

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: December 21, 2012
PROJECT ANALYST: Gloria C. Hale
CHIEF: Craig R. Smith
PROJECT I.D. NUMBER: J-10016-12 / University of North Carolina Hospitals at Chapel Hill/ Acquire a PET MR pursuant to Policy AC-3 in the 2012 SMFP/ Orange County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

The University of North Carolina at Chapel Hill School of Medicine (SOM) received an exemption from CON review on September 15, 2011 to acquire a Positron Emission Tomography Magnetic Resonance (PET MR) Scanner for research activities at the SOM Biomedical Research Imaging Center (BRIC). The exemption was based on N.C.G.S. 131E-179 which includes subsection (b) as follows:

“ After a health service facility has received an exemption pursuant to subsection (a) of this section, it shall not offer the new institutional health services, or use a facility acquired through the capital expenditure, in a manner which affects the charges of the facility for the provision of medical or other patient care services, other than the services which are included in the research and shall not charge patients for the use of the service for which an exemption has been granted, without first obtaining a certificate of need from the Department; provided, however, that any facility or service acquired or developed under the exemption provided by this section shall not be subject to the foregoing restrictions on its use if the facility or service could otherwise be offered or developed without a certificate of need.

University of North Carolina Hospitals at Chapel Hill (“UNC Hospitals”) proposes to acquire, pursuant to Policy AC-3 in the 2012 State Medical Facilities Plan (2012 SMFP), the use of the research PET MR Scanner for clinical purposes. The applicant’s proposal is subject to review pursuant to N.C.G.S. 131E-178(b) which states,

“No person shall make an acquisition by donation, lease, transfer, or comparable arrangement without first obtaining a certificate of need from the department, if the acquisition would have been a new institutional health service if it had been made by purchase. In determining whether an acquisition would have been a new institutional health service, the capital expenditure for the asset shall be deemed to be fair market value of the asset or the cost of the asset, whichever is greater.”

The applicant states, in Section II.1, page 17,

*“**PET MR** is a new type of molecular imaging system that actually has the MRI scanner “fully integrated” with the PET scanner as one unit, specifically for the performance of advanced molecular imaging. The new imager allows for the first time, the simultaneous acquisition of morphology, function, and metabolism. The precisely aligned images are astonishingly more advanced enabling new insights in to the progress of disease, unlocking new paths to treatments, new areas of research, and providing the ability to expand understanding of the disease.”*

According to the 2012 SMFP, “there is no need for additional fixed dedicated PET scanners anywhere in the state and no reviews are scheduled.” UNC Hospitals is applying pursuant to Policy AC-3 in the 2012 SMFP. Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects states,

“Exemption from the provisions of need determinations of the North Carolina State Medical Facilities Plan shall be granted to projects submitted by Academic Medical Center Teaching Hospitals designated prior to January 1, 1990 provided the projects are necessary to meet one of the following unique academic medical needs:

- 1. Necessary to complement a specified and approved expansion of the number or types of students, residents or faculty, that are specifically required for an expansion of students or residents, as certified by the head of the relevant associated professional school; the applicant shall provide documentation that the project is consistent with any relevant standards, recommendations, or guidance from specialty education accrediting bodies; or*
- 2. With respect to the acquisition of equipment, is necessary to accommodate the recruitment or retention of a full-time faculty member who will devote a majority of his or her time to the combined activities of teaching (including teaching within the clinical setting), research, administrative or other academic responsibilities within the academic medical center teaching hospital or medical school; or*

3. *Necessary to accommodate patients, staff or equipment for a specified and approved expansion of research activities, as certified by the head of the entity sponsoring the research; and including, to the extent applicable, documentation pertaining to grants, funding, accrediting or other requirements, and any proposed clinical application of the asset; or*
4. *Necessary to accommodate changes in requirements of specialty education accrediting bodies, as evidenced by copies of documents issued by such bodies.*

A project submitted by an Academic Medical Center Teaching Hospital under this policy that meets one of the above conditions shall demonstrate that the Academic Medical Center Teaching Hospital's teaching or research need for the proposed project cannot be achieved effectively at any non-Academic Medical Center Teaching Hospital provider which currently offers and has capacity within the service for which the exemption is requested and which is within 20 miles of the Academic Medical Center Teaching Hospital."

The Medical Facilities Planning Branch of the Division of Health Service Regulation designated UNC Hospitals as an academic medical center teaching hospital prior to January 1, 1990.

The applicant specifically addresses options one and two of Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects. Option one states that proposed projects under Policy AC-3 must be,

"Necessary to complement a specified and approved expansion of the number or types of students, residents or faculty, that are specifically required for an expansion of students or residents, as certified by the head of the relevant associated professional school; the applicant shall provide documentation that the project is consistent with any relevant standards, recommendations, or guidance from specialty education accrediting bodies."

The applicant states that the proposed utilization of the research PET MR will be essential for the development of a Fellowship in Nuclear Radiology and for residency training. The Fellowship in Nuclear Radiology will require training in the PET MR as the focal point for one planned fellowship slot. The Chief Executive Officer and Dean of the UNC School of Medicine certifies the use of the PET MR for clinical scanning in regard to the fellowship in a letter provided in Exhibit 10, page 284, that states, in part:

"The UNC School of Medicine and UNC Hospitals have approved the development of a Nuclear Radiology Fellowship which is contingent on the clinical access to this innovative technology. The fellowship provides enhanced training in all aspects of nuclear radiology including the new field of molecular imaging which is represented by this technology. Candidates who complete this training will be eligible for

certification by the American Board of Radiology in Diagnostic Radiology as well as sub-certification from the American Board of Nuclear Medicine. I certify that the proposed purchasing of a minor amount of scanning services for clinical patient care is necessary to complement this specific and approved expansion of this fellowship.”

In addition to the development of a Nuclear Radiology Fellowship, the applicant discusses the necessity of the proposed project, in Section II.5, pages 21-23, for the recruitment and expansion of faculty that will complement the Department of Radiology, in conjunction with the School of Medicine’s Biomedical Research Imaging Center (BRIC). The proposed expansion of faculty is “*certified by the head of the relevant associated professional school*” in a letter provided in Exhibit 10, page 284, signed by the Chief Executive Officer of the UNC Health Care System and Dean of the UNC School of Medicine, which states,

“I am writing to certify that the proposed purchase of a small number of scanning services from the existing research MR-PET at the UNC School of Medicine, specifically for clinical scanning, is necessary for the following reasons:

- *To complement a specific and approved expansion of the faculty, and*
- *To accommodate the recruitment and retention of full-time faculty members who will devote a majority of their time to the combined activities of teaching (including teaching within the clinical setting), research, administrative, or other academic responsibilities with the academic medical center teaching hospital or medical school.”*

In addition, the applicant demonstrates that it meets the second option under Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects, which states,

“With respect to the acquisition of equipment, is necessary to accommodate the recruitment or retention of a full-time faculty member who will devote a majority of his or her time to the combined activities of teaching (including teaching within the clinical setting), research, administrative or other academic responsibilities within the academic medical center teaching hospital or medical school;”

The applicant states, in Section II.5, pages 21-23, the faculty member recruited to complement the Department of Radiology, in conjunction with the School of Medicine’s Biomedical Research Imaging Center (BRIC), will serve as both Chief of the Division of Nuclear Medicine and Chief of the Molecular Imaging Translation Program. The applicant states that having the proposed clinical access to the PET MR “*is critical in attracting top quality candidates for this elevated position.*” In Exhibit 11, the applicant provides a description of this position which states,

“...the Department of Radiology is seeking outstanding candidates to serve as the Chief of Nuclear Medicine as well as to develop a translational molecular imaging program. ...The primary academic appointment will be in the Department of Radiology with membership in the Cancer Center and the BRIC. ...The candidates will have two major responsibilities, clinical administration and research development. The candidates will provide administrative leadership in the area of budget, long-range planning, resource allocation, clinical services and faculty development in the Nuclear Medicine Division. The candidates will work with the BRIC and Cancer Center to develop and implement strategies for promoting translational molecular imaging research program at UNC.”

In addition, a current faculty member who is an Assistant Professor of Radiology joined the faculty in July 2012, anticipating access to both research and clinical services involving the research PET MR scanner. The applicant states that *“His retention is tied heavily to our ability to use this unit in a clinical environment.”*

Plans also include the development of a nuclear medicine subspecialty certificate administered through the Department of Radiology. Additional information on this certificate program is provided in Exhibit 12. In addition, educational benefits would accrue to UNC Hospitals’ School of Nuclear Medicine Technology and Molecular Imaging where students would have improved clinical access to this technology. Moreover, radiology students from Wilkes Regional Medical Center, Vance-Granville Community College, and others who already have observation time in the PET service, would benefit from expanded observation time through clinical access to the research PET MR.

Moreover, Policy AC-3 requires the following,

“A project submitted by an Academic Medical Center Teaching Hospital under this policy that meets one of the above conditions shall demonstrate that the Academic Medical Center Teaching Hospital’s teaching or research need for the proposed project cannot be achieved effectively at any non-Academic Medical Center Teaching Hospital provider which currently offers and has capacity within the service for which the exemption is requested and which is within 20 miles of the Academic Medical Center Teaching Hospital.”

The applicant states in Section III.1, page 55, that the *“fully integrated”* PET MR technology is only one of four such scanners in the United States. There are no other non-Academic Medical Center Teaching Hospital providers offering or having the capacity within the service for which the exemption is requested and which are within 20 miles of UNC Hospitals. The other providers with PET MR scanners are located at Massachusetts General Hospital in Boston, Massachusetts, the National Institutes of Health in Bethesda, Maryland, and the Mallinckrodt Institute of Radiology in St. Louis, Missouri. Therefore, no other PET MR scanners are within 20 miles of UNC Hospitals.

The applicant adequately demonstrates that the proposed clinical access to the research PET MR at UNC School of Medicine is necessary to complement a specified and

approved expansion of residents and faculty, and to accommodate the recruitment or retention of a full-time faculty member who will devote a majority of his or her time to the combined activities of teaching, research, administrative or other academic responsibilities within the teaching hospital or medical school.

In addition, the applicant adequately demonstrates that the teaching need for the research PET MR scanner cannot be achieved effectively at a non-academic medical center teaching hospital provider located within 20 miles of UNC Hospitals since there are no such providers located within 20 miles that have a PET MR.

Therefore, the proposal is consistent with Policy AC-3 in the 2012 SMFP and the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

UNC Hospitals proposes to purchase services from an existing research PET MR scanner at the UNC School of Medicine (SOM) Biomedical Research Imaging Center (BRIC) for use in clinical care. The existing research PET MR scanner is owned and operated by the SOM BRIC under a Research Exemption granted by the Division of Health Service Regulation, Certificate of Need Section. The applicant provides a copy of the Research Exemption granted for this unit in Exhibit 2.

Population to be Served

In Section III.4(b), pages 66-67, the applicant provides the patient origin for the patients receiving Positron Emission Tomography (PET) services at UNC Hospitals in FY2011, which is summarized as follows.

PET services: FY2011 Patient Origin - UNC Hospitals

County	# of Patients	% of Total
Wake	390	13.57%
Orange	349	12.14%
Alamance	231	8.03%
Chatham	215	7.48%
Cumberland	177	6.16%
Durham	155	5.39%
Lee	118	4.10%
Harnett	91	3.17%
Johnston	69	2.40%
Subtotal	1795	62.40%
Other NC Counties*	995	34.60%
North Carolina Total	2790	97.00%
Other US Total	85	3.00%
Total	2875	100.00%

*The counties in the "Other NC Counties" category are identified in Section III.4(b), pages 66-67. Each of these counties account for less than 2.40% of patients. Percentages might be slightly off due to rounding.

The applicant provides projected patient origin from supplemental information obtained by the CON Analyst for all PET services for the first two years following project completion as summarized below.

Projected PET Patient Origin by County, Years 1 and 2

County	Year 1	% of Total	Year 2	% of Total
Wake	511	13.57	546	13.57
Orange	457	12.14	488	12.14
Alamance	303	8.03	323	8.03
Chatham	282	7.48	301	7.48
Cumberland	232	6.16	248	6.16
Durham	203	5.39	216	5.39
Lee	154	4.10	166	4.10
Harnett	119	3.17	127	3.17
Johnston	90	2.40	96	2.40
Subtotal	2351	62.60	2511	62.50
Other NC Counties*	1295	34.50	1436	35.80
North Carolina Total	3646	0.97	3896	0.97
Other US Total	111	0.03	119	0.03
Total	3757	100	4015	100

*The counties in the "Other NC Counties" category are identified from supplemental information provided. Each of these counties account for less than 2.40% of patients. Percentages might be slightly off due to rounding.

In Section III.5(d), pages 69-70, the applicant states:

“The methodology for projecting cases/ patient origin was based on the most recent fiscal year data for UNC Hospitals’ services. Patient origin for most services has remained relatively consistent over the last several years. Because historic patient origin is often the best indicator of future patient origin, the FY 2011 actual proportions from each county were applied in Years 1 and 2 utilization projections. Complete FY 12 information is not yet available. UNC Hospitals anticipates that any changes in patient origin for the service components involved in this application will be insignificant.”

The applicant adequately identified the population to be served.

Need for the PET MR Scanner

One research PET MR Scanner is owned and operated by the UNC School of Medicine (SOM). It is housed in the Radiological Research Laboratory on the Health Affairs Campus of UNC. According to supplemental information provided by the applicant, the research PET MR Scanner performed 109 MR-only research scans from March 28, 2012 through November 28, 2012 and 26 PET MR research scans from July 24, 2012 through November 28, 2012. The applicant states, in Section III.1(a), page 18,

“...patients who do not “qualify” for a research study cannot benefit from this advanced imaging system. Additionally, UNC Faculty estimate that less than 2% of all disease appropriate patients end up “qualifying” for a research PET MR scan.”

Therefore, all patients who could benefit from PET MR services are not currently being served. The applicant states in Section III.1, page 38, that the expanded use of these services *“...is a function of increasing cancer incidence...as well as growing utilization of oncology, neurology and cardiology services which inherently feed the increased need for educational programs at UNC Hospitals.”*

In Section II.1(a), page 23, the applicant discusses how clinical access to the research PET MR scanner would be beneficial. Patients can be spared delays in care since imaging using the research PET MR scanner could be accomplished during one visit rather than two separate visits where patients would need testing from both a PET and a MRI machine. In Section I.1(a), page 17, the applicant states that images from both of these devices will no longer need to be combined which creates potential *“issues...with respect to motion artifacts, spatial alignment, differences in metabolic rates, patient positioning, etc.”* In addition, innovative approaches could be used in imaging, allowing for the use of new, approved radiopharmaceuticals or those in clinical trial status. Moreover, as stated in Section II.5, page 22, radiation dosages would be lessened for pregnant patients and pediatric patients, who otherwise would require PET CT scans, with the CT portion resulting in a larger dose of radiation than the PET MR. Lastly, UNC Hospitals has readily available technologists certified in both nuclear medicine and magnetic resonance imaging on staff and has the only hospital-based nuclear medicine technology program in the state. In Section II.5, page 24, the applicant states, *“The addition of this equipment would allow us to produce*

North Carolina graduates with the ability and national certifications required to operate the scanners in any state in the country.”

The applicant summarizes the need for clinical access to the research PET MR scanner in Section III.1, pages 38-39, as follows:

- To accommodate the recruitment and retention of a full-time faculty member to serve as Chief of the Division of Nuclear Medicine and head of the Molecular Imaging Translation program;
- To support development of a Fellowship in Nuclear Radiology and other educational opportunities within the School of Nuclear Medicine Technology and Molecular Imaging;
- To be more responsive to North Carolina residents with cancer, as it is now the state’s leading cause of death and is increasing in incidence due to the aging population and increasing life expectancies;
- To provide clinicians with the most accurate diagnostic information possible due to the PET MR scanner’s ability to acquire two images simultaneously, allowing for direct comparison of images, to produce images with greater detail, including concurrent acquisition of morphology, function, and metabolism, and to lower radiation dosages as compared to PET CT; and
- To enable UNC Hospitals to be more responsive to the needs of North Carolina residents.

Projected Utilization

In Section IV.1, pages 72-75, the applicant provides historical and projected utilization for existing PET CT scans, PET MR scans, and for both combined. The applicant states in supplemental information provided that the PET MR services are part of the applicant’s PET service. The table below illustrates the following: fiscal years 2010-2011 are the two fiscal years prior to the submission of the application, FY 2012 is the year the application was submitted, FY 2013 represents the interim fiscal year during which the project will be developed and completed, and fiscal years 2014-2016 represent the first three full fiscal years after completion of the proposed project.

				Interim	1st Full FY	2nd Full FY	3rd Full FY
	FY10	FY11	FY12	FY13	FY14	FY15	FY16
PET CT scans	2720	2875	2666	2526	3155	3243	3334
PET MR scans	n/a	n/a	n/a	207*	602	772	976
Combined	2720	2875	2666**	2733	3757	4015	4310
Annual Growth from prior FY	5%	6%	-7%	3%	37%	7%	7%

*Note: Figure includes only 4 months of clinical PET MR scans as the first day of use would be 3/1/13. UNC Hospitals' FY is from July through June. **Note: Utilization differs from utilization reported in the 2012 LRA (shows 2,793 patients) because the data in the 2012 LRA is for 10/1/10 – 9/30/11 and the data in the table above is for UNC Hospitals FY, which is 7/1/10 – 6/30/11.

The applicant states that the utilization projections are based on both historical analysis and physician input, the latter indicating that one scan per patient would be a reasonable projection. In addition, physicians projected that PET MR volume would be mostly additional scans beyond the PET CT volume. The negative growth in PET CT scans for FY 2012, shown in the table above, is due to the temporary suspension of the use of a Rubidium device which contains a radioactive tracer used in cardiac cases. The FDA issued an “alert” for this device on July 15, 2011 due to an “*isotope breakthrough problem*”, and subsequently, the device manufacturer voluntarily recalled the device. The applicant states, in Section IV.1(d), page 74,

“...overall, the other PET CT procedure volumes increased enough during FY 12 through natural growth to offset most of the triple digit loss. It is expected that a replacement of Rubidium chloride will soon be available, just prior to or during FY 14, and this lost volume will return. Thus, the growth in PET is projected to rebound approximately by the same volume that was lost when the tracer was withdrawn. This explains the projected 25% resurgence of PET CT in FY 14.”

In addition, in Section IV.1(d), page 74-75, the applicant provides an explanation of the growth of the PET MR scans once introduced in FY 2013, as follows:

“It is expected that initial growth will build as the usefulness of the “fully integrated” PET MR technology and the quality of the resulting images becomes more well-known. For the first actual 12 months of operation (4 months in FY 13 and 8 months in FY 14) the physicians expect a volume averaging about 2 scans per day, which is based on their discussions with colleagues, knowledge of the uses of the PET MR scanner, and their experience in the adoption of other new technologies. Scans per days are expected to increase annually as the technology becomes more accepted, to almost 4 scans per working day by FY 16. In summary, the annual initial growth projections for PET MR appear drastic at 191%, however FY 13 volume only includes 4 months of operation. FY 14 through FY 16 PET MR volumes are expected to increase at a much greater annual growth than the PET CT volumes as physicians become aware of the uses of this new technology.”

The applicant adequately demonstrates conformance of the proposed project with Policy AC-3 and that the projected utilization rates are based on reasonable assumptions. Therefore, the applicant adequately demonstrates the need to purchase the clinical services of one research PET MR. Consequently, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section III.3, pages 63-64, the applicant discusses the alternatives considered, including: 1) maintaining the status quo; 2) pursuing Policy AC-3 to acquire a PET MR scanner for installation on the main campus; or 3) co-locating a PET scanner and an MRI scanner in the same room. Regarding maintaining the status quo, the applicant states that without having clinical access to the research PET MR scanner, recruitment of a Division Chief of Nuclear Medicine and Chief of Molecular Imaging Translation, in addition to retaining key physicians who need clinical access to this technology to meet professional requirements, would be hindered. Moreover, a Fellowship in Nuclear Radiology would not be possible.

For Alternative 2, pursuing Policy AC-3 to acquire a PET MR scanner for installation on the main campus, the applicant states that the fair market value of a PET MR scanner is \$6 million dollars. Costs for renovations and installation would be additional, and the project would take several years to complete, during which patients could not benefit from the technology. In addition, many of the researchers are also the clinicians who currently use the research PET MR scanner, therefore they are already involved in translational research that will benefit clinical care. The addition of another PET MR scanner would not be cost effective.

The last alternative provided, involving the co-location of a PET scanner and an MRI scanner in the same room, would not be optimal for imaging, would be costly, would not aid in the recruitment and retention of faculty, and would adversely affect the caliber of the Fellowship in Nuclear Radiology to be developed. The applicant explains this in detail, as follows:

“The issue with this solution is that the patient still “moves” positionally between the two scanners and motion differs internally within the patient’s body because the scans are not simultaneous and fully integrated. Scan time is not reduced. The ability to effectively fuse the images is still problematic. The cost of the 2 units, construction and renovations, would become quite hefty, plus the cost of the systems required to “fuse” the images. The resulting clinical imaging would not be that much more effective than the existing situation. This would not necessarily assist in the recruitment of key Nuclear Medicine and Translational Molecular Imaging faculty, the retention of at least one current faculty, and the development of a Fellowship in Nuclear Radiology, of the highest caliber, which all require clinical access to a PET MR scanner. Thus, this alternative is not considered the most effective solution at this time.”

The applicant’s proposal seeks to purchase the clinical services of an existing research PET MR that is currently approved for use in selected patients who qualify for participation in research studies. The expanded use of this device would allow UNC Hospitals to recruit a Division Chief of Nuclear Medicine and Chief of Molecular Imaging Translation, to retain key physicians who need clinical access to this technology to meet professional requirements, and to establish a Fellowship in Nuclear Radiology. Moreover, clinical access to this technology would provide better diagnostic images and would benefit more patients.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. University of North Carolina Hospitals at Chapel Hill shall materially comply with all representations made in the certificate of need application and supplemental responses. In those instances where representations conflict, University of North Carolina Hospitals at Chapel Hill shall materially comply with the last-made representation.**
- 2. University of North Carolina Hospitals at Chapel Hill shall acquire the clinical services of no more than one research Positron Emission Tomography Magnetic Resonance (PET MR) Imaging Scanner pursuant to Policy AC-3 in the 2012 SMFP.**
- 3. For each of the first five years of operation University of North Carolina Hospitals at Chapel Hill shall submit to the Certificate of Need Section a detailed description of how the project achieves the academic requirements of the appropriate section(s)**

of Policy AC-3, paragraph 2 [items 1 through 4] as proposed in the certificate of need application.

4. **University of North Carolina Hospitals at Chapel Hill shall report the Policy AC-3 asset (PET MR Imaging Scanner) on the appropriate annual license renewal application for the asset. The information to be reported for the PET MR Imaging Scanner shall include: (a) the number of approved units; (b) the annual volume of cases or procedures performed for the reporting year; and (c) the patient origin by county.**
 5. **University of North Carolina Hospitals at Chapel Hill shall continue to use the Positron Emission Tomography Magnetic Resonance (PET MR) Imaging Scanner, acquired pursuant to G.S. 131-179, for research projects.**
 6. **If the PET MR Imaging Scanner ceases to be used for clinical teaching or research, University of North Carolina Hospitals at Chapel Hill shall surrender the certificate of need.**
 7. **University of North Carolina Hospitals at Chapel Hill shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**
 8. **Prior to issuance of the certificate of need, University of North Carolina Hospitals at Chapel Hill shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.2, page 104, the applicant projects the total capital cost for the project will be \$122,500, comprised as follows:

Movable Equipment Purchase	\$ 88,000
Furniture/workstations/chairs	\$ 10,000
Other (Contingency)	<u>\$ 24,500</u>
Total	\$ 122,500

In Section VIII.4(e), page 105, the applicant states that the capital cost will be financed with accumulated reserves. In Section IX, page 108, the applicant indicates there will be no start up or initial operating expenses.

Exhibit 41 of the application contains a letter dated August 8, 2012 from the Senior Vice President and Chief Financial Officer of UNC Hospitals confirming the availability of funds that states, *“This letter is to confirm the availability of funding in excess of \$122,500 specifically for use for the capital costs associated with the development of the above referenced project.”* Exhibit 42 contains the most recent audited financial statement for FY 2011 for UNC Hospitals which shows that, as of June 30, 2011, the applicant had cash and cash equivalents of \$119,165,388 and total net assets of \$1,126,731,376. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project. The applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

PET Services with Addition of PET MR	Project Year 1	Project Year 2	Project Year 3
Projected # of Scans	3757	4015	4310
Projected Average Charge (Gross Patient Revenue / Projected # of Scans)	\$4,961	\$5,208	\$5,468
Gross Patient Revenue	\$18,640,994	\$20,911,832	\$23,566,512
Deductions from Gross Patient Revenue	\$11,818,983	\$13,348,491	\$8,415,210
Net Patient Revenue	\$6,822,011	\$7,563,341	\$8,415,210
Total Expenses	\$4,986,496	\$5,542,170	\$6,186,820
Net Income	\$1,835,515	\$2,021,171	\$2,228,390

The applicant also projects a positive net income for the entire facility in each of the first three operating years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See page 122 of the application for the assumptions regarding costs and charges. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this criterion.

In Section II.1(a), pages 19-20, the applicant discusses the arrangement it will have with the SOM BRIC and the Centers for Medicaid and Medicare Services (CMS) for purchasing the clinical operational time of the research PET MR on a fee per scan basis. Under CMS “under arrangements” requirements, UNC Hospitals will be able to bill for services provided to patients using the research PET MR scanner even though it is not located in UNC Hospitals space. The applicant states, “*CMS allows “under arrangements” most typically for the provision of specialized services that the hospital does not offer itself, and generally when offered on an occasional basis*”. CMS also indicates “*that services should be provided “under arrangements” only to a limited extent “in situations where cost-effectiveness or clinical considerations, or both, necessitate the provision of services by someone other than the provider’s own staff” 65 Fed. Re. 18434, 18505 (April 7, 2000).*” In addition, the applicant must be responsible for the services provided, including quality controls, admission and registration policies, complete patient records, maintaining a liaison with the patient’s attending physician, utilization review regarding medical necessity of the services provided, performance improvement, and all hospital outpatient requirements for diagnostic services. Exhibit 7 contains a copy of the draft MOU between UNC Hospitals and UNC SOM for the expanded use of the research PET MR.

The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and charges and the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

UNC Hospitals proposes to purchase the clinical use of an existing research PET MR scanner owned and operated by UNC SOM BRIC under a Memorandum of Agreement. See Criterion (1) for discussion regarding the applicant’s conformance with Policy AC-3. The applicant adequately demonstrates that the project would not result in unnecessary duplication of existing or approved PET MR scanners based on the fact that the research PET MR scanner is the only one in the state and is one of four in the nation. The other research PET MR scanners are located in: Boston, Massachusetts; Bethesda, Maryland; and St. Louis, Missouri.

The application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1(a)(b), page 98, the applicant provides current and projected staffing of the existing PET service and for the proposed project at UNC Hospitals, as shown in the following table.

Position	Total # of FTE Positions Currently Employed	Proposed # of FTEs to be Employed	Average Annual Salary per FTE position
Nuclear Medicine Technologist	4.00	4.50	63,051
Nuclear Medicine Manager	0.14	0.14	89,000
Nuclear Medicine Supervisor	0.07	0.07	74,329
RadioPharmacist	0.01	0.01	101,000
Radiation Safety Officer	0.04	0.04	63,530
Total	4.26	4.76	N/A

In Section VII.3(a)(b), page 99, the applicant states that the proposed access to PET MR scanner services will require one additional 0.50 FTE for a nuclear medicine technologist to provide for patient continuity. UNC Hospitals standard recruitment practices will be utilized which include advertising, recruitment visits, and working with educational programs and professionals in the field to identify candidates. Local and regional community colleges will also be utilized for recruitment. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed services. Therefore, the application is conforming with this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In Section II.2, page 20, the applicant states that all necessary ancillary and support services are already available at UNC Hospitals and are currently being provided to the existing PET service. A list of all ancillary and support services is provided. In addition, in Exhibit 8, the applicant provides a letter dated August 8, 2012 from the Executive Vice President and Chief Operating Officer of UNC Hospitals that further attests to the availability of such services in the hospital and for the proposed services. UNC Hospitals has established relationships within the five health professional schools at the UNC at Chapel Hill where interns, residents, and fellows in a variety of disciplines benefit from inpatient and outpatient services housed at the hospital. The Department of Radiology is also a major clinical training site for students at Pitt Community College's Radiologic Technology and Medical Sonography programs, Johnston Community College's Radiologic Technology program, and Wilkes Community College's Radiology program. In addition, the applicant states in Section V.3(a), page 84, "*The faculty of the School of Medicine has developed strong relationships with local physicians through numerous*

referral and educational activities.” The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

- (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.

- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

There will be no construction costs incurred since the applicant proposes to use the existing research PET MR scanner for the proposed clinical services. The existing research PET MR scanner will be utilized in its current location at the UNC School of Medicine, Biomedical Research Imaging Center on the UNC Health Affairs Campus. In Section X.2, page 113, the applicant states “*There will be no incremental increase in patient charges resulting from this proposed capital project. There will be no additional charges for these services.*” Although no construction is planned, the applicant states that they will assure improved energy efficiency and water conservation, should these be affected by the project.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.12, page 95, the applicant provides the payor mix for inpatient days provided by UNC Hospitals in FY2011 (7/1/10 – 6/30/11), as shown in the following table.

Payors FY 2011	Percent of Total Inpatient Days
Self Pay/Indigent/Charity	6.4%
Medicare / Medicare Managed Care	29.7%
Medicaid	30.3%
Commercial Insurance	1.0%
Managed Care	26.4%
Other	6.2%
Total	100.0%

In Section VI.13, page 96, the applicant provides the payor mix for PET scans provided by UNC Hospitals for preliminary FY2012 (7/1/11 – 6/30/12). The proposed clinical use of the research PET MR scanner will be a service of the Department of Radiology.

Payors Prelim. FY 2012	Percent of PET scans
Self Pay/Indigent/Charity	5.9%
Medicare/ Medicare Managed Care	39.6%
Medicaid	27.0%
Commercial Insurance	0.3%
Managed Care	22.8%
Other	4.4%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for the three counties with the highest patient utilization for PET services at UNC Hospitals and statewide. The data in the table was obtained on November 15, 2012. More current data, particularly with regard to the estimated percentages of the uninsured, was not available.

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Wake	10.0%	3.3%	18.4%
Orange	9.0%	3.5%	18.9%
Alamance	16.0%	6.2%	21.0%
Statewide	17.0%	6.7%	19.7%

* More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those aged 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations have adequate access to UNC Hospitals existing services and the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.11, page 95, the applicant states,

“UNC Hospitals has long since satisfied its “free care” obligation under the Hill-Burton Act. Charity care provided by UNC Hospitals for the year ending June 30, 2011 was \$133,844,195 (13.23% of net revenue). UNC Hospitals provides care to all persons based only on their need for care, and without regard to minority status or handicap/disability.”

In Section VI.10, page 95, the applicant states that it has not been notified of any civil rights access complaints being filed against UNC Hospitals or any of the facilities or services owned by UNC Hospitals within the past five years. The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14, page 97, the applicant provides the projected payor mix for all inpatient days in the second operating year (FY2015) following project completion, as shown in the following table.

Payors FY 2015	Percent of Total Inpatient Days
Self Pay/Indigent/Charity	6.4%
Medicare / Medicare Managed Care	29.7%
Medicaid	30.3%
Commercial Insurance	1.0%
Managed Care	26.4%
Other	6.2%
Total	100.0%

In Section VI.15, page 97, the applicant provides the payor mix for PET scans in FY2015, as depicted in the following table:

Payors FY 2015	Percent of Total PET Scans
Self Pay/Indigent/Charity	5.9%
Medicare/ Medicare Managed Care	39.6%
Medicaid	27.0%
Commercial Insurance	0.3%
Managed Care	22.8%
Other	4.4%
Total	100.0%

In Section VI.15, page 97, the applicant states,

“Projections are based on actual payor mix. No significant change is projected in the categories and the percentages of total revenue and utilization for the services involved in this proposal. These patient mixes are projected to continue in the future.”

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming with this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9, page 93, the applicant states that patients will have access to PET services through physician referrals from existing services. Referral resources are discussed in Section V.3(a), pages 84-85, and include local physicians with whom the faculty of the School of Medicine has developed strong relationships with

through referral and educational activities, the Carolina Consultation Centre which provides “*convenient access to all UNC physicians through a single toll-free telephone number*”, through managed care contracts, and through the Department of Radiology’s updates to local community physicians about the role of Radiology for diagnosing various diseases. The information provided in Sections V.3(a) and VI.9 is reasonable and credible and supports a finding of conformity with this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1 (a-c), pages 76-80, the applicant documents the numerous health professional training programs available at UNC Hospitals, stating that it is “*the only Academic Medical Center in North Carolina, and one of only a few nationwide, that has all 5 of the health professional schools on campus and actively learning at their affiliated teaching hospital.*” In addition to its 5 health professional schools whose students utilize UNC Hospitals as a clinical teaching site for a wide variety of health care disciplines, community physicians and health care workers are invited to visit the department for seminars and educational training programs, cancer rounds and tumor boards. UNC Hospitals Department of Radiology is also affiliated with other nuclear medicine clinical training programs, including those at Pitt Community College, Johnston Community College, and Wilkes Community College. Moreover, it has developed a relationship with Durham Regional Hospital and Duke Medical Center to provide continuing education programs to Radiologic Technicians employed by these two institutions. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to purchase scanning services from the University of North Carolina School of Medicine Biomedical Research and Imaging Center’s research PET MR scanner for clinical use. The expanded use of the research PET MR is intended to increase access to educational programs that have been approved for expansion, to enhance physician training

programs, recruit and retain faculty, and increase access to high quality diagnostic services to patients in the service area. In Section III, pages 38 - 53, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. See also Sections II, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need to purchase services from an existing research PET MR for use in clinical patient care and that it is a cost-effective alternative;
- ◆ The applicant has and will continue to provide quality services; and
- ◆ The applicant has and will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

UNC Hospitals is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming with this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching

hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

UNC Hospitals proposes to purchase the clinical services of a research PET MR Scanner. Therefore, the Criteria and Standards for Positron Emission Tomography Scanner in 10A NCAC 14C .3700 and 10A NCAC 14C .2700 are applicable to this review. The application is conforming to all applicable Criteria and Standards for Positron Emission Tomography. The specific criteria are discussed below.

**CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY
SCANNER**

.3702 INFORMATION REQUIRED OF APPLICANT

.3702(a) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall use the Acute Care Facility/Medical Equipment application form.”*

-C- The applicant used the Acute Care Facility/Medical Equipment application form.

.3702(b)(1) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: (1) The projected number of procedures to be performed and the projected number of patients to be served for each of the first three years following completion of the proposed project. Projections shall be listed by clinical area (e.g., oncology, cardiology), and all methodologies and assumptions used in making the projections shall be provided.”*

-C- The applicant provides utilization projections and historical volumes in Section IV. All assumptions and methodologies are provided and are reasonable.

.3702(b)(2) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: ... (2) Documentation that all of the following services were provided, at each facility where the PET scanner will be operated, continuously throughout the 12 months immediately prior to the date on which the application is filed:*

(A) *nuclear medicine imaging services;*

- (B) *single photon emission computed tomography (including brain, bone, liver, gallium and thallium stress);*
- (C) *magnetic resonance imaging scans;*
- (D) *computerized tomography scans;*
- (E) *cardiac angiography;*
- (F) *cardiac ultrasound; and*
- (G) *neuroangiography.”*

-C- The applicant provides all of the services listed above and a letter from the Executive Vice President and Chief Operating Officer of UNC Hospitals attests to this and is included in Exhibit 8.

.3702(b)(3)(A) This rule states “*An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: ... (3) Documentation that the facility will: (A) establish the clinical PET unit, and any accompanying equipment used in the manufacture of positron-emitting radioisotopes, as a regional resource that will have no administrative, clinical or charge requirements that would impede physician referrals of patients for whom PET testing would be appropriate.*”

-C- In Section II.3(a), page 27, the applicant states, “*The PET service operates as a state and regional resource. The PET scanner service does not and will not have administrative, clinical or charge requirements that would impede physician referral of patients for whom PET scanning would be appropriate.*”

.3702(b)(3)(B) This rule states “*(a) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, ... (3) Documentation that the facility will: ... (B) provide scheduled hours of operation for the PET scanner of a minimum of 60 hours per week, except for mobile scanners.*”

-C- In Section II.8(3)(B), page 27, the applicant states, “*PET services are available at UNC Hospitals 24 hours a day, 7 days a week. Scans can be scheduled Monday through Friday from 6:00 am until 6:00 pm. Emergency and after-hours coverage is provided on an on-call basis. The PET MR scanner would be available for clinical use between the laboratory’s hours of 7:30 am and 4:00 pm, Monday through Friday.*”

.3702(c) This rule states “*An applicant proposing to acquire a mobile PET scanner shall provide copies of letters of intent from and proposed contracts with all of the proposed host facilities at which the mobile PET scanner will be operated.*”

-NA- The applicant does not propose to acquire a mobile PET scanner.

.3702(d) This rule states *“An applicant proposing to acquire a mobile PET scanner shall demonstrate that each host facility offers or contracts with a hospital that offers comprehensive cancer services including radiation oncology, medical oncology, and surgical oncology.”*

-NA- The applicant does not propose to acquire a mobile PET scanner.

.3702(e) This rule states *“An applicant shall document that all equipment, supplies and pharmaceuticals proposed for the service have been certified for use by the U.S. Food and Drug Administration or will be used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services' regulations.”*

-C- The applicant states that UNC SOM BRIC's existing research PET MR scanner equipment is FDA-approved and provides documentation of this from the FDA Office of Device Evaluation in Exhibit 18. The pharmaceutical being used, Rubidium, is FDA approved but has recently been under an FDA alert due to an *“isotope breakthrough problem.”* The device manufacturer has voluntarily recalled the device and the hospital has been assured that a replacement will soon become available.

.3702(f)(1) This rule states *“An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: (1) quality control measures and assurance of radioisotope production of generator or cyclotron-produced agents.”*

-C- In Section II.8, page 28, the applicant states that all existing UNC Hospitals' policies and procedures will be followed in the provision of clinical patient scans on the existing research PET MR, as are required approvals with the equipment. Exhibit 19 contains copies of UNC Hospital's existing policies.

.3702(f)(2) This rule states *“An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing requirements. The following shall be addressed: ... (2) quality control measures and assurance of PET tomography and associated instrumentation.”*

-C- In Section II.8, page 28, the applicant states that a quality assurance plan is in place for the PET service which follows recommendations and guidelines of the American Association of Medical Physicists. Exhibit 20 contains copies of the existing policies.

.3702(f)(3) This rule states *“An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (3) radiation protection and shielding.”*

-C- In Section II.8, page 28, the applicant states *“...under our current procedure protocol, PET CT studies are being conducted using the radioisotopes FDG and Rubidium. Our experience at UNCH has demonstrated that the shielding of the shipping container for FDG is sufficient for the containment of the FDG radiation. Patients are given FDG in individual administration rooms where they wait until scanned and, thus, have no exposure to other patients. Patient waiting areas are sufficiently far from patients injected with FDG so that there is no significant increase in radiation to individuals in the waiting area. Similarly, our experience with the Rubidium generator has indicated that shielding of the generator is adequate for containment of the radiation from this radiopharmaceutical. This agent is administered to the patient in the scanning area and these patients do not wait in a waiting room after the dose is given.”*

.3702(f)(4) This rule states *“An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (4) radioactive emission to the environment.”*

-C- In Section II.8, page 29, the applicant states that both FDG and Rubidium are received in liquid form as received from the vendor, the former being kept in the shielded shipping container until ready for injection into the patient and the latter remaining in the generator system until administered to the patient. Further, the applicant states in regard to FDG, *“no radioactivity is released into the environment, because of the liquid form and because of the short half-life of the radioisotope.”*

.3702(f)(5) This rule states *“An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (5) radioactive waste disposal.”*

-C- In Section II.8, page 29, the applicant states that it does not dispose of radioactive FDG since it has a decay factor of 0.0001 at 24 hours. Similarly, the used Rubidium generator is exchanged for a new one each month through a vendor, therefore there is no radioactive waste to dispose of.

.3703 PERFORMANCE STANDARDS

.3703(a)(1) This rule states “An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that: (1) the proposed dedicated PET scanner, including mobile dedicated PET scanners, shall be utilized at an annual rate of at least 2,080 PET procedures by the end of the third year following completion of the project.”

-C- The applicant provides historical utilization volumes and projections in Section IV which project a combined PET CT and PET MR volume of 4,310 scans in Year Three, illustrated as follows:

				Interim	1st Full FY	2nd Full FY	3rd Full FY
	FY10	FY11	FY12	FY13	FY14	FY15	FY16
PET CT scans	2720	2875	2666	2526	3155	3243	3334
PET MR scans	n/a	n/a	n/a	207*	602	772	976
Combined	2720	2875	2666* *	2733	3757	4015	4310
Annual Growth from prior FY	5%	6%	-7%	3%	37%	7%	7%

*Note: Figure includes only 4 months of clinical PET MR scans as the first day of use would be 3/1/13. UNC Hospitals’ FY is from July through June. **Note: Utilization differs from utilization reported in the 2012 LRA (shows 2,793 patients) because the data in the 2012 LRA is for 10/1/10 – 9/30/11 and the data in the table above is for UNC Hospitals FY, which is 7/1/10 – 6/30/11.

.3703(a)(2) This rule states “An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that:...(2) if an applicant operates an existing dedicated PET scanner, its existing dedicated PET scanners, excluding those used exclusively for research, performed an average of 2,080 PET procedures per PET scanner in the last year.”

-NA- This application does not propose to acquire a dedicated PET scanner. However, in Section IV(d), page 72, the applicant states that the existing PET CT scanner performed 2,875 procedures during Fiscal Year 2011 (July 1, 2010 to June 30, 2011), which was the last full fiscal year of operation prior to submission of the application. [Note: Rule 3701 (3) defines dedicated PET Scanners as PET Scanners as defined in the applicable SMFP. The 2012 SMFP, page 146, states “Dedicated PET scanners used exclusively for PET imaging.”

.3703(a)(3) This rule states “An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that: ... (3) its existing and approved dedicated PET scanners shall

perform an average of at least 2,080 PET procedures per PET scanner during the third year following completion of the project.”

-NA- This application does not propose to acquire a dedicated PET scanner. However, in Section IV(d), page 72, the applicant projects that in FY 2016, 3,334 PET CT scans and 976 PET MR scans will be provided for a combined total of 4,310 for two scanners for an average of 2,155 PET procedures per scanner.

.3703(b) This rule states *“The applicant shall describe the assumptions and provide data to support and document the assumptions and methodology used for each projection required in this Rule.”*

-C- The applicant adequately describes the assumptions and methodology used for each projection required in this rule. These are discussed in Section IV, pages 72 – 75. Therefore, the application is conforming to this rule.

.3704 SUPPORT SERVICES

.3704(a) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that radioisotopes shall be acquired from one or more of the following sources and shall identify the sources which will be utilized by the applicant: (1) an off-site medical cyclotron and radioisotope production facility that is located within two hours transport time to each facility where the PET scanner will be operated; (2) an on-site rubidium-82 generator; or (3) an on-site medical cyclotron for radio nuclide production and a chemistry unit for labeling radioisotopes.”*

-C- The applicant states in Section II.(a), on page 30, *“F 18 radioisotopes used for PET/CT scanner procedures at UNC Hospitals are currently supplied by PETNET Pharmaceuticals, a radiopharmacy located in Durham. PETNET’s production facility is located within two hours transport time to UNC Hospitals.”* Exhibit 24 contains a letter from the Director of Operations, Mid-Atlantic Region, of PETNET, confirming availability of the required radioisotopes. In addition, a Rubidium generator is shipped every 28 days by Bracco Medical. It is then placed on an infusion cart. UNC Hospital does not have an on-site cyclotron for radioisotope production.

.3704(b) This rule states *“An applicant proposing to acquire an on-site cyclotron for radioisotope production shall document that these agents are not available or cannot be obtained in an economically cost effective manner from an off-site cyclotron located within 2 hours total transport time from the applicant’s facility.”*

-NA- Not applicable. The applicant does not propose to acquire a cyclotron.

.3704(c) This rule states “*An applicant proposing to develop new PET scanner services, including mobile PET scanner services, shall establish a clinical oversight committee at each facility where the PET scanner will be operated before the proposed PET scanner is placed in service that shall: (1) develop screening criteria for appropriate PET scanner utilization; (2) review clinical protocols; (3) review appropriateness and quality of clinical procedures; (4) develop educational programs; and (5) oversee the data collection and evaluation activities of the PET scanning service.*”

-NA- Not applicable. This application does not propose the development of a new PET scanner service. However, the applicant states that the existing oversight structure, which consists of an oversight committee, will meet on a quarterly basis and as needed to improve existing policies and protocols related to the PET scanning service. The committee’s responsibilities are discussed in Section II.(c)(5), pages 31-32, and summarized as follows:

- *“Develop screening criteria for appropriate PET scanner utilization;*
- *Review clinical protocols for PET studies;*
- *Review appropriateness and quality of PET studies;*
- *Develop educational programs related to PET Imaging;*
- *Oversee the data collection and educational activities of the PET scanning service; and*
- *Conduct other business or reviews as required.”*

.3705 STAFFING AND STAFF TRAINING

.3705(a)(1) This rule states “*An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: (1) One or more full-time nuclear medicine imaging physicians who:*

- (A) *are licensed by the State to handle medical radioisotopes;*
- (B) *have specialized in the acquisition and interpretation of nuclear images, including tomographic studies, for at least one year;*
- (C) *have acquired knowledge about PET through experience or postdoctoral education; and*
- (D) *have had practical training with an operational PET scanner.”*

-C- In Section II.8, page 32, the applicant states there are three Nuclear Medicine physicians who are responsible for “*the performance, supervision*

and interpretation of PET studies performed in the PET service.” All three physicians meet the qualifications set forth in .3705 (A-D). Exhibits 3-5 contain curriculum vitae for each of these physicians.

- .3705(a)(2) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: ... (2) Engineering and physics personnel with training and experience in the operation and maintenance of PET scanning equipment.”*

-NA- This application does not propose the development of a new PET service. However, the applicant names a physicist for the Nuclear Medicine Section at UNC Hospitals who is also Clinical Associate Professor of Radiology, Nuclear Physicist, and Adjunct Associate Professor, in the Department of Biomedical Engineering who spends half of her time with the PET service and the other half with the Nuclear Medicine Service. Her curriculum vita is included in Exhibit 25.

- .3705(a)(3) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: ... (3) Radiation safety personnel with training and experience in the handling of short-lived positron emitting nuclides.*

-C- In Section II.8, page 36, the applicant states that it has a Radiation Safety Officer in charge of Radiation Safety at UNC Hospitals and UNC at Chapel Hill. His curriculum vita is included in Exhibit 26.

- .3705(a)(4) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: ... (4) Nuclear medicine technologists certified in this field by the Nuclear Medicine Technology Certification Board or the American Registry of Radiologic Technologists with training and experience in positron emission computed tomographic nuclear medicine imaging procedures.”*

-C- In Section II.8, page 36, the applicant states that it has four nuclear medicine technologists who are certified by either of the stated certifying bodies and who have received training or have experience in PET imaging procedures. Exhibit 27 contains copies of the Nuclear Medicine Technologists’ certifications.

- .3705(b) This rule states *“An applicant proposing to acquire a cyclotron shall document that the cyclotron shall be staffed by radiochemists or radiopharmacists who: (1) have at least one year of training and experience in the synthesis of short-lived positron emitting radioisotopes;*

and (2) have at least one year of training and experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical synthesis.”

-NA- The applicant does not propose to acquire a cyclotron.

- .3705(c) This rule states *“An applicant proposing to acquire a PET scanner, a mobile PET scanner, or a cyclotron, shall document that the personnel described in Paragraphs (a) and (b) of this Rule shall be available at all times that the scanner or cyclotron are operating.”*

-C- In Section II.8, page 36, the applicant states that the personnel identified in paragraphs (a) and (b) above will be available during regular operating hours and on an on-call basis for emergencies and after-hour coverage.

- .3705(d) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that a program of continuing staff education will be provided that will insure training of new personnel and the maintenance of staff competence as clinical PET applications, techniques and technology continue to develop and evolve.”*

-C- In Section II.8, page 37, the applicant states that there is a continuing staff education program in place for staff of the PET scanner service. Exhibit 28 contains a copy of the training requirements and staff competency requirements for new and existing PET scanner staff.