CHAPTER 203
STANDARDS FOR CERTIFICATE OF NEED REVIEW

[Prior to 7/29/87, Health Department[470] Ch 203]

641—203.1(135) Acute care bed need. Rescinded **ARC 2297C**, IAB 12/9/15, effective 1/13/16.

641—203.2(135) Cardiac catheterization and cardiovascular surgery standards.

203.2(1) *Purpose and scope.*

a. These standards are measures of some of those criteria found in Iowa Code sections 135.64(1)*"a"* to *"q,"* 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 cardiac catheterization and cardiovascular surgery standards include:

(1) Proposals to commence or expand capacity to perform cardiac catheterization.

(2) Proposals to add new or replace cardiovascular surgery services.

(3) Any other applications which relate to cardiac catheterization or cardiovascular surgery.

203.2(2) *Definitions.*

a. Adult cardiac catheterization laboratory—a diagnostic facility exclusively for intracardiac or coronary artery catheterization on adults.

b. Pediatric cardiac catheterization laboratory—the same as adult cardiac catheterization laboratory, except exclusively for children and infants.

c. Cardiac catheterization—

(1) Intracardiac—a diagnostic study of the heart, and pulmonary arteries, or both, in which a small catheter passes through a vein or artery in the neck, leg or arm and advances into the great vessels, the heart or the pulmonary arteries. Through this procedure one can measure pressure within the heart and in adjacent veins and arteries, collect blood samples for blood gas analysis and inject radiopaque material, visualize cardiac and vessel anatomy. The procedure permits detection of congenital and acquired heart abnormalities, the study of ventricular function, the estimation of the orifice size, the placement of pacemakers, etc. Cardiac catheterization is incomplete without cineangiography, intracardiac pressure measurements, blood gas analysis and the ability to diagnose intracardiac shunts.

(2) Coronary artery catheterization—a diagnostic study of the coronary arteries, in which a small catheter passes through an artery in the leg, neck or arm into a coronary artery orifice. Intravascular pressure measurements are taken, and angiography of the coronary arteries is performed. Catheterization and cineangiocardiography of the left ventricle are an integral part of this procedure.

d. Angiography.

The photographic recording of X-ray or radiologic images of blood vessels, in any part of the body—the heart, the head, the great vessels, the kidney, etc. In the procedure blood vessels are injected with a radiopaque chemical. Immediately following injection, X-rays are employed to image the path of the injected chemical. These X-ray images are then photographically recorded.

Angiocardiography.

The recording of moving X-ray images (fluoroscopic images) of the heart and great vessels. After injection of radiopaque chemicals, moving X-rays of the chemical's flow are projected on a screen called a fluoroscope. Moving pictures (cineangiocardiography) or still pictures in sequence (serialography) may be recorded of the X-ray image.

e. Adult cardiovascular surgery—cardiovascular surgery exclusively for adults.

f. Pediatric cardiovascular surgery—cardiovascular surgery exclusively for infants and children.

g. Cardiovascular surgery—the services associated with and surgery performed for congenital or acquired diseases of the heart, great vessels, or pericardium, including the placement of travenous and epicardial pacemakers.

(1) Open heart surgery—cardiovascular surgery in which an incision of sufficient size is made to allow direct vision of the area. Open heart surgery requires temporary use of a heart-lung

(cardiopulmonary bypass) machine, as blood flow through the heart is greatly reduced or stopped altogether.

(2) Coronary artery surgery—surgery to correct inadequate blood flow to the heart through using revascularization techniques to bypass significantly obstructed coronary artery lesions.

h. Closed heart surgery—cardiovascular surgery in which a small incision and repairs are made without direct vision of the area.

203.2(3) *Availability of services.*

a. Minimum utilization—cardiovascular surgery (Iowa Code sections 135.64(1)*"c," "g," "h"*).

(1) Adult cardiovascular surgical programs should project an annual minimum rate of over 200, or no approval shall be granted. Higher case loads over 200 per annum, are encouraged.

(2) Pediatric cardiovascular surgical units should project a minimum of 100 pediatric heart operations after the first year, at least 75 of which must be open heart procedures.

(3) Combined adult/pediatric cardiovascular surgery units should project the minimum projected annual rates for both adult and pediatric surgery, or no approval shall be granted.

(4) Applicants should project utilization of cardiovascular surgery, catheterization and cardiac care units based upon service area population demographics, current regional or national utilization rates of the service, disease incidence and prevalence rates, current cardiac care treatment modes, and in consideration those adult cardiovascular surgery units currently operating in Iowa, and bordering states within two hours surface travel time, if the applicant proposes an adult unit; and in consideration of pediatric cardiovascular surgery units currently operating in Iowa and bordering states within three hours surface travel time, if the applicant's proposed unit is pediatric. If a combined unit is proposed both the two- and three-hour considerations for existing adult and pediatric units apply. The assumptions, data and methodology used to arrive at projections shall be provided in each application.

b. Expansions—cardiovascular surgery (sections 135.64(1)*"c," "d," "e," "g," "h"*).

(1) There should be no additional adult cardiovascular surgery units initiated unless each existing unit within two hours surface travel time is operating at a minimum of 350 open heart surgery cases per year.

(2) There should be no additional pediatric cardiovascular surgery units initiated, unless each existing unit within three hours surface travel time is operating at 130 surgeries per year. (If one team serves more than one institution the numbers for those institutions should be combined.)

(3) No additional cardiovascular surgery units should be approved which will reduce the volume of existing services below 350 procedures annually for adults and 130 annually, 75 of which are open heart, for pediatric units. The applicant will demonstrate that an attempt was made to determine with the cooperation of existing providers whether such a reduction would occur. Existing providers of consequence are within two hours surface travel time for adult services and within three for pediatric services.

(4) Adult cardiovascular surgical service units should be granted only to institutions which can demonstrate an unserved population base of 500,000 persons. An unserved area is one which lies outside of an existing unit's service area.

(5) Pediatric cardiovascular surgical services should be granted unto institutions which can demonstrate an unserved population base of 2.5 million with 30,000 live births per year.

c. Minimum utilization—cardiac catheterization (sections 135.64(1)*"c," "d," "g," "h"*).

(1) Adult cardiac catheterization laboratories should be projected to operate at a minimum of 300 catheterizations per annum.

(2) Pediatric catheterization laboratory units should project a minimum of 150 catheterizations annually.

(3) Combined units should meet each of the adult and pediatric standards.

(4) Applicant should project utilization of cardiac catheterization units based upon service area population demographics, current regional or national utilization rates of the service, disease incidence and prevalence rates, current cardiac care treatment modes, and in consideration those adult cardiovascular surgery units currently operating in Iowa, and bordering states within two hours surface travel time if the proposed unit is for adults; and in consideration of pediatric cardiovascular surgery

units currently operating in Iowa, and bordering states within three hours surface travel time if the proposed unit is for children. If a combined unit is proposed both time considerations shall apply. The assumptions, data and methodology used to arrive at projections shall be provided in the application.

d. Expansions—cardiac catheterizations (sections 135.64(1)*"c," "d," "e," "g," "h"*).

(1) There should be no additional adult cardiac catheterization unit opened unless the number of studies per year in each existing unit within two hours surface travel time is greater than 500. No additional pediatric unit should be opened unless the number of studies per year in each existing unit within three hours surface travel time is greater than 250.

(2) There should be no additional cardiac catheterization units initiated which would reduce the volume of existing units below 500 adult catheterizations, 200 of which are intracardiac or coronary artery catheterizations, or 150 pediatric catheterizations, or both for combined units. The applicant must attempt and demonstrate that an attempt was made to determine with the cooperation of existing providers whether such a reduction would occur. Existing providers of consequence are those within two hours surface travel time for adults or three hours for pediatrics.

e. There should be no new cardiac catheterization unit open in any facility not performing open heart surgery (sections 135.64(1)*"e," "g," "h," "k"*).

203.2(4) *Costs.*

a. Financial feasibility. (Sections 135.64(1)*"f," "i," "p"*) Cardiovascular surgery and catheterization equipment, and associated remodeling or construction should be depreciated over a period consistent with American Hospital Association schedules as limited by existing reimbursement payors.

b. Cost-effectiveness. Proposed new or replacement cardiac catheterization laboratories cost per catheterization and cardiovascular surgery services estimated costs per surgery should when compared to their peers demonstrate cost-effectiveness.

203.2(5) *Accessibility.* (Sections 135.64(1)*"c," "d"*)

a. Cardiovascular surgery units and cardiac catheterization labs should be available 24 hours a day, seven days a week for emergency coverage.

b. Facilities with cardiovascular surgery/cardiac catheterization should have available 24-hour, seven days a week ambulance and emergency room service.

c. Travel distance should be within two hours surface travel time or less for 80 percent of the projected service area for pediatric services.

d. Cardiac catheterization and cardiovascular surgery service should be provided regardless of ability to pay, in consideration of those programs available in the state which serve the medically indigent.

203.2(6) *Quality.* (Sections 135.64(1)*"i," "k"*)

a. Each surgery unit and cardiac catheterization lab shall demonstrate a reasonable set of criteria that are used in selecting appropriate candidates for surgery and catheterization.

b. Staffing minimums.

(1) The open heart surgery team should minimally consist of:

1. At least two certified or board eligible cardiovascular surgeons for the first 75 to 130 pediatric open heart surgeries. If pediatric surgery is performed, one surgeon must have special training and experience in surgery for congenital cardiac defects.
2. A board certified or board eligible adult or pediatric cardiologist(s). The latter only if pediatric surgery is performed, the former only if adult surgery is performed.
3. Board certified or board eligible anesthesiologist with special training in the management of cardiovascular cases' respiratory care.
4. Radiologist trained in the cardiovascular field.
5. Pathologist familiar with cardiac problems.
6. Specially trained in heart disease surgical nursing staff.
7. Cardiopulmonary bypass pump technicians.
8. Other ancillary staff as needed.

(2) Each applicant shall document that the proposed surgery unit can be so staffed when completed and operational.

c. Equipment and facilities. The applicant seeking to provide cardiovascular surgery should demonstrate that the following support services will be available:

(1) General X-ray diagnostic facilities and facilities for emergency X-rays on a 24-hour basis.

(2) A cardiac catheterization laboratory or angiography lab available on a 24-hour basis.

(3) A cardiographics laboratory, with facilities for recording the following tests: EKG, vector cardiogram, phonocardiogram, echocardiogram, and exercise stress testing.

(4) A supporting blood bank and hematology laboratory.

(5) A microbiology laboratory.

d. Cardiac catheterization labs serving infants and children should have biplane angiographic equipment, either cineangiocardiographic or cut film. Pediatric cardiac catheterization labs should be supervised by board certified or board eligible pediatric cardiologists; adult cardiac catheterization labs should be supervised by a board certified or board eligible adult cardiologist.

203.2(7) *Continuity.* (Sections 135.64(1)*"g," "h," "i," "k"*)

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

b. The applicant should provide documentation that emergency medical transport services will be available.

c. Institutions providing cardiovascular surgery services should include mechanisms for comprehensive medical followup including adequate medical records exchange.

203.2(8) *Acceptability.* (Section 135.64(1)*"c"*) Facilities with cardiovascular surgery and cardiac catheterization indicate 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.

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.

641—203.4(135) Computerized tomography standards.

203.4(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code sections 135.64(1)*"a"* to *"l."* 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 computerized tomography standards include:

(1) Proposals to commence or expand the capacity of computerized tomography services.

(2) Any other applications which relate to computerized tomography services.

203.4(2) *Definitions.*

a. Computerized tomographic (CT) scanner—a diagnostic tool which rotates about and which sends X-ray beams through cross-sectional layers of the body or brain. The X-ray beams which emerge from the body or brain are absorbed by a detector. Differences in the amount of X-rays absorbed by the detector indicate differences in tissue density. As the scanner rotates it takes many images of a cross-section. The images on the detector are transmitted to a computer which displays on a TV a reconstructed cross-sectional picture or slice. Contrast media is then usually injected to alter absorption of the detector, and the scan repeated; this is called enhancement.

(1) Whole body scanner—one capable of imaging the entire body.

(2) Head scanner—one capable of imaging only the brain and structures adjacent to the head.

b. Enhanced scan—a scan performed on a patient who has been treated with a contrast medium so that specific organs or areas of the body will be displayed more distinctly on the scan image.

c. Arteriography—imaging of blood vessels supplying the area of interest following injection of contrast media.

d. Pneumoencephalogram—the X-ray imaging of the skull and its content after introducing air or gas into the fluid-filled spaces within and around the brain and spinal cord.

e. Radioisotope brain scan—nuclear imaging of the concentration of radioactive isotopes which have been injected by biochemical or physiological actions into the brain, referred to later as nuclear brain scan.

f. H.E.C.T. (head equivalent C.T. unit)—a unit by which to measure the capacity of a CT scanner, and being defined as the average number of minutes necessary to perform a single unenhanced CT head study on a body scanner (including the room and equipment preparation time).

By comparing the average times for performing various types of scan procedures to the time necessary to perform an unenhanced head scan, the following table of equivalencies was determined:

On a head scanner—

One unenhanced head scan = 1.05 HECTs

One enhanced head scan = 1.26 HECTs

A procedure involving both types of scans = 1.85 HECTs

On a body scanner—

One unenhanced head scan = 1.00 HECTs

One enhanced head scan = 1.16 HECTs

A procedure involving both types of scans = 1.74 HECTs

One unenhanced body scan = 1.48 HECTs

One enhanced body scan = 2.00 HECTs

A procedure involving both types of scans = 2.75 HECTs

g. Operational capacity for a CT scanner—the operational capacity of a scanner is 3000 HECTs per year, plus or minus 10 percent.

h. Minimum shared-market area for a scanner (hereafter referred to as "area")—the smallest geographic area within which any scanner installation is judged to affect the utilization rate of any other scanner is the community (as defined by the U.S. Bureau of the Census) or a Standard Metropolitan Statistical Area (where an area is so designated).

i. Emergency medical service (EMS) level II trauma service—the level of various services and staffing that qualify a facility to be designated by the emergency medical service division of the Iowa department of public health, using the facilities categorization criteria of such services that is in effect on the date of the enactment of this standard.

j. Shared service agreements—a multi-institutional arrangement for coordination or consolidation of services or sharing of support services. Among the various types of arrangements are referred services, purchased or joint contract services, multisponsored services and regional services.

k. CT consortia—a cooperative venture in which two or more institutions form a separate entity which is created for the purpose of owning, leasing, planning for, and maintaining the use of the scanner. Each facility in the consortium maintains its autonomy for all other services.

l. Applicant—an applicant may be a facility or a consortium of facilities within an area, or a physician or group of physicians.

m. General imaging procedures—a radiological diagnostic procedure performed on an X-ray machine or similar radiological diagnostic instrument.

n. Active oncology service—full, multidisciplinary cancer care, provided by a medical team that would include: surgery, gynecology, medical oncology, radiation oncology, pathology, diagnostic radiology and nuclear medicine. The surgery specialties that might be available would include: thoracic, abdominal, genitourinary and gynecological. The active oncology staff would include those specialists with training in oncology, hematology, and pathology and who spend at least half of their time at the institution.

o. Radiotherapy service—the therapeutic application of megavoltage radiation, using a linear accelerator or cobalt unit. The availability of such service at a hospital would necessitate personnel trained in the therapeutic application of radiology.

p. Chemotherapy service—the treatment of cancer by chemical agents.

203.4(3) *Determination of need.*

a. Applicants who do not now have a scanner, or who have a scanner and seek a certificate for one or more additional scanners.

(1) Applicants in areas with no other scanners.

i. Applicants must have performed at least 30,000 general imaging procedures during the past calendar year or 12 months, or

ii. Demonstrate that during the past calendar year or 12 months, the applicant performed diagnostic procedures equivalent to 1500 HECTs, using the following scale:

50% of the number of radioisotopic brain scans × 1.75

25% of the number of cerebral angiograms/arteriograms × 1.75

100% of the number of pneumoencephelograms × 1.75

100% of the number of echoencephelograms × 1.17

10% of the number of skull X-rays × 1.75

100% of the number of patients referred to other facilities for CT diagnosis × 1.75 (in the case of head scans) and 2.75 (in the case of body scans)

(2) Applicants in areas with one or more scanners.

i. An applicant must meet the requirement of need, described in 203.4(3)*"a"*(1), and

ii. The average level of utilization for scanners within the area was at least 3000 HECTs (plus or minus 10 percent) for the past calendar year or 12 months. The average level of utilization will be determined by adding the number of HECTs performed during the period at all area facilities divided by the number of facilities.

iii. The University of Iowa Hospitals and Clinics is specifically exempted from consideration under ii., directly above, because it has a service area that encompasses the entire state and adjoining states. The utilization statistics for the University Hospital will therefore neither affect nor be affected by Mercy Hospital, Iowa City. Additionally, the utilization statistics for scanners at the University of Nebraska Hospitals and Clinics and St. Joseph's Hospital (both in Omaha) will not affect the need for scanners at hospitals in Council Bluffs.

b. Replacement scanners—applicants who currently have a scanner.

(1) All applicants seeking to replace a scanner with another scanner, head or body.

i. The applicant must demonstrate that the applicant's use of the applicant's current scanner was at least at the operating capacity level during the last calendar year or 12 months, or

ii. Below the operating capacity level, but above 1500 HECT level, and the applicant must demonstrate reasons for permanently utilizing their scanner below operating capacity level and demonstrate that discontinuation of their scanner service would impair the applicant's ability to respond to the emergency needs of the area. Reasons for utilizing the scanner below the capacity should include a unique patient or procedure mix which would define the capacity level differently for this applicant.

(2) Applicants seeking to replace a head scanner with a body scanner.

i. The applicant must meet the requirements listed in 203.4(3)*"a,"* and

ii. The applicant must meet the requirements for applicants seeking body scanners in 203.4(6), "Quality."

203.4(4) *Costs—whole body and head scanners.*

a. Financial feasibility. (Sections 135.64(1)*"f," "i," "p"*) CT scanners should be depreciated over a period of not less than seven years. Remodeling shall be depreciated as appropriate by generally accepted accounting principles.

b. Cost-effectiveness.

(1) Applicants should demonstrate for themselves and the health care system that the most cost-effective method of providing CT services has been chosen. If a CT scanner which requires less than 20 seconds to produce one section is chosen, the applicant should demonstrate the scanner's cost-effectiveness over scanners requiring greater than 20 seconds to produce one section. If a CT scanner which requires 20 seconds to 2 minutes to produce one scan is chosen, the applicant should demonstrate the scanner's cost-effectiveness over scanners requiring greater than 2 minutes to produce one section.

(2) Proposed new and replacement CT scanner's cost per CT scan should, when compared to their peers, demonstrate cost-effectiveness.

203.4(5) *Accessibility.* (Sections 135.64(1)*"c," "d"*)

a. All scanners must be available for emergency use 24 hours a day, less any down time. (Section 135.64(1)*"d."*)

b. Services should be provided to all patients regardless of the patient's ability to pay, taking into consideration the availability of those programs available in the state which serve the medically indigent.

c. Applicants will demonstrate a willingness to accept referrals for CT services from all area physicians.

d. All applicants must demonstrate through documented correspondence that an attempt has been made to form shared CT service agreements with all facilities within the area.

203.4(6) *Quality.* (Sections 135.64(1)*"i," "k"*)

a. Data on use and costs of the CT scanners should be submitted to the Iowa department of public health as a condition of approval. (Sections 135.64(1)*"a," "h"*)

b. All scanners.

(1) All applicants must demonstrate that they have on their staff or will acquire on their staff a full-time diagnostic radiologist, trained in the use of the CT scanner, or other physicians with comparable training and expertise.

(2) All applicants must document that they have on their medical staff individuals who are qualified to operate a scanner and interpret and act upon the diagnostic results. Such documentation may include reference to board certification, apprenticeship, academic credentials or such other qualifications that would prompt a medical staff to accept the responsibility for offering this new service. Applicants who intend to acquire staff with the desired expertise should provide signed letters of intent from the incoming medical personnel. Applicants who intend to upgrade the specialty skills of their staff should document a plan for training their current staff in the use of CT scanners.

(3) All applicants should have a complement of other diagnostic modalities available. Applicants seeking body scanners should also have available ultrasound, radionuclide scanning and conventional X-ray services.

(4) All applicants should have the facilities for treating the conditions diagnosed by imaging with the scanner or should demonstrate referral agreements with treatment facilities, in the event that the scanner will be used as a screening device.

(5) All applicants should have on their staff or available on a consultative basis the services of a biomedical engineer or radiation physicist, with special training in CT applications. These functions may also be provided by contract with the scanner manufacturer.

c. Head scanner only.

(1) Applicants for a head scanner should be a facility which qualifies for EMS Level II Trauma Service.

(2) If an applicant does not qualify for Level II Trauma Services, it must demonstrate that it has or will acquire a specialty practice in the field of diagnosing neurologic disorders, exclusive of neuropsychiatric disorders.

d. Body scanner only.

(1) Applicants for a body scanner must meet the criteria for EMS Level II Trauma Service.

(2) Applicants for a body scanner must be a hospital with 200 or more acute care beds. An applicant who does not meet the 200-bed rule may qualify for a body scanner if the applicant directly provides active oncology services with radiotherapy or chemotherapy treatment services, or both.

203.4(7) *Continuity.* (Sections 135.64(1)*"g," "h," "i," "k"*)

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

b. The applicant should provide documentation that emergency medical transport services will be available.

c. The applicant should demonstrate an emphasis on the availability of outpatient CT procedures, and that an appropriate percentage of all CT procedures on head and whole body units will be done on an outpatient basis.

203.4(8) *Acceptability.* (Section 135.64(1)*"k"*) Providers of CT services should indicate a willingness to observe the rights of patients.

203.4(9) Rescinded effective 1/28/81.

641—203.5(135) Long-term care.

203.5(1) *Purpose and scope.*

a. These standards are measures of criteria found in Iowa Code sections 135.64(1)*"a"* to *"g."* 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 standards include applications to:

(1) Construct, develop, offer new, modernize, replace, renovate, or relocate intermediate care or skilled nursing care beds in nursing homes or hospitals.

(2) Expand bed capacity in intermediate care or skilled nursing care facilities or designated units in hospitals.

203.5(2) *Definitions.*

"Intermediate care facility" (ICF) means any institution, place, building, or agency providing for a period exceeding 24 consecutive hours accommodation, board, and nursing services, the need for which is certified by a physician, to three or more individuals, not related to the administrator or owner thereof within the third degree of consanguinity, who by reason of illness, disease, or physical or mental infirmity require nursing services which can be provided only under the direction of a registered nurse or a licensed practical nurse.

"Rural counties" means all counties not designated by the U.S. Census as SMA (Standard Metropolitan Area) counties.

"Skilled nursing facility" (SNF) means any institution, place, building, or agency providing for a period exceeding 24 consecutive hours accommodation, board, and nursing services, the need for which is certified by a physician, to three or more individuals not related to the administrator or owner thereof within the third degree of consanguinity who by reason of illness, disease, or physical or mental infirmity require continuous nursing care services and related medical services, but do not require hospital care. The nursing care services provided must be under the direction of a registered nurse on a 24-hour-per-day basis.

"Urban counties" means those counties designated by the U.S. Census as SMA (Standard Metropolitan Area) counties.

203.5(3) *Availability and need.* (Iowa Code sections 135.64(1)*"c," "d," "e," "g," "h"*)

a. The following formula shall be used as a means of projecting the approximate number of intermediate and skilled nursing care beds needed to serve the projected population five years into the future:

(1) Rural counties:

[.09(65 + population) + .0015 (64 – population)] × 110% equals total long-term care bed need
Combined SNF and ICF bed need equals 2/3 (total long-term care bed need)
Assumed RCF bed need equals 1/3 (total long-term care bed need).

(2) Urban counties:

[.07(65 + population) + .0015 (64 – population)] × 110% equals total long-term care bed need
Combined SNF and ICF bed need equals 2/3 (total long-term care bed need)
Assumed RCF bed need equals 1/3 (total long-term care bed need).

(3) Department of economic development population projections are adopted for use in the determination of long-term care bed need.

(4) The department of public health will calculate long-term care bed need figures annually, using population projections five years into the future.

b. For purposes of comparing "need" to "existing" beds in a given county, the following shall be considered in the calculation of "existing" beds:

(1) ICF and SNF beds licensed at freestanding facilities in the county.

(2) Additional ICF and SNF beds previously approved through certificate of need but not yet licensed.

(3) ICF and SNF beds in designated units in hospitals in the county.

c. The statistical calculation of bed need shall serve as a guideline for the health facilities council in reviewing need for the proposed long-term care beds. Other factors which may be considered by the council include, but are not limited to:

(1) The availability and utilization of other ICF and SNF services in the county, or within the applicant's service area.

(2) The availability and utilization of other long-term care services in nearby hospitals, such as skilled care available through the swing bed program.

(3) The availability of supportive living arrangements which may or may not be licensed as residential care facilities (RCF).

(4) The availability of home health and other in-home services.

(5) The availability of other services to the elderly.

(6) The availability of ICF and SNF services in neighboring counties.

(7) Utilization by out-of-state residents of facilities in counties bordering other states, where the applicant provides evidence that in-migration of long-term care patients exceeds out-migration to the bordering state.

(8) Programs and services directed at special populations whose needs cannot otherwise be met, or whose needs cannot be met cost-effectively at other facilities.

d. In documenting need for a project, the applicant shall identify the service area and target population, including a description of the methodology used by the applicant in determining need for the requested beds and the expected sources of referrals. The applicant shall document that the number of beds requested is appropriate to address the identified need. The applicant shall also identify how the target population is currently being cared for, and what hardship is being experienced by the absence of the proposed beds.

203.5(4) *Quality.* (Iowa Code sections 135.64(1)*"i," "k"*) The applicant shall document that the applicant has contacted the health facilities division of the department of inspections and appeals to conform with physical standards, staffing requirements, and other licensing requirements to assess the potential for provision of quality care at the facility. When necessary, the applicant shall attempt to arrange an on-site visit to the facility to determine compliance with physical requirements, and shall provide documentation of this site visit or attempts to arrange such a site visit.

203.5(5) *Continuity.* (Iowa Code sections 135.64(1)*"g," "h," "k"*)

a. The applicant shall document the relationship of the facility's proposed services to other health and long-term care services in the community such as physician and hospital services, habilitation, rehabilitation, transportation or other services. The facility should be capable of providing or arranging for the provision of a continuum of long-term care services.

b. The facility should be capable of providing or arranging for the provision of a comprehensive program of coordinated patient services. The applicant shall provide evidence of contracts for services, appropriate staffing patterns and ratios, and licensure of personnel as necessary.

203.5(6) *Accessibility and acceptability.* (Iowa Code sections 135.64(1)*"c," "d"*)

a. Population subgroups which have traditionally been underserved, such as adolescents, the elderly, women, racial minorities, mentally ill, mentally retarded, and developmentally disabled should be considered when planning for or reviewing long-term care facilities.

b. The applicant shall document to what extent Medicaid patients will be served by the proposed beds, using past Medicaid utilization as an indicator or, in the case of a new facility, projecting anticipated Medicaid utilization.

203.5(7) *Costs and financial feasibility.* (Iowa Code sections 135.64(1)*"e," "f," "i," "p"*)

a. The applicant shall identify capital and operating costs associated with the project, identify sources of funding to cover those costs, and demonstrate that the project is financially feasible.

b. Construction costs shall be in line with construction costs of other similar projects.

c. The applicant shall provide budgets for the first three years of operation, including documentation of all assumptions used. The budget shall include anticipated sources of revenue, including the percentage of revenue from private pay, Medicaid, Medicare and other patient revenues.

d. Proposed charges per patient day should be justifiable when compared to current charges of other similarly licensed facilities in the applicant's service area, or other similar facilities elsewhere in the state. If charges are significantly higher or lower, the applicant shall provide a description of proposed programs or services which explain the difference in charges.

641—203.6(135) Bed need formula for mentally retarded. Rescinded **ARC 2297C**, IAB 12/9/15, effective 1/13/16.

641—203.7(135) End-stage renal disease standards. Rescinded **ARC 2297C**, IAB 12/9/15, effective 1/13/16.

These rules are intended to implement Iowa Code section 135.72.

641—203.8(135) Financial and economic feasibility.

203.8(1) *Purpose and scope.*

a. These standards are measures of some of those criteria 1[1](a to q) found in Iowa Code section 135.64. Criteria 1[1](a to q) which are measured by a standard are cited below:

Financial feasibility subrule 203.8(3), paragraph *"b,"* criteria 1[1] *"b," "c," "p"*; subrule 203.8(3), paragraph *"c,"* criteria 1[1] *"f," "p"*; subrule 203.8(3), paragraph *"d,"* criteria 1[1] *"c," "f," "p," "q."*

Economic feasibility subrule 203.8(4), paragraph *"a,"* criteria 1[1] *"e," "f," "g," "i," "p," "q."*

b. Certificate of need applications which are to be evaluated against these financial and economic feasibility standards include institutional health facilities, as defined in Iowa Code section 135.61.

203.8(2) *Definitions.*

a. Project. The remodeling, replacing or equipping of existing buildings, as well as the building or equipping of new structures.

b. Financial feasibility. The applicant's demonstration that it has the money, or that it can reasonably expect to obtain moneys equal to the estimated project costs, to any debt associated with the project, and to the annual expenses of providing the service, as well as the demonstration of overall institutional financial strength.

c. Financial ratio analysis. Evaluation of the financial position of an organization through creating indexes of income, revenue, assets, liabilities, etc. Financial ratios can be classified into liquidity, capital structure, activity and profitability ratios. Financial ratios measure financial feasibility.

(1) Net margin. The net income (after taxes if the applicant is not tax-exempt) minus nonoperating revenue divided by gross revenue.

(2) Net operating margin. Net income (after taxes if the applicant is not tax-exempt) minus nonoperating revenue divided by total operating revenue.

(3) Current asset ratio (current ratio). Current assets divided by current liabilities.

(4) Debt ratio. Total long-term debts divided by total fixed assets.

(5) Debt service coverage. The total of net income, interest expense, amortization of financing costs, and depreciation plus amortization and interest divided by the annual debt service.

(6) Days revenue in accounts receivable. Gross accounts receivable divided by gross patient revenue divided by 365.

d. Debt financing. Any portion of the cost of projects to be financed through borrowing either at the time the project is undertaken or at anytime subsequent thereto.

e. (Gross) revenue. Total of operating and nonoperating revenues.

f. Nonoperating revenues. Revenues not related to patient care or normal day-to-day operations, including unrestricted gifts, unrestricted endowments, income from the sale of a fixed asset, unrestricted income from a restricted or unrestricted fund, rental of facilities not used in operation, etc. (restricted funds are specifically excluded, unless expended during the accounting period, in which case they are accounted for either as operating or nonoperating revenues).

g. Operating revenues. Net patient service revenues (patient revenues minus deduction for charity, contractual and bad debt allowances) and other operating revenues.

h. Excess (or deficiency) of gross revenues over (or under) expenses. Net income.

i. Excess (or deficiency) of operating revenues over (or under) expenses. Net operating income.

j. Economic feasibility. The applicant's demonstration that its project will provide for the allocation of scarce resources within a community in a manner that is of maximum benefit to that community, in other words demonstration that the project will be cost-effective and will contain health care costs to the greatest extent possible.

k. Expense. An expired cost (cost = price paid for operations and assets, including leased assets vis-a-vis cash outlay, indebtedness incurred, or cash equivalent) incurred directly or indirectly in earning revenue. Expenditures may be expended over many years.

l. Asset. Economic potentials from which future benefits are expected to result, include leased capital equipment.

m. Liabilities. Debts or obligations.

n. Gross patient revenues. Patient service revenues before allowances for bad debt and charity and contracts.

o. Debt service. The payment of matured interest and principal; the outlay needed, supplied, or accrued for meeting such payments during any given accounting period; a budget or operating statement heading such items.

p. Current assets. Liquid assets which can be expected to directly or indirectly be converted into cash within one year or the operating cycle, whichever is longer (includes leased assets).

203.8(3) *Financial feasibility analysis.*

a. The applicant will provide financial feasibility analysis of the project's (facility's) past and projected costs, as requested by the Iowa department of public health.

b. The applicant shall show evidence of sound financial planning.

(1) If the sponsor has a long-range institutional plan, the project should be consistent with it. If the sponsor has no long-range institutional plan, the applicant shall demonstrate that the proposal helps meet the long-range needs of the community.

(2) The project should be consistent with the sponsor's three-year capital expenditure plan which all hospital and skilled nursing facilities must have.

c. The applicant shall demonstrate the financial feasibility of the services (institution) at completion and, shall show evidence of sound historical, financial, and operational management.

(1) The net operating margin should be positive. If a net loss is projected following completion of the project, an explanation of source funds should be given. Institutions funded by tax levy or endowment shall demonstrate that money from those sources has been historically applied to cover operating expenses if those institutions have a negative net operating margin.

(2) The net margin should be positive. If net loss is projected an explanation of source funds should be given.

(3) The past and projected current ratio should be at least 2:1.

(4) Past and projected debt service coverage ratio should be at least 2:1.

(5) The debt financing of a project should not increase the debt ratio above .8 unless debt service payments will derive from sources other than operating revenues.

(6) Days revenues in accounts receivable should not have been more than 65 days.

(7) If third party payment can be expected for the project, then some documentation indicating that the type of project which is proposed is generally third party reimbursable should be provided.

d. Sponsors shall show evidence of past efficient utilization. Standards (1) and (2) below apply to hospital project applications for:

—Construction of new acute care beds;

—Modernization or renovation of acute care beds/patient nursing units;

—Conversion of acute care beds from one service use to another;

—Addition to the square footage space of the hospital, where it might be architecturally feasible and cost-effective to convert excess bed space.

(1) Hospitals should have been no lower than 5 percent below the implicit target occupancy rate according to the bed need formula for the last year. Additionally hospitals with lower than target occupancy rates should show a trend during the last three years of increasing occupancy rates. This 5

percent refers to deviation on a scale of 1-100 percent and not to 5 percent of the target occupancy rate itself. Long-term care facilities should have had a 90 percent average occupancy for the last three years.

(2) Hospitals should have an average length of stay by service no greater than 10 percent above the average of their size category for the last three years.

Standards (1) and (2) above do not amend rule 641—203.1(135) acute bed care need methodology. But are additional measures of financial viability which supplement rule 641—203.1(135).

(3) Prior to the project's initiation, the full-time equivalent employees per adjusted patient day as reported in the most recent American Hospital Association Hospital Statistics should be no greater than 110 percent of the state average for hospitals of similar size. Categories of hospitals of similar size are:

Beds
6-24
25-49
50-99
100-199
200-299
300-399
400-499
500+

Adjusted patient day as used here is defined in Hospital Statistics, AHA, 1978.

Nursing homes shall meet regulations for licensure personnel requirements.

(4) Prior to initiation of a project, the cost per patient day of a hospital should be within 10 percent of the state average for hospitals within that size category. (See standard 203.8(3)*"d"*(3) for size categories.) An applicant's costs, which are incurred as a result of shared service contracts with other entities, and which are not charged to patients within the applicant's facility should not be included in the estimation of costs per patient day.

203.8(4) *Economic feasibility.*

a. The project as proposed shall be cost-effective.

(1) The applicant should demonstrate that the project represents the most cost-effective alternative. Such alternatives include, among others, new construction versus renovation and new service versus shared or contracted services.

(2) The applicant should demonstrate that of the financing methods available, the financing method chosen is the least costly alternative.

(3) Applicants shall demonstrate that construction or renovation costs are reasonable when compared to similar projects of the most recent year.

(4) The net operating margin should not exceed a percentage sufficient to provide for the organization's financial requirements, as defined in "Financial Requirements of Health Care Institutions and Services" (American Hospital Association, S031, February 1979), and limited by existing reimbursement payors.

(5) Facilities should show evidence that they have considered alternate energy sources within their institutions; and energy efficiency in project construction design.

b. Reserved.

This rule is intended to implement Iowa Code section 135.74.

[1] Iowa Code section 135.64(1).

641—203.9(135) Obstetrical services and neonatal intensive care unit standards. Rescinded **ARC 2297C**, IAB 12/9/15, effective 1/13/16.

641—203.10(135) Designated pediatric units standards. Rescinded **ARC 2297C**, IAB 12/9/15, effective 1/13/16.

641—203.11(135) Designated inpatient substance abuse treatment unit standards. Rescinded **ARC 2297C**, IAB 12/9/15, effective 1/13/16.

641—203.12(135) Magnetic resonance imaging services standards.

203.12(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code sections 135.64(1)*"a"* to *"q."* 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 standards include:

(1) Proposals to commence or expand the capacity of magnetic resonance imaging services.

(2) Proposals to replace a magnetic resonance imaging unit.

(3) Any other applications which relate to magnetic resonance imaging.

203.12(2) *Definitions.*

"Area" means the community or a metropolitan statistical area (as defined by the U.S. Office of Management and Budget and used by the U.S. Census Bureau).

"CT (computed tomography) procedure" means a CT study of a single site of anatomic interest during an individual patient visit.

"Magnetic resonance imaging (MRI)" means a diagnostic modality which employs a combination of magnetic and radio frequency fields and computers to produce images of body organs and tissues.

"MRI procedure" means each discrete MRI study of one patient.

"MRI unit" means the essential equipment and facility necessary to operate one MRI system.

203.12(3) *Availability and need.* (Iowa Code sections 135.64(1)*"c," "d," "e," "g," "h"*)

a. Applicants in areas with no other MRI units. Applicant must document a CT procedure volume of at least 4,500 CT procedures during the most recent calendar or fiscal year period. For purposes of calculating the volumes required, the applicant may use the combined total of more than one facility if the application involves joint ownership of the equipment, or the applicant provides evidence of referral arrangements for the proposed MRI service from the facilities whose procedure or patient volumes are included in the calculations.

b. Applicants in areas with one or more MRI units currently in operation or approved by certificate of need for operation.

(1) Applicant must meet the requirement of need described in 203.12(3)*"a"* and

(2) The other MRI unit(s) within the area must have been operating at a minimum of 3,000 MRI procedures annually (or 750 in three months), or proportionately more if the MRI unit runs more than one ten-hour shift.

(3) If the annual utilization of the other MRI unit(s) within the area has been below 3,000 procedures, future utilization above that current level must be reasonably projected or reasons for permanently utilizing the equipment below the 3,000 procedure level must be demonstrated.

c. Applicants seeking to replace an MRI unit.

(1) The applicant must demonstrate that the existing MRI unit has been operating at the level of at least 3,000 procedures during the most recent annual period.

(2) If the applicant's annual utilization has been below 3,000 procedures, the applicant must reasonably project future utilization above that level or demonstrate reasons for permanently utilizing the equipment below that level.

d. Applicants seeking to add an additional MRI unit.

(1) The applicant must demonstrate that the existing MRI unit(s) has been operating at the level of at least 3,500 procedures during the most recent annual period.

(2) The applicant must demonstrate that the demand significantly exceeds the 3,500 procedures annually.

e. The provisions of subrule 203.12(3) shall be effective until June 30, 1995. Prior to that time the Iowa department of public health shall reconvene a task force to recommend continuing use of the need methodology outlined or develop a new or revised methodology to use in projecting future MRI needs. The department shall promulgate a new subrule 203.12(3) accordingly.

203.12(4) *Quality and continuity.* (Iowa Code sections 135.64(1)*"g," "h," "i," "k"*)

a. The proposed MRI unit must function as a component of a comprehensive inpatient or outpatient diagnostic service. The proposed MRI unit must have the following modalities on-site or through referral arrangements:

(1) Ultrasound

(2) Computed tomography — whole body unit

(3) Angiography

(4) Nuclear medicine

(5) Conventional radiography

b. The proposed MRI unit must be located in a facility which has, either in-house or through referral arrangement, the resources necessary to treat most of the conditions diagnosed or confirmed by MRI. The following medical specialties must be available during MRI service hours on-site or by referral arrangements: neurology or neurosurgery, oncology and cardiology.

c. A proposal to provide new or expanded MRI must include satisfactory assurances that the services will be offered in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing agencies' requirements.

d. The applicant must provide evidence that the proposed MRI equipment has been certified for clinical use by the U.S. Food and Drug Administration or will be operated under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations.

e. Applicants for MRI shall document that the necessary qualified staff are available to operate the proposed unit. The following minimum staff shall be available to the MRI unit:

1. A full-time board eligible or board certified radiologist or nuclear medicine imaging physician or any other board eligible or board certified licensed physician whose exclusive responsibility for at least a two-year period prior to submission of a certificate of need request has been in the acquisition and interpretation of clinical images. This individual shall have a knowledge of MRI through training, experience, or documented postgraduate education. The individual shall also have training with a functional MRI facility.

2. Qualified engineering personnel, available to the institution during MRI service hours, with training and experience in the operation and maintenance of the MRI equipment.

3. Diagnostic radiologic technologists or other certified technologists with expertise in computed tomography or other cross-sectional imaging methods, at a staffing level consistent with the hospital's expected MRI service volume.

4. Other appropriate physicians shall be available during MRI service hours in clinical specialties such as neurology or neurosurgery, oncology and cardiology.

f. The applicant shall demonstrate how emergencies within the MRI unit will be managed in conformity with accepted medical practice.

203.12(5) *Accessibility and acceptability.* (Iowa Code sections 135.64(1)*"c," "d"*)

a. MRI facilities should have adequate scheduled hours to avoid an excessive backlog of cases and MRI shall be available 24 hours a day, seven days a week on an emergency (on-call) basis.

b. Selection of patients for clinical MRI studies must guarantee equal access to all persons regardless of insurance coverage or ability to pay.

c. In addition to accepting patients from participating institutions, facilities performing clinical MRI procedures shall accept appropriate referrals from other local providers. These patients shall be accommodated to the extent possible by extending the hours of service and by prioritizing patients according to standards of need and appropriateness rather than source of referral.

203.12(6) *Costs and financial feasibility.* (Iowa Code sections 135.64(1)*"e," "f," "i," "p"*)

a. The applicant shall identify capital and operating costs associated with the proposed MRI unit, identify sources of funding to cover those costs, and demonstrate that the project is financially feasible.

b. The applicant shall provide budgets for the first three years of operation, including documentation and justification of all assumptions used.

c. The applicant must document its projected average cost per procedure and charge per procedure for the first three years. Charges for MRI should be reasonably related to service cost, and comparable to MRI charges at other facilities in the state.

d. The applicant shall demonstrate that alternatives were considered and the proposed application is the most cost-effective and will accomplish the goals of the project.

e. To provide a data base for evaluation of subsequent MRI applications by the health facilities council, applicants granted a certificate of need shall provide to the certificate of need office the following data upon request of the Iowa department of public health. The department will request the following data on an annual basis.

1. Total number of procedures performed;
2. Total number of inpatient procedures;
3. Total number of outpatient procedures;
4. Average charge per procedure;
5. Hours of operation of the MRI unit;
6. Total revenues and expenses for the MRI unit for the year.

This rule is intended to implement Iowa Code section 135.64.

641—203.13(135) Positron emission tomography services standards.

203.13(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code sections 135.64(1)*"a"* to *"q."* 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 standards include:

(1) Proposals to commence or expand the capacity of positron emission tomography services.

(2) Proposals to replace a positron emission tomography unit.

(3) Any other applications which relate to positron emission tomography.

203.13(2) *Definitions.*

"Area" means the community or a metropolitan statistical area (as defined by the U.S. Office of Management and Budget and used by the U.S. Census Bureau).

"CT (computed tomography)" means an imaging method in which a cross-sectional image of the structures in a body plane is reconstructed by a computer program from the X-ray absorption of beams projected through the body in the image plane.

"Cyclotron" means an apparatus for accelerating protons or neutrons to high energies by means of a constant magnet and an oscillating electric field.

"MRI (magnetic resonance imaging)" means a diagnostic modality which employs a combination of magnetic and radio frequency fields and computers to produce images of body organs and tissues.

"Radiopharmaceutical" means a radioactive pharmaceutical used for diagnostic or therapeutic purposes.

"PET procedure" means an image-scanning sequence derived from a single administration of PET, equated with a single injection of the tracer.

"Positron emission tomography (PET)" means an imaging method in which positron-emitting radionuclides, which are produced either by a cyclotron or generator, and a nuclear camera are used to create pictures of organ function rather than structure. PET installations generally take one of two forms: a PET scanner using only generator-produced tracers (basic PET unit), or a PET scanner with a cyclotron (enhanced PET unit).

"SPECT (single photon emission computed tomography)" means a camera-based imaging system using the radionuclides in the routine practice of nuclear medicine.

203.13(3) *Availability and need.* (Iowa Code sections 135.64(1)*"c," "d," "e," "g," "h"*)

a. Applicants in areas with no other basic or enhanced PET units.

(1) Applicants should demonstrate a reasonable potential utilization of a PET unit based on diversified inpatient and outpatient case mix thresholds including:

1. Intracranial cases

- Primary brain tumors 50/year
- Metastasis 100/year
- Cerebral vascular disease 200/year

- Organic brain disease and dementia/psychiatric diagnoses (including epilepsy-seizure disorders) 500/year
- Spinal 100/year

2. Cardiovascular cases
- Ischemic heart disease (including acute and chronic infarction) 1200/year

3. Neoplasms (head, neck, thorax (excluding heart), abdomen, pelvic and musculoskeletal 1300/year

4. If the application is for a basic unit, the above case mix and numbers should be adjusted according to the proposed use of the unit.

(2) Applicants should have other diagnostic capabilities, on-site or through referral arrangements, with appropriate volumes including:

	Proposed Threshold
Nuclear medicine imaging services	7,000
Single photon emission computed tomography (including brain, bone, liver, Gallium and Thallium stress)	2,000
CT	10,000
MRI	3,000
Cardiac angiography	1,500
Cardiac ultrasound	7,000

(3) Applicants must demonstrate secondary and tertiary service capability, on-site or through referral arrangements, including cardiac surgery, cardiology, internal medicine, general surgery, hematology/oncology, neurology, pathology, thoracic surgery and psychiatry.

b. Applicants in areas with one or more basic or enhanced PET units currently in operation or approved by the certificate of need program for operation.

(1) Applicant should have access to cyclotron-produced radiopharmaceuticals.

(2) Existing PET units within the area (whether basic or enhanced) must have been operating at a minimum of 1000 PET procedures during the most recent annual period as reported to the certificate of need program according to 203.13(6)*"e."*

c. The provisions of subrule 203.13(3) shall be effective until June 30, 1995. Prior to that time the Iowa department of public health shall reconvene a task force to recommend continuing use of the need methodology outlined or develop a new or revised methodology to use in projecting future PET needs. The department shall promulgate a new subrule 203.13(3) accordingly.

203.13(4) *Quality and continuity.* (Iowa Code sections 135.64(1)*"g," "h," "i," "k"*)

a. The proposed PET unit must function as a component of a comprehensive inpatient or outpatient diagnostic service. The proposed PET unit must have the following modalities (and capabilities) on-site or through referral arrangements:

(1) Computed tomography — (whole body)

(2) Magnetic resonance imaging — (brain and whole body)

(3) Nuclear medicine — (cardiac, SPECT)

(4) Conventional radiography

b. The proposed PET unit must be located in a facility which has, either in-house or through referral arrangement, the resources necessary to treat most of the conditions diagnosed or confirmed by PET. The following medical specialties must be available during PET service hours on-site or by referral arrangements: cardiology, neurology, neurosurgery, oncology, and psychiatry.

c. A proposal to provide new or expanded PET must include satisfactory assurances that services will be offered in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing agencies' requirements. The following areas are to be addressed:

(1) Quality control and assurance of radiopharmaceutical production of generator or cyclotron-produced agents;

(2) Quality control and assurance of PET tomograph and associated instrumentation;

(3) Radiation protection and shielding;

(4) Radioactive emissions to the environment.

d. The applicant must provide evidence that the proposed PET equipment has been certified for clinical use by the U.S. Food and Drug Administration or will be operated under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations.

e. Applicants for PET shall document that the necessary qualified staff are available to operate the proposed unit. The applicants shall document the PET training and experience of the staff. The following minimum staff shall be available to the PET unit:

(1) One or more nuclear medicine imaging physician(s) available on a full-time basis to the PET unit who have been licensed by the state for the handling of medical radionuclides and whose primary responsibility for at least a one-year period prior to submission of the certificate of need application has been in acquisition and interpretation of tomographic images. This individual shall have knowledge of PET through training, experience, or documented postgraduate education. The individual shall also have training with a functional PET facility.

(2) Qualified PET radiochemist or radiopharmacist personnel, available to the facility during PET service hours, with at least one year of training and experience in the synthesis of short-lived positron-emitting radiopharmaceuticals. The individual(s) shall have experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical syntheses.

(3) Qualified engineering and physics personnel, available to the facility during PET service hours, with training and experience in the operation and maintenance of the PET equipment.

(4) Qualified radiation safety personnel, available to the facility at all times, with training and experience in the handling of short-lived positron-emitting nuclides.

(5) Certified nuclear medicine technologists with expertise in computed tomographic nuclear medicine imaging procedures, at a staffing level consistent with the proposed center's expected PET service volume.

(6) Other appropriate physicians shall be available during PET service hours which may include certified nuclear medicine technologists, computer programmers, nurses, and radiochemistry technicians.

f. The applicant shall demonstrate how emergencies within the PET unit will be managed in conformity with accepted medical practice.

203.13(5) *Accessibility and acceptability.* (Iowa Code sections 135.64(1)*"c," "d"*)

a. PET facilities should have adequate scheduled hours to avoid an excessive backlog of cases.

b. Selection of patients for clinical PET studies must guarantee equal access to all persons regardless of insurance coverage or ability to pay.

c. In addition to accepting patients from participating institutions, facilities performing clinical PET procedures shall accept appropriate referrals from other local providers. These patients shall be accommodated to the extent possible by extending the hours of service and by prioritizing patients according to standards of need and appropriateness rather than source of referral.

203.13(6) *Costs and financial feasibility.* (Iowa Code sections 135.64(1)*"e," "f," "i," "p"*)

a. The applicant shall identify capital and operating costs associated with the proposed PET unit, identify sources of funding to cover those costs, and demonstrate that the project is financially feasible.

b. The applicant shall provide budgets for the first three years of operation, including documentation and justification of all assumptions used.

c. The applicant must document its projected average cost per procedure and charge per procedure for the first three years. Charges for PET should be reasonably related to service cost and comparable to PET charges at other facilities in the state.

d. The applicant shall verify whether the service is eligible for reimbursement by public and private third-party payers.

e. The applicant shall demonstrate that alternatives were considered and the proposed application is the most cost-effective and will accomplish the goals of the project.

f. To provide a data base for evaluation of subsequent PET applications by the health facilities council, applicants granted a certificate of need shall provide to the certificate of need office the following data upon request of the Iowa department of public health. The department will request the following data on an annual basis.

(1) Total number of procedures performed;
(2) Total number of inpatient procedures (indicate type of procedure);
(3) Total number of outpatient procedures (indicate type of procedure);
(4) Average charge per specific procedure;
(5) Hours of operation of the PET unit;
(6) Total revenues and expenses for the PET unit for the year.

This rule is intended to implement Iowa Code section 135.64.

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