N.J.A.C. TITLE 8

CHAPTER 43A

STANDARDS FOR

LICENSURE OF AMBULATORY CARE FACILITIES

AUTHORITY

N.J.S.A. 26:2H-5 and 26:2H-8

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

INFECTION AND PREVENTION CONTROL SERVICES
SUBCHAPTER 14

§ 8:43A-14.1. Administrator's responsibilities

(a) The administrator, or designee, shall ensure the development and implementation of an infection prevention and control program.

(b) The administrator shall designate an infection control professional who shall be responsible for the direction, provision, and quality of infection prevention and control services. The designated person shall be responsible for, but not limited to, developing and maintaining written objectives, policies and procedures, an organizational plan, and a quality improvement program for the infection prevention and control service. The infection control professional may be a consultant; however, there must be a health care professional on site who is responsible for the day to day activities related to infection control.

(c) The infection control professional shall have education or training in surveillance, prevention, and control of nosocomial infections. The infection control professional shall be certified in infection control within five years of beginning practice of infection control and shall maintain certification through the Certification Board of Infection Control (CBIC).

§ 8:43A-14.2. Infection control policies and procedures

(a) The facility shall establish an infection control committee which shall include the medical director, the infection control professional, and representatives from at least administration and the nursing service. If this facility is owned or operated by an acute care hospital, then the facility may participate in the hospital's infection control program.

(b) The infection control committee, with assistance from each service in the facility, shall develop, implement, and review, every three years or more frequently as necessary, written policies and procedures regarding infection prevention and control, including, but not limited to, policies and procedures regarding the following:

1. In accordance with N.J.A.C. 8:57 (Communicable Diseases), a system for investigating, reporting, and evaluating the occurrence of all infections or diseases which are reportable or conditions which may be related to activities and procedures of the facility;

2. Identifying and reporting of HIV/AIDS as specified in N.J.A.C. 8:57-2, Reporting of Acquired Immunodeficiency Syndrome and Infection with Human Immunodeficiency Virus;

3. A system for identifying and monitoring nosocomial infections, in conformance with the "CDC Definitions for Nosocomial Infections, 1988" (order number PB 88-187117) incorporated herein by reference;

4. Infection control practices, including universal precautions, in accordance with the Occupational Safety and Health Administration (OSHA) rule 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens, incorporated herein by reference;

5. Control measures or studies to be initiated following identification of an infection control problem;

6. Aseptic technique, employee health in accordance with N.J.A.C 8:43A-3.7, and staff training in regard to infection control;

7. Care of patients with communicable diseases;

8. Exclusion from work, and authorization to return to work, for personnel with communicable diseases; and

9. Surveillance techniques to identify sources and minimize transmission of infection.

NOTE: Centers for Disease Control publications can be obtained from:
National Technical Information Service
U.S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161

or

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

Copies of the OSHA rule 29 CFR Part 1910.1030, which was published in the Federal Register on December 6, 1991, can be obtained from:
OSHA Office of Publications
U.S. Department of Labor
Room N3101
200 Constitution Ave., NW
Washington, DC 20210

§ 8:43A-14.3 Infection prevention measures

(a) Infection prevention activities shall be based on the Centers for Disease Control and Prevention Guidelines, and Hospital Infection Control Practices Advisory Committee (that is, HICPAC) recommendations listed below, incorporated herein by reference, as amended and supplemented:

1. Guideline for Prevention of Catheter-Associated Urinary Tract Infections (1981);

2. Guideline for Prevention of Intravascular Device-Related Infections (Infection Control and Hospital Epidemiology 1996; 17:438-73 and American Journal of Infection Control 1996; 24:262-93);

3. Guidelines for Prevention of Surgical Site Infections (1999) (Infection Control and Hospital Epidemiology 1999; 20:247-278);

4. Guidelines for Preventing Health-Care-Associated Pneumonia, 2003: Recommendation of CDC and the Healthcare Infection Control Practices Advisory Committee, published in the Morbidity and Mortality Weekly Report at MMWR 2004; 53 (No. RR-3), published by the Coordinating Center for Health Information and Service, available at http://www.cdc.gov/mmwr/PDF/rr/rr5303.pdf and at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5303a1.htm;

5. Guideline for Hand Hygiene in Health-Care Settings: Recommendation of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force, published in the Morbidity and Mortality Weekly Report at MMWR 2002; 51 (No. RR-16), published by the Coordinating Center for Health Information and Service, available at http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf and at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm;

6. Guideline for Infection Control in Hospital Personnel (1998);

7. Guideline for Isolation Precautions in Hospitals (Infection Control and Hospital Epidemiology 1996; 17:53-80 and the American Journal of Infection Control 1996; 24:24-52);

8. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Facilities (Morbidity and Mortality Weekly Report 1994; 43:11-22); and

9. HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance (Infection Control and Hospital Epidemiology 1995; 16:105-113).

(b) The guidelines listed in (a) above are available from the National Technical Information Service (NTIS) by calling 1-800-553-6847 or writing the NTIS, 5285

Port Royal Road, Springfield, Virginia 22161. The complete set of the seven Guidelines for the Prevention and Control of Nosocomial Infections are listed under the publication number: PB86133022. Further information is available on the Centers for Disease Control and Prevention National Center of Infectious Diseases website at: http://www.cdc.gov/ncidod/hip. The HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance is available on the CDC website at: http://www.cdc.gov/ncidod/vancom.htm. CDC's Hospital Infections Program's Methicillin-resistant Staphylococcus Aureus: Facts for Healthcare Workers is available at: http://www.cdc.gov/ncidod/hip/aresist/mrsahcw.htm.

(c) The Department shall allow facilities to diverge from the guidelines and recommendations listed at (a) above, provided that there is a sound infection control rationale based upon scientific research or epidemiologic data for the diversion.

§ 8:43A-14.4. Sterilization of patient care items

(a) 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 Gultaraldehyde-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. **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;**

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

8. **Society of Gastroenterology Nurses and Associates (SGNA), "Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes," (2000).**

(b) The documents referenced in (a) 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.

(c) Emphasis shall be placed on cleaning of these devices 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, excluding scopes, must be sterilized by a process that can demonstrate a sterility assurance level of 10[-6].**

    (i) 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 the manufacturers' written recommendations or according to policy established by the facility's infection control committee.

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 into contact with intact skin but not with mucous membranes. Noncritical items shall at a minimum be exposed to a low level disinfectant.**

(d) 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 an ambulatory setting.

(d) At the completion of each sterilization cycle, the following documentation shall be recorded and maintained on site for at least one year:

1. **Time, temperature and pressure readings shall be verified and the print out/chart initialed by the operator before items are removed; and**

2. **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 facility policy, whichever is greater.**

(f) Each package shall be labeled with sterilization date and load number.

(g) The manufacturer's instructions for cleaning, testing, disassembly, and sterilization of equipment shall be readily available and followed by employees.

1. **All hinged instruments shall be processed in an open position.**

2. **All instruments that can be disassembled shall be disassembled for decontamination and sterilization.**

(h) Sterilized materials shall be stored, handled and transported to maintain sterility. Package integrity shall be maintained until used.

(i) Sterile supplies which bear an expiration date shall not exceed the shelf life date as recommended by the manufacturer of the packaging selected or the device contained therein.

1. **A policy and procedure to retrieve and reprocess outdates shall be established and enforced.**

(j) If the facility is using an event-related sterility program, the process shall include a continuous quality plan with documentation of facility compliance with the following:

1. **Proper transportation of sterile product;**

2. **Proper storage conditions of sterile product;**

3. **Proper rotation of sterile product; and**

4. **Maintenance of sterile pack integrity.**

(k) All sterilization equipment shall be installed and operated in accordance with the sterilizer manufacturer's written instructions.

(l) Single use patient care items shall be reprocessed under the following conditions:

1. **The manufacturer provides written documentation for cleaning and sterilization of the item and the facility has the resources to meet those specifications;**

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 CFR, Part 807, incorporated herein by reference, as amended and supplemented; and**

ii. **Quality system regulations as specified in 21 CFR Part 807, incorporated herein by reference, as amended and supplemented; and**

3. **If the facility retains an outside firm to provide its sterile processing, 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.**

(m) Shared reprocessing by outside healthcare 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 managers.**

2. **Instruments and devices transported off site for processing shall be inventoried and pre-cleaned prior to transportation.**

i. **Soiled instruments shall be contained in impervious, closed containers which are either locked or sealed in covered carts.**

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

i. **Manufacturer's written instructions for processing of all specialty devices shall be obtained, followed and kept on file at the processing facility.**

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. 8:43A-14.5(a).**

5. **Immediate notification shall be made to the receiving facility upon a positive biological result.**

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

§ 8:43A-14.5. Care and use of sterilizers, ethylene oxide, peracetic acid, low temperature gas, plasma, and steam

(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;

4. Steam sterilizers--weekly;

5. A biological monitor with live spores shall be performed following repair or breakdown of the above mentioned equipment; and

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

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

1. A rapid read out biological monitor must be incubated to obtain a spore kill reading. The length of incubation shall comply with the written instructions provided by the manufacturer of the biological indicator.

2. A chemical indicator/integrator, applicable to the sterilization process used, shall be used in the following:

i. Each package processed in steam;

ii. Each package processed in ethylene oxide;

iii. Each package processed in low temperature gas plasma; and

iv. Each load, as directed by the manufacturer, for peracetic acid.

3. A prevacuum air removal test shall be performed daily on each prevacuum sterilizer and following repair or breakdown of the prevacuum sterilizer.

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

i. Documentation of actions taken shall be maintained on site.

ii. There shall be an established recall system in effect.

5. The individual responsible for reprocessing reusable medical instruments shall be certified by a national central service certification program upon hire or within two years of employment.

6. All personnel involved in the use of ethylene oxide shall have the appropriate licensure from the New Jersey Department of Environmental Protection (NJDEP).

§ 8:43A-14.6. Maintenance of sterile processing environment

(a) The following environmental surfaces shall be maintained as follows in decontamination and clean processing areas:

1. **Hard surface floors shall be kept clean.**
2. **Walls shall be cleaned of spills and splashes as necessary.**
3. **Ceilings, ventilation system vents, and sterilizer vents shall be clean and free from dust.**
4. **Storage shelves shall be kept clean.**
5. **All horizontal surfaces shall be disinfected each shift and as needed.**

(b) There shall be separation between clean and contaminated work areas and activities.

§ 8:43A-14.7. Infection control quality improvement methods

The infection control professional shall develop and implement a program of quality improvement that is integrated into the facility quality improvement program and includes regularly collecting and analyzing data to help determine the effectiveness of infection control practices. When corrective actions need to be taken based on data collected, the infection control committee shall recommend, implement, and monitor those actions. The infection control professional shall supervise these quality improvement activities. These quality improvement activities shall be overseen by the continuous quality improvement program. (See Subchapter 18).

HOUSEKEEPING, SANITATION AND SAFETY
SUBCHAPTER 17

8:43A-17.1 Housekeeping policies and procedures

(a) The housekeeping service shall have written policies and procedures that are reviewed every three years or as needed, revised as needed, and implemented. They shall include, at least, 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 facility together with their Safety Data Sheets (SDS).

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

8:43A-17.2 Housekeeping staff

(a) There shall be an individual responsible for the housekeeping or environmental services. This individual may be a contracted provider.

(b) Housekeeping personnel shall be trained upon hire and on an annual basis or more frequently as necessary. Training should focus on cleaning procedures, including the selection and use of appropriate chemicals in the cleaning and care of equipment and surfaces.

8:43A-17.3 Housekeeping patient services

(a) All areas, including areas with limited access such as cabinet, drawers, locked medication rooms, and storage areas, shall be kept clean to sight and touch and free of condensation, mold growth and noxious odors.

(b) All equipment and materials necessary for cleaning, disinfecting, and sterilizing (if applicable) shall be provided.

(c) All household and cleaning products in the facility shall be identified, labeled, and securely stored in a cabinet, closet, or room which is inaccessible to patients.

(d) Housekeeping and cleaning supplies shall be selected and approved by the Infection Control Committee. They shall be measured and used correctly according to the manufacturers' written instructions.

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

(f) Toilet tissue, soap, and disposable towels or air driers shall be provided in each bathroom at all times. Soap and disposable towels or air driers shall be provided at each handwashing sink at all times.

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

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

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

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

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

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

(m) Nonskid wax shall be used on all waxed floors.

(n) All communal toys shall be washed after each use. No stuffed animals shall be allowed except for personal use.

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

8:43A-17.4 Environmental patient care services

(a) The following environmental conditions shall be met:

1. Thermometers which are accurate to within three degrees Fahrenheit shall be kept in a visible location in refrigerators, freezers, and storerooms used for perishable and other items subject to deterioration. Records shall be kept for 12 months;

2. 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;

3. There shall be separate refrigerators for medications, laboratory specimens, and food. There shall be a separate designated area for all food items and beverages. Records shall be kept for 12 months;

4. Draperies, upholstery, and other fabrics or decorations shall be fire-resistant and flameproof;

5. Latex foam pillows shall be prohibited;

6. Equipment requiring drainage shall be drained to a sanitary connection, in accordance with State and local codes;

7. During warm weather conditions, the temperature of the facility shall not exceed 82 degrees Fahrenheit. The facility shall establish a written heat emergency action plan which specifies procedures to be followed in the event that the indoor air temperature is 82 degrees Fahrenheit or higher for a continuous period of four hours or longer. The facility shall provide adequate ventilation in all areas used by patients;

8. The temperature in the facility shall be kept at a minimum of 72 degrees Fahrenheit (22 degrees Celsius) when patients are in the facility;

9. Throw rugs or scatter rugs shall not be used in the facility;

10. All equipment shall have unobstructed space provided for operation;

11. Combustible materials shall not be stored in heater rooms or within 18 feet of any heater located in an open basement;

12. Paints, varnishes, lacquers, thinners, and all other flammable materials shall be stored outside the building. Minimum supplies may be kept in the building in a locked storage room or in closed, locked metal cabinets or containers in a non-patient area of the facility;

13. All furnishings shall be clean and in good repair, and mechanical equipment shall be in good working order. Equipment shall be kept covered to protect from contamination and accessible for cleaning and inspection. Broken or worn items shall be repaired, replaced, or removed promptly;

14. 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;

15. All equipment and environmental surfaces shall be kept clean to sight and touch; and

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

8:43A-17.5 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.

1. Plastic bags shall be used for solid waste removal from patient care units and support 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.

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

3. 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.

4. All solid waste that is not regulated medical waste shall still be disposed of in a manner approved by the New Jersey Department of Environmental Protection. Disposal shall be as frequent as necessary to avoid creating a nuisance.

5. Indoor storage containers for solid waste shall be fireproof and kept covered when necessary to control odors or other nuisances.

6. Solid waste shall be stored within the containers provided for it in an area that is kept clean. Waste shall be collected from the 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.

(b) The facility shall comply with the provisions of N.J.S.A. 13:1E-48.1 et seq., the Comprehensive Regulated Medical Waste Management Act, and all rules promulgated pursuant to the aforementioned act.

(c) All liquid waste shall be collected, stored, and disposed of in accordance with the rules of the New Jersey Department of Environmental Protection.

8:43A-17.6 (reserved)