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.