481—2203.3(10A) Radiation therapy standards.

2203.3(1) *Purpose and scope.*

a. These standards provide guidelines to assist the council in applying those criteria in Iowa Code sections 10A.714(1)*"a"* through *"r"* and 10A.714(3). Criteria that are measured by a standard are cited in parentheses following each standard.

b. Certificate of need applications that 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 that relate to megavoltage radiation therapy.

2203.3(2) *Definitions.*

"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 that 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 that 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 need 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.

2203.3(3) *Availability.*

a. Minimum utilization. (Iowa Code section 10A.714(1)*"c,""g,""h"*)

(1) A megavoltage radiation therapy unit and cobalt units should treat at least 250 new occurrences annually within three years after initiation of the service.

(2) The expected number of new occurrences needing megavoltage radiation therapy annually in a service area should be calculated as follows:

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

2. Multiply this product times .5 (50 percent of all new 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.

(6) Institutions that form a conjoint oncology center should have at least 500 new occurrences annually.

b. Simulator availability. A simulator should be available within a radiation oncology department.

2203.3(4) *Accessibility.* (Iowa Code section 10A.714(1)*"c,""d"*) Radiation therapy services should be provided regardless of ability to pay, in consideration of those programs available in the state that serve the medically indigent.

2203.3(5) *Quality.* (Iowa Code section 10A.714(1)*"i,""k"*)

a. Minimum staffing requirements for radiation therapy facilities:

(1) Each facility will have the services of at least one radiation oncologist.

(2) Each facility will have the services of at least one radiation therapy physicist.

(3) Each facility will have the services of radiation therapy technologists that 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 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. Each conjoint center will have at least two cancer biologists available.

c. Each conjoint center will have one radiation technologist available for each simulator.

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

e. Multidisciplinary tumor boards should be established in all institutions housing megavoltage machines.

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

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

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

2203.3(6) *Continuity.* (Iowa Code section 10A.714(1)*"g,""h,""i,""k"*) 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.

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