CHAPTER 124
STANDARDS FOR CERTIFICATE OF NEED REVIEW

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

441—124.1(135) Computerized tomography standards.

124.1(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code section 135.63(1)*"a"* through *"l."* 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 computerized tomography standards include:

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

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

124.1(2) *Definitions.* The following definitions apply to the terms used in this rule:

"Applicant" means a facility or a consortium of facilities within an area or a physician or group of physicians.

"Computerized tomographic (CT) scanner" means a diagnostic tool that rotates around the body and that sends X-ray beams through the body or brain. The X-ray beams that 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 volume or cross-section. The images on the detector are transmitted to a computer that displays on a monitor a reconstructed cross-sectional slice or volume. Contrast media is often injected to alter absorption of the detector. If the scan is repeated, it is called enhancement. Studies of the heart, arteries and veins may be done with contrast only.

"CT consortia" means a cooperative venture in which two or more institutions form a separate entity that 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.

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

"Enhanced scan" means a scan performed on a patient who has been administered a contrast medium so that specific organs or areas of the body will be displayed more distinctly on the scan image.

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

"Head scanner" means a scanner capable of imaging only the brain and structures adjacent to the head.

"Minimum shared-market area for a scanner" (hereafter referred to as "area") means the smallest geographic area within which any scanner installation is judged to affect the utilization rate of any other scanner in the community (as defined by the U.S. Bureau of the Census) or a standard metropolitan statistical area (where an area is so designated).

"Radiotherapy service" means 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.

"Shared service agreement" means 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.

"Whole body scanner" means a scanner capable of imaging the entire body.

124.1(3) *Determination of need.*

a. An applicant who does not have a scanner or an applicant who has a scanner and seeks a certificate for one or more additional scanners.

(1) An applicant in areas with no other scanners.

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

2. An applicant must demonstrate that during the past calendar year or 12 months, the applicant has performed diagnostic procedures equivalent to 1,500 head equivalent CTs (HECTs), using the following: 100 percent 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) An applicant in an area with one or more scanners.

1. An applicant must meet the requirement of need described in subparagraph 124.2(3)*"a"*(1), and

2. The average level of utilization for scanners within the area was at least 3,000 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.

3. University of Iowa Health Care is specifically exempted from consideration under numbered paragraph 124.3(2)*"a"*(2)"2" because it has a service area that encompasses the entire state and adjoining states. The utilization statistics for scanners at the University of Nebraska Medical Center and Creighton University Medical Center – Bergan Mercy (both in Omaha) will not affect the need for scanners at hospitals in Council Bluffs.

b. Replacement scanners—applicant who currently has a scanner.

(1) An applicant seeking to replace a scanner with another scanner, head or body.

1. An 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

2. An applicant must demonstrate that the applicant's use of the applicant's current scanner was at least below the operating capacity level, but above the 1,500 CT scan level, and the applicant must demonstrate reasons for permanently utilizing the applicant's scanner below operating capacity level and demonstrate that discontinuation of the applicant's 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 that would define the capacity level differently for the applicant.

(2) Reserved.

124.1(4) *Costs and financial feasibility.* (Iowa Code section 135.63(1)*"f," "i,"* and *"p"*)

a. 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. An applicant should demonstrate for the applicant and the health care system that the most cost-effective method of providing CT services has been chosen. A proposed new and replacement CT scanner's cost per CT scan should, when compared to the applicant's peers, demonstrate cost-effectiveness.

124.1(5) *Accessibility.* (Iowa Code section 135.63(1)*"c"* and *"d"*)

a. All scanners must be available to meet the needs of the communities the scanners are meant to serve.

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

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

124.1(6) *Quality.* (Iowa Code section 135.63(1)*"i"* and *"k"*)

a. Data on use and costs of the CT scanners should be submitted to the Iowa department of health and human services as a condition of approval. (Iowa Code section 135.63(1)*"a"* and *"h"*)

b. All scanners.

(1) An applicant must demonstrate that the applicant has on its staff or will acquire on its staff a full-time diagnostic radiologist trained in the use of the CT scanner or other physicians with comparable training and expertise.

(2) An applicant must document that the applicant has on its 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. An applicant that intends to acquire staff with the desired expertise should provide signed letters of intent from the

incoming medical personnel. An applicant that intends to upgrade the specialty skills of its staff should document a plan for training its current staff in the use of CT scanners.

(3) An applicant should have a complement of other diagnostic modalities available. An applicant seeking body scanners should also have available ultrasound and conventional X-ray services.

(4) An applicant 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) An applicant should have on its staff or available on a consultative basis the services of a biomedical engineer or medical physicist with special training in CT applications. These functions may also be provided by contract with the scanner manufacturer.

124.1(7) *Continuity.* (Iowa Code section 135.63(1)*"g," "h," "i,"* and *"k"*)

a. An applicant should demonstrate that an attempt was made to solicit letters of support from area hospitals and physicians to indicate a community need for the proposed service.

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

c. An applicant should demonstrate an emphasis on the availability of outpatient CT procedures and that an appropriate percentage of all CT procedures will be done on an outpatient basis.

124.1(8) *Acceptability.* (Iowa Code section 135.63(1)*"k"*) Providers of CT services should indicate a willingness to observe the rights of patients.

[**ARC 0320D**, IAB 5/27/26, effective 7/1/26; **ARC 0769D**, IAB 11/25/26, effective 1/1/27]

441—124.2(135) Long-term care.

124.2(1) *Purpose and scope.*

a. These standards are measures of criteria found in Iowa Code section 135.63(1)*"a"* through *"g."* 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 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.

124.2(2) *Definitions.* The following definitions apply to the terms used in this rule:

"Intermediate care facility" or *"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 that can be provided only under the direction of a registered nurse or a licensed practical nurse.

"Skilled nursing facility" or *"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.

124.2(3) *Availability and need.* (Iowa Code section 135.63(1)*"c," "d," "e," "g,"* and *"h"*)

a. The following formula will be used as a means of projecting the approximate number of beds needed by level of care (intermediate or skilled nursing care) to serve the projected population one year into the future using county-level characteristics:

(1) County-level bed need = County-level bed-days / days in time period

County-level bed-days = exp(Linear Predictor)

Linear Predictor = Intercept

+ Weight for Log of Total Population × Log of Total Population

+ Weight for Percent age 65-74 × Percent age 65-74

+ Weight for Percent age 75-84 × Percent age 75-84
+ Weight for Percent age 85 plus × Percent age 85 plus
+ Weight for Level of care × Level of care
+ Weight for Time Trend × Time Trend
+ Weight for Level of care × Time Trend × Level of care × Time Trend
+ Month effect for applicable month
+ County effect for applicable county

(2) For the purposes of using this formula, the lower and upper bounds of the weights for each variable in this section can be found on the department's website at hhs.iowa.gov/certificate-need-con-program.

(3) Bed need formula projections will consider county of facility, seasonal variation in need, age range of population, future population change projections, and other relevant factors and controls.

(4) The department will review the bed need formula at least every three years.

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 department in reviewing need for the proposed long-term care beds. Other factors that may be considered by the department include but are not limited to:

(1) The availability and utilization of other ICF and SNF services in the county or within an 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 that may or may not be licensed as an 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 an 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, an 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.

124.2(4) *Quality.* (Iowa Code section 135.63(1)*"i"* and *"k"*) An applicant shall document that the applicant has contacted the health and safety division of the department of inspections, appeals, and licensing 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.

124.2(5) *Continuity.* (Iowa Code section 135.63(1)*"g," "h,"* and *"k"*)

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

124.2(6) *Accessibility and acceptability.* (Iowa Code section 135.63(1)*"c"* and *"d"*)

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

b. An 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.

124.2(7) *Costs and financial feasibility.* (Iowa Code section 135.63(1)*"e," "f," "i,"* and *"p"*)

a. An 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. An 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 an 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 that explain the difference in charges.

These rules are intended to implement Iowa Code section 135.71.

[**ARC 0320D**, IAB 5/27/26, effective 7/1/26; **ARC 0769D**, IAB 11/25/26, effective 1/1/27]

441—124.3(135) MRI services standards.

124.3(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 magnetic resonance imaging services.

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

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

124.3(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.

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

"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.

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

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

124.3(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 MRI units. The applicant must document a future utilization of reasonably projected MRI procedure volume for the fiscal year period after projected installation.

b. An applicant in an area with one or more MRI units currently in operation or approved by certificate of need for operation.

(1) An applicant must meet the requirement of need described in paragraph 124.3(3)*"a,"* and

(2) The other MRI unit(s) within the area must have been operating at a minimum of 2,000 MRI procedures annually (or 500 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 2,000 procedures, future utilization above that current level must be reasonably projected or reasons for permanently utilizing the equipment below the 2,000 procedure level must be demonstrated.

c. An applicant seeking to replace an MRI unit.

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

d. An applicant seeking to add an additional MRI unit.

(1) An 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) An applicant must demonstrate that the demand significantly exceeds the 2,000 procedures annually.

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

124.3(4) *Quality and continuity.* (Iowa Code section 135.63(1)*"g," "h," "i,"* and *"k"*)

a. The proposed MRI unit should 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.

(3) Angiography.

(4) Nuclear medicine.

(5) Conventional radiography.

b. The proposed MRI unit must 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 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 a new or an 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. An 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 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 MRI should document that the necessary qualified staff are available to operate the proposed unit. The following minimum staff will be available to the MRI unit:

(1) A board-eligible or board-certified radiologist 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 CT 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. An applicant shall demonstrate how emergencies within the MRI unit will be managed in conformity with accepted medical practice.

124.3(5) *Accessibility and acceptability.* (Iowa Code section 135.63(1)*"c"* and *"d"*)

a. An MRI facility should have adequate scheduled hours to avoid an excessive backlog of cases and to meet the needs of the communities the scanners are meant to serve.

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

124.3(6) *Costs and financial feasibility.* (Iowa Code section 135.63(1)*"e," "f," "i,"* and *"p"*)

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

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

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

[**ARC 0320D**, IAB 5/27/26, effective 7/1/26; **ARC 0769D**, IAB 11/25/26, effective 1/1/27]

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.

[**ARC 0320D**, IAB 5/27/26, effective 7/1/26; **ARC 0769D**, IAB 11/25/26, effective 1/1/27]

These rules are intended to implement Iowa Code sections 135.61 through 135.78.

[Filed ARC 0320D (Amended Notice ARC 0175D, IAB 4/1/26; Notice ARC 9796C, IAB 12/10/25), IAB 5/27/26, effective 7/1/26]

[Filed ARC 0769D (Notice ARC 0618D, IAB 9/30/26), IAB 11/25/26, effective 1/1/27]