641—203.3(135) Radiation therapy or radiotherapy standards.

203.3(1) *Purpose and scope.*

a. These standards are measures of some of those criteria 1 (a to q) and 3 found in Iowa Code section 135.64. Criteria which are measured by a standard are cited in parentheses following each standard.

b. Certificate of need applications which are to be evaluated against these radiation therapy standards include:

(1) Proposals to commence or expand the kind or capacity of megavoltage radiation therapy services.

(2) Proposals to replace a radiation therapy unit.

(3) Any other applications which relate to radiation therapy.

203.3(2) *Definitions.*

a. Radiation modality. The method of applying ionizing radiation in the treatment of patients with malignant disease. Externally applied modes.

Superficial X-ray therapy. The use of a conventional X-ray machine, which generates X-rays of up to 150 kilovolts (150 kv), to treat superficial lesions, such as skin cancer.

Orthovoltage X-ray therapy. The use of a conventional X-ray machine which generates X-rays between 150 kv up to and including 800 kvs. (These X-rays are of insufficient energy to avoid preferential bone absorption or to be "skin sparing".)

Megavoltage therapy. The use of ionizing radiation in excess of one million electron volts. Energies above one million electron volts cause considerably less skin damage, increase depth dose markedly, and result in much less scatter from the therapeutic beam. Megavoltage machines are classified as follows:

1. Particle accelerators. These machines use a supply of electrons, which are accelerated into high energy beams. These beams are either caused to strike a target resulting in high energy X-ray production, or are used themselves as the treatment beam. Particle accelerators generate from 4 million up to as many as 45 million electron volts. Most common particle accelerators are the linear accelerator and the betatron.

2. Isotope sources (gamma ray teletherapy units).

Cobalt 60 units—emit gamma rays of approximately 1.2 million electron volts.

Cesium teletherapy units—utilize gamma rays of approximately 650 kv.

b. Megavoltage therapy unit. A piece of megavoltage therapeutic radiologic equipment.

c. Radiation therapy facility. A piece of megavoltage therapeutic radiologic equipment, the accompanying support equipment, and the physical space which houses the equipment.

d. Treatment (procedure). All those radiation fields applied in a single patient visit. Interstitial/intracavitary treatment counts as one visit.

e. Dosimetrist. A technologist who calculates, verifies, and develops maps for the dose distribution of radiation within the patient. The technologist is an essential member of the treatment planning team.

f. Radiation therapist (radiation oncologist). A physician who is board certified or board eligible in therapeutic radiology or in general radiology and who devotes full time to the practice of radiation therapy.

g. Radiation therapy technologist. An individual registered or eligible for registration by the American Board of Radiologic Technologists, or its equivalent, in radiation therapy.

h. Transverse tomograms. A special diagnostic X-ray procedure to determine the depth of the tumors inside the body.

i. Conjoint radiation oncology center (cancer center). A multi-institution, multidisciplinary network to provide radiation therapy for cancer patients. Each institution has an equal voice in decision making and direction of the work of the center. Integration of patient care management, common utilization of personnel and equipment, and a single system of records between center institutions assures optimal care regardless of entry portal. A common cancer registry of all patients treated by center hospitals is maintained.

j. Simulator. Used to reproduce the geometry of the external beam treatment technique, and consists of an isocentrically mounted X-ray source with X-rays passing per a collimation system to reproduce the therapy beam.

k. New patient. A patient receiving treatment for the first time at a given radiation therapy facility.

203.3(3) *Availability.*

a. Minimum utilization. (Sections 135.64(1)*"c," "g," "h*")

(1) A megavoltage radiation therapy unit which is of relatively low energy, including small linear accelerators (4-10 MEVs), cobalt units and cesium teletherapy units, should serve a population of at least 200,000 persons, and treat at least 300 new patients annually within three years after initiation of the service.

(2) A megavoltage radiation therapy unit which is of medium energy, including linear accelerators of 12-20 MEVs should only be placed in facilities which are currently treating with megavoltage radiation therapy a minimum of 500 new patients annually.

(3) A megavoltage radiation therapy unit which is of high energy, including those linear accelerators of greater than 20 MEVs, should only be placed in facilities which are currently treating at least 750 new patients annually with megavoltage radiation therapy.

(4) To determine the number of new patients needing megavoltage radiation therapy annually in a service area, the following formula shall be applied:

Multiply the service area population times .00304 (3.04/1,000 population was the mean cancer incidence rate in 1976 in Iowa as filed by the Surveillance, Epidemiology, and End Results Program—SEER). A service area population is determined by each facility's catchment area as reported in the most recent patient origin study of the Iowa department of public health.

Multiply this product times .5 (50 percent of all new cancer patients require radiation therapy).

(5) Institutions which form a conjoint oncology center should have at least 500 new patients annually who are amenable to megavoltage therapy.

b. Expansions. (Sections 135.64(1)*"c," "d," "e," "g," "h"*)

(1) There should be no additional megavoltage units of comparable size approved unless each existing megavoltage unit of that size within 90 minutes travel time of the proposed unit is performing at least 6,000 treatments per annum.

(2) Proposed new small megavoltage units within 90 minutes travel time of other small units must identify an unserved population base of 200,000 apart from that 200,000 currently served by institutions in the service area.

(3) Megavoltage treatments per annum should be projected by multiplying the number of projected new patients needing megavoltage therapy times 20.

(4) There should be no additional megavoltage radiation therapy units of comparable size within 90 minutes surface travel time of existing units which would reduce the projected volume of treatments per annum in existing units of comparable size to less than 6,000 treatments per annum and which would result in less than 300 projected new patients per annum for that existing unit. The applicant will attempt and demonstrate that an attempt was made to determine with the cooperation of existing providers whether such a reduction would occur.

(5) New conjoint centers should be justified if more than 3,000 new patients are currently being treated by radiation therapy in an existing center.

c. A simulator which can accurately reproduce the geometry of each external beam technique should be available for every two megavoltage units in a radiation oncology department.

203.3(4) *Costs.*

a. Financial feasibility. (Sections 135.64(1)*"f," "i," "p"*)

(1) Megavoltage radiation therapy units should be depreciated over a period no shorter than that indicated by "Estimated Useful Lives of Depreciable Hospital Assets" published by the American Hospital Association. Associated remodeling should be depreciated according to generally accepted accounting principles and over a period no shorter than indicated in the above-named publication.

(2) Recognizing anticipated volume rate structure, and third party reimbursement, the applicant should present a breakeven analysis for the service. If the analysis shows breakeven will fail to occur

after three years of the service's initiation, the applicant should demonstrate why operating a service with the revenues below costs appears desirable.

(3) Charges will be based on actual or projected yearly treatments, but not less than 6,000 treatments.

b. Cost-effectiveness. (Section 135.64(1)*"e"*) Costs per unit of service should not exceed 10 percent of the state average unit cost for the service. If costs exceed 10 percent of that average the applicant shall demonstrate how the proposal represents the most cost-effective way to deliver the service and explain why the project was chosen instead of alternative ways of meeting the need for the service.

203.3(5) *Accessibility.* (Sections 135.64(1)*"c," "d"*)

a. Travel distance shall be within 90 minutes auto travel time for the projected service area population.

b. Radiation therapy services should be provided regardless of ability to pay, in consideration of those programs available in the state which serve the medically indigent.

203.3(6) *Quality.* (Sections 135.64(1)*"i," "k"*)

a. Minimum staffing requirements for radiation therapy facilities:

(1) Each facility shall have the services of radiation therapists which should be staffed at a level of one therapist per 400 new cancer patients needing treatment.

(2) Each facility shall have the services of radiation physicists which should be staffed at a level of one physicist per 800 new patients.

(3) Each facility shall have the services of radiation therapy technologists which should be staffed at a level of two technologists per megavoltage unit.

(4) Each facility should have the services of nurses.

(5) Each facility should have the services of dosimetrists which should be staffed at a level of one dosimetrist per 500 new patients.

b. Reserved.

c. Each conjoint center shall have at least two cancer biologists available.

d. Each conjoint center shall have one radiation technologist available for each simulator.

e. Replacement or development of orthovoltage treatment should not occur.

f. The long-range plans for radiation therapy services shall be submitted to the Iowa department of public health.

g. Multidisciplinary tumor boards should be established in all institutions housing megavoltage or orthovoltage machines.

h. A source of continuing education should exist within each conjoint center to reach participating community referral hospitals and physicians.

i. Each conjoint center should have a unified training program in radiation therapy for radiation therapists.

j. Each radiation therapy facility should offer psychosocial counseling services and nutritional counseling.

203.3(7) *Continuity.* (Sections 135.64(1)*"g," "h," "i," "k"*)

a. The applicant should demonstrate that an attempt was made to solicit letters and establish referral agreements from area hospitals and physicians to indicate their willingness to participate in a cooperative endeavor to refer to the proposed service.

b. A minimum of 75 percent of all radiation therapy procedures should be projected to be done on an outpatient basis. If the applicant believes that 75 percent is inappropriate for its facility, then documentation which shows how its facility is different and why it sufficiently justifies not meeting this 75 percent outpatient rate, shall be provided.

203.3(8) *Acceptability.* (Section 135.64(1)*"c"*) Facilities with radiation therapy services shall document a willingness to observe and respect the rights of patients as stated in the "Patients Bill of Rights" adopted by the American Hospital Association February 6, 1973, and reprinted in 1975. Provisions for counseling services shall be available.