care items shall be scrupulously cleaned prior to sterilization or disinfection. The selection and use of disinfection and/or sterilization methods for patient care items or equipment shall be divided into the following three categories:

1. Critical items are objects that enter sterile tissue or the vascular system. These instruments other than scopes must be sterilized by a process that can demonstrate a sterility assurance level of 10^{-6} .

2. Semicritical items are objects which come into contact with mucous membranes or with skin that is not intact. Semicritical items require high-level disinfection or intermediate level disinfection. (At a minimum, the disinfectant must be labeled as tuberculocidal.)

3. Noncritical items are objects that come in contact with intact skin, but not with mucous membranes. Noncritical items require intermediate level disinfection or low-level disinfection.

(b) Laparoscopes, arthroscopes, and other scopes that enter normally sterile areas of the body shall be sterilized or given high-level disinfection after each use according to manufacturers' written recommendations or according to policy established by the hospital's infection control committee.

(c) Reusable linens shall be inspected and delinted in a segregated room with adequate ventilation to prevent excess dust and lint accumulation.

1. An illuminated worktable shall be provided to examine linen used for wrapping sterile supplies for tears, pinholes, and other defects.

2. Reusable linens shall be repaired using a heat patch machine.

(d) Flash sterilization and peracetic acid processes are considered just in time sterilization processes.

("Just in time" means for immediate use only.)

1. Flash sterilization should be used for emergency situations only.

2. All items that are flash sterilized shall be thoroughly cleaned and decontaminated prior to sterilization.

3. All items in each flash sterilization cycle shall be documented.

(e) The efficacy of chemicals used for high-level disinfection shall be verified by the use of a test method specific to the chemical if a valid and reliable test method is available and feasible for use in a hospital setting.

(f) There shall be a system for monitoring the processing of all equipment and instruments in the hospital for adherence to central service policies and procedures.

8:43G-8.8 Monitoring the sterilization cycle

(a) Biological monitoring with live spores, or an FDA approved equivalent, shall be performed as follows:

1. Ethylene oxide - in each load;

2. Peracetic acid – weekly;

3. Low temperature gas plasma - daily in the working load; and

4. Steam sterilizers - weekly.

(b) The biological indicator shall be applicable for the sterilization process used and be stored and used in accordance with the manufacturer's recommendations.

(c) A biological monitor with live spores shall be performed following repair or breakdown of the equipment in (a) above.

(d) A biological monitor, or spore based enzyme, shall be used with each load containing implantables and the implantable shall not be used until the negative biological test is received.

(e) A chemical indicator/integrator, applicable to the sterilization process used, shall be used in the following:

1. Each package processed in steam;
2. Each package processed in ethylene oxide;
3. Each package processed in low temperature gas plasma;
4. Each load as directed by the manufacturer for peracetic acid; and
5. A prevacuum air removal test shall be performed daily on each prevacuum sterilizer and following repair or breakdown of the prevacuum sterilizer.

(f) In the event of positive biological test results on a sterilizer, effective corrective action shall be taken including retesting and recalls if indicated.

1. Documentation of actions taken shall be maintained on site.
2. There shall be an established recall system in effect.

8:43G-8.9 (Reserved)

8:43G-8.10 Central service quality improvement methods

There shall be a program of quality improvement for central service that is integrated into the hospital quality improvement program and includes regularly collecting and analyzing data to help identify health service problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data.

8:43G-8.11 Sterilizer patient services

(a) All hinged instruments shall be processed in an open position.

(b) All instruments and equipment shall be visually inspected for cracks, pitting, rust, or any condition that would impede cleaning/sterilization. Defective instruments and equipment shall not be used.

(c) Sterilizers in use shall be cleaned on a scheduled basis.

(d) Sterilizer drains shall be flushed at least weekly, unless otherwise specified by the manufacturer.

(e) Sterilizer door gaskets shall provide effective sealing.

(f) A record of each sterilization/disinfection load, including the date, load/cycle number and the specific contents of the load shall be retained for a least one year or per hospital policy whichever is greater.

(g) Instruments and medical devices sterilized by ethylene oxide shall be aerated in a mechanical aerator according to manufacturer's recommendations, or if these recommendations are not available, they shall be aerated at 140 degrees Fahrenheit for a minimum of eight hours or at 122 degrees Fahrenheit for a minimum of 12 hours.

(h) An indicating thermometer, accurate to three degrees Fahrenheit, shall be located in all ethylene oxide aeration equipment.

(i) All sterilizers shall be operated and maintained in accordance with the manufacturer's instructions.

8:43G-8.12 and 8:43G-8.13 (Reserved)

Link to the NJ Dept of Health Standard referring to Central Service on page 69-76
http://www.state.nj.us/health/healthfacilities/documents/ac/njac43g_hoslicstd.pdf