

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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8:33I-1.6 General criteria

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 dis-

courage 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).

Case Notes

Regulations governing certificate eligibility for radiation oncology services were not implementation of State Health Plan, and thus the regulations did not conflict with amendment to Health Care Cost Reduction Act and Health Care Facilities Planning Act and were valid. *Colkitt v. Siegel*, 140 N.J. 200, 657 A.2d 1202 (1995).

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.