441—124.4(135) PET services standards.

124.4(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code section 135.63(1)*"a"* through *"q."* Criteria that are measured by a standard are cited in parentheses following each standard.

b. Certificate of need applications that are to be evaluated against these 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 that relate to positron emission tomography.

124.4(2) *Definitions.* The following definitions apply to the terms used in this rule:

"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).

"Computed tomography" or *"CT"* 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.

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

"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" or *"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.

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

"Single photon emission computed tomography" or *"SPECT"* means a camera-based imaging system using the radionuclides in the routine practice of nuclear medicine.

124.4(3) *Availability and need.* (Iowa Code section 135.63(1)*"c," "d," "e," "g,"* and *"h"*)

a. An applicant in an area with no other PET units.

(1) An applicant 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 per year.
- Metastasis: 100 per year.
- Cerebral vascular disease: 200 per year.
- Organic brain disease and dementia/psychiatric diagnoses (including epilepsy-seizure disorders): 500 per year.
- Spinal: 100 per year.

2. Cardiovascular cases.

- Ischemic heart disease (including acute and chronic infarction): 1,200 per year.

3. Neoplasms (head, neck, thorax (excluding heart), abdomen, pelvic, prostate and musculoskeletal): 1,300 per year.

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

	Proposed Threshold
Nuclear medicine imaging services	5,600
Single photon emission computed tomography (including brain, bone, liver, gallium and thallium stress)	1,600
CT	8,000
MRI	2,400

(3) An applicant should 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. An applicant in an area with one or more PET units currently in operation or approved by the certificate of need program for operation.

Existing PET units within the area (whether basic or enhanced) should have been operating at a minimum of 1,000 PET procedures during the most recent annual period as reported to the certificate of need program according to paragraph 124.4(4)*"e."*

124.4(4) *Quality and continuity.* (Iowa Code section 135.63(1)*"g," "h," "i,"* and *"k"*)

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

(1) CT.

(2) MRI.

(3) Nuclear medicine—cardiac, SPECT.

(4) Conventional radiography.

b. A proposed PET unit should be located in a facility that 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 should 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. An applicant will 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 the approval and authority of an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations.

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

(1) One or more nuclear medicine imaging physician(s) available 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. The individual(s) will demonstrate 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 personnel should be available during PET service hours, which may include certified nuclear medicine technologists, computer programmers, nurses, and radiochemistry technicians.

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

124.4(5) *Accessibility and acceptability.* (Iowa Code section 135.63(1)*"c"* and *"d"*)

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

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

c. In addition to accepting patients from participating institutions, a facility performing clinical PET procedures should accept appropriate referrals from other local providers. These patients will 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.

124.4(6) *Costs and financial feasibility.* (Iowa Code section 135.63(1)*"e," "f," "i,"* and *"p"*)

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

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

c. An applicant will 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. An applicant should verify whether the service is eligible for reimbursement by public and private third-party payers.

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

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