

CHAPTER 33I

CERTIFICATE OF NEED: MEGAVOLTAGE RADIATION ONCOLOGY SERVICES

Authority

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

Source and Effective Date

R.1995 d.146, effective February 16, 1995.
See: 26 N.J.R. 4875(b), 27 N.J.R. 1287(a).

Executive Order No. 66 (1978) Expiration Date

Chapter 33I, Certificate of Need: Megavoltage Radiation Oncology Services, expires on August 16, 1996.

Chapter Historical Note

Chapter 33I, Certificate of Need: Megavoltage Radiation Oncology Units, became effective November 2, 1981 as R.1981 d.206. See: 13 N.J.R. 506(b), 13 N.J.R. 756(b). (This chapter was previously codified as N.J.A.C. 8:31-27.) Amendments became effective November 5, 1984 as R.1984 d.501. See: 16 N.J.R. 2205(a), 16 N.J.R. 3027(a). This chapter was readopted effective September 15, 1986 with amendments effective October 6, 1986 as R.1986, d.417. See: 18 N.J.R. 1436(a), 18 N.J.R. 2010(a). Chapter 33I expired on September 15, 1991, pursuant to Executive Order No. 66 (1978). A new Chapter 33I was adopted as R.1993 d.88, effective February 16, 1993. See: 24 N.J.R. 4222(a), 25 N.J.R. 701(a).

Pursuant to Executive Order No. 66 (1978), Chapter 33I was readopted as R.1995 d.146. See Source and Effective Date. See, also, section annotations.

CHAPTER 33I CERTIFICATE OF NEED: MEGAVOLTAGE RADIATION ONCOLOGY UNITS

Expired on September 15, 1991 pursuant to Executive Order No. 66 (1978).

This expired chapter contained the following subchapters and sections:

SUBCHAPTER 1. STANDARDS AND CRITERIA FOR THE PLANNING AND CERTIFICATION OF NEED OF MEGAVOLTAGE RADIATION ONCOLOGY UNITS IN HEALTH CARE FACILITIES

- 8:33I-1.1 Definitions
Amended by R.1984 d.501, effective November 5, 1984.
See: 16 N.J.R. 2205(a), 16 N.J.R. 3027(a).
Section was originally "Utilization standards".
Amended by R.1986 d. 417, effective October 6, 1986.
See: 18 N.J.R. 1436(a), 18 N.J.R. 2010(a).
Added text "equal to".
- 8:33I-1.2 Utilization of megavoltage units and programs
R.1984 d.501, effective November 5, 1984.
See: 16 N.J.R. 2205(a), 16 N.J.R. 3027(a).
Old section was "New megavoltage programs" and was recodified to 1.3.
Amended by R.1986, d.417, effective October 6, 1986.
See: 18 N.J.R. 1436(a), 18 N.J.R. 2010(a).
Added (b)5 and 6.
Amended by R.1990 d.132, effective February 20, 1990.
See: 21 N.J.R. 3640(a), 22 N.J.R. 633(b).

N.J.A.C. 8:33I-1.2(a)2ii added.

- 8:33I-1.3 New megavoltage programs
R.1984 d.501, effective November 5, 1984.
See: 16 N.J.R. 2205(a), 16 N.J.R. 3027(a).
Old section 1.3 recodified to 1.5.
Amended by R.1986 d.417, effective October 6, 1986.
See: 18 N.J.R. 1436(a), 18 N.J.R. 2010(a).
Added text "in the event ... new megavoltage services".
Repeal and New Rule, R.1990 d.132, effective February 20, 1990.
See: 21 N.J.R. 3640(a), 22 N.J.R. 633(b).
Repealed section was "New megavoltage programs."

- 8:33I-1.4 Personnel standards
R.1984 d.501, effective November 5, 1984.
See: 16 N.J.R. 2205(a), 16 N.J.R. 3027(a).
Recodified from 1.2 and revised.

- 8:33I-1.5 General criteria
R.1984 d.501, effective November 5, 1984.
See: 16 N.J.R. 2205(a), 16 N.J.R. 3027(a).
Recodified from 1.3; "502, P.O. Box 1540" changed to "404, CN360".
Amended by R.1990 d.132, effective February 20, 1990.
See: 21 N.J.R. 3640(a), 22 N.J.R. 633(b).
N.J.A.C. 8:33I-1.5(a)1, regarding the provision of written evidence of consistency with long-range planning, deleted; N.J.A.C. 8:33I-1.5(a)2 through 8 recodified.

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SUBCHAPTER 1. GENERAL CRITERIA AND STANDARDS

8:33I-1.1 Scope and purpose

The purpose of the chapter is to establish criteria and standards for the review of certificate of need applications for existing or potential providers of megavoltage radiation oncology services. The chapter establishes minimum criteria for the initiation, retention, or expansion of megavoltage radiation oncology services. The chapter also seeks to promote megavoltage services that contain multiple units that are capable of providing a full range of photon and electron beam energies, as opposed to the promotion of multiple single unit programs in the State. In addition, the chapter prohibits the establishment of new megavoltage programs in the absence of demonstrated need in an effort to encourage multiple unit services Statewide and to discourage the unnecessary proliferation and duplication of services which would generate unwarranted additional costs to payers of health care.

Law Review and Journal Commentaries

Health Law—Certificates of Need. P.R. Chenoweth, 137 N.J.L.J. No. 1, 46 (1994).

8:33I-1.2 Definitions

(a) For purposes of this subchapter, the following definitions shall apply:

“Local advisory board region” means a cluster of counties in a particular area of the State. For the purpose of this chapter, the local advisory board regions in New Jersey are as follows:

1. Local Advisory Board Region I: Passaic, Morris, Sussex, and Warren Counties;
2. Local Advisory Board Region II: Bergen and Hudson Counties;
3. Local Advisory Board Region III: Essex and Union Counties;
4. Local Advisory Board Region IV: Hunterdon, Mercer, Middlesex, and Somerset Counties;
5. Local Advisory Board Region V: Burlington, Camden, Cumberland, Gloucester, and Salem Counties;
6. Local Advisory Board Region VI: Monmouth, Ocean, Atlantic and Cape May Counties.

“Megavoltage program” means an entire therapy department or facility which may house single or multiple megavoltage units.

“Megavoltage unit” means an individual piece of radiotherapy equipment generating beam energies in excess of 1,000 kilovolts.

“MeV” refers to electron beam energy.

“MV” refers to photon beam energy.

(b) “Energy levels” of megavoltage units shall be defined as follows:

1. Low energy means four to six MV X-ray energy (exclusive of electron energy capability and inclusive of cobalt 60 units with source to skin distance of equal to or greater than 80 centimeters).
2. Medium/high energy—means greater than six MV X-ray or MeV electron energy up to 20 MV X-ray or MeV electron energy.
3. Higher energy means energies in excess of 20 MV X-ray or MeV electron.

Amended by R.1995 d.146, effective March 20, 1995.
See: 26 N.J.R. 4875(b), 27 N.J.R. 1287(a).

8:33I-1.3 Utilization of megavoltage units and programs

(a) Single unit megavoltage programs shall be subject to the following:

1. Minimum annual utilization for megavoltage unit replacement in single unit megavoltage programs is 300 total patients or 6,200 patient visits. Consideration of minimum utilization standard compliance will take into account the output of Cobalt 60 devices and the age of the equipment. Compliance with these minimum standards will be based on the actual utilization of each megavoltage unit for the most recent calendar year required to be reported to the Department immediately prior to the Commissioner’s call for certificate of need applications to replace the equipment.

2. Failure to achieve an average minimum utilization as defined in (a)1 above during any 36 consecutive months shall form a sufficient basis for the Commissioner to delicense the service.

3. Single unit megavoltage programs shall have on-site simulation capability, in accordance with State licensing requirements at N.J.A.C. 8:43G-28.18.

- i. Megavoltage units with medium/high energy capability or some combination thereof (commonly referred to as dual energy units) will be approved for single unit megavoltage programs where they have documented compliance with minimum utilization requirements as defined in (a)1 above and can justify the equipment in terms of clinical effectiveness and cost efficiency.

(b) Multiple unit megavoltage programs shall be subject to the following:

1. Applicants for a second megavoltage unit at an existing megavoltage program shall document minimum acceptable annual utilization level (on its existing unit) of 9,000 actual patient visits or 500 actual patients and project the achievement of 10,500 patient visits and 600 patients within two years of installation of the second megavoltage unit. Compliance with these minimum utilization standards will be based on the actual utilization of each megavoltage unit for the most recent calendar year required to be reported to the Department immediately prior to the Commissioner’s call for certificate of need applications.

2. Multiple unit megavoltage programs shall have medium/high energy equipment capability (as defined at N.J.A.C. 8:33I-1.2(b)) and have on-site simulation capability.

3. Dual energy megavoltage units will be considered for second units in multiple unit megavoltage programs that meet the utilization requirements identified in (b)1 above.

4. Applicants for a third megavoltage unit at an existing multiple unit megavoltage program shall meet a minimum acceptable annual utilization level (on its existing two units) of 16,000 actual patient visits or 900 actual patients. Compliance with these minimum utilization standards will be based on the actual utilization of each megavoltage unit for the most recent calendar year required to be reported to the Department immediately prior to the Commissioner's call for certificate of need applications.

5. Failure to achieve projected minimum utilization as defined in (b)1 above, within three years of installation of the additional megavoltage equipment, shall form a sufficient basis for the Commissioner to delicense the service.

6. Multiple unit programs failing to achieve an average annual minimum utilization level as defined at (b)1 or (b)4 above, whichever is applicable, during any period of 36 consecutive months shall form a sufficient basis for the Commissioner to delicense the service.

Amended by R.1995, d.146, effective March 20, 1995.
See: 26 N.J.R. 4875(b), 27 N.J.R. 1287(a).

Law Review and Journal Commentaries

Health Law—Hospitals. Steven P. Bann, 136 N.J.L.J. No. 5, 66 (1994).

8:33I-1.4 Megavoltage Radiation Oncology Resource Allocation Policy

(a) The Department of Health will process certificate of need applications for new Radiation Oncology Programs consistent with the provisions of the Certificate of Need Policy Manual (N.J.A.C. 8:33) and only from local advisory board regions where all existing licensed Radiation Oncology Programs meet minimum annual levels of utilization as specified at N.J.A.C. 8:33I-1.3. In addition, the annual patient treatment capacity levels for existing and approved megavoltage equipment must exceed 90 percent for the most recent calendar year required to be reported to the Department of Health prior to the Commissioner's call for certificate of need applications for new services pursuant to N.J.A.C. 8:33-4.1(a).

1. For purposes of this section, annual megavoltage equipment treatment capacity is defined as 500 patients per unit for linear accelerators and 250 patients per unit for Cobalt-60 units.

(b) No more than one new radiation oncology program shall be approved in each local advisory board region as defined at N.J.A.C. 8:33I-1.2, where all existing megavoltage radiation oncology programs are operating at least at minimum levels of utilization as specified at N.J.A.C. 8:33I-1.3. Additional new facilities will be considered only when both existing and approved facilities in a given local advisory board region are operating at minimum levels of utilization as specified at N.J.A.C. 8:33I-1.3.

(c) Applications for new and additional radiation oncology programs in a health service area will be evaluated on the basis of their ability to meet the standards established in this subchapter. In addition, the following factors will also be considered in the review process:

1. Demonstration of institutional and provider competence in delivering the proposed service and the availability of American College of Radiology (ACR) approved detection services (that is, mammography) and other appropriate cancer screening and detection services;

2. Capacity to perform the proposed service at the recommended minimum level within the stated period of time;

3. Commitment from the hospital's Board to establish the proposed service program;

4. Examination of the treatment capacity (as defined at (a)1 above) of existing facilities in the referral area;

5. Evidence that essential support services in the hospital (for example, counseling and social support services) are readily available and are capable of providing the necessary support services to both the patient and family members, when appropriate;

6. Evidence that the project would be financially feasible;

7. Evidence that demographic and cancer disease incidence and prevalence statistics in the local advisory board (LAB) region support service growth;

8. Evidence that the proposed service is compatible with overall health planning goals and recommendations for the State as identified in the State Health Plan and for the local advisory board area;

9. Evidence that barriers to access to care do not exist, including access to cancer screening and detection programs, and that if no barriers exist, that access to care will remain constant or improve for individuals in the service area; and

10. Evidence that the applicant has participated in cancer disease prevention and health promotion activities throughout the communities to be served by this proposed regional cancer treatment service. Applicants shall document specific programs, targeted populations, and the frequency, duration and volume of participation for these disease prevention and health promotion activities.

(d) Waivers from the requirements of (a) and (b) above may be considered where an applicant and the local advisory board have been able to document specific and quantifiable evidence that, in the absence of a waiver, serious problems of access to a needed service would result. Documentation should also be provided that indicates that existing area providers of this service will not be jeopardized (for example, experience a significant decline in volume) by the

proposed new provider will meet all requirements contained in this subchapter.

(e) All certificate of need applications for new megavoltage radiation oncology programs shall document the ability of the applicant to meet the minimum standards and criteria contained in this subchapter within three years from the initiation of the service. The inability to achieve minimum utilization levels during the third year of operations or thereafter will form a sufficient basis for the Commissioner to delicense the service as specified at N.J.A.C. 8:33I-1.3(a)2, (b)5 and (b)6.

Amended by R.1995, d.146, effective March 20, 1995.
See: 26 N.J.R. 4875(b), 27 N.J.R. 1287(a).

8:33I-1.5 Personnel standards

(a) Each applicant for a certificate of need for a megavoltage radiation therapy unit shall provide the Department with written documentation that the following minimal staff complement shall be available:

1. A radiation oncologist directing radiation therapy for each program in accordance with State licensing requirements at N.J.A.C. 8:43G-28.14(a).

i. For the purpose of this regulation a qualified radiation oncologist shall be considered to be one who has been:

(1) Certified or is eligible for certification by the American Board of Radiology in general radiology prior to 1976; or

(2) Certified or eligible for certification by the American Board or the American Osteopathic Board of Radiology in radiation oncology since 1976.

2. Adequate coverage by a qualified radiological physicist to insure that Cobalt-60 units and other energy units are calibrated and employed properly in keeping with the volume of patients in accordance with State licensing requirements at N.J.A.C. 8:43G-28.14(d).

i. For the purposes of this section, qualified radiologist physicist shall mean one who:

(1) Is certified by the American Board of Radiology in either radiological physics or therapeutic radiological physics;

(2) Is eligible for such certification;

(3) Has a bachelor's degree in the physical sciences and three years full-time experience in clinical radiation therapy physics working under the direction of a physicist certified (or board eligible) by the American Board of Radiology or has a doctorate or master's degree in physical sciences and two years' such experience; or

(4) Has a doctorate or master's degree in radiological or medical physics and two years of post-graduate clinical therapeutic physics experience.

3. Radiation therapists (licensed by the State of New Jersey in accordance with N.J.S.A. 26:2D-24 et seq. and N.J.A.C. 7:28-19) shall be available in accordance with State licensing requirements at N.J.A.C. 8:43G-28.14(c);

4. A registered professional nurse shall be available in accordance with State licensing requirements at N.J.A.C. 8:43G-28.14(e); and

5. A professional member of the social work department shall be available to meet the psychosocial needs of radiation therapy patients and families, in accordance with State licensing requirements at N.J.A.C. 8:43G-28.14(f).

Amended by R.1995 d.146, effective March 20, 1995.
See: 26 N.J.R. 4875(b), 27 N.J.R. 1287(a).

8:33I-1.6 General criteria

(a) As part of the application for a megavoltage radiation therapy unit, each application shall meet the following minimum general criteria:

1. Provide full compliance with Nuclear Regulatory Commission (N.R.C.) radiation standards as contained in Title 10, Code of Federal Regulations (1976, section 19 and 20), and the State of New Jersey Department of Environmental Protection radiation standards as contained in N.J.A.C. 7:28-14.1. If not in full compliance, a written estimate of applicable costs necessary to achieve full compliance shall be furnished by the applicant to the Department as part of the certificate of need application;

2. Provide for a multi-disciplinary approach to the management of cancer patients by involving all cancer disciplines in a joint treatment program. Such a program should include the establishment of an American College of Surgeons-approved cancer program, a tumor registry and a follow-up program;

3. Provide full written documentation of the purchase and operational costs of the proposed megavoltage unit. The applicant shall include both direct and indirect costs, that is, personnel, maintenance agreements, supplies and overhead. The cost of the remodeling or renovating necessary to accommodate the therapy unit should be included. Projections of anticipated revenues during the first two years of operation shall be supplied with the certificate of need application;

4. Provide written documentation in the form of an institutional policy statement that the center will accept referrals from physicians not ordinarily having access to the applicant's facilities;

5. Each applicant shall provide evidence that social and psychological counseling services will be available for its therapy patients. Such counseling shall be conducted by staff or by arrangement with other community resources or facilities;

6. Each applicant shall document the availability of adequate radiation treatment planning services;

7. Each applicant shall provide written documentation that it will not, directly or indirectly, refuse referrals on the basis of the patient's race, religion, sexual orientation, age or ability to pay. The applicant shall certify in writing compliance with all Federal and State laws in this regard;

8. Each applicant shall maintain and provide basic statistical data on the operation of the unit and report the data to the New Jersey State Department of Health at

least annually, and no more than quarterly on a standardized form prepared by the Department. Data shall include, but not be limited to, number of personnel, number of patients, number of patient visits, and number of patients simulated. Copies of the required reporting forms may be obtained upon written request to the New Jersey State Department of Health, Center for Health Statistics, Room 404, CN 360, Trenton, New Jersey 08625;

9. Megavoltage programs shall be limited to a single licensed facility or single site, for example, the immediate campus location of the service. Existing providers of megavoltage services who submit certificate of need applications to locate megavoltage equipment off the site of their existing service shall be required to satisfy the requirements of N.J.A.C. 8:33I-1.4, concerning new megavoltage programs.