

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

**Proposing rule making related to radiation therapy standards
and providing an opportunity for public comment**

The Public Health Department hereby proposes to amend Chapter 203, “Standards for Certificate of Need Review,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 135.62(2)“e”(5).

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 135.61(18)“m”(4) and 135.61(18)“g” to “j.”

Purpose and Summary

Rule 641—203.3(135) sets out radiation therapy standards for the purpose of writing and reviewing Certificate of Need applications for the initiation of external beam radiation therapy services or the purchase of associated equipment (e.g., a linear accelerator). The rules related to radiation therapy were originally promulgated in the late 1970s when the Certificate of Need program was implemented in Iowa. Based on research conducted on the history of rule 641—203.3(135), this rule has not been updated since it was written. The rule is outdated, and parts no longer apply in review of applications. The proposed amendments to the rule eliminate those portions that are completely outdated and are no longer needed or used, and update the remaining portions to modern radiation therapy standards.

After consultation with and approval from the State Health Facilities Council, a stakeholder group of individuals was created representing various health systems—University of Iowa Hospitals and Clinics, MercyOne, UnityPoint Health, Methodist Jennie Edmundson Hospital—and radiation therapy-related occupations including radiation physicists, health physicists, radiation oncologist (retired), and others involved in radiation oncology services. Additional participants included two attorneys who represent health facilities on Certificate of Need-related issues, a hospital president, the director of operations for the Iowa Cancer Registry, and the Iowa Hospital Association. The stakeholder group had several meetings from February 2020 through October 2020 to review the contents of the rule and propose changes/updates as needed. The State Health Facilities Council, pursuant to Iowa Code section 135.62(2)“e”(5), has the duty to review and approve, prior to promulgation, all rules adopted by the Department under this subchapter and is also fulfilling this role through this rule-making process.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department’s waiver provisions contained in 641—Chapter 178.

Public Comment

Any interested person may submit written or oral comments concerning this proposed rule making. Written or oral comments in response to this rule making must be received by the Department no later than 4:30 p.m. on June 8, 2021. Comments should be directed to:

Rebecca Swift
Department of Public Health
Lucas State Office Building
321 East 12th Street
Des Moines, Iowa 50319
Email: rebecca.swift@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)“b,” an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Amend rule 641—203.3(135) as follows:

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

203.3(1) Purpose and scope.

~~a. These standards are measures of some of those~~ provide guidelines to assist the council in applying those criteria 1 (a to q) and 3 found in Iowa Code section 135.64 sections 135.64(1) “a” to “r” and 135.64(3). 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 megavoltage radiation therapy unit.~~
- ~~(3) Any other applications which relate to megavoltage 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.~~

~~“Conjoint radiation oncology center” or “cancer center” means a multi-institution, multidisciplinary network to provide radiation therapy for cancer patients. Integration of patient care management, common utilization of personnel and equipment, and a single system of records between center institutions ensures optimal care regardless of entry portal.~~

~~“Dosimetrist” means a staff member who calculates, verifies, and develops treatment plans for the radiation dose distributions that will be delivered to patients. The dosimetrist is an essential member of the treatment planning team and works closely with radiation oncologists and radiation physicists.~~

~~“Megavoltage therapy” means 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. Electron accelerator. A machine such as a linear accelerator that uses a supply of electrons, which are accelerated into high energy beams. These electron beams are either caused to strike a target resulting in high energy X-ray production or are used themselves as the treatment beam. Electron accelerators generate over one million electron volts.~~

~~2. Heavy Particle Accelerator. A machine such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, carbon ions, or other heavy ions with masses greater than that of an electron.~~

~~3. Isotope sources (gamma ray teletherapy units).~~

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

“Megavoltage therapy unit” means a piece of megavoltage therapeutic radiologic equipment that provides megavoltage therapy.

“New occurrence” means a course of treatment for a new occurrence on a given patient at a given radiation therapy facility. First-time radiation therapy at a new facility is based on each round of treatment.

“Radiation modality” means the method of applying ionizing radiation in the treatment of patients with malignant disease using megavoltage external beam equipment.

“Radiation oncologist” means a physician authorized user trained in accordance with 641—subrule 41.3(5).

“Radiation therapy facility” or “facility” means the physical space which houses a megavoltage therapy unit and accompanying support equipment.

“Radiation therapy physicist” means an individual who works closely with radiation oncologists and is responsible for the safe and accurate delivery of radiation to patients. A radiation therapy physicist conducts quality control programs for the equipment and procedures, as well as calibrating the equipment. A radiation therapy physicist shall practice in accordance with 641—subrule 41.3(6).

“Radiation therapy technologist” means an individual who possesses an Iowa permit to practice as a radiation therapist in accordance with rule 641—42.7(136C).

“Service area” means the county in which the facility is located and any other counties from which the applicant expects to draw patients with a cancer diagnosis who are in need of radiation therapy treatment.

“Simulation” means the precise mock-up of a patient treatment with an apparatus that uses planar X-rays, magnetic resonance imaging device, or computed tomography scanner, which is used in reproducing the two-dimensional or three-dimensional internal or external geometry to the patient, for use in treatment planning and delivery.

“Superficial X-ray therapy” means 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.

“Treatment” means radiation fields applied in a single patient visit fraction or delivery session.

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), and cobalt units and cesium teletherapy units, should serve a population of at least 200,000 persons, and should treat at least 300 250 new patients occurrences 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) (2) ~~To determine the~~ The expected number of new patients occurrences needing megavoltage radiation therapy annually in a service area, the following formula shall be applied should be calculated as follows:

1. Multiply the service area population times ~~0.00304~~ 0.00582 (~~3.04/1,000~~ 5.82/1,000 population was the mean cancer incidence rate in ~~1976~~ 2017 in Iowa as filed by the Surveillance, Epidemiology, and End Results (SEER) 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.

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

(3) The expected volume of utilization sufficient to support the need for a new megavoltage therapy unit should be calculated as follows: each unit shall provide a minimum of 5,000 treatments per annum.

Megavoltage treatments should be projected by multiplying the number of projected new occurrences needing megavoltage therapy times 20, which will result in no fewer than 5,000 treatments per annum.

(4) Applicants shall account for other providers of radiation therapy in the service area including, but not limited to, factors such as technological capability and quality. Applicants shall address in their application other providers and the impact on those providers in the service area and compare technological capability and quality.

(5) Applicants should provide a map of the expected service area.

(5) (6) Institutions which form a conjoint oncology center should have at least 500 new patients occurrences 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.

e. b. Simulator availability. A simulator which can accurately reproduce the geometry of each external beam technique should be available for every two megavoltage units in should be available within 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) 203.3(4) Accessibility. (Sections Iowa Code section 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) 203.3(5) Quality. (Sections Iowa Code section 135.64(1) "i," "k")

- a. Minimum staffing requirements for radiation therapy facilities:
- (1) Each facility shall have the services of at least one radiation therapists which should be staffed at a level of one therapist per 400 new cancer patients needing treatment oncologist.
 - (2) Each facility shall have the services of at least one radiation physicists which should be staffed at a level of one physicist per 800 new patients therapy physicist.
 - (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~~ at least one dosimetrist.
 - (6) Each facility should have the services of one radiation therapist or radiation technologist competent to operate a CT simulator.

~~b. Reserved.~~

~~e. b.~~ Each conjoint center shall have at least two cancer biologists available.

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

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

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

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

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

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

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

~~203.3(7)~~ **203.3(6)** *Continuity.* (Sections Iowa Code section 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)~~ **203.3(8)** *Acceptability.* (Section 135.64(1) "e") 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.