

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED REVIEW STANDARDS FOR
POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES

(By authority conferred on the Certificate of Need Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code that involve PET scanner services.

(2) A PET scanner service is a covered clinical service for purposes of Part 222 of the Code. A PET scanner previously approved pursuant to Section 8 of these standards or recognized by the Department prior to the effective date of these standards as a dedicated research PET scanner and listed in Appendix B, now seeking approval to operate pursuant to sections 3, 4, or 5, shall be considered as a person requesting Certificate of Need approval to initiate or expand, as applicable, a PET scanner service.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 10, and 11, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use sections 10 and 11, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Accelerator" means an apparatus, such as a linear accelerator or cyclotron, for accelerating charged particles to high energies by means of electromagnetic fields.

(b) "Acquisition of an existing PET scanner service" means obtaining possession or control of an existing PET service/unit(s) by contract, ownership, lease, or other comparable arrangement.

(c) "Anatomical site" means the physical area that can be imaged by a single PET scan.

(d) "Arterial sampling" means the insertion of an in-dwelling intra-arterial catheter for the withdrawal of arterial blood as part of a PET procedure.

(e) "Bed position" means the anatomical site being imaged. A change in bed position occurs when a different anatomical site is imaged and the scan requires the physical relocation of the patient relative to the PET scanner.

(f) "Central service coordinator" means the legal entity that has, or will have, operational responsibility for a mobile PET scanner and that is authorized to do business in the state of Michigan and was so authorized on or before the date the letter of intent was received by the Department.

(g) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 ~~et seq.~~ of the Michigan Compiled Laws.

(h) "Continuous data acquisition" means the continuous recording of scintigraphic events by a PET scanner for a specified period of time.

(i) "Cyclotron" means an apparatus for accelerating charged particles to high energies by means of electromagnetic fields.

(j) "Dedicated research PET scanner" means a PET scanner approved pursuant to Section

8 of these standards or a PET scanner recognized by the Department prior to the effective date of these standards as a dedicated research PET scanner and listed in Appendix B. The Department shall modify Appendix B based on decisions made on Certificates of Need and Certificate of Need applications.

(k) "Department" means the state agency known as the Michigan Department of Community Health.

(l) "Department inventory of PET scanners" or "Department Inventory" means the list, maintained by the Department on a continuous basis, of: (i) the PET scanners operating pursuant to a valid Certificate of Need issued under Part 222 or former Part 221; (ii) PET scanners that are not yet operational but have a valid Certificate of Need issued under Part 222 or former Part 221; (iii) proposed PET scanners under appeal from a final Department decision made under former Part 221 or Part 222 or pending a hearing from a proposed decision issued under Part 222 of the Code; and (iv) proposed PET scanners that are part of a completed application under Part 222 of the Code (other than the application or applications in the comparative group under review). The list will not include PET scanners approved pursuant to Section 8 of these standards or PET scanners recognized by the Department as dedicated research PET scanners prior to the effective date of these standards.

(m) "Dynamic PET scan" means a PET scan that is closely timed to the administration of a radiopharmaceutical in order to capture the perfusion of the tracer.

(n) "Existing PET scanner service" means the PET service at one geographic location listed on the Department Inventory of PET Scanners.

(o) "Expand a fixed PET scanner service" means increasing the number of fixed PET scanners at the same geographic location of an existing fixed PET scanner service.

(p) "Expand a mobile PET scanner service" means the addition of a mobile PET scanner that will be operated by a central service coordinator in the same planning area in which the CSC is approved primarily to operate one or more mobile PET scanners as of the date an application is submitted to the Department.

(q) "FDGs" means 2-{fluorine-18} fluoro-2-deoxy-D-glucose radiopharmaceuticals.

(r) "Health service area" or "HSA" means the groups of counties listed in Section 18.

(s) "Hospital" means a health facility licensed under Part 215 of the Code.

(t) "Host site" means the geographic address at which a mobile PET scanner is authorized by Certificate of Need to provide PET scanner services.

(u) "Initiate a mobile PET host site" means the provision of PET services at a host site that has not received any approved mobile PET services within 12 months from the date an application is submitted to the Department. The term does not include the renewal of a lease for the mobile PET service(s).

(v) "Initiate a PET scanner service" means begin operation of a PET scanner service/scanner, either fixed or mobile, at a geographic location that does not offer (or has not offered within the last consecutive 12-month period) approved PET scanner services and is not listed on the Department Inventory of PET Scanners on the date on which an application is submitted to the Department.

(w) "Institutional review board" or "IRB" means an institutional review board as defined by Public Law 93-348 which is regulated by Title 45 CFR 46.

(x) "Medicaid" means the program for medical assistance established under the Social Welfare Act, Act No. 280 of the Public Acts of 1939, being sections 400.1 to 400.119b of the Michigan Compiled Laws.

(y) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(z) "Mobile PET scanner" means a PET scanner unit and transporting equipment, operated by a central service coordinator, that serves two or more host sites.

(aa) "Mobile PET scanner network" means the route (i.e., all host sites) the central service

coordinator is authorized to serve under Certificate of Need. The mobile PET unit shall operate under a contractual agreement for the provision of PET services on a regularly scheduled basis at each host site.

(bb) "Out-state Michigan" means health service areas two (2) through eight (8).

(cc) "Patient visit" means a single session lasting no more than one day utilizing a PET scanner during which 1 or more PET procedures are performed.

(dd) "Pediatric patient" means, for purposes of these standards, any patient less than 15 years of age.

(ee) "PET data unit" means the result of the methodology as used in Section 13.

(ff) "PET equivalent" means the number calculated in accordance with Section 12 for a single patient visit.

(gg) "PET procedure" means the acquisition of a single image or image sequence involving a single injection of tracer.

(hh) "PET scan" means one (1) or more PET procedures performed during a single patient visit.

(ii) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and digital detectors and iterative reconstruction. Further, the term does include PET/CT scanner hybrids. If the PET/CT scanner will be used for computed tomography (CT) scans only in conjunction with the PET scan, then no separate CON is required for that CT use. The term does not include single-photon emission computed tomography systems (SPECT), x-ray CT systems, magnetic resonance, ultrasound computed tomographic systems, gamma cameras modified for either non-coincidence or coincidence imaging, or similar technology.

(jj) "PET scanner services" or "PET services" means either the utilization of a PET unit(s) at one site in the case of a fixed PET service or in the case of a mobile PET service, the utilization of a mobile PET unit at each host site.

(kk) "Planning area" means the health service area(s), as applicable, and identified in Section 19.

(ll) "Radionuclide generator" means the source of radioactive material, other than an accelerator or nuclear reactor, used to produce radiopharmaceuticals.

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

(nn) "Replace a PET scanner" means an equipment change, other than an upgrade, involving either a PET scanner, an accelerator if located on site, or other equipment related to the operation of the PET scanner service proposed by an applicant that results in that applicant operating the same number of PET scanners before and after project completion.

(oo) "Rural county" means a county not located in a metropolitan area as that term is defined pursuant to the "Revised Standards for Defining Metropolitan Areas in the 1990's" by the Statistical Policy Office of the Office of Information and Regulatory Affairs of the United States Office of Management and Budget, 55 F.R. p. 12154 (March 30, 1990).

(pp) "SPECT" means single photon emission computed tomography.

(qq) "Static PET scan" means any PET scan that is not dynamic.

(rr) "Tracer" means a radiopharmaceutical developed for use in PET scanner services which allows the quantification and/or qualitative images of chemistry, metabolism, and/or perfusion *in vivo*.

(ss) "Transmission scan" means transmission computed tomography using a sealed radioactive photon source or x-ray tube photon source applied to the attenuation correction of the emission scan data

(tt) "Upgrade a PET scanner" means an equipment change proposed by an applicant involving either or both the PET scanner and accelerator, if located at the same site, that involves a capital expenditure (whether purchase, lease, donation, or other arrangement) of \$500,000 or more during any period of time of no more than 24 consecutive months.

- (2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements for approval for all fixed and mobile host sites

Sec. 3. (1) An applicant proposing to provide PET scanner services, shall provide, at the time an application is submitted to the Department, the following services:

- (a) nuclear medicine as documented on the certificate issued by the Department of Environmental Quality,
- (b) SPECT as documented on the Annual Hospital Statistical Questionnaire,
- (c) CT scanning,
- (d) magnetic resonance (MR) imaging, and
- (e) cardiac catheterization.

If the applicant does not provide any of the services listed in this subsection at the same geographic location at which the proposed PET scanner will be located, the applicant shall include in the application, on the date it is submitted to the Department, written contracts or agreements with a hospital(s) located within 1) the HSA in which the proposed PET scanner is to be located when that location is within an HSA that includes any rural counties or 2) the HSA and a 20-mile radius of the proposed PET scanner location when that location is within an HSA other than an HSA that includes any rural counties, for the provision of these services. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(2) An applicant shall demonstrate that it provides, at the time the application is submitted to the Department and as documented by submission of the current (updated within the last 12 months) curriculum vitae for each department director, the following medical specialty services:

- (a) open heart surgery,
- (b) thoracic surgery,
- (c) cardiology,
- (d) oncology,
- (e) radiation oncology,
- (f) neurology,
- (g) neurosurgery, and
- (h) psychiatry.

If the applicant does not provide any of the medical specialty services listed in this subsection at the same geographic location at which the proposed PET scanner will be located, the applicant shall include in the application, on the date it is submitted to the Department, written contracts or agreements with a hospital(s) located within 1) the HSA in which the proposed PET scanner is to be located when that location is within an HSA that includes any rural counties or 2) the HSA and a 20-mile radius of the proposed PET scanner location when that location is within an HSA other than an HSA that includes any rural counties, for the provision of these medical specialty services. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(3) If a proposed PET scanner service does not involve an on-site source of radiopharmaceuticals, an applicant must provide in the application, on the date it is submitted to the Department, a written contract or agreement that demonstrates that a reliable supply of radiopharmaceuticals will be available to the proposed PET scanner service for the proposed uses.

If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

Section 4. Requirements for approval for applicants proposing to initiate a PET scanner service

Sec. 4. (1) An applicant proposing to initiate a fixed PET scanner service shall project an operating level of at least 2,600 PET data units for each proposed PET scanner based on the methodology used in Section 13.

(2) An applicant proposing to initiate a mobile PET scanner service shall project 2,100 PET data units for each proposed PET scanner based on the methodology used in Section 13.

(a) Of the 2,100 PET data units, the applicant(s) shall project a minimum of 360 PET data units, within the same planning area and a 20-mile radius of the proposed host site, for each proposed PET scanner service site located in a planning area that does not include any rural counties and a minimum of 240 PET data units, within the same planning area as the proposed host site, for each PET scanner service site located in a planning area that includes any rural counties.

(b) The requirements of subsection (2) shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant, the central service coordinator, demonstrates that the mobile PET scanner service operates predominantly outside of Michigan and that all of the following requirements are met:

(i) The proposed host site will be located in HSA 8.

(ii) The proposed host site in HSA 8 demonstrates a minimum of 240 PET data units based on the methodology in Section 13.

(3) Initiation of a mobile PET host site does not include the provision of mobile PET services at a host site if the applicant, whether the host site or the central service coordinator, demonstrates or provides, as applicable, each of the following:

(a) The host site has received mobile PET services from an existing approved mobile PET unit within the most recent 12-month period as of the date the application is submitted to the Department.

(b) The addition of a host site to a mobile PET unit will not increase the number of PET units operated by the central service coordinator or by any other person.

(c) Notification to the Department of the addition of a host site prior to the provision of PET services by that mobile PET unit in accordance with (d).

(d) A signed certification, on a form provided by the Department, whereby each host site for each mobile PET unit has agreed and assured that it will provide PET services in accordance with the terms for approval set forth in Section 10 of these standards, as applicable. The central service coordinator also shall identify all current host sites and route schedules, on this form, that are served by the mobile route as of the date of the signed certification, or are committed in writing to be served, by the mobile route.

(e) The central service coordinator requires, as a condition of any contract with each host site, compliance with the requirements of these standards by that host site, and the central service coordinator assures compliance, by that host site, as a condition of the Certificate of Need issued to the central service coordinator.

(4) One applicant proposing to initiate a fixed PET scanner in out-state Michigan shall be exempt from Section 4(1) for its first proposed clinical fixed PET scanner if that applicant meets all of the following conditions:

(a) The applicant operates a cyclotron capable of producing radioactive fluorine-18 and proposes to supply FDGs for use by at least four (4) other PET services or proposed services, fixed or mobile, in out-state Michigan. The applicant shall include, in its application, written agreements with at least those four (4) other PET services or proposed services to fulfill this requirement. The application approval shall be conditional upon the four services having received, or subsequently receiving, CON approval for PET services.

(b) All FDGs provided to other PET services in out-state Michigan, referenced in subdivision (a), shall be provided at the cost of production and distribution. The written agreements required by subdivision (a) shall include specific provisions for resolving any disagreements, between the parties, about the subsequent terms and conditions for assuring that the FDGs will be provided at the cost of production and distribution.

Section 5. Requirements for approval for applicants proposing to expand a PET scanner service

Sec. 5. An applicant proposing to increase the number of PET scanners (second, third, etc.), whether fixed or mobile, unless otherwise specified, in addition to a PET scanner previously approved for the same applicant, shall demonstrate the following:

(a) All of the applicant's PET scanners, both fixed and mobile, at the same geographic location as the proposed additional PET unit, have performed an average of at least 6,000 PET equivalents per PET scanner during the most recent 12-month period for which the Department has verifiable data.

(b) In the case of a fixed PET scanner service, the additional PET scanner shall be located at the same geographic location as the applicant's existing fixed PET scanner/service. If the scanner will not be located at the same geographic location, the applicant must meet the requirements to initiate or expand a PET scanner service ~~at the proposed location/site~~, in accordance with Section 4 or Section 5, respectively.

Section 6. Requirements for approval for applicants proposing to replace or upgrade a PET scanner

Sec. 6. (1) An applicant proposing to replace or upgrade an existing PET scanner(s), whether fixed or mobile, shall demonstrate the volume of PET equivalents performed during the most recent 12-month period for which the Department has verifiable data, meets subdivision (a):

(a) All of the applicant's existing fixed PET scanners, operated at the same geographic location, have performed an average of 4,500 PET equivalents, or all of the applicant's existing mobile PET scanners have performed an average of 3,000 PET equivalents, as applicable.

(b) An exemption to subdivision (a) may be made by the Department, if an applicant demonstrates to the satisfaction of the Department, the following:

(i) The existing PET scanner is technologically incapable of performing the applicable minimum number of PET equivalents. An applicant proposing a replacement under this subsection shall provide documentation, satisfactory to the Department, from a person or an organization with recognized professional expertise regarding that type of equipment, other than the applicant or a representative of a manufacturer or vendor of that type of equipment, indicating the number of PET equivalents the existing equipment is technologically capable of performing. The applicant also shall provide documentation, satisfactory to the Department, that the number of PET equivalents performed during the most recent 12-month period, for which the Department has verifiable data, was the number the equipment is technologically capable of performing.

(2) An applicant proposing to replace a PET scanner(s), whether fixed or mobile, shall demonstrate:

(a) the equipment to be replaced is fully depreciated according to generally accepted accounting principles or

(b) either of the following:

(i) the existing equipment clearly poses a threat to the safety of the public and the applicant's staff as determined by the Department or other qualified agency or individual (physicist, US Department of Energy, applicant's radiation safety committee, etc.) or

(ii) the proposed replacement PET scanner(s) offers technological improvements that enhance quality of care, increase efficiency, and reduce operating costs and patient charges.

(3) In the case of a fixed PET scanner service, the PET scanner will be located at the same geographic location as the applicant's existing fixed PET scanner/service to be replaced/upgraded. If the scanner will not be located at the same geographic location, the applicant must meet the requirements to initiate or expand a PET scanner service at the proposed site, in accordance with Section 4 or Section 5, respectively.

Section 7. Requirement for approval - applicants proposing to acquire an existing PET scanner service

Sec. 7. An applicant proposing to acquire an existing PET scanner service, whether fixed or mobile, shall demonstrate that it meets all of the following:

(a) The project is limited solely to the acquisition of an existing PET scanner/service and does not involve a change in the geographic location of the scanner(s).

(b) The project will not change the number of PET scanners listed on the Department Inventory of PET Scanners at the geographic location of the PET scanner service being acquired, unless the applicant demonstrates that the project is in compliance with the requirements of Section 3, 4, or 5, as applicable.

(c) The project will not result in the replacement of the PET scanner(s) at the PET scanner service to be acquired unless the applicant demonstrates that the requirements of Section 6 also have been met.

(d) All PET scanners to be acquired are listed on the Department Inventory of PET Scanners on the date the application is submitted to the Department.

(e) The applicant agrees to operate the PET scanner service in accordance with all applicable project delivery requirements set forth in Section 10 of these standards.

Section 8. Requirements for approval - applicants proposing a dedicated research fixed PET scanner

Sec. 8. (1) An applicant proposing to operate a fixed PET scanner (whether new or replacement) to be used exclusively for research shall demonstrate each of the following:

(a) The PET scanner shall operate under a protocol approved by the applicant's Institutional Review Board.

(b) The applicant agrees to operate the PET scanner in accordance with the terms of approval in Section 10(1)(a), (b), (c)(vi), (d)(iii), (iv) and (v); 10(2); 10(3); and 10(4).

(c) The applicant has an on-site cyclotron.

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 3, 4, 5, 6, 7, and 10(1)(c)(i), (ii), (iii), (iv), (v), (d)(i), and (d)(ii) of these standards.

Section 9. Additional requirements – for mobile PET service(s)/scanner(s)

Sec. 9. (1) An applicant proposing to begin operation of a mobile PET service/scanner shall demonstrate all of the following:

(a) A separate Certificate of Need application has been submitted by the central service coordinator and each proposed host site.

(b) A proposed regular route schedule, the procedures for handling emergency situations, and copies of all proposed contracts related to the mobile PET service/scanner have been included in the Certificate of Need application at the time it was submitted to the Department. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(c) The requirements of sections 3, 4, 5, and 6, as applicable, have been met.

(2) An applicant proposing to become a host site on an existing mobile PET scanner network shall demonstrate that it meets all of the following:

(a) Approval of the application will not result in an increase in the number of mobile PET scanners listed on the "Department Inventory of PET Scanners" unless the requirements of Section 5 have been met.

(b) A proposed regular route schedule, the procedures for handling emergency situations, and copies of all proposed contracts related to the mobile PET scanner have been included in the Certificate of Need application at the time it was submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

Section 10. Project delivery requirements--terms of approval for all applicants

Sec. 10. (1) An applicant shall agree that, if approved, the services provided by the PET service shall be delivered in compliance with the following terms of Certificate of Need approval:

(a) Compliance with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards:

(i) The approved PET scanner shall be operating at the applicable required volumes specified in these standards. In meeting this requirement, an applicant shall ~~not~~ include any patient visits conducted by dedicated research PET scanners.

(ii) An applicant shall establish and maintain (A) a standing medical staff and governing body (or its equivalent) requirement that provides for the medical and administrative control of the ordering and utilization of PET patient visits and (B) a formal program of utilization review and quality assurance. These responsibilities may be assigned to an existing body of the applicant, as appropriate.

(iii) A PET service, whether fixed or mobile, shall be staffed so that screening of requests for PET procedures and/or interpretation of PET procedures will be carried out by a physician(s) with appropriate training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined. For purposes of evaluating this subsection, the Department shall consider it *prima facie* evidence as to the training of the physician(s) if the physician is board certified or board qualified in nuclear medicine or nuclear radiology. However, an applicant may submit, and the Department may accept, other evidence that the physician(s) is qualified to operate the PET service/scanner. The physician(s) must be on-site or available through telecommunication capabilities to participate in the screening of patients for PET procedures and to provide other consultation services.

(iv) An applicant shall establish a PET service team. A PET service team shall be responsible for (A) developing criteria for procedure performance, (B) developing protocols for procedure performance, (C) developing a clinical data base for utilization review and quality assurance purposes, (D) transmitting requested data to the Department, (E) screening of patients to assure appropriate utilization of the PET scanner, (F) taking and interpreting scans, and (G) coordinating PET activity at a PET host site(s) for a mobile pet service(s)/scanner(s).

(v) At a minimum, the PET service team shall include the following personnel, employed directly by the applicant or on a contractual basis: (A) a team leader, (B) technologists with training in PET scanning, (C) radiation safety personnel, and (D) a physicist(s). The physicist(s) must be board certified or eligible for certification by the American Board of Radiology or an equivalent organization. Other personnel that may be appropriate members of the PET service team, depending on the type of operation and PET procedures performed, include but are not limited to nurses, computer technicians, radio-chemists, radio-chemistry technicians, radio-pharmacists, and instrument maintenance technicians. If the team leader is not a physician, the PET service team

also shall include a physician with appropriate training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined.

(vi) The applicant shall have, within the PET service, equipment and supplies to handle clinical emergencies that might occur within the PET service, with PET staff trained in CPR and other appropriate emergency interventions, and a physician on-site or immediately available to the PET service at all times when patients are undergoing PET procedures.

(d) Compliance with the following requirements:

(i) The applicant shall accept referrals for PET scanner services from all appropriately licensed practitioners.

(ii) The applicant, to assure that the PET scanner services will be utilized by all segments of the Michigan population, shall (A) not deny PET scanner services to any individual based on ability to pay or source of payment, (B) provide PET scanning services to any individual based on the clinical indications of need for the service, and (C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(iii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but are not limited to annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the Department or its designee. The applicant shall provide the required data on a separate basis for each separate and distinct site or PET service as required by the Department, in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records. If the applicant intends to include research PET equivalents conducted by a PET scanner other than a dedicated research PET scanner in its utilization statistics, the applicant shall submit to the Department a copy of the research protocol with evidence of approval by the Institutional Review Board. The applicant shall submit this at the time the applicant intends to include research procedures in its utilization statistics. The applicant shall separately report to the Department any PET equivalents conducted by a dedicated research PET scanner.

(iv) PET equipment to be replaced shall be removed from service on or before beginning operation of the replacement equipment.

(v) Within 10 days after beginning operation of a PET service/scanner, the applicant shall provide the Department with a notice stating the first date on which the PET service/scanner began operating on a regular basis.

(2) An applicant for a dedicated research PET scanner under Section 8 shall agree that the services provided by the PET scanner approved pursuant to Section 8 shall be delivered in compliance with the following terms of Certificate of Need approval:

(a) The capital and operating costs relating to the dedicated research PET scanner approved pursuant to Section 8 shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The dedicated research PET scanner approved pursuant to Section 8 shall not be used for any purposes other than as approved by the Institutional Review Board unless the applicant has obtained Certificate of Need approval for the PET scanner pursuant to Part 222 and these standards, other than Section 8.

(3) The operation of and referral of patients to the PET service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(4) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 11. Project delivery requirements – additional terms of approval for applicants involving mobile PET service(s)/scanner(s)

Sec. 11. (1) In addition to the provisions of Section 10, an applicant for a mobile PET service(s)/scanner(s) shall agree that the services provided by the mobile PET scanner(s) shall be delivered in compliance with the following terms of Certificate of Need approval:

(a) The central service coordinator for a mobile PET service, with an approved Certificate of Need, shall notify the administrative unit of the Department of Community Health responsible for administering the Certificate of Need program 30 days prior to dropping an existing host site.

(b) Each host site must have at least one physician who is board certified or board eligible in nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for (i) establishing patient examination and infusion protocol and (ii) providing for the interpretation of scans performed by the mobile PET service/scanner.

(c) Each mobile PET scanner service shall have an operations committee with members representing each host site, the central service coordinator, and the medical director. This committee shall oversee the effective and efficient use of the PET scanner, establish the regular route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile PET scanner service on at least a quarterly basis.

(d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile PET scanner equipment as well as the vehicle transporting the equipment. In addition, to preserve image quality and minimize PET scanner downtime, calibration checks shall be performed on the PET scanner unit at least once each work day or in accordance with the manufacturer's requirements. Routine maintenance services shall be provided on a regularly scheduled basis, at least once a week or in accordance with the manufacturer's requirements, during hours not normally used for patient procedures.

(e) Each host site shall provide a properly prepared parking pad, for the mobile PET scanner unit, of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as an enclosed canopy or an enclosed corridor). Each host site also must provide the capability for processing the film and maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.

(f) A mobile PET scanner service shall operate under a contractual agreement that includes the provision of PET services at each host site on a regularly scheduled basis.

(g) The volume of utilization at each host site shall be reported to the Department by the central service coordinator under the terms of Section 10(1)(d)(iii).

(h) At least 85 percent of the PET scans provided by the mobile PET scanner/service, annually, must be provided within the single planning area from which 85 percent of the diagnosis specific new cancer case, diagnostic cardiac catheterization, and/or intractable epilepsy data, as referenced in sections 14, 16, and 17, as applicable, was obtained for approval of the mobile PET scanner network.

(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the owner or the governing body of the applicant or its authorized agent.

Section 12. Determination of PET equivalents

Sec. 12. For purposes of these standards, PET equivalents shall be calculated as follows:

(a) Each actual patient visit performed during the time period specified in the applicable section(s) of these standards shall be assigned a number of PET equivalents based on the sum of the applicable values set forth in subsections (i) through (vii).

- (i) A single patient visit 1.0
- (ii) Number of chemically different tracers used during a single patient visit.
 - 1 tracers = 0
 - ≥2 tracers = 0.8
- (iii) Number of tracer injections performed during a single patient visit.
 - 1 tracer injection = 0
 - 2 tracer injections = 0.3
 - ≥3 tracer injections = 0.6
- (iv) Dynamic scan(s) performed during a single patient visit. 0.5
- (v) Number of bed positions used during a single patient visit.
 - 1 bed position = 0
 - ≥2 bed positions = 0.2 for each additional position
- (vi) Arterial sampling performed during a single patient visit. 0.5
- (vii) Transmission scan .4 per bed position

Total PET Equivalents for a Single Patient Visit

- (b) For each pediatric patient visit, the PET equivalent(s) determined pursuant to subdivision (a) shall be multiplied as follows:
 - patient < 5 years of age multiply by 2.0
 - patient >5<10 years of age multiply by 1.75
 - patient >10<15 years of age multiply by 1.5
- (c) The PET equivalents for each patient visit determined pursuant to subdivisions (a) and (b) shall be summed to determine the total PET equivalents for the time period specified in the applicable section(s) of these standards.

Section 13. Methodology for computing the projected number of PET data units

Sec. 13. The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in computing the projected number of PET data units.

(1)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the requirements of Section 14.

(b) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes 9590-9729), melanoma (morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411, C470 OR C490 excluding C440-C444 (skin of head and neck)]. Use the name "combined" for this grouping.

(c) Multiply the number resulting from the calculation in "combined" cancer cases identified in subsection (1)(b) by 0.8, which is the estimated probability that a "combined" cancer case will require a PET scan.

(d) Multiply the number resulting from the calculation in subsection (1)(c) by 2.5, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(2)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the requirements of Section 14.

(b) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the estimated probability that a breast cancer case will require a PET scan.

(c) Multiply the number resulting from the calculation in subsection (2)(b) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(3)(a) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the requirements of Section 16 by 0.1, which is the estimated probability that a patient having a diagnostic cardiac catheterization will require a PET scan.

(b) Multiply the number resulting from the calculation in subsection (3)(a) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(4)(a) Multiply the number of intractable epilepsy cases (ICD-9-CM Codes 345.01, 345.11, 345.41, 345.51, 345.61, 345.71, 345.81, OR 345.91) identified in accord with the requirements of Section 17 by 1.0, which is the estimated probability that a patient having an intractable epilepsy procedure will require a PET scan.

(b) Multiply the number resulting from the calculation in subsection (4)(a) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the total number of projected PET data units.

(6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is proposing to serve only Planning Area 6 to determine the total number of projected PET data units.

(7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is proposing to serve only Planning Area 5 to determine the total number of projected PET data units.

Section 14. Commitment of diagnosis specific new cancer cases

Sec. 14. (1) An applicant proposing to use diagnosis specific new cancer cases shall demonstrate all of the following:

(a) Only those cancer diagnoses identified in Section 13(1) and 13(2) shall be included.

(b) Each entity contributing diagnosis specific new cancer case data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of diagnosis specific cancer cases being committed to the application and that states no current or future diagnosis specific new cancer case data will be used in support of any other application for a PET unit for the duration of the PET service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(c) For fixed PET scanner services, the geographic location of each entity contributing diagnosis specific new cancer case data is in the same planning area as the proposed PET unit/service.

(d) For mobile PET scanner services, at least 85 percent of the diagnosis specific new cancer case data is from a single planning area in which 85 percent of the proposed mobile PET service (patient visits) will be provided.

(e) No entity contributing diagnosis specific new cancer case data is listed on the "Department Inventory of Pet Scanners," nor does it have a pending application to initiate PET scanning service.

(2) No entity currently operating or approved to operate a unit listed on the "Department Inventory of PET Scanners" shall contribute diagnosis specific new cancer cases to support any PET service/scanner.

(3) No entity that has contributed any diagnosis specific cancer case data to another PET application for which the approved PET scanner service still is operational shall commit cancer case data to any other application.

(4)(a) The Department may not consider a withdrawal of diagnosis specific new cancer case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application has been issued.

(b) The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific certificate of need application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

Section 15. Documentation of diagnosis specific new cancer case data

Sec. 15. (1) An applicant required to document volumes of diagnosis specific new cancer cases shall submit, as part of its application at the time it is submitted to the Department, documentation from the Division for Vital Records and Health Statistics verifying the number of diagnosis specific new cancer cases provided in support of the application for the most recent calendar year for which verifiable data are available from the State Registrar. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(2) Diagnosis specific new cancer case data supporting an application under these standards shall be submitted to the Division for Vital Records and Health Statistics using a format and media specified in instructions from the Department of Community Health.

Section 16. Commitment and documentation of diagnostic cardiac catheterization data

Sec. 16. (1) An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate all of the following:

(a) Each entity contributing diagnostic cardiac catheterization data [pursuant to Section 13(3)(a)] provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of diagnostic cardiac catheterization cases (sessions) committed to the application and that states no current or future diagnostic cardiac catheterization data will be used in support of any other application for a PET unit for the duration of the PET service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(b) For fixed PET scanner services, the geographic location of each entity contributing diagnostic cardiac catheterization data is in the same planning area as the proposed PET unit/service.

(c) For mobile PET scanner services, at least 85 percent of the diagnostic cardiac catheterization data is from a single planning area in which 85 percent of the proposed mobile PET service (patient visits) will be provided.

(d) No entity contributing diagnostic cardiac catheterization data is listed on the "Department Inventory of Pet Scanners," nor does it have a pending application to initiate PET scanning service.

(e) The diagnostic cardiac catheterization case data is from the most recently completed report(s) of the "Annual Hospital Statistical Questionnaire" produced by the Department, and the contributing entity has Certificate of Need Approval to provide diagnostic cardiac catheterization services.

(2) No entity currently operating or approved to operate a PET scanner listed on the "Department Inventory of PET Scanners" shall contribute diagnostic cardiac catheterization case data to support any PET service/scanner.

(3) No entity that has contributed any diagnostic cardiac catheterization case data to another PET application for which the approved PET scanner service still is operational shall commit diagnostic cardiac catheterization case data to any other application.

(4)(a) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application has been denied.

(b) The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific certificate of need application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

Section 17. Commitment and documentation of intractable epilepsy data

Sec. 17. (1) An applicant proposing to use intractable epilepsy cases shall demonstrate all of the following:

(a) Each entity contributing intractable epilepsy data [pursuant to Section 13(4)(a)] provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of intractable epilepsy cases committed to the application and that states no current or future intractable epilepsy case data will be used in support of any other application for a PET unit for the duration of the PET service for which the data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable

designated application date after all required documentation is received by the Department.

(b) For fixed PET scanner services, the geographic location of each entity contributing intractable epilepsy case data is in the same planning area as the proposed PET unit/service.

(c) For mobile PET scanner services, at least 85 percent of the intractable epilepsy data is from a single planning area in which 85 percent of the proposed mobile PET service (patient visits) will be provided.

(d) No entity contributing intractable epilepsy case data is listed on the "Department Inventory of Pet Scanners," nor does it have a pending application to initiate PET scanning service.

(e) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base (MIDB) available to the Department.

(2) No entity currently operating or approved to operate a unit listed on the "Department Inventory of Pet Scanners" shall contribute intractable epilepsy case data to support any PET service/scanner.

(3) No entity that has contributed any intractable epilepsy case data to another PET application for which the approved PET scanner service still is operational shall commit intractable epilepsy case data to any other application.

(4)(a) The Department may not consider a withdrawal of intractable epilepsy case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application has been denied.

(b) The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific certificate of need application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

Section 18. Health Service Areas

Sec. 18. Counties assigned to each health service area are as follows:

HEALTH SERVICE AREA	COUNTIES		
1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw
2	Clinton Eaton	Hillsdale Ingham	Jackson Lenawee
3	Barry Berrien Branch	Calhoun Cass Kalamazoo	St. Joseph Van Buren
4	Allegan Ionia Kent Lake	Mason Mecosta Montcalm Muskegon	Newaygo Oceana Osceola Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac Bay Clare Gladwin Gratiot	Huron Iosco Isabella Midland Ogemaw	Roscommon Saginaw Sanilac Tuscola
7	Alcona Alpena Antrim Benzie Charlevoix Cheboygan	Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee	Missaukee Montmorency Oscoda Otsego Presque Isle Wexford
8	Alger Baraga Chippewa Delta Dickinson	Gogebic Houghton Iron Keweenaw Luce	Mackinac Marquette Menominee Ontonagon Schoolcraft

Section 19. Planning Areas

Sec. 19. Health service areas assigned to each planning area are as follows:

PLANNING AREA 1

COUNTIES

HSA 1

Livingston
Macomb
Wayne

Monroe
Oakland

St. Clair
Washtenaw

PLANNING AREA 2

HSA 2

Clinton
Eaton

Hillsdale
Ingham

Jackson
Lenawee

HSA 3

Barry
Berrien
Branch

Calhoun
Cass
Kalamazoo

St. Joseph
Van Buren

PLANNING AREA 3

HSA 4

Allegan
Ionia
Kent
Lake

Mason
Mecosta
Montcalm
Muskegon

Newaygo
Oceana
Osceola
Ottawa

PLANNING AREA 4

HSA 5

Genesee
Arenac
Bay
Clare
Gladwin
Gratiot

Lapeer
Huron
Iosco
Isabella
Midland
Ogemaw

Shiawassee
Roscommon
Saginaw
Sanilac
Tuscola

PLANNING AREA 5

HSA 7

Alcona
Alpena
Antrim
Benzie
Charlevoix
Cheboygan

Crawford
Emmet
Gd Traverse
Kalkaska
Leelanau
Manistee

Missaukee
Montmorency
Oscoda
Otsego
Presque Isle
Wexford

PLANNING AREA 6

HSA 8

Alger
Baraga
Chippewa
Delta
Dickinson

Gogebic
Houghton
Iron
Keweenaw
Luce

Mackinac
Marquette
Menominee
Ontonagon
Schoolcraft

Section 20. Department Inventory of PET Scanners

Sec. 20. Appendix A sets forth the PET scanners listed on the "Department Inventory of PET Scanners" as of the effective date of these standards. Modification to Appendix A shall be made by the Department pursuant to decisions on Certificate of Need applications and Certificates of Need.

Section 21. Comparative reviews; effect on prior planning policies

Sec. 21. (1) Proposed projects reviewed under these standards shall not be subject to comparative review except for applicants under Section 4(4) that may be subject to comparative review.

(2)(a) These Certificate of Need review standards supersede and replace the Certificate of Need Standards for Positron Emission Tomography approved by the Certificate of Need Commission on February 2, 1994 and effective March 25, 1994. Further, the requirements of these standards are applicable only to applications submitted to the Department on or after the effective date of these revised standards approved by the CON Commission on December 11, 2001.

(b) The Department shall transfer an applicant's application fee from any PET application that is pending prior to the effective date of these standards to any new application for PET scanner/service from the applicant if the pending PET application is withdrawn so that the applicant may submit a new application under these standards. The new application must be submitted to the Department within six (6) months from the effective date of these standards.

Section 22. Public Hearing for future revisions to standards

Sec. 22. The Certificate of Need Commission shall hold a public hearing to consider the formation of an ad hoc advisory committee, on or before March 31, 2004, to review and recommend, at a minimum, changes to Section 4 (initiation) of these standards.

DEPARTMENT INVENTORY OF PET SCANNERS

PET Facility Location	Number of PET Scanners
William Beaumont Hospital Royal Oak (Oakland)	1
Children's Hospital of Michigan Detroit (Wayne)	1
University of Michigan Hospitals Ann Arbor (Washtenaw)	1

DEDICATED RESEARCH PET SCANNERS

PET Facility Location	Number of Dedicated Research PET Scanners
University of Michigan Hospitals Ann Arbor (Washtenaw)	1
Mid-Michigan MRI East Lansing (Ingham)	1