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.