

CHAPTER 43G
HOSPITAL LICENSING STANDARDS

Authority

N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5(b).

Source and Effective Date

R.2005 d.279, effective July 22, 2005.
 See: 37 N.J.R. 709(a), 37 N.J.R. 3365(a).

Chapter Expiration Date

Chapter 43G, Hospital Licensing Standards, expires on July 22, 2010.

Chapter Historical Note

Chapter 43G, Certificate of Need: Capital Policy, was adopted as R.1986 d.375, effective September 8, 1986. See: 18 N.J.R. 1242(a), 18 N.J.R. 1817(a).

Chapter 43G, Certificate of Need: Capital Policy, was repealed by R.1988 d.114, effective March 21, 1988. See: 19 N.J.R. 2365(b), 20 N.J.R. 645(d).

Subchapter 1, General Provisions, Subchapter 2, Licensure Procedure, Subchapter 5, Administration and Hospital-Wide Services, Subchapter 19, Obstetrics, Subchapter 21, Oncology, Subchapter 22, Pediatrics, Subchapter 24, Plant Maintenance and Fire and Emergency Preparedness, Subchapter 26, Psychiatry, Subchapter 29, Physical and Occupational Therapy, Subchapter 30, Renal Dialysis, Subchapter 31, Respiratory Care, and Subchapter 35, Postanesthesia Care, were adopted as new rules by R.1990 d.95, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 2926(a), 22 N.J.R. 441(b).

Subchapter 4, Patient Rights, was adopted as new rules by R.1990 d.98, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 2160(b), 22 N.J.R. 484(a).

Subchapter 6, Anesthesia, was recodified from N.J.A.C. 8:43B-18 by R.1990, d.77, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 2925(a), 22 N.J.R. 488(a).

Subchapter 7, Cardiac, was adopted as new rules by R.1990 d.97, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 2162(a), 22 N.J.R. 488(b).

Subchapter 8, Central Supply, was adopted as new rules by R.1990 d.96, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1609, 22 N.J.R. 496(a).

Subchapter 9, Critical and Intermediate Care, was adopted as new rules by R.1990 d.94, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 2167(a), 22 N.J.R. 498(a).

Subchapter 10, Dietary, was adopted as new rules by R.1990 d.78, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1611(a), 22 N.J.R. 505(a).

Subchapter 11, Discharge Planning, was adopted as new rules by R.1990 d.93, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1612(a), 22 N.J.R. 507(a).

Subchapter 12, Emergency Department, was adopted as new rules by R.1990 d.92, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1613(a), 22 N.J.R. 510(a).

Subchapter 13, Housekeeping and Laundry, was adopted as new rules by R.1990 d.91, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1616(a), 22 N.J.R. 514(a).

Subchapter 14, Infection Control and Sanitation, was adopted as new rules by R.1990 d.90, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1618(a), 22 N.J.R. 517(a).

Subchapter 15, Medical Records, was adopted as new rules by R.1990 d.88, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 2171(a), 22 N.J.R. 520(a).

Subchapter 16, Medical Staff, was adopted as new rules by R.1990 d.89, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1621(a), 22 N.J.R. 524(a).

Subchapter 17, Nurse Staffing, was adopted as new rules by R.1990 d.87, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1623(a), 22 N.J.R. 530(a).

Subchapter 18, Nursing Care, was adopted as new rules by R.1990 d.86, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1624(a), 22 N.J.R. 531(a).

Subchapter 20, Employee Health, was adopted as new rules by R.1990 d.85, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 2173(a), 22 N.J.R. 535(a).

Subchapter 23, Pharmacy, was adopted as new rules by R.1990 d.84, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1626(a), 22 N.J.R. 537(a).

Subchapter 25, Post Mortem, was adopted as new rules by R.1990 d.83, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1628(a), 22 N.J.R. 541(a).

Subchapter 27, Quality Assurance, was adopted as new rules by R.1990 d.82, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1630(a), 22 N.J.R. 542(a).

Subchapter 28, Radiology, was adopted as new rules by R.1990 d.81, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 2174(a), 22 N.J.R. 544(a).

Subchapter 32, Same-Day Stay, and Subchapter 34, Surgery, were adopted as new rules by R.1990 d.80, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 2177(a), 22 N.J.R. 548(a).

Subchapter 33, Social Work, was adopted as new rules by R.1990 d.79, effective February 5, 1990, operative July 1, 1990. See: 21 N.J.R. 1631(a), 22 N.J.R. 555(a).

Pursuant to Executive Order No. 66(1978), Chapter 43G, Hospital Licensing Standards, was readopted as R.1995 d.124, effective February 3, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Pursuant to Executive Order No. 66(1978), Chapter 43G, Hospital Licensing Standards, was readopted as R.2000 d.71, effective January 27, 2000. See: 31 N.J.R. 2732(a), 32 N.J.R. 707(a).

Subchapter 36, Satellite Emergency Department, was adopted as new rules by R.2000 d.466, effective November 20, 2000. See: 32 N.J.R. 2184(a), 32 N.J.R. 4127(a).

Subchapter 37, Extracorporeal Shock Wave Lithotripsy, was adopted as new rules by R.2002 d.143, effective May 20, 2002. See: 33 N.J.R. 2624(a), 34 N.J.R. 1834(a).

Subchapter 38, Long Term Acute Care Hospitals General Requirements, was adopted as new rules by R.2003 d.49, effective January 21, 2003. See: 34 N.J.R. 490(a), 35 N.J.R. 4141(a).

Chapter 43G, Hospital Licensing Standards, was readopted as R.2005 d.279, effective July 22, 2005. As a part of R.2005 d.279, Subchapter 30, Renal Dialysis, was repealed and adopted as new rules by R.2005 d.279, effective September 6, 2005. See: Source and Effective Date. See, also, section annotations.

Subchapter 7A, Stroke Centers, was adopted as new rules by R.2007 d.35, effective February 5, 2007. See: 38 N.J.R. 91(a), 39 N.J.R. 439(a).

Subchapter 17A, Mandatory Staff Level Posting and Reporting Standards, was adopted as new rules by R.2008 d.63, effective March 17, 2008. See: 39 N.J.R. 1363(a), 40 N.J.R. 1647(a).

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4. Ophthalmic surgery;
5. Obstetric-gynecologic surgery;
6. Plastic surgery;
7. Oral/maxillofacial surgery;
8. Thoracic surgery;
9. Cardiology;
10. Internal medicine;
11. Pulmonary medicine;
12. Pediatrics; and
13. Radiology.

(e) For Level I trauma centers, there shall be physicians on call and promptly available in each of the following additional specialties:

1. Microvascular surgery (replant/flaps);
2. Hand surgery;
3. Cardiac surgery;
4. Pediatric surgery; and
5. Infectious disease.

New Rule, R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-12.18 Trauma services patient services

(a) The trauma service is required to provide on-site specialized services, including, at a minimum:

1. Acute hemodialysis;
2. Radiological services as follows:
 - i. Angiography;
 - ii. Computerized tomography, with a technician present in the hospital 24 hours a day; and
 - iii. Nuclear scanning;
3. For Level I trauma centers, cardiac surgery designation; and
4. A critical care unit for trauma center patients with a nurse:patient ratio of at least 1:2 on each shift.

New Rule, R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-12.19 Trauma services environment

There shall be an immediately available and adequately staffed operating room in-hospital 24 hours a day, for any emergency operative procedures needed by trauma center patients.

New Rule, R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-12.20 Trauma services quality improvement

(a) There shall be an organized quality improvement program at Level I and Level II trauma centers that is integrated into the hospital quality assurance 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.

(b) The quality improvement program shall include periodic collection and review of data in at least the following areas:

1. All trauma deaths and other cases identified by clinical indicators as potential problems;
2. Morbidity review;
3. Multidisciplinary trauma conference;
4. Medical nursing audit, utilization review, tissue review;
5. Review of prehospital trauma care; and
6. Any instances of bypass or diversion of major trauma patients.

New Rule, R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-12.21 Trauma services trauma registry

(a) Each Level I and Level II trauma center shall maintain a trauma registry enumerating demographic, injury scene, prehospital, emergency department, inpatient, and discharge/outcome data for all patients treated or evaluated by the trauma center. The trauma registry shall include all items in a minimum data set defined by the Department.

(b) All other hospitals shall maintain a trauma registry for major trauma patients, including all items in an abbreviated data set determined by the Department.

(c) In accordance with procedures which shall be established and promulgated by the Department by December 20, 2000, all hospitals shall periodically submit computerized trauma registry data to the Office of Emergency Medical Services, New Jersey Department of Health and Senior Services, for inclusion in the New Jersey State Trauma Registry.

(d) The Department shall not publicly disclose trauma registry data that identifies patients, staff, quality improvement determinations, or any data related to mortality or mortality rates for identified hospitals.

New Rule, R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-12.22 Trauma services compliance

(a) After designation, Level I and Level II trauma centers shall demonstrate continuing compliance with the applicable

requirements of this subchapter according to the following process:

1. Trauma centers shall maintain current verification at Level I or Level II in accordance with the verification review program conducted by the Committee on Trauma of the American College of Surgeons (ACS), described in Chapter 22 (page 97) of "Resources for the Optimal Care of the Injured Patient 1999," published by the Committee on Trauma, American College of Surgeons, 633 N. St. Clair Street, Chicago, IL 60611-3211, (312) 202-5456, incorporated herein by reference;

2. Trauma centers shall undergo ACS reverification reviews, at the hospital's expense, prior to expiration of current verification. The trauma center shall arrange for staff of the Office of Emergency Medical Services (OEMS) at the Department of Health and Senior Services to be present at such reviews;

3. The trauma center shall submit a copy of the written report of the ACS Verification Review Committee site visit to OEMS, and shall certify that it has corrected "criteria" deficiencies and addressed "non-criteria" recommendations contained in the ACS report within six months of receiving the report. However, individual patient chart reviews shall be considered confidential information, are not required to be submitted, and shall not be disclosed to the public;

4. The Department may use information from ACS verification reviews in the conjunction with other survey methods to determine whether licensure deficiencies have occurred, in accordance with the provisions of N.J.A.C. 8:43E; and

5. The Department may terminate the Level I or Level II designation of a trauma center for failure to maintain ACS verification or other licensure deficiencies if a continuing pattern of substandard care is demonstrated which adversely affects patient outcomes and which has not been corrected within six months. Proposed termination shall follow the process for enforcement remedies and hearings set forth in N.J.A.C. 8:43E.

New Rule, R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-12.23 Pediatric trauma services

(a) In addition to meeting the requirements in N.J.A.C. 8:43G-12.12 through 12.22, each Level I and Level II trauma center shall continuously maintain verification by the Committee on Trauma of the American College of Surgeons (ACS) as an adult trauma center for caring for injured children, in accordance with Chapter 10 (pages 39-42) of the ACS publication identified in N.J.A.C. 8:43G-12.22(a)1, except as otherwise provided in (b) below.

(b) A Level II trauma center which cannot meet the ACS pediatric trauma requirements specified in (a) above shall enter into a transfer agreement with the Level I trauma center for its region for the triage or transfer of pediatric trauma cases which the Level II trauma center does not have the capabilities to treat.

(c) Level I and Level II trauma centers shall have licensed general pediatric beds at the same site as other trauma center facilities and resources.

New Rule, R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

SUBCHAPTER 13. HOUSEKEEPING, LAUNDRY, AND SANITATION

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 Materials Safety Data Sheet (MSDS).

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

(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.

Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Rewrote (a).
Amended by R.2004 d.302, effective August 2, 2004.
See: 35 N.J.R. 2847(a), 35 N.J.R. 3782(a), 36 N.J.R. 3538(a).

In (c), substituted "with their Materials Safety Data Sheet (MSDS)" for "with a list of their antidotes"; in (d), substituted "with their Materials Safety Data Sheet (MSDS)" for "with a description of their antidotes"; in (e), inserted "as specified by the manufacturer" preceding "including"; added (f).

(e) There shall be seven duplex receptacles for each infant care station.

(f) Storage facilities for the neonatal intensive care nursery shall be as follows:

1. There shall be storage and counter space for immediate use within the infant's room for each infant care station; and

2. There shall be at least 30 square feet of floor space for equipment for each infant care station immediately accessible to the nursery.

(g) A soiled utility room shall be provided.

(h) A clean utility room or area shall be provided.

(i) A free-standing handwashing sink with hands free controls shall be provided at the entrance to the intensive care nursery. One sink shall be provided for every three infant care stations within the nursery.

(j) There shall be on-call room(s) for staff on the same floor of the hospital with an adjoining toilet, lavatory and shower.

(k) There shall be at least three multi-purpose rooms available for consultation, breast feeding, lactation training and conferences.

New Rule, R.1990 d.422, effective September 4, 1990.
See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).
Recodified from N.J.A.C. 8:43G-19.52 and amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).
Rewrote the section. Former N.J.A.C. 8:43G-19.37, General newborn care functional area requirements, recodified to N.J.A.C. 8:43G-19.31.

8:43G-19.38 Shared services

(a) If the intermediate care and neonatal intensive care nurseries are located in the same suite, then the following services may be shared:

1. Janitor's closet;
2. Soiled utility;
3. Clean utility;
4. The three multi-purpose rooms required for a intensive care nursery;
5. Storage room;
6. Male/female staff lockers, lounge and toilets; and
7. On-call room.

New Rule, R.1990 d.422, effective September 4, 1990.
See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).
Recodified from N.J.A.C. 8:43G-19.53 and amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Rewrote the section. Former N.J.A.C. 8:43G-19.38, Staff offices and lounge, repealed.

8:43G-19.39 (Reserved)

New Rule, R.1990 d.422, effective September 4, 1990.
See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).
Repealed by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).
Section was "Infant formula facilities".

8:43G-19.40 (Reserved)

New Rule, R.1990 d.422, effective September 4, 1990.
See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).
Repealed by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).
Section was "Neonatal unit soiled utility room".

8:43G-19.41 (Reserved)

New Rule, R.1990 d.422, effective September 4, 1990.
See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).
Repealed by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).
Section was "Neonatal unit clean work area or room".

8:43G-19.42 (Reserved)

New Rule, R.1990 d.422, effective September 4, 1990.
See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).
Repealed by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).
Section was "Neonatal unit janitor's closet".

8:43G-19.43 (Reserved)

New Rule, R.1990 d.422, effective September 4, 1990.
See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).
Repealed by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).
Section was "Neonatal unit clerical area".

8:43G-19.44 (Reserved)

New Rule, R.1990 d.422, effective September 4, 1990.
See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).
Repealed by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).
Section was "Neonatal unit multipurpose rooms".

8:43G-19.45 (Reserved)

New Rule, R.1990 d.422, effective September 4, 1990.
See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).
Repealed by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).
Section was "Neonatal unit nursery area".

8:43G-19.46 (Reserved)

Recodified to N.J.A.C. 8:43G-19.32 by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-19.47 (Reserved)

Recodified to N.J.A.C. 8:43G-19.33 by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-19.48 (Reserved)

Recodified to N.J.A.C. 8:43G-19.34 by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-19.49 (Reserved)

New Rule, R.1990 d.422, effective September 4, 1990.

See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

Repealed by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Section was "Continuing care/growing area".

8:43G-19.50 (Reserved)

Recodified to N.J.A.C. 8:43G-19.35 by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-19.51 (Reserved)

Recodified to N.J.A.C. 8:43G-19.36 by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-19.52 (Reserved)

Recodified to N.J.A.C. 8:43G-19.37 by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

8:43G-19.53 (Reserved)

Recodified to N.J.A.C. 8:43G-19.38 by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

SUBCHAPTER 20. EMPLOYEE HEALTH**8:43G-20.1 Employee health policies and procedures**

(a) Employee health 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 shall be readily available for employees to review and include at least the following:

1. The content and frequency of employee health examinations performed by a registered professional nurse, physician, or other qualified medical personnel as defined at N.J.A.C. 8:43G-20.2(a);
2. Precautionary measures to prevent the transmission of communicable diseases from employees to patients;
3. Requirements for a physician note approving an employee's return to work after an absence due to a communicable disease; and
4. Clinical restrictions for employees exposed to rubella or rubeola who are seronegative and unvaccinated.

Amended by R.1992 d.72, effective February 18, 1992.

See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Clinical restrictions added at (a)5.

Amended by R.1995 d.124, effective March 20, 1995.

See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Amended by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

In (a), substituted "at least once every three years, revised more frequently" for "annually, revised" in the introductory paragraph, and rewrote 1.

8:43G-20.2 Employee health services

(a) Each new employee shall receive an initial health evaluation, which includes at least a documented history, which may be performed by a registered professional nurse, physician or other qualified personnel (defined as a licensed physician assistant or a certified nurse practitioner/clinical nurse specialist), and a physical examination.

(b) Employee health records shall be maintained for each employee. Employee health records shall be confidential, and kept in the employee health office separate from personnel records.

(c) The employee health record shall include documentation of all medical screening tests performed and the results.

(d) Tuberculosis screening: The facility shall establish policies and procedures for the detection and control of the transmission of *M. tuberculosis* that include, but are not limited to, developing a Tuberculosis Exposure Control Plan ("TB plan"), according to the guidelines set forth in "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994," The Morbidity and Mortality Weekly Report published by the Epidemiology Program Office, Centers for Disease and Control and Prevention (CDC) and available from the Superintendent of Documents, US Government Printing Office, Washington, DC 20402-9325 (MMWR), October 28, 1994, Volume 43, Number RR-13, p. i-132, pursuant to the Occupational Safety and Health Act (OSH Act) of 1970, incorporated herein by reference as amended and supplemented.

1. Newly hired employees: The facility shall establish policies and procedures that will identify a new employee's baseline status of exposure to *M. tuberculosis*. Upon employment, the facility shall administer a two-step Mantoux tuberculin skin test, using five tuberculin units of purified protein derivative, to all employees. Employees are defined, for the purposes of this subsection, as full and part-time employees, volunteer staff, and physicians, either salaried by the facility or with clinical privileges to provide medical care at the facility.

i. Employees with a "negative" (less than 10 mm of induration or less than five mm of induration if the individual is immunosuppressed) result following the first Mantoux skin test are administered a second test in one to three weeks.

ii. Employees with a "positive" (greater than 10 mm of induration or greater than five mm of induration if the individual is immunosuppressed) result following either the first or second test are referred for a medical evaluation to determine whether there is evidence of latent tuberculosis infection or active tuberculosis disease.

(1) The medical evaluation shall include, but is not limited to, a chest X-ray.

(2) The facility shall permit employees with positive Mantoux test results to begin working after the employee has submitted written medical clearance to the facility.

iii. Exceptions:

(1) Employees who provide documentation of negative results of a single Mantoux skin test performed within the 12 months preceding the start of employment shall receive only one Mantoux skin test upon hire.

(2) Employees with prior documentation of negative results of two Mantoux skin tests performed within 12 months preceding the start of employment, and without signs and symptoms of active tuberculosis, shall not be required to be tested upon hire; however, a Mantoux skin test shall be required within 12 months of the last tuberculin skin test.

(3) Employees who provide documentation of positive Mantoux skin test results shall be exempt from screening.

(4) Employees who provide documentation of having received and completed appropriate medical treatment for active tuberculosis disease or latent tuberculosis infection shall be exempt from screening.

2. Periodic screening of personnel: The facility shall establish policies and procedures for the periodic screening of *M. tuberculosis* in eligible personnel, including, but not limited to:

i. Testing: The facility shall administer a Mantoux skin test to all tuberculin-negative employees annually at minimum. Frequency of testing shall be determined by the level of risk assigned by the facility's TB plan.

ii. Recordkeeping: The facility shall maintain records of the results of employee Mantoux tuberculin testing.

3. Further information: Questions regarding tuberculosis control may be directed to:

New Jersey Department of Health and Senior Services
Tuberculosis Program
PO Box 369
Trenton, NJ 08625-0369
(609) 588-7522

(e) Rubella screening: Each employee, including members of the medical staff employed by the hospital, shall be given a rubella screening test using the rubella hemagglutination inhibition test or other rubella screening test. The only exceptions are employees who can document seropositivity from a previous rubella screening test or who can

document inoculation with rubella vaccine, or when medically contraindicated.

1. Each new employee, including members of the medical staff employed by the hospital, shall be given a rubella screening test upon employment.

(f) Measles (Rubeola) Screening: Each employee, including members of the medical staff employed by the hospital, born in 1957 or later shall be given a measles (rubeola) screening test using the Hemagglutination inhibition test or other rubeola screening test. The only exceptions are employees who can document receipt of live measles vaccine on or after their first birthday, physician-diagnosed measles, or serologic evidence of immunity.

1. Each new employee, including members of the medical staff employed by the hospital, born in 1957 or later shall be given a rubeola screening test, upon employment.

(g) The hospital shall offer rubella and rubeola vaccination to all employees and medical staff.

(h) The hospital shall maintain a list identifying the name of each employee who is seronegative and unvaccinated.

(i) The hospital shall comply with the reporting requirements of the Department of Health and Senior Services' Division of Epidemiology, Environmental and Occupational Health Services for tuberculin and rubella test results, pursuant to N.J.A.C. 8:57. Information regarding testing and reporting can be obtained from:

New Jersey State Department of Health and Senior Services
Communicable Disease Control Services
PO Box 369
Trenton, NJ 08625-0369

(j) The hospital shall provide initial health care for employees who become ill or have a work-related illness or injury. "Initial health care" means that the ill or injured employee shall be seen and evaluated by a physician, licensed physician assistant, or certified nurse practitioner/clinical nurse specialist and stabilized prior to referral for further treatment, as appropriate.

(k) Personnel who are absent from work because of any reportable communicable disease, infection, or exposure to infection, as defined in N.J.A.C. 8:57, shall be excluded from working in the hospital until they have been examined by a physician and certified by the physician as no longer endangering the health of patients or employees. If the absence is less than three full days, the hospital's employee health nurse may certify that the employee is able to return to work.

(l) The hospital shall have a program addressing the needs of impaired employees, which at a minimum, shall

include methods or mechanisms to identify and refer impaired employees to rehabilitation programs.

Amended by R.1992 d.72, effective February 18, 1992.
See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Text added at (f)-(i) on rubella/rubeola.
Amended by R.1995 d.124, effective March 20, 1995.
See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Rewrote (a) and (m); in (d), inserted "(which will count as the first step; a second step shall be given prior to employment)" in the second sentence of the introductory paragraph, and added 3; in (g), deleted "in accordance with (e) above" at the end; in (h), deleted "by March 1, 1992" at the end of the first sentence; in (i), deleted ". in accordance with (g) above" at the end; and in (n), added a second sentence.
Amended by R.2004 d.302, effective August 2, 2004.

See: 35 N.J.R. 2847(a), 35 N.J.R. 3782(a), 36 N.J.R. 3538(a).
Rewrote the section.

8:43G-20.3 (Reserved)

8:43G-20.4 Employee health education

Requirements for the employee health education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-20.5 (Reserved)

8:43G-20.6 Employee health continuous quality improvement methods

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

Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Substituted references to continuous quality improvement for references to quality assurance throughout.

SUBCHAPTER 21. ONCOLOGY

8:43G-21.1 Scope of oncology standards

The standards in this subchapter shall apply only to hospitals that have a separate, designated patient care unit for oncology.

8:43G-21.2 Oncology structural organization

(a) There shall be a multidisciplinary cancer committee, chaired by a physician, that is responsible for at least the development of oncology policies and procedures, tumor review, and tumor registry.

(b) There shall be a formal mechanism for communication between the oncology service and each of the following clinical areas: nursing, dietary, social work, and pharmacy.

8:43G-21.3 (Reserved)

8:43G-21.4 Oncology policies and procedures

(a) The unit 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 least:

1. Criteria for admission;
2. Guidelines for mixing chemotherapy, when performed on the unit, that reference Occupational Safety and Health Administration (OSHA) guidelines: "Work Practice Guidelines for Personnel Dealing with Cytotoxic Drugs," OSHA Instruction PUB 8-1.1, PB 89203301 Office of Occupational Medicine;
3. Guidelines for administering chemotherapy that follow national Oncology Nursing Society guidelines; available from the Oncology Nursing Society, 1016 Greentree Road, Pittsburgh, PA 15220-3125, telephone 412-921-7373.
4. Training of nursing and housekeeping staff in the disposal of chemotherapeutic agents;
5. Use, handling, storage, and disposal of specific chemicals, agents, and body wastes;
6. Assuring informed consents to chemotherapy; and
7. Psychological/social and spiritual aspects of patient care.

(b) There shall be written visiting policies for patients that allow for visits by children and 24-hour visitation rights for designated visitors.

Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

In (a), substituted "at least once every three years, revised more frequently" for "annually, revised" in the introductory paragraph.

8:43G-21.5 Oncology staff qualifications

(a) There shall be a clinical coordinator with responsibility to administer the program of care who is a registered professional nurse with the equivalent of two years of full-time experience in oncology.

(b) There shall be a clinical resource person who is a registered professional nurse with the equivalent of two years of clinical experience in oncology who is available to the unit.

8:43G-21.6 (Reserved)

8:43G-21.7 Oncology staff time and availability

(a) A member of social work services shall be assigned to the unit to provide psychosocial services, assist with discharge planning, and provide information regarding financial aspects of care.

(b) A registered dietitian shall be assigned to the oncology service.

8:43G-21.8 (Reserved)**8:43G-21.9 Oncology patient services**

(a) There shall be multidisciplinary patient care team meetings that take place on a regularly scheduled basis and include at least a physician or physician's appointed designee, a nurse, a social worker, a dietitian, and other disciplines as necessary.

(b) Patient and family teaching shall be provided in any case where the patient and family are in need of and able to receive instruction.

(c) Criteria shall be developed in consultation with the social work department for identifying patients in need of social work services and/or discharge planning and making referrals as needed.

(d) There shall be a system to refer patients, family and staff to in-house and community support groups and services.

8:43G-21.10 (Reserved)**8:43G-21.11 Oncology space and environment**

(a) There shall be food-warming facilities on the unit for use by patients and their families.

(b) Single bedrooms shall be available as needed to accommodate patients with neutropenia, bone marrow transplants, or radiation implants.

8:43G-21.12 (Reserved)**8:43G-21.13 Oncology supplies and equipment**

A Class 2 Vertical Laminar Air Flow Hood shall be used during the preparation of all chemotherapy on the unit. Occupational Safety and Health Administration (OSHA) guidelines: "Work Practice Guidelines for Personnel Dealing with Cytotoxic Drugs," OSHA Instruction PUB 8-1.1, Office of Occupational Medicine, shall be used to develop procedures for preparing chemotherapy.

8:43G-21.14 (Reserved)**8:43G-21.15 Oncology staff education**

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

8:43G-21.16 (Reserved)**8:43G-21.17 Oncology continuous quality improvement methods**

There shall be a program of continuous quality improvement for oncology that is integrated into the hospital continuous 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.

Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Substituted references to continuous quality improvement for references to quality assurance throughout.

SUBCHAPTER 22. PEDIATRICS**8:43G-22.1 Scope of pediatric and pediatric intensive care standards**

The standards in this subchapter shall apply only to hospitals that have a separate, designated unit or service for pediatrics and pediatric intensive care.

8:43G-22.2 Pediatrics and pediatric intensive care policies and procedures

(a) The 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 least:

1. The age below which all patients must be admitted to a pediatric service;
2. The age above which patients are admitted to a pediatric service only at the discretion of the physician director of the service;
3. Admission and discharge criteria specific to the service;
4. A visitors policy that allows for 24 hour visitation by designated visitors and specifies the number of visitors permitted each patient at any one time;
5. Criteria for those pediatric patients who require a pediatric consultation or case management by a pediatrician;
6. Infection control protocols;
7. Protocols for specific types of patient emergencies;

8. An emergency transfer policy which specifies mechanisms for transport of pediatric patients requiring specialized or intensive care services to facilities providing such care; and

9. Safety measures for the purpose of preventing electrical and bodily injury to patients.

(b) Every patient under 18 years of age who is admitted temporarily to the adult intensive care unit shall receive a pediatric consultation.

(c) If the hospital does not have pediatric intensive care services, the hospital must state the conditions under which a pediatric patient may be temporarily admitted to the adult intensive care unit. The hospital shall establish and implement protocols for the stabilization and transfer of these patients to a facility providing pediatric intensive care services.

(d) The pediatric services shall participate in developing anesthesia and pain management policies for infants and children.

Amended by R.1992 d.72, effective February 18, 1992.
See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Safety requirements added at (a)9.
Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

In (a), substituted "at least once every three years, revised more frequently" for "annually, revised" in the introductory paragraph.

8:43G-22.3 Pediatrics and pediatric intensive care patient services

(a) The nursing assessment of each pediatric patient shall include assessment of the patient's developmental needs. Nursing care shall be structured around this assessment.

(b) All standard blood studies on pediatric patients shall use at least micro methodology.

(c) There shall be documented evidence of pediatric medical and nursing staff participation in the development of policies and procedures of pediatric patients in any department where pediatric patients may receive treatment. At a minimum, this shall include the areas of dietary, emergency department, laboratory, pharmacy services, radiology, rehabilitation, and social work.

(d) Criteria shall be developed in consultation with the social work department for identifying patients in need of social work and/or discharge planning and making referrals as needed.

(e) The parents or guardians of pediatric patients shall be included in the development of the nursing patient plan of care.

Amended by R.1992 d.72, effective February 18, 1992.
See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).
Guardians added at (e).

8:43G-22.4 (Reserved)**8:43G-22.5 Pediatrics and pediatric intensive care supplies and equipment**

Emergency equipment shall be child-sized or adaptable for children.

8:43G-22.6 Pediatrics and pediatric intensive care staff education

Requirements for the pediatrics and pediatric intensive care education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-22.7 (Reserved)**8:43G-22.8 Pediatric and pediatric intensive care continuous quality improvement methods**

There shall be a program of continuous quality improvement for each pediatric service that is integrated into the hospital continuous 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. The data shall include, but not be limited to, the number of pediatric admissions to the adult intensive care unit.

Amended by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Substituted references to continuous quality improvement for references to quality assurance throughout, and added a second sentence.

8:43G-22.9 Scope of pediatrics standards

The standards in N.J.A.C. 8:43G-22.10 through 22.12 shall apply only to hospitals that have a separate, designated unit or service for pediatrics.

8:43G-22.10 Pediatric staff qualifications

(a) The physician director of the pediatric service shall be board certified in pediatrics.

(b) The nurse with administrative responsibility for nursing care in pediatrics shall be a registered professional nurse with at least three years of experience in pediatrics.

8:43G-22.11 (Reserved)**8:43G-22.12 Pediatrics space and environment**

(a) A minimum of 10 percent of the beds used for pediatric care shall be capable of functioning as isolation rooms.

(b) Each pediatric unit shall have at least one playroom with recreation equipment and child-size tables and chairs.

(c) There shall be an adult supervising when children under seven years of age are present in the recreation room or playroom.

Amended by R.1992 d.72, effective February 18, 1992.

See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Safety requirements deleted (sec 22.2).

8:43G-22.13 Scope of pediatric intensive care standards

The standards in N.J.A.C. 8:43G-22.14 through 22.22 shall apply only to hospitals that have a separate, designated unit or service for pediatric intensive care.

8:43G-22.14 Pediatric intensive care structural organization

There shall be a multidisciplinary pediatric intensive care committee or its equivalent that includes at least representatives of nursing, medical staff, administration, respiratory therapy, and social work. This committee shall meet regularly to discuss unit administration and ways of improving interdisciplinary communication on the pediatric intensive care unit.

8:43G-22.15 Pediatric intensive care staff qualifications

(a) There shall be a full-time physician director of the pediatric intensive care service who is board certified or board eligible in pediatric critical care.

(b) The pediatric intensive care unit shall be covered at all times by at least one physician, present in the hospital or on call, who is board certified or board eligible in pediatrics and has either five years of experience in pediatrics or has completed a fellowship in a pediatric subspecialty.

(c) The pediatric intensive care unit shall have physicians with each of the following pediatric subspecialties on staff: anesthesiology, cardiology, hematology/oncology, infectious diseases, nephrology, neurology, pulmonary, radiology, and surgery.

(d) The pediatric intensive care unit shall have a formal consultative relationship with physicians in the following pediatric subspecialties: endocrinology, gastroenterology, neurosurgery, otolaryngology, and urology.

(e) Specific privileges for physicians who admit patients to the pediatric intensive care unit shall be delineated by the hospital with participation of the physician director of the pediatric intensive care unit.

(f) The nurse with administrative responsibility for nursing in the pediatric intensive care unit shall be a registered professional nurse with specialized training in pediatric critical care and at least three years of experience in a pediatric intensive care unit.

(g) There shall be a health professional trained in resuscitation of children available within the unit at all times.

(h) Effective January 1, 1992, there shall be a health professional certified in advanced pediatric life support available within the unit at all times.

8:43G-22.16 Pediatric intensive care staff time and availability

(a) There shall be a physician who can handle pediatric emergencies, other than the physician assigned to the emergency department, in the hospital at all times.

(b) There shall be at least one registered professional nurse to every two patients in the pediatric intensive care unit.

(c) There shall be at least one full-time clerical support staff person assigned full or part time to the pediatric intensive care unit.

(d) The services of the following staff with specialized training or experience in pediatrics shall be available to pediatric intensive care unit patients and their families: child-life specialist, social worker, physical therapist, occupational therapist, psychiatrist, and nutritionist.

(e) The hospital shall have available a transport team staffed by health professionals with special training in pediatrics.

8:43G-22.17 Pediatric intensive care patient services

(a) The following services shall be available to the pediatric intensive care unit at all times:

1. Blood bank;
2. Dialysis;
3. Hematology;
4. Laboratory;
5. Nuclear medicine;
6. Pharmacy;
7. Radiology;
8. Computer tomography; and
9. Respiratory therapy.

(b) There shall be a system that is available to the pediatric intensive care unit at all times for transporting acutely ill children between hospitals.

(c) There shall be a policy that addresses optional overnight stays in the hospital or adjacent buildings for parents or guardians of pediatric intensive care patients.

Amended by R.1992 d.72, effective February 18, 1992.
See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).
Parent overnight stay added at (c).

8:43G-22.18 (Reserved)**8:43G-22.19 Pediatric intensive care space and environment**

(a) There shall be at least one isolation room in the pediatric intensive care unit. There shall be additional isolation rooms based on a ratio of one room to every six pediatric intensive care beds.

(b) The pediatric intensive care unit shall be a closed unit, and no traffic to other departments or units shall pass through it.

(c) There shall be a room nearby the pediatric intensive care unit where the physician can sleep.

(d) There shall be a sitting room or lounge area nearby the pediatric intensive care unit for the families of patients in the unit.

8:43G-22.20 Pediatric intensive care supplies and equipment

(a) The pediatric intensive care unit shall have immediate access to equipment that has the capability for continuous monitoring of at least:

1. Arterial pressure;
2. Central venous pressure;
3. Electrocardiogram;
4. Heart rate;
5. Intracranial pressure;
6. Pulmonary arterial pressure;
7. Respiration;
8. Temperature; and
9. Three simultaneous pressure capability.

(b) The pediatric intensive care unit shall have immediate access to the following equipment:

1. Defibrillator;
2. Intravenous fluid warmer;
3. Metabolic bed scale; and
4. Pulse oximeter.

(c) The pediatric intensive care unit shall have access to the following equipment within the hospital:

1. Bilirubin lights;
2. End tidal carbon dioxide measurement; and
3. Isolation equipment.

(d) Provisions shall be available for emergency repair of biomedical equipment in the pediatric intensive care unit.

Amended by R.1992 d.72, effective February 18, 1992.
See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).
Stylistic changes.

8:43G-22.21 (Reserved)**8:43G-22.22 Pediatric intensive care continuous quality improvement methods**

The continuous quality improvement program for pediatric intensive care shall include interhospital exchanges or information and case reviews with pediatric specialists in other hospitals.

Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Substituted a reference to continuous quality improvement for a reference to quality assurance.

SUBCHAPTER 22A. LICENSURE OF CHILDREN'S HOSPITAL DESIGNATION
Authority

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

Source and Effective Date

R.2002 d.339, effective October 21, 2002.
See: 34 N.J.R. 1305(a), 34 N.J.R. 3637(b).

8:43G-22A.1 Scope of children's hospital designation standards

The standards set forth in this subchapter shall apply only to hospitals that are licensed as children's hospitals.

8:43G-22A.2 Organizational structure

(a) The hospital shall have a governing body, which shall carry out the following responsibilities: safeguard the program's resources; approve the children's program's long range plan; and approve the children's program's operation plans. The governing body shall meet either of the following criteria:

1. Constitute a separate, autonomous governing body of either a subsidiary corporation or multi-hospital system; or
2. Constitute a standing committee of the governing body charged with ongoing children's program review, together with a dedicated fundraising program for the children's hospital, which reports periodically to the standing committee.

(b) There shall be an individual responsible for the administration of the children's program and for patient care services, particularly for the coordination and direction of nursing services, who shall be accountable to the standing committee of the governing body.

(c) The children's program shall have fiscal autonomy which shall conform with either of the following:

1. A separate Medicare provider number;
2. A separate operating budget, with separate control over income and expenses; or
3. Defined costs for the children's program, with:
 - i. Discrete cost centers which allocate the cost of all services provided, including, but not limited to, overhead, indirect costs; and
 - ii. A separate staffing plan.

8:43G-22A.3 Continuous quality improvement

The hospital shall have an organized quality improvement program for each pediatric service which 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. The data shall include, but not be limited to, the number of child admissions.

8:43G-22A.4 Medical staff and teaching program

(a) The hospital shall be a teaching site for an organized academic department of pediatrics of an approved medical school program.

(b) The hospital shall be engaged in an ongoing clinical research program.

(c) The pediatric teaching program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education (ACGME) or any other group approved by the State Board of Medical Examiners for a minimum of 12 pediatric resident positions.

8:43G-22A.5 Building and facilities

(a) The children's program shall have adequate physical space and facilities provided either in a separate building(s) or in a defined and contiguous space within a building reserved for the housing of children which shall include:

1. Inpatient facilities separate from obstetrics;
2. Organized and accessible outpatient clinics for children that shall have, at a minimum, space reserved for children at scheduled times; and
3. A discrete pediatric area within the emergency department by October 21, 2005.

8:43G-22A.6 Essential special care services

(a) By October 21, 2003, all licensed children's hospitals shall operate a pediatric intensive care unit in accordance with N.J.A.C. 8:43G-22.

(b) A licensed children's hospital not licensed to operate a pediatric intensive care unit on October 21, 2002 shall file a licensing application to initiate such a unit in accordance with (a) above. Such a licensing application shall be filed in accordance with the procedures described in N.J.A.C. 8:43G-2.2 through 2.5, as applicable.

(c) By October 21, 2003, all licensed children's hospitals shall operate a regional perinatal center in accordance with N.J.A.C. 8:43G-19, and applicable provisions of N.J.A.C. 8:33C, including N.J.A.C. 8:33C-3.4(a) 3 through 10.

(d) A licensed children's hospital not licensed to operate a regional perinatal center on October 21, 2002 shall file a licensing application to initiate such a service, including neonatal intermediate and intensive care unit(s), in conformance with (c) above. Such a licensing application shall be filed in accordance with the procedures described in N.J.A.C. 8:43G-2.2 through 2.5, as applicable.

(e) A licensed children's hospital not also licensed to operate a pediatric intensive care unit or a regional perinatal center on October 21, 2002 shall not be required to obtain certificate of need approval to establish such a unit or center, including neonatal intensive or intermediate care unit(s) within the center.

1. A licensed children's hospital without a licensed pediatric intensive care unit may establish such a unit with a maximum size of six beds without certificate of need approval.

2. A licensed children's hospital without a licensed neonatal intermediate or intensive care unit may establish such a unit(s) with a maximum size of four bassinets for an intermediate care nursery and six bassinets for an intensive care nursery without certificate of need approval.

Case Notes

Given the presumption of validity and reasonableness accorded to administrative regulations, N.J.A.C. 8:43G-22A.6(c) and (e), which required all licensed children's hospitals in the State to operate a regional perinatal center and exempted already licensed children's hospitals from the requirement to obtain a certificate of need before establishing the regional perinatal center, were valid. *St. Peter's Univ. Hosp. v. Lacy*, 185 N.J. 1, 878 A.2d 829, 2005 N.J. LEXIS 950 (2005).

SUBCHAPTER 23. PHARMACY

8:43G-23.1 Pharmacy structural organization

(a) A hospital shall have a pharmacy that is licensed by the New Jersey State Board of Pharmacy, with a current Drug Enforcement Administration registration and a controlled dangerous substance registration from the State Department of Health.

(b) A multidisciplinary pharmacy and therapeutics committee, or an equivalent multidisciplinary body which in-

cludes a pharmacist licensed to practice pharmacy in New Jersey, shall meet at least quarterly and document its activities, findings, and recommendations.

Amended by R.1992 d.72, effective February 18, 1992.
See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).
Pharmacist added to (b).

8:43G-23.2 Pharmacy policies and procedures

(a) The pharmacy and therapeutics committee, or its equivalent, shall review, approve, and ensure implementation of policies and procedures addressing at least the following areas:

1. Outpatient pharmacy services;
2. Administration of drugs;
3. Use of patients' previously acquired drugs, including requirement for physician orders and pharmacy identification of the drugs before use;
4. Admixture of intravenous solutions, including quality control and safety procedures for laminar airflow hoods and labeling;
5. Storage and distribution of drugs, including at least dispensing devices (if used in the hospital), emergency drugs and kits, and control and accountability of controlled substances in accordance with applicable laws and regulations;
6. Stop orders and discontinue orders, including the length of time all orders stay in effect, stoppage of drugs on the day a patient undergoes surgery in conformance with the prescriber's specifications, and notification of the prescriber of the expiration of a drug order;
7. Identification, reporting, reviewing, and monitoring of adverse drug reactions and medication errors;
8. Identification and prevention of food/drug interactions and responsibility of pharmacy, nursing, and dietary services, including responsibility for the following:
 - i. Ensuring that appropriate food or fluid requirements are met when administering medication;
 - ii. Adjusting the contents of the patient's meal tray whenever an increase or decrease in a specific nutrient is ordered; and
 - iii. Educating the patient about potential food/drug interactions prior to discharge and
9. Current reference materials kept at drug distribution stations and in the pharmacy, and made available to medical and nursing staff;
10. Control and limitation of use of drugs marked "sample";
11. Approval and maintenance of an up-to-date formulary;

12. Pharmacists' clarifications of physician orders; and

13. Self-administration of drugs, if permitted by the hospital, including a requirement for written prescriber orders, storage of drugs, labeling of drugs, documentation of self-administration in the patient medical record, patient training and education, and precautions to ensure that a patient does not take the drugs of another patient.

Amended by R.1992 d.72, effective February 18, 1992.

See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Text on self-administration of drugs added at (a)13.

Amended by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Rewrote (a)8.

8:43G-23.3 Pharmacy staff qualifications

(a) Pharmaceutical services shall be directed by a registered pharmacist licensed to practice pharmacy in New Jersey.

(b) A pharmacist licensed to practice pharmacy in New Jersey shall be responsible for compounding, preparing, labeling, transferring between containers, and dispensing drugs, including direct supervision of supportive personnel, as defined at N.J.A.C. 13:39-1.2.

8:43G-23.4 Pharmacy staff time and availability

(a) A pharmacist licensed to practice pharmacy in New Jersey shall be on duty or on call at all times.

(b) When, in the pharmacist's absence from the hospital, a registered professional nurse removes a drug from the designated pharmacy stock or night cabinet for use in an emergency, this action shall be recorded by the nurse and checked by a pharmacist on a daily basis.

(c) If the hospital operates a decentralized pharmaceutical service, there shall be a pharmacist licensed to practice pharmacy in New Jersey assigned to each satellite pharmacy during the satellite pharmacy's hours of operation.

8:43G-23.5 (Reserved)

8:43G-23.6 Pharmacy patient services

(a) Pharmaceutical services shall be available to patients at all times.

(b) The hospital shall have in effect a unit dose drug distribution system with individual cassettes or containers which bear the patient's identification. The system shall cover at least the medical/surgical, obstetric, pediatric, and psychiatric units and include scheduled cart exchanges at least every 24 hours, including weekends and holidays.

1. An alternative method of distributing drugs approved by the Department of Health may be substituted for the unit dose drug distribution system if the method has been demonstrated to the Department to have at least equivalent clinical effectiveness.

(c) The dispensing of fractional and multiple dosages shall be at the discretion of the pharmacy and therapeutics committee or its equivalent, provided cautionary instructions and ancillary information about these dosages are communicated to the personnel responsible for administering them.

(d) The pharmacy service shall develop and implement a system of control for legend drug doses. A pharmacist licensed to practice pharmacy in New Jersey shall check each cassette or container of drugs prepared by supportive personnel, as defined at N.J.A.C. 13:39-1.2, before it is delivered to a patient care unit.

(e) The hospital shall have a pharmacy-based intravenous infusion admixture program, which includes services related to preparation of total parenteral nutrition, antineoplastic agents, and large and small, continuous or intermittent volume products for infusion. A pharmacist licensed to practice pharmacy in New Jersey, or supportive personnel,

as defined at N.J.A.C. 13:39-1.2, shall prepare, sterilize if necessary, and label parenteral medications and solutions, except in those areas or situations that have been excluded by the pharmacy and therapeutics committee or its equivalent.

(f) Cautionary instructions and ancillary information about medications shall be communicated in writing to the personnel responsible for administering medications.

(g) All medication orders shall specify the name of the drug, dose, frequency, and route of administration, and shall be dated and signed (or approved by authorization code if ordered through computer entry) by the prescriber.

(h) Allergies, including allergy to latex, shall be documented in the patient's pharmacy profile.

(i) Drugs in single dose or single use containers which are open or which have broken seals, drugs in containers missing drug source and exact identification (such as lot number), and outdated medications shall be returned to the pharmacy for disposal.

(j) Initials or identifying codes shall be used by pharmacy personnel, and a list of these initials or codes and the corresponding printed or typed names and signatures shall be kept for at least five years after termination of pharmacy service employment.

(k) Current antidote information shall be provided in the pharmacy. The telephone number of the designated State-wide or regional New Jersey Poison Information and Education System (1-800-962-1253) shall be provided in the pharmacy and in each patient care unit or area.

(l) Current Federal and State drug law information shall be available to the pharmacy service.

(m) Drug product defects shall be reported in accordance with the drug product problem reporting system of the United States Pharmacopoeia or of the Food and Drug Administration.

Amended by R.1992 d.72, effective February 18, 1992.

See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Written communication specified at (f).

Amended by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

In (h), inserted a reference to allergy to latex.

8:43G-23.7 (Reserved)

8:43G-23.8 Pharmacy space and environment

(a) The pharmacy shall maintain drugs under proper conditions, as indicated in the United States Pharmacopoeia, product labeling, and/or package inserts.

(b) All drugs, needles, and syringes shall be kept in locked storage areas except those drugs exempted by the

pharmacy and therapeutics committee or its equivalent under specified conditions.

8:43G-23.9 Pharmacy staff education and training

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

8:43G-23.10 Pharmacy continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for the pharmacy service that is integrated into the hospital continuous 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.

(b) The pharmacy service shall have in effect a patient profile system for monitoring drug therapy. This system shall be used by the hospital to identify inappropriate prescribing practices.

(c) The pharmacy service shall inspect at least once every two months all patient care areas in the hospital, and at least once every three months all other areas of the hospital where drugs intended for administration to patients are dispensed, administered, or stored. The pharmacy service shall maintain a record of the inspections. Identified problems shall be addressed.

(d) A quality improvement program of the pharmacy service shall monitor, at a minimum, the use of drugs, including medication errors and use of antibiotics. Serious or consistent patterns of medication error shall be reported to the pharmacy and therapeutics committee or its equivalent.

Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

In (a), substituted references to continuous quality improvement for references to quality assurance throughout; and in (d), substituted a reference to quality improvement for a reference to quality assurance.

8:43G-23.11 (Reserved)

SUBCHAPTER 24. PLANT MAINTENANCE AND FIRE AND EMERGENCY PREPAREDNESS

8:43G-24.1 Plant maintenance structural organization

(a) There shall be a multidisciplinary safety committee that develops a comprehensive hospital-wide safety program that is reviewed at least once every three years, revised more frequently as needed, and implemented.

(b) There shall be a mechanism to report all incidents, injuries and safety hazards to the safety committee.

(c) The safety committee shall review all reports and be responsible for ensuring that all reports are referred appropriately and follow-up action is documented.

Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

In (a), substituted "at least once every three years, revised more frequently" for "annually, revised" following "reviewed".

8:43G-24.2 Plant maintenance policies and procedures

(a) The building maintenance service shall have written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and implemented.

(b) The building maintenance service shall have a written preventive maintenance program for buildings, equipment and utilities.

Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

In (a), substituted "at least once every three years, revised more frequently" for "annually, revised" following "reviewed".

8:43G-24.3 Plant maintenance staff qualifications

(a) The building maintenance service shall be under the supervision of an employee with at least one of the following qualifications:

1. Five years of experience in health care plant maintenance, three of which shall be in a supervisory capacity;
2. A baccalaureate degree in engineering from an accredited college or university and three years of experience in health care plant maintenance, two of which shall be in a supervisory capacity; or
3. A current professional engineer license in New Jersey and three years of experience in health care plant maintenance, two of which shall be in a supervisory capacity.

(b) There shall be an in-hospital or contracted biomedical electronics equipment maintenance and safety program under the supervision of an individual with at least:

1. A two-year associate's degree in biomedical engineering from an accredited college or university and two years of experience in the field of biomedical engineering; or
2. Four years of combined experience and/or training from an accredited technical school or military program.

8:43G-24.4 Plant maintenance services

(a) Records of preventive maintenance inspections and repairs of electrical and mechanical systems shall be maintained for at least one year.

(b) The building maintenance service shall be provided with copies of the written instructions for operating and maintaining departmental and unit equipment. These instructions shall be systematically retained in the departments or units in which the equipment is used.

(c) All life-sustaining equipment shall be plugged into outlets connected to the emergency power supply.

(d) Routine maintenance inspections of elevators shall be conducted in accordance with local ordinances.

(e) The standby emergency generator shall be checked weekly, tested under load monthly, and serviced in accordance with accepted engineering practices.

(f) Floors, ceilings, and walls shall be free of cracks and holes, discoloration, residue build-up, water stains, and other signs of disrepair.

8:43G-24.5 (Reserved)

8:43G-24.6 Plant maintenance staff education

Requirements for the plant maintenance education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-24.7 (Reserved)

8:43G-24.8 Physical plant general compliance for new construction, alteration or renovation

(a) The hospital shall comply with the New Jersey Uniform Construction Code (N.J.A.C. 5:23 under Use Group I-2), standards imposed by the United States Department of Health and Human Services (HHS), the New Jersey Department of Health and Senior Services and Community Affairs, and the Guidelines for Design and Construction of Hospital and Healthcare Facilities (2001 edition, as published by The American Institute of Architects Press, 1735 New York Ave., NW, Washington, D.C. 20006, ISBN 1-57165-992-04, as amended and supplemented, incorporated herein by reference. In order to avoid conflict between N.J.A.C. 5:23 and the other standards listed above, Sections 501.3, 610.4.1, 704.0, 705.0, 706.0, 708.0, and 916.5 of the 1987 BOCA Basic Building Code of the New Jersey Uniform Construction Code shall not govern with respect to health care facilities.

(b) The hospital shall submit plans and specifications to Health Plan Review, Division of Codes and Standards, Department of Community Affairs, P.O. Box 815, Trenton, New Jersey 08625-0815, for approval prior to construction, alteration, or renovation.

Amended by R.2004 d.302, effective August 2, 2004.
See: 35 N.J.R. 2847(a), 35 N.J.R. 3782(a), 36 N.J.R. 3538(a).
Rewrote the section.

8:43G-24.9 Construction and renovation

(a) Whenever construction and renovation projects are planned in and around a health care facility, a risk assessment shall be conducted to determine the impact of the project on patient areas, personnel, and mechanical systems.

1. The infection control program shall review areas of potential risk and populations at risk. The infection control program shall approve control measures, if necessary.

(b) The design phase shall include commissioning specifications of ventilation requirements used during and at completion of the construction project.

(c) An education program shall be established for facility employees of the areas affected, the contractor's employees, and the contractor to define the impact, risks, interventions and compliance issues.

Repealed by R.1995 d.124, effective March 20, 1995.
See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Formerly "Physical plant general compliance for construction, alteration or renovation completed during the period of July 1, 1979 through May 7, 1981 or May 8, 1981 through October 1, 1987; mandatory".
New Rule, R.2004 d.302, effective August 2, 2004.
See: 35 N.J.R. 2847(a), 35 N.J.R. 3782(a), 36 N.J.R. 3538(a).

8:43G-24.10 (Reserved)

Repealed by R.1995 d.124, effective March 20, 1995.
See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Formerly "Physical plant general compliance for construction, alteration or renovation completed during the period of August 1, 1977 through July 1, 1979; mandatory".

8:43G-24.11 (Reserved)

Repealed by R.1995 d.124, effective March 20, 1995.
See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Formerly "Physical plant general compliance for construction, alteration or renovation completed during the period of September, 1974 to August 1, 1977; mandatory".

8:43G-24.12 (Reserved)

Repealed by R.1995 d.124, effective March 20, 1995.
See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Formerly "Physical plant maintenance general compliance for construction, alteration or renovation completed prior to September, 1974; mandatory".

8:43G-24.13 Fire and emergency preparedness

(a) The hospital shall comply with the 1985 edition of the National Fire Protection Association "Life Safety Code" (N.F.P.A. 101, Chapter 12 for new construction and Chapter 13 for existing construction), available from NFPA, 1 Batterymarch Park, Quincy, MA, 02169, (1-800-344-3555). If the building was constructed prior to 1968, the hospital shall have the option of applying for approval from the State Department of Health under Fire Safety Evaluation System (FSSES) requirements. Such approval shall be obtained prior to the annual licensure inspection survey and shall include prearranged inspection by a State Department of Health surveyor.

(b) All employees, including part-time employees, temporary agency personnel, and private duty nurses shall be trained in procedures to be followed in the event of a fire and instructed in the use of fire-fighting equipment and patient evacuation of hospital buildings as part of their initial orientation and at least annually thereafter.

(c) All employees, including part-time employees, temporary agency personnel, and private-duty nurses, shall receive printed instructions on procedures to be followed in case of emergency, including patient evacuation of the buildings.

(d) A written evacuation diagram specific to the unit that includes evacuation procedure, location of fire exits, alarm boxes, and fire extinguishers shall be posted conspicuously on a wall in each patient care unit.

(e) Exits, stairways, doors, and corridors shall be kept free of obstructions.

(f) Fire drills shall be conducted at least 12 times per year, with at least one drill on each shift and one drill on a weekend.

(g) Fire extinguishers shall be visually inspected at least monthly; fully inspected at least annually, recharged, repaired and hydrotested as required by manufacturer's instructions; and labeled with the date of the last inspection.

(h) Fire detectors and alarm systems shall be inspected and tested at least twice a year by a certified testing agency. Written reports of the last two inspections shall be kept on file.

(i) Fire suppression systems shall be tested at least twice a year by an approved and certified testing agency. Written reports of the last two inspections shall be kept on file.

(j) There shall be a comprehensive, current, written preventive maintenance program for fire detectors, alarm systems, and fire suppression systems that includes regular visual inspection. This program shall be documented.

(k) There shall be a procedure for investigating and reporting fires. All fires that result in a patient or patients being moved shall be reported to the New Jersey State Department of Health immediately by telephone at (609) 588-7725 or (609) 392-2020 after business hours and followed up in writing within 72 hours. In addition, a written report of the investigation shall be forwarded to the Department of Health as soon as it becomes available.

(l) The hospital shall have an alternate emergency power supply. If such emergency power supply is a diesel emergency power generator, there shall be enough stored fuel to maintain power for at least 24 hours.

Amended by R.1992 d.72, effective February 18, 1992.
See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).
Most recent two inspections to be on file.

8:43G-24.14 (Reserved)

SUBCHAPTER 25. POST MORTEM

8:43G-25.1 Policies and procedures

(a) The hospital shall have written policies and procedures for post mortem services that are reviewed at least once every three years, revised more frequently as needed, and implemented. These policies shall delineate the responsibilities of the medical staff, nursing, and post mortem services staff, and shall include procedures for at least the following:

1. Identifying the body;
2. Safe and proper handling to prevent damage to the body;
3. Safeguarding personal effects of the deceased and release of personal effects to the appropriate individual;
4. Handling of toxic chemicals by morgue and house-keeping staff;
5. Infection control, including disinfection of equipment;
6. Identifying and handling high-risk and/or infectious bodies, in accordance with Centers for Disease Control guidelines, and in compliance with N.J.S.A. 26:6-8;
7. Release of the body to the county morgue or funeral director;
8. Autopsy requests;
9. Availability of autopsy reports, including reports of microscopic autopsy findings, to physicians and in medical records, within specified time frames; and
10. Completion of autopsy, including microscopic and other procedures, within specified time frames.

Amended by R.1992 d.72, effective February 18, 1992.
See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Identification, handling and reporting requirements further specified at (a)6, 7 and 10.

Amended by R.1999 d.436, effective December 20, 1999.
See: 31 N.J.R. 376(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

In (a), substituted a reference to hospitals for a reference to morgues and substituted "at least once every three years, revised more frequently" for "annually, revised" following "reviewed" in the first sentence, and substituted a reference to post mortem services staff for a reference to morgue staff in the introductory paragraph.

8:43G-25.2 Post mortem staff qualifications

The physician who routinely performs or supervises the performance of autopsies shall be Board Certified in Pathology.

8:43G-25.3 Post mortem patient services

(a) Bodies and body parts in the morgue shall be kept refrigerated or in chemical fixation in a non-putrescent state.

(b) The medical staff shall attempt to secure autopsies in cases of unusual deaths, deaths from unknown causes, and cases of medicolegal and educational interest, unless otherwise provided for by law.

(c) Autopsies shall be performed only with the consent of the patient's family or guardian in accordance with N.J.S.A.

26:6-50. Consent shall not be required for medical examiner cases.

(d) The hospital shall notify the county medical examiner or prosecutor immediately upon a patient's death when the circumstances of the death fall within the criteria specified in N.J.S.A. 52:17B-86 of the State Medical Examiners Act, N.J.S.A. 52:17B-78 et seq.

8:43G-25.4 Post mortem space and environment

The morgue shall be equipped with refrigerated space to store at least two bodies. Hospitals with more than 100 beds shall provide additional space using a ratio of one space to every additional 100 beds.