N.J.A.C. TITLE 8

CHAPTER 43G

HOSPITAL LICENSING STANDARDS

AUTHORITY *N.J.S.A. 26:2H-1 et seq.*

Department of Health and Senior Services
Division of Healthcare Quality & Oversight
Certificate of Need and Acute Care Licensure Program

CENTRAL SERVICE
SUBCHAPTER 8

§ 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 or as needed, revised 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 publications, incorporated herein by reference, as amended and supplemented:

1. Sterilization, Part 1: Sterilization in Health Care Facilities, 2017 Edition. The Association for the Advancement of Medical Instrumentation (AAMI). This book is available from AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: (703) 525-4890. Fax: (703) 525-1424. Website: www.aami.org. E-mail: sloughlin@aami.org;

and

2. Society of Gastroenterology Nurses and Associates. "Standard of Infection Prevention in the Gastroenterology Setting" (2015), which is available from the Society of Gastroenterology Nurses and Associates, Inc., 330 North Wabash , Suite 2000, Chicago, IL 60611. Phone (800) 245-SGNA or (312) 321-5165. Fax: (312) 673-6694. Website: www.sgna.org. E-mail: SGNA@smithbucklin.com

§ 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 Department.**

(c) **All personnel involved in sterile processing shall be certified through a national sterile processing program recognized by the Department within three years of employment.**

(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:

i. 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

3. Include annual in-service education as part of mandatory Infection Control in-servicing.

§ 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 21 C.F.R. Part 807, incorporated herein by reference, as amended and supplemented; and

ii. Quality system regulations shall be as specified in 21 C.F.R. 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 Bloodborne Pathogens Standard (2011), 29 CFR 1910.1030, available at https://www.osha.gov/pls/publications, 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 pre-cleaned 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 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 delineated 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 sterilizer 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 (Reserved)

§ 8:43G-8.13 (Reserved)

HOUSEKEEPING, LAUNDRY & SANITATION
SUBCHAPTER 13

§ 8:43G-13.1 Housekeeping policies and procedures

(a) The housekeeping service shall have written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and implemented. They shall include, at a minimum, scope of responsibility, assignment by designated unit, and responsibility for all cleaning tasks.

(b) The housekeeping service shall have a written schedule that determines the frequency of cleaning and maintaining cleanliness for all equipment, structures, areas, and systems within its scope of responsibility.

(c) There shall be a list available at all times of all cleaning and disinfecting agents used in the hospital together with their Safety Data Sheet (SDS).

(d) Records of all pesticides and herbicides used at the hospital shall be maintained on-site, together with their Safety Data Sheet (SDS).

(e) All cleaning and disinfecting agents shall be correctly labeled with the name of the product and its use, as specified by the manufacturer, including agents that have been repackaged from a bulk source.

(f) All pesticides shall be applied in accordance with State Pesticide Control Code, N.J.A.C. 7:30.

§ 8:43G-13.2 Housekeeping staff qualifications

There shall be a house keeping or environmental service with a designated director who has at least two years of experience in institutional housekeeping or environmental services.

§ 8:43G-13.3 (Reserved)

§ 8:43G-13.4 Housekeeping patient services

(a) All areas, including areas with limited access such as cabinets, drawers, locked medication rooms, and storage areas, shall be kept clean to sight and touch.

(b) All toilets and bathrooms shall be kept clean to sight and touch, in good repair, and free of odors that reflect poor housekeeping practices.

(c) Reusable hand-cleanser dispensers shall be clean inside and out. Disposable dispensers shall be discarded and not refilled.

(d) Floors shall be kept clean.

(e) Hard surfaced floors shall be coated with a slip-resistant floor finish.

(f) Carpeting shall be kept clean and odor free and shall not be frayed, worn, torn, or buckled.

(g) Window and partitioning curtains and drapes shall be kept clean to sight and touch and odor-free.

(h) Walls, ceilings, and vents shall be kept clean to sight and touch and odor-free.

(i) Windows and screens shall be kept clean to sight and touch, and in good repair.

(j) Mattresses, mattress pads and coverings, pillows, bedsprings, and other furnishings shall be properly maintained and kept clean. They shall be thoroughly cleaned and disinfected upon discharge of each patient.

(k) All equipment and environmental surfaces shall be kept clean to sight and touch.

(l) When areas of the hospital are undergoing renovation or new construction, protective measures shall be taken to contain dust and redirect traffic in patient care areas.

(m) Effective and safe controls shall be used to minimize or eliminate the presence of rodents, flies, roaches, and other vermin in the hospital. The premises shall be kept in such condition as to prevent the breeding, harboring, or feeding of vermin. All openings to the outer air shall be effectively protected against the entrance of insects.

(n) Fly strips shall not be located over food preparation and service areas or in patient care areas.

(o) Periodic documented inspections of buildings and grounds shall be performed. Buildings and grounds shall be maintained in a clean and safe condition.

(p) Articles in storage shall be elevated from the floor and away from walls, ceilings, and air vents to facilitate cleaning. Storage units shall be non-porous and cleanable.

(q) All communal toys shall be washed daily or more frequently as needed. No stuffed animals shall be allowed except for personal use.

(r) Plants and flowers shall not be allowed in patient treatment areas (such as operating rooms and procedure rooms) or sterile processing areas.

§ 8:43G-13.5 Housekeeping supplies and equipment

(a) Toilet tissue and proper waste receptacles shall be provided in all toilet areas.

(b) Hand cleanser, sanitary towels, and waste receptacles or hand-drying machines shall be provided at each handwashing unit. Hand cleanser and hand-drying machines shall be approved by the infection control committee.

(c) All portable equipment, such as carts, stretchers, intravenous poles, and wheelchairs, shall be kept clean and maintained in good repair.

(d) When not in use, cleaning and disinfecting agents shall be stored on separate shelves from other supplies and in enclosed areas.

§ 8:43G-13.6 (Reserved)

§ 8:43G-13.7 Housekeeping staff education and training

(a) Requirements for the housekeeping education program shall be as provided in N.J.A.C. 8:43G-5.9.

(b) Orientation for new housekeeping employees shall include training in cleaning and infection control techniques.

(c) For specialty units, including at least the newborn nursery, surgical suite, emergency department, pediatrics, critical care, renal dialysis, post mortem, and central services

(d) sterile preparation, housekeeping staff shall be specifically trained jointly by housekeeping and the unit staff to clean the unit to which they are assigned.

§ 8:43G-13.8 Housekeeping quality improvement methods

(a) There shall be a program of quality improvement for housekeeping that is coordinated with the hospital quality improvement program and includes collecting and analyzing data to help identify problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data. (See N.J.A.C. 8:43G-27, Continuous Quality Improvement).

(b) Hospitals that contract with a commercial housekeeping service shall use quality improvement measures to ensure that the same standards are met as apply to an in-house housekeeping service.

§ 8:43G-13.9 Laundry policies and procedures

(a) The laundry service shall have written policies and procedures, which are reviewed every three years or more frequently as needed, revised as needed, implemented, and followed, and which include at least a policy that identifies special handling practices for soiled laundry.

(b) All used laundry shall be considered contaminated and handled according to the hospital's written policies and procedures, which are approved by the infection control committee.

§ 8:43G-13.10 Laundry staff qualifications

There shall be a designated director or supervisor of laundry with a minimum of two years of experience in institutional laundry service.

§ 8:43G-13.11 Laundry patient services

(a) All laundry from patient rooms and other service areas shall be transported in such a way that no leakage occurs.

(b) Laundry carts shall be in good repair, kept clean, and identified for use with either clean linen or soiled laundry.

(c) Clean linen shall be transported in covered carts and stored in a covered or enclosed area.

(d) Bedding (sheets, pillowcases, draw sheets, and blankets) and clothing provided to staff and patients shall be clean and in good repair.

§ 8:43G-13.12 Laundry space and environment

(a) Soiled laundry shall be stored in containers provided for it in a clean, ventilated, vermin-proof and vermin-free area, separate from other supplies. It shall be collected from the storage area regularly so that it does not overflow or accumulate beyond the capacity of the storage containers.

(b) Soiled laundry shall be stored, sorted, rinsed, and laundered only in areas specifically designated for those purposes.

(c) If a laundry chute is used, it shall be kept locked.

(d) If a laundry chute is used, it shall be maintained in good repair and cleaned, and there shall be no build-up of visible soil.

(e) Laundry chutes shall empty into an enclosed room.

(f) If the hospital has an in-house laundry for the bulk of the hospital's linens, it shall provide a receiving, holding, and sorting area with hand washing facilities. The walls, floor, and ceiling of the area shall be kept clean and in good repair.

(g) If the hospital has a limited-use, home-style laundry (for example, for the use of the psychiatric unit or for laundering items such as cubicle curtains), the walls, floor, and ceiling of the area shall be kept clean and in good repair.

(h) If the hospital contracts with a commercial laundry service, the hospital shall have areas for sorting and receiving laundry. These areas shall be kept clean and in good repair.

(i) A written schedule shall be developed and implemented for removing lint from laundry areas on a routine basis.

(j) If the hospital has an in-house laundry, the flow of ventilating air shall be from clean to soiled areas, and ventilation shall be adequate to prevent odor build-up. Soiled laundry and clean linen shall be kept separate.

§ 8:43G-13.13 Laundry supplies and equipment

(a) The hospital shall have on-site an adequate supply, in good repair, of sheets, pillowcases, draw sheets, blankets, towels, washcloths, and scrub suits.

1. All hospitals shall provide laundered scrub suits in the following areas: surgical suites, obstetrical surgical suites, postanesthesia care unit, central services, and those areas as determined by hospital policy.

(b) If the hospital has an in-house laundry, an established protocol shall be followed to reduce the number of bacteria in the fabrics. Equipment and surfaces that come into contact with soiled laundry and clean linen shall be sanitized.

(c) The laundry service shall monitor, and retain documentation for one year, at least the following:

1. Unsafe objects found;

2. Linen supply;

2. Stained linens; and

3. pH. A random sample of all laundry batches from all sources shall be sour tested to ensure neutralization of alkaline residues from built detergents. Sour testing is a test performed to indicate the degree of acidity or alkalinity of linens. Built detergents are a mixture of one or more alkaline detergents that contains not less than 50 percent anhydrous soap (pure soap, free from water). Fabric pH shall be maintained at 7.0 or below after souring when built detergents are used.

§ 8:43G-13.14 Laundry staff education and training

(a) Requirements for the laundry staff education program shall be as provided in N.J.A.C. 8:43G-5.9.

(b) Orientation for new laundry employees shall include protocols for handling and receiving soiled laundry and clean linen.

§ 8:43G-13.15 Laundry continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for the laundry service that is coordinated with the hospital continuous quality improvement program and includes regularly collecting and analyzing data to help identify problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data. (See N.J.A.C. 8:43G-27, Continuous Quality Improvement).

(b) Hospitals that contract with a commercial laundry service shall use continuous quality improvement measures to ensure that the standards of N.J.A.C. 8:43G-13.9 through this section are met.

§ 8:43G-13.16 Sanitation policies and procedures

The sanitation service shall have written policies and procedures that are reviewed every three years, revised as needed, and implemented. They include, at least, scope of responsibility, assignment by designated unit, and responsibility for all sanitation tasks.

§ 8:43G-13.17 Sanitation staff qualifications

There shall be a designated director or supervisor of sanitation with specialized training or education in institutional sanitation service. A consultant may be used to fulfill this role.

§ 8:43G-13.18 Sanitation patient services

(a) The water supply shall be adequate in quantity, of a safe sanitary quality, and from a water system that is constructed, protected, operated, and maintained in conformance with the New Jersey Safe Drinking Water Act, N.J.S.A. 58:12A-1 et seq., and N.J.A.C. 7:10 and other applicable laws, ordinances, and regulations.

(b) Hot running water (between 105 and 120 degrees Fahrenheit or 41 to 49 degrees Celsius) and cold running water shall be provided in patient care areas.

§ 8:43G-13.19 Sanitation space and environment

(a) Water piping carrying non-potable water shall be clearly labeled as such.

(b) The sewage disposal system shall be maintained in good repair and operated in compliance with State and local laws, ordinances, and regulations.

(c) There shall be no direct physical connections between city and well water supplies. Any physical connection between a public community water supply and an unapproved water supply, such as a well used by a hospital for emergency purposes, must be approved by the New Jersey Department of Environmental Protection and the owner of the public community water supply and must conform with N.J.A.C. 7:10-10.

(d) There shall be no back siphonage conditions present.

(e) Equipment requiring water drainage, such as ice machines, shall be drained to a sanitary connection in a way that avoids splatter or overflow.

§ 8:43G-13.20 Sanitation quality improvement methods

The hospital shall adhere to the water sampling schedule and the chemical and biological monitoring requirements of the water supply system set by the New Jersey Department of Environmental Protection. Records of the sampling and monitoring shall be maintained.

§ 8:43G-13.21 Regulated medical waste policies and procedures

(a) The hospital shall develop and implement and the Infection Control Program shall review, approve, and audit written policies and procedures for collection, storage, handling, transport and disposal transport of medical waste, in conformance with applicable Federal and State laws and regulations.

(b) The hospital shall comply with the provisions of 42 U.S.C. § 6903, the Medical Waste Tracking Act of 1988 and N.J.S.A. 13:1E-48 et seq., the Comprehensive Regulated Medical Waste Management Act and all rules and regulations promulgated pursuant to the aforementioned Acts.

§ 8:43G-13.22 Regulated medical waste and solid waste management

(a) Policies and procedures for solid waste and recyclables shall be established and enforced to ensure appropriate collection, storage and disposal and to maintain them clean and odor-free and to prevent the breeding of insects or vermin.

(b) Solid waste shall be stored within the containers provided for it in an area that is kept clean. Waste shall be collected from storage area regularly to prevent nuisances such as odors, flies, other vermin, or rodents, and so that waste does not overflow or accumulate beyond the capacity of the storage containers.

(c) Plastic bags shall be used for solid waste removal from patient care units and supporting departments. Bags shall be of sufficient strength to safely contain waste from point of origin to point of disposal and shall be effectively closed prior to disposal.

(d) Garbage compactors shall be located on an impervious pad that is graded to a drain. The drain shall be kept clean and shall be connected to the sanitary sewage disposal system.

(e) Outside storage containers for solid waste shall be kept covered, except those used for corrugated cardboard, recyclables, or construction materials.