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## CHAPTER 33I

### (RESERVED)

#### 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). Chapter 33I was readopted as R.1986, d.417, effective September 15, 1986, with

amendments effective October 6, 1986. See: 18 N.J.R. 1436(a), 18 N.J.R. 2010(a). Amendments became effective February 20, 1990 as R.1990 d.132. See: 21 N.J.R. 3640(a), 22 N.J.R. 633(b). 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, effective February 16, 1995. See: 26 N.J.R. 4875(b), 27 N.J.R. 1287(a). Pursuant to Executive Order No. 66(1978), Chapter 33I, Certificate of Need: Megavoltage Radiation Oncology Services, expired on August 16, 1996.

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).

#### Case Notes

Standing to appeal determination on application for certificate of need. *Associates In Radiation Oncology, P.A. v. Siegel*, 272 N.J.Super. 208, 639 A.2d 729 (A.D.1994).

Determination that certificate of need was not required; remand required for specific findings of fact. *Associates In Radiation Oncology, P.A. v. Siegel*, 272 N.J.Super. 208, 639 A.2d 729 (A.D.1994).

Acting Commissioner did not have discretion to remove condition in certificate of need for linear accelerator. In re Certificate of Need Application of Chilton Memorial Hosp., 269 N.J.Super. 426, 635 A.2d 986 (A.D.1993).

#### 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;