

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.1997 d.214, effective May 19, 1997.
See: 28 N.J.R. 4184(a), 29 N.J.R. 2455(a).

Executive Order No. 66(1978) Expiration Date

Chapter 33I, Certificate of Need: Megavoltage Radiation Oncology Services, expires on August 18, 1998.

Chapter Historical Note

Chapter 33I, Certificate of Need: Megavoltage Radiation Oncology Units, was adopted as R.1981 d.206, effective November 2, 1981. See: 13 N.J.R. 506(b), 13 N.J.R. 756(b). Chapter 33I was previously codified at N.J.A.C. 8:31-27. Chapter 33I was amended by R.1984 d.501, effective November 5, 1984. See: 16 N.J.R. 2205(a), 16 N.J.R. 3027(a).

Pursuant to Executive Order No. 66(1978), Chapter 33I was readopted as R.1986 d.417, effective September 15, 1986. See: 18 N.J.R. 1436(a), 18 N.J.R. 2010(a). Chapter 33I was amended by R.1990 d.132, effective February 20, 1990. See: 21 N.J.R. 3640(a), 22 N.J.R. 633(b). Pursuant to Executive Order No. 66(1978), Chapter 33I, Certificate of Need: Megavoltage Radiation Oncology Units, expired on September 15, 1991.

Chapter 33I, Certificate of Need: Megavoltage Radiation Oncology Services, 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.

Chapter 33I, Certificate of Need: Megavoltage Radiation Oncology Services, was adopted as R.1997 d.214, effective May 19, 1997. See: Source and Effective Date.

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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.

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 a 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).

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 and Senior Services 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 and Senior Services 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).