

July 1, 2013
Novant Health, Inc. and Novant Health Kernersville Medical Center
Comments Regarding the May 15, 2013
PET/CT Scanner CON Application (CON Project I.D. # G-10133-13)
Of North Carolina Baptist Hospital, Winston-Salem, NC
Pursuant to a Need Determination in the
2013 SMFP for One New Fixed PET/CT Scanner in Health Service Area II

Introduction

Two CON Applications were filed on May 15, 2013 seeking the state's approval for a new fixed PET/CT Scanner based on a Need Determination in the 2013 SMFP in Table 9N. One of those CON Applications was filed by North Carolina Baptist Hospital ("NCBH") seeking the state's approval to use an existing research-only PET/CT scanner, which NCBH identifies as utilized at only 25% of capacity.¹ This research-only PET/CT scanner was obtained via a statutory exemption in the CON law at North Carolina General Statutes Section 131E-179, "Research Activities." In part, the statute provides that in exchange for a provider purchasing an asset, that might otherwise require a CON Application filing, a provider may acquire such asset via a CON Exemption process, so long as the provider "does not charge patients for the use of the service for which an exemption has been granted."² So essentially in this project, NCBH is seeking the state's CON approval so that it can also use 75% of the capacity of this research-only PET/CT scanner to perform clinical PET/CT studies for paying patients.

Moreover, during summer 2012, NCBH filed a letter asking the SHCC to zero out the need for the new PET/CT scanner in HSA II that was identified in Chapter 9 of the draft 2013 SMFP. NCBH's request was an indication that it did not believe it had a need for another fixed PET/CT scanner or more PET/CT scanner clinical capacity. The NCBH petition was denied by the SHCC Medical Equipment and Technology Committee and by the full SHCC at its fall 2012 meeting. Thus, the need determination for a new PET/CT scanner for HSA II remained in the 2013 SMFP.

NCBH Currently Has Sufficient Operational PET/CT Scanner Capacity On Its Campus

NCBH and Wake Forest Baptist Health currently own and operate three fixed PET/CT scanners on their campus.³

1. NCBH's GE "**clinical**" **PET/CT Scanner** located on the Main Floor in Reynolds Tower on the NCBH campus, operating 7 am – 5 pm, Monday-Friday. This scanner was approved by the CON Agency in July 2003.
2. The Radiation Oncology Department's **SMFP Policy AC-3 PET/CT Scanner (GE)** located on the first floor of the NCBH Comprehensive Cancer Center, Radiation Oncology Department. The AC-3 PET/CT scanner is used by the Radiation Oncology

¹NCBH 5/15/2013 PET/CT scanner CON Application at page 15.

² N.C. Gen. Stat. § 131E-179 is found at page 439 of the 2013 SMFP.

³ NCBH 5/15/2013 PET/CT Scanner CON Application at page 12. CON for this NCBH Clinical PET/CT scanner is in **Exhibit D**.

Department to perform radiation treatment planning simulations for Cancer Center patients.⁴ During early 2010, NCBH obtained a Declaratory Ruling Decision from the Director of North Carolina Division of Health Service Regulation to permit the temporary use of this AC-3 PET/CT scanner to perform clinical PET scans for a period of about 6 weeks, while the existing NCBH clinical PET/CT scanner was being replaced and relocated on campus from the PET Center to the Reynolds Tower. See **Exhibit A** for a copy of the DRR request and decision. Thus, the AC-3 PET/CT scanner is clearly capable of performing clinical PET/CT studies, as well.

3. **Wake Forest Baptist Health's Research-Only GE PET/CT scanner** located on the Ground Floor of the MRI building on the NCBH campus, with hours of operation 8 a.m. – 5 p.m., Monday-Friday. See **Exhibit E** for a copy of the January 2004 Research Exemption Request pursuant to N.C. Gen. Stat. § Section 131E-179 for a Positron Emission Mammography Flex scanner and the CON Agency's decision.

There are very few hospitals in North Carolina today that own and operate three fixed PET/CT scanners. Duke owns and operates 3 fixed PET/CT scanners (1 Research Scanner; 1 AC-3 Scanner; and 1 Clinical Scanner) as reported on its 2013 HLRA at page 14. Duke does report on its HLRA, volumes for the PET studies performed on its AC-3 PET/CT scanner. UNC Hospitals reports on its 2013 HLRA reports two PET/CT scanners (1 AC-3 PET/CT scanner and 1 clinical PET/CT scanner). UNC-Hospitals does report on its HLRA volumes for the PET studies performed on its AC-3 PET/CT scanner. Vidant Medical Center/Pitt Memorial reports one clinical PET scanner and its volumes on the 2013 HLRA. Only Academic Medical Centers, such as NCBH, Duke, UNC-Hospitals, and Vidant Medical Center qualify to use SMFP Policy AC-3 to obtain PET/CT scanner outside the SMFP PET/CT scanner need determinations.

Curiously, since 2009, NCBH has not reported its inventory of one AC-3 PET/CT scanner on its annual Hospital Licensure Renewal Application ("HLRA"), although page 14 of the state's HLRA contains a line item where the AC-3 PET/CT scanner inventory and annual PET/CT scans are to be reported. Likewise, NCBH has not reported the annual PET scan volumes performed on the AC-3 PET/CT scanner on the state's annual HLRA form for the past several years.⁵ There is clearly a place on the HLRA to report that information to the state. As noted in its pending CON Application, NCBH owns and operates an AC-3 PET/CT scanner, for which a CON was issued nine years ago in July 2004. In the NCBH 2008 HLRA, it reported 98 PET/CT scans performed during FFY 2007 on the AC-3 PET/CT scanner. The NCBH 2007 HLRA reported 48 PET/CT scans performed during FFY 2006 on the AC-3 PET/CT scanner. More current information is not available, as it has not been publicly reported by NCBH. See documentation included in **Exhibit C**.

⁴ See page 3 of the NCBH AC-3PET/CT and MRI Scanners CON Application filed 5/15/2003 (CON Project I.D. # G-6816-03). The CON for this AC-3 PET/CT scanner was issued by the Agency on 7/8/2004. A copy of the Certificate of Need for the NCBH AC-3 PET/CT scanner is found in **Exhibit B**.

⁵ See page 14 of the NCBH 2013 Annual Hospital Licensure Renewal Application in **Exhibit C**. The AC-3PET/CT scanner and its annual volumes were not reported on the NCBH annual HLRA's for 2013, 2012, 2011, 2010, and 2009. These NCBH HLRA pages for PET/CT Scanner reporting, including AC-3 PET/CT scanners, are also found in **Exhibit C**.

NCBH's Utilization Projections are Flawed and Non-Conforming with Criterion (3)

NCBH currently operates three PET/CT scanners on its campus in Winston-Salem. For the proposed project, NCBH intends to expand the use of an exempt research-only PET/CT scanner to include clinical PET/CT scans. NCBH indicates the need for this conversion is based on numerous factors including population growth, cancer incidence rates in the service area, impact of Amyvid Imaging for Alzheimer's patients, the impact of the Affordable Care Act and the Advisory Board PET growth projections.

Non-Cancer Cases Requiring PET/CT Scans

In Step 3 of NCBH's methodology, NCBH fails to adequately explain why it chose to increase its non-cancer cases by 10% annually, in both Tables 10 and 11. See the 10% growth rates for Project Years 1-2-3 on pages 54-55 of the NCBH application. These growth rates are unsupported and unreasonable. An applicant is required to document all the assumptions in its methodology and NCBH has failed to do so.

Market Share Percentages

It appears that NCBH has miscalculated its market share percentages in comparison to its actual experience reported in its most recent 2013 HLRA. On page 14 of the NCBH application, it reports the projected number of NCBH PET patients using a "constant 3 year average market share". However, a review of the PET patient origin from NCBH's 2013 HLRA indicates NCBH is projecting significant increases in a number of counties in the proposed service area. See the following chart for a comparison:

County	2013 HLRA ; page 28 – FFY 10/1/11-9/30/12 Data – PET Patients	Table 14 – Projected NCBH PET Patients for 2014; Application page 58	% Change from FFY 2011-12 to 2014
Alleghany	31	44	41.9%
Ashe	24	88	266.7%
Burke	54	143	164.8%
Caldwell	35	69	97.1%
Davidson	204	261	27.9%
Forsyth	460	490	6.52%
Guilford	141	222	57.4%
Randolph	68	136	100.0%
Rowan	41	140	241.4%
Surry	131	206	57.3%
Watauga	31	133	329.0%
Wilkes	86	170	97.7%

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NCBH fails to provide any explanation as to why its market share would increase at such exorbitant rates in roughly a two-year time frame during the interim period (during which the

project would not be implemented). Of the 12 counties listed in the table above, 9 show market share increases of 50% or more and 5 of 12 counties show market share increases of 100% or more. NCBH's market share calculations for its proposed project are unreasonably high and are unsupported by its actual operating experience as reported in its 2013 HLRA. Based on this finding, the remaining projections offered by NCBH are unreliable, unreasonable, and unsupported. Thus, the application must be found non-conforming with Criterion 3.

Alzheimer's Research and PET Scans

NCBH relies heavily on its participation in the Alzheimer's Disease Cooperative Study (ACDS) in its discussion of need for the proposed PET/CT scanner conversion. In fact, without the additional Alzheimer's research scans, the project would fall short of the required 2,080 procedures in Year 3 of operation. See Step 8⁶, Table 20, page 62 of NCBH CON application. Moreover, on page 60 of the application NCBH also notes that "Amyvid is expected to receive CMS approval by FY 2015;" however if this approval is not obtained by that date this will jeopardize the validity and timing of the Amyvid/Amyloid PET scans for Alzheimer's patients, on which NCBH depends to achieve the required number of PET/CT scans by the end of PY 3.

The projections related to the Alzheimer's research scans fail to connect with the narrative discussion offered by NCBH. For example, the application on page 60 states "research scans are expected to increase by 20% per year in preparation for the development of an Alzheimer's Institute and based on current research grants at NCBH". If that is so, then there is no reason to convert the research-exempted scanner to a clinical scanner. NCBH further states that currently 10 clinical Amyvid PET scans and 30 research Amyvid PET scans are performed. NCBH estimates that 100 Alzheimer patients would be treated in this program in 2014 (Table 18, Application page 61) although there is no definite or clear explanation on how that number was derived. Furthermore, despite indicating previously that research scans are expected to increase by 20%, NCBH projects a 300% increase in the number of Alzheimer patients (from 25 to 100 patients) and a 300% increase in scan volume (from 25 to 100 PET scans) beginning in 2014 and continuing through 2016. Again, if research is projected to be robust, then the scanner should remain as a research scanner and not be converted to a clinical scanner.

It is also unclear how the research Alzheimer's Amyvid PET studies will be reimbursed on the converted PET/CT scanner.

The NCBH CON Application Fails to Discuss the Reduction of the Research PET/CT Scan Program Resulting in a Non-Conformity with Criterion (3a)

Dual Use of the Proposed PET/CT Scanner for Both Research & Clinical PET Studies is Not Reasonable

N.C. Gen. Statutes §131E-183(a)(3a) contains the requirement that the applicant must provide information for the Agency to assess the impact of a reduction in an existing :

⁶At pages 60 through 62 of the application, the numbering of the "Steps" in the PET need method are mis-labeled. Step 7 is referenced twice, first on page 59 and then again on page 60. So Step 7 on page 60 is probably supposed to be Step 8 and Step 8 on page 62 should probably be numbered as Step 9.

“in the case of a reduction or elimination of a service...the applicant shall demonstrate that the needs of the population presently served will be 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, and handicapped persons and other underserved groups and the elderly to obtain needed health care.”

As described in the NCBH Research PET/CT Scanner CON Exemption filing, included as **Exhibit E**, the NCBH Research PET Scanner was originally obtained to “to evaluate Positron Emission Mammography (“PEM”) technology through an agreement with Navigan PET Systems.”⁷ In its June 2004 CON Research Exemption Request NCBH also agreed not to charge patients for the research PEM scans, as required by N.C. Gen. Statute §131E-179. The 2004 Research PET scanner was replaced within the past two years by another PET/CT scanner that is described on page 16 of the NCBH application as “a GE Discovery VCT PET/CT scanner with large open 60cm bore with 2-D and 3-D imaging capabilities and a 64-slice CT.”

Since NCBH obtained this research-only PET/CT scanner under the CON Law’s “Research Exemption” at N.C. Gen. Stat. § 131E-179, it took on an obligation to make this PET/CT scanner available for research use. NCBH has a duty to materially comply with the representations it made to the CON Section when it made the request for the research exemption. NCBH does not explain what happened to the Positron Emission Mammography scans that were initially performed on the Research PET/CT scanner and whether they can be performed on the GE Discovery VCT PET/CT scanner.

In addition, in its pending application, NCBH states that it intends to continue to perform research PET/CT scans, as well as the proposed new clinical PET/CT scans. NCBH has failed to answer the question of where the research PET/CT scans would be performed in the future if the demand for research PET/CT scans expands due future grant monies or other funding. At various places in its application (pages 60-63)⁸, NCBH suggests that research PET studies will expand over time. If that is the case, will clinical patients be bumped in favor of research studies? This is a serious issue as NCBH is, first and foremost, a research institution. Yet NCBH does not explain in the application what it will do, if for example, it were to be awarded a grant that would cause the number of research scans to rise.

NCBH also does not explain how the logistics of research and clinical needs will be balanced on this scanner. For instance, when will the research scans be scheduled? How will the scheduling of PET patients be managed for the cancer patients needing clinical PET/CT scans and the research patients needing Amyvid/Amyloid scans described on pages 60-63 of the NCBH application? It is not clear whether access to the PET/CT scanner for these patient types must be segregated into separate blocks of time on different days or can be performed on the same day. NCBH does not explain how this will be handled. Nor does NCBH explain what steps it will take to ensure that the scanner and its associated space will be operated to accommodate the

⁷ See Lynn Pittman’s Jan. 16, 2004 letter included in **Exhibit E**.

⁸These pages discuss clinical and research Amyvid/Amyloid PET/CT scans for Alzheimer’s patients at the NCBH Alzheimer’s Institute.

multiple types of PET/CT scan patients it proposes to serve on the dual use clinical/research PET/CT scanner..

The absence of information in NCBH's application to explain both the potential reduction in research PET/CT scans on the proposed dual use clinical/research PET/CT scanner and the impact on the population to be served, including continued access for medically underserved persons, creates a non-conformity with Criterion (3a) for the proposed NCBH dual use clinical/research scanner.

The NCBH Timelines for Project Years 1-2-3 and the Capital Cost for the Project Includes Errors and Other Inconsistencies Which Indicate Non-Conformity with Criterion (5)

CON Application Section VIII Total Capital Cost Sheet Contains Math Errors & Other Mistakes

When filing a CON Application for review by the CON Section, the applicant is seeking review for the service, facility or equipment identified in its application and the associated capital cost to implement the project. It is essential for these costs to be stated accurately, as the CON Law is primarily a cost control statute. See N.C. Gen. Stat. § 131E-175 (findings of fact for CON Law).

In Section VIII of the NCBH PET CON Application, the Projected Capital Cost page contains significant math errors.

CON App Section VIII Capital Cost Components	NCBH CON App Section VIII Dollar Amounts	<i>Math Errors</i>
Row 7- Site Costs	N/A	
Row 11-Subtotal Construction Contract	\$0	
Row 13-Equipment Cost	\$1,565,505.62	
Row 17-Consultant Fees/Other-CON Agency	\$50,000	
Row 17-SubTotal Consultant's Fees	\$20,000	<i>\$20,000 should be \$50,000 (understated \$30,000)</i>
Row 21-SubTotal Miscellaneous	\$1,585,505.62	<i>\$1,585,505.62 should be \$1,615,505.62* =(\$30,000 + \$1,585,505.62)</i>
Row D- Total Capital Cost of Project	\$1,585,505.62	<i>Total Capital Cost understated by \$30,000</i>

The Agency cannot determine the amount of capital for which NCBH is seeking approval. The applicant is "required to furnish only that information necessary to determine whether the new institutional health service is consistent with review criteria implemented under G.S. 131E-183 and with duly adopted standards, plans, and criteria." See N.C. Gen. Stat. § 131E-182(b). Due to

the mathematically incorrect and understated NCBH capital cost, the applicant has failed to supply necessary information to the CON Section to allow the Agency to determine consistency with Criterion (5).

In addition, these math errors in the total capital cost also impact the amount of the depreciation expense used in the applicant's CON ProForma financial projections, Form C, "Statement of Revenues & Expenses for Each Service Component." The above error would result in the depreciation expense being understated in Form C, which could negatively impact the financial feasibility of the project.⁹

The Equipment Cost for the Proposed PET/CT Scanner is Understated and Out of Date

NCBH uses the GE Healthcare Asset Purchase Amount of \$1,565,505.62 (**NCBH Exhibit #27**), for the buyout of the existing leased research only-PET/CT scanner as the capital cost for the Equipment on the CON Application Capital Cost page in CON Application Section VIII, page 106. The equipment cost is the single largest dollar item comprising the capital cost for the proposed project. NCBH refers to **Exhibit 27** as the source for the equipment cost. However, the documentation in NCBH CON Application **Exhibit 27** is flawed:

- First, the GE Vendor quote amount became invalid after July 20, 2012 as stated on the face of the quote. The quote for this the proposed PET/CT scanner is expired;
- Second, the Acceptance/Acknowledgement line on the GI Healthcare Vendor Quote was not signed by a representative of NCBH before the quote expired last year; and
- Third, to capture the full capital cost of the equipment the applicant should have included not only the buyout amount of \$1.565 Million, but also the lease payments to GE for the first two years of operation¹⁰ of the research only-PET/CT scanner. This is the only way to reflect the full capital cost of the PET/CT scanner to which NCBH seeks to layer clinical scans on top of the existing research scans. The capital cost of the equipment is materially understated by an amount that is unknown to the CON Agency.

Thus, the capital cost for the PET/CT scanner project proposed by NCBH is either unknown, incorrect, or materially understated. The flawed capital cost amount would also negatively impact the NCBH CON Application Pro Forma Financial Projections. At the very least the depreciation expense in the projected income statements (Forms B and C), is understated. This impacts the Agency's ability to determine the financial feasibility of this project pursuant to CON Statutory Review Criterion (5).

⁹In addition, understatement of the capital costs leads to understatement of the required CON filing fee pursuant to N.C. Gen. Stat. § 131E-182(c). In this case, the amount of understatement is approximately \$90. On this basis, the CON Section could legitimately refuse to review the application because the correct filing fee is supposed to be paid before the review starts; otherwise, the application is not deemed complete for review. The review of NCBH's application started on June 1, 2013.

¹⁰In its pending CON application, the applicant states that the research-only PET/CT scanner is two years old.

Total Costs of the Project May be Understated

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Throughout NCBH's CON Application the applicant seems to suggest that no renovation or construction, no equipment relocation, and no other expenditures other than the buy-out of the lease for the existing research-only PET/CT scanner will be required to expand the use of the research-only PET/CT scanner on the ground floor of the MRI building to include clinical PET studies. For example the application states:

- No capital cost is required for construction or renovation of the space, to accommodate the existing research PET/CT scans and the addition of 1,999¹¹ to 2,091 new clinical PET/CT scans annually
- See the applicant's responses in CON Application Section VIII (application page 105) with \$0 projected for construction, expansion, or renovation of the existing PET scanner space
- No start-up costs are included in CON Application Section IX (application page 111) for the conversion of the under-utilized research-only PET/CT scanner to the proposed well-utilized dual use research and clinical PET/CT scanner
- The applicant does not provide a certified estimate of any construction cost by a licensed North Carolina architect or engineer as requested in CON Application Section XI, Question 5(a) (application page 120); the applicant points to **Exhibit 27** in its response and **Exhibit 27** is a GE Equipment Vendor Asset Purchase proposal for the PET Scanner, which expired in July 2012.

The applicant should have included a certified architect's letter confirming that no renovation or construction was required for the existing PET/CT scanner space to accommodate over 2,000 new clinical PET/CT scans per year in a space where today this research only PET/CT scanner is utilized at only 25%¹², which may amount to no more a few hundred PET/CT scans per year. The NCBH Application does not include any specific information about the number of annual research scans performed on the existing research only PET/CT scanner and is not required to report that information on the its annual HLRA.

The applicant has failed to address the question whether this research scanner and the support space on the ground floor of the MRI building have sufficient capacity for elements of an efficient and effective dual use clinical and research PET/CT program. The support elements not discussed in the NCBH CON Application include the hot lab, the patient dressing rooms and toilets, patient prep room for the injection & uptake for the radioactive agent, parking spaces, PET check-in area and waiting room, etc. Many of these components are not included on the line drawing supplied by NCBH in **Exhibit 28** or are so small that they are not readable. The applicant fails to include square footage information in CON Application Section XI for the existing research only PET/CT scanner in the MRI Building, Ground Floor. CON Application Section XI does include square footage information for the NCBH AC-3 PET/CT Scanner in the Cancer Center/Radiation Oncology Department and for the existing clinical use PET/CT scanner

¹¹ Calculation: 3,993 annual PET scans in PY1 for 2 PET scanners = 1,999 scans per scanner; 4,182 annual PET scans for PY3 for 2 PET scanners = 2,091 scans per scanner. See date in Table 20 of the NCHB Application at page 62.

¹² See NCBH CON Application at page 15.

in the NCBH Reynolds Tower. However, the applicant fails to provide necessary square footage information about the research-only PET/CT scanner space which is the subject of their application.

And if it is truly the case that there is no construction associated with this project, then it makes no sense that it would take two to four years to implement the project.

The Applicant's PET/CT Scan Utilization Projections¹³, Financial Projections¹⁴, and CON Application Section XII Actual Proposed Schedule¹⁵ Have Inconsistent Timelines

In the applicant's PET/CT Scan utilization projections found in CON Applications Sections III and IV (at pages 48-62 and 81-82), NCBH identifies the start of Project Year 1 as 7/1/15. So presumably for Sections III & IV, NCBH intends that PY 1 = 7/1/15-6/30/16 and PY 3 = 7/1/17 – 6/30/18. In the CON ProForma financial projections, NCBH also uses the start of PY1 as 7/1/2015. However in CON Application Section XII (page 124), NCBH identifies the start of Project Year 1 as 7/1/2017, which is two years later than the start of PY 1 as noted in CON App Sections III & IV and the ProFormas (7/1/2015).

Thus, if the 7/1/2017 is assumed to be the correct start date, NCBH has failed to project the financial feasibility of the project out for three years from the 7/1/2017 start date. With a 7/1/2017 start date, Project Year 3 would be defined as 7/1/2019- 6/30/2020. The 7/1/2017 start date would require that both PET scan utilization projections and PET scan financial projections be projected through 6/30/2020. NCBH has not demonstrated the financial feasibility of the project and is non-conforming with Criterion (5), as the NCBH Pro Forma financial projections end on 6/30/2018. Also, NCBH has not demonstrated the need for the project, as 2 years of PET scan volume projections are missing for years 7/1/18-6/30/16 and 7/1/19-6/30/20, resulting in a non-conformity with Criterion (3).

Moreover, the CON Section must question why this scanner, which is already in place at NCBH, would need two to four years' lead time to become operational as a clinical PET scanner. NCBH offers no explanations for this.

NCBH's PET/CT Scan Application is Non-Conforming with Provisions of the CON Criteria and Standards for Positron Emission Tomography Scanner

Performance Standards & PET/CT Scan Utilization Projections and Assumptions

As discussed above in the Comments pertaining to Criterion (3), the NCBH PET/CT scan utilization projections are unsupported, unreasonable, and unreliable. Thus, the application is non-conforming with 10A NCAC 14C.3702(b)(1), 10A NCAC 14C.3703(a)(1) & (3), and 10A NCAC 14C.(b).

¹³ NCBH PET/CT Scanner CON Application, Sections III & IV.

¹⁴ NCBH PET/CT Scanner CON Application ProForma Financial Projections

¹⁵ NCBH PET/CT Scanner CON Application Section XII, at pages 123-124.

Proposed PET/CT Scanner Required to Operate 60 Hours Per Week

The state's PET/CT Scanner regulations at 10A NCAC 14C.3702(3)(b)(3)(B) require that the applicant for a fixed PET/CT scanner:

“Document that the facility will: provide scheduled hours of operation for the PET/CT scanner of a minimum of 60 hours per week, except for mobile scanners.”

NCBH addresses this requirement in an inconsistent manner at two different places in its Application. On Application Page 28, NCBH provides the operational hours for its existing clinical PET/CT scanner (located in Reynolds Tower), which is not the subject of this application. In addition, the scheduled hours of operation for this exiting clinical PET/CT scanner are reported by the applicant to be 10 hours per day or 50 hours per week (which is less than the required 60 hours per week), “with flexibility for evening, weekend, and emergency cases, which equates to approximately 60 hours per week of actual operating time. The above regulatory provision states that 60 hours per week is the minimum. Thus, one can infer that there is some opportunity to expand the capacity of this NCBH existing clinical PET/CT scanner by expanding scheduled hours of operation. Also on page 28, the applicant states that as volumes ramp up and the second scanner comes on line, the hours will increase to 7am – 7 pm. However it is not clear whether the applicant is stating that the PET/CT scanner that is the subject of this CON Application will operate 60 hours per week or that one of the two NCBH PET/CT scanners will operate 60 hours per week.

On page 102 of the NCBH application, the applicant states:

“PET/CT Services are available from 7am to 7pm. On call and emergencies are available 24 hours per day, 7 days per week for PET/CT services.”

Again, it is unclear from this narrative whether the applicant is saying that in the future both PET/CT scanners will operate the minimum 60 hours per week or one of the other of these clinical PET/CT scanners will operate 60 hours per week.

The CON PET/CT regulation provision requires that the applicant clearly indicate that the PET/CT scanner that is the subject of the pending application “will provide scheduled hours of operation...of a minimum of 60 hours per week.” The applicant has failed to clearly state whether it will meet this minimum number of hours per week for the PET/CT scanner that it proposes to use for both clinical and research patients.

Other Issues with the NCBH PET/CT Scanner CON Application

NCBH Declines to Respond to Two CON Application Questions Deeming Them Not Applicable to the Review of This Project

On pages 78-79 of the Application, NCBH declines to respond to CON Application Questions III.6(a) and III.6(b). These two questions pertain to: (1) identification of all providers in HSA II who provide PET Scans and providing the most recent historical PET/Scan annual utilization,

Deleted: Since NCBH obtained this research only PET/CT scanner under the CON law's "Research Exemption" at NCGS Section 131E-179, they took on an obligation to make this PET/CT scanner available for research use. In addition, in their pending application, NCBH states that it intends to continue to perform research PET/CT scans, as well as the proposed new clinical PET/CT scans. NCBH has failed to answer the question of where the research PET/CT scans would be performed in the future if the demand for research PET/CT scans expands due to future grant monies or other funding.

which information is readily available in the 2013 hospital licensure renewal applications; and (2) documentation of the inability of existing providers to meet the need. NCBH's response to these two questions was:

"This question is not applicable to the review of this project, pursuant to NC General Statute Section 131E-183(b)."

That statutory provision states, in part:

"The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to the criteria...in subsection (a)...and may vary according to the purpose for which the particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require that an academic medical center teaching hospital, as defined by the SMFP, 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."

The two questions that NCBH declined to answer are not a "rule" developed by the CON Section. The application form is not a rule. Rather the two questions are part of the state's CON Application form for Acute Care Facilities and Medical Equipment project. The responses to those questions are designed to provide the CON Section with necessary information¹⁶ to determine if the applicant has provided the Agency with sufficient information to assess if each applicant has demonstrated the need for the proposed medical equipment.

Moreover, NCBH's citation of N.C. Gen. Stat. § 131E-183(b) in the context is essentially irrelevant in the context of this review, as the need for one additional fixed PET/CT scanner in Health Service Area II has been established by the 2013 SMFP. The more relevant question is whether NCBH has demonstrated the need for the project proposed in its 5/15/2013 PET/CT scanner CON Application.

Based on Several Comparative Factors the NCBH PET/CT Scanner is Not the Superior Project

In competitive CON Application reviews such as the one for the HSA II Fixed PET/CT Scanner Need in the 2013 SMFP, the Agency often compares the competing applications on certain factors.

Access To Medically Underserved Populations

The access that each provider will provide to medically underserved populations is typically measured by the payor mix information (Medicare, Medicaid, and Charity Care) for the service under review, as provided by each applicant in CON Application Section VI, Question 15. A

¹⁶See NCGS Section 131E-182(b).

comparison of the Novant Health Kernersville Medical Center (“NHKMC”) and NCBH Applications is in the table below.

**Projected PET/CT Scan Payor Mix
Project Year 2**

Payor Category	NCBH	NHKMC	Notes
Charity Care	2.8%	3.69%	NHKMC higher
Medicare	57.9%	61.41%	NHKMC higher
Medicaid	12.9%	4.19%	NCBH higher

The data shows that in two of the three medically underserved categories, NHKMC proposes to provide a greater proportion of its PET/CT scans to Charity Care and Medicare patients.

PET/CT Scan Charge Comparison

Another factor the Agency often considers in a comparative analysis is cost effectiveness as measured by the charge for the service under review. In the NCBH and NHKMC Applications, comparative charge information is found in each applicant’s CON Application ProForma Form D, Gross Patient Revenue Worksheet¹⁷. See the table below for the comparison of the applications.

**Projected PET/CT Scan Charges
Project Year 2**

Payor Category	NCBH Avg Projected PET Scan Charge	NHKMC Avg Projected PET Scan Charge	Difference
Self-Pay/Charity Care	\$7,922	\$6,530.50	(\$1,391.50)/-21%
Medicare/Mcare Mged Care	\$8,374	\$6,569.22	(\$1,804.78)/-27%
Medicaid	\$8,537	\$6,569.00	(\$1,986)/-30%
Commercial Ins	\$7,965	\$6,569.00	(\$1,387)/-21%
Managed Care	\$8,268	\$6,551.99	(\$1,716.01)/-26%
Other	\$9,229	\$6,569.00	(\$2,660)/-40%

In each payor category of PET/CT Scan charge comparison, NHKMC has significantly lower PET/CT scan charges than NCBH. NHKMC’s PET/CT scan charges are \$1,300 to \$2,660 less than NCBH’s PET/CT scan charges. Or stated another way, NHKMC’s PET/CT scan charges are 20% to 40% lower than NCBH’s charges. This comparison also holds true whether the PET/CT scan charges are compared for Project Year 1, 2 or 3. NHKMC is clearly the more cost-effective provider of PET/CT scans in this review.

¹⁷Form D is found at page 128 in the NHKMC application.

Demonstration of Need: Number of PET/CT Scans Performed During the Past 5 Years

Both applicants¹⁸ have each operated a single fixed, non-research, non-Policy AC-3 PET/CT scanner over the past five years. It is useful to compare the total cumulative number of PET/CT scans provided by each entity (FMC and NCBH) over that timeframe on their single respective operational clinical PET/CT scanners.

**FFY 2009-FFY 2012
Total Number of PET Scans HSA II
FMC & NCBH**

	FFY 2008	FFY 2009	FFY 2010	FFY 2011	FFY 2012	5-Year Total
FMC	3,208	3,762	3,346	2,875	2,615	15,806
FMC % of HSA II	38%	38%	36%	33%	34%	36%
NCBH	2,011	2,161	2,337	2,571	2,009	10,529
NCBH % of HSA II	24%	22%	25%	29%	26%	24%
Total HSA II	8,518	9,924	9,314	8,770	7,713	44,239

During the most recent five years for which publicly-reported PET/CT scans are available, FMC (the parent of Novant Health KMC) has performed 5,277 more PET/CT scans than NCBH. In addition, of the total PET/CT scans performed at HSA II PET/CT scan programs, FMC has consistently performed a greater proportion of HSA II PET/CT scans than NCBH, by 36% of HSA II PET/CT scans for NHFMC to 24% for NCBH. This demonstrates a more efficient and effective utilization of PET/CT scanner operations by FMC than by NCBH. This is a relevant predictor that NHKMC will also be a more efficient and effective user of the new PET/CT scanner, since NHKMC operates under the existing acute care hospital license of NHFMC. The PET/CT scan program at NHKMC will be integrated with and coordinated with the PET/CT Program at NHFMC, including many of the same PET/CT Technologists in a rotation to cover both NHKMC and NHFMC and professional coverage provided by the same Nuclear Medicine radiologists at both the NHKMC and NHFMC PET program sites.

Demonstration of Need: Number of Radiation Therapy Cancer Program Treatments Delivered Over the Past 3 Years

PET/CT scanners are an essential element of the type of full-service community hospital Cancer Center satellite program that NHKMC is preparing to offer on its campus. Moreover, the same radiologists, oncologic surgeons, gynecologic oncologists, and hematologist oncologists who practice as part of the NHFMC Cancer Center program will be on site at NHKMC. Some of the NHFMC cancer patient volume will shift to the NHKMC satellite cancer program when it opens during the next two-three months and all of the NHFMC clinical expertise will be available at the NHKMC satellite cancer center and its patients.

¹⁸NHKMC operates as a satellite hospital under the existing acute care hospital license of Novant Health Forsyth Medical Center.

During the past three years, NHFMC has consistently operated one of the three busiest radiation therapy treatment cancer programs in North Carolina as measured by the annual ESTV-weighted radiation therapy treatment volumes reported in the NHFMC HLRA's and presented in the annual State Medical Facilities Plans. ESTV-weighting factors account for the complexity of a variety of radiation therapy treatments, the types of patients treated, and imaging that occurs concurrent with the radiation therapy treatments. For the past three years, the Derrick L. Davis Forsyth Regional Cancer Center at Novant Health Forsyth Medical Center has operated the 3rd or 4th busiest radiation therapy treatment program of the 71-72 North Carolina radiation therapy facilities. See the tables below.

In addition, the NHFMC linear accelerators have operated reliably at annual volumes well above the North Carolina statewide average annual ESTV-weighted linear accelerator radiation therapy treatments. For example, using FFY 2012 data, the North Carolina statewide annual average ESTV radiation therapy treatments per linear accelerator was 4,967 and FMC's annual average per (operational) linear accelerator was 6,181. See the tables below.

NHFMC, its physicians, and other highly trained and expert clinical personnel are a very skilled team and high quality operators of radiation therapy programs. The types are radiation therapy treatments offered include: external beam radiation therapy, intensity-modulated radiation therapy, stereotactic radiosurgery, and SAVR. During FFY 2012, while statewide radiation therapy treatment volumes dropped by almost 15,000, FMC remained one of the top five busiest radiation therapy programs in NC. This is a testament to the accessibility of the service and the quality of care and outcomes. For more information see the following links:

www.facingcancerwithforsyth.com and
www.forsythmedicalcenter.org/home/services/cancer.aspx

By comparison, during the period FFY 2010 – FFY 2012, NCBH's Radiation Therapy program has delivered fewer annual ESTV-weighted radiation therapy treatments than NHFMC. The ESTV-weighting factors account for any assertion that NCBH might make that its cancer patients are more complex or sicker, in an effort to suggest that the comparison is invalid. The NCBH Radiation Therapy program, measured by annual ESTV-weighted radiation therapy treatments has been the 9th busiest radiation therapy program for the past three years. Moreover, the NCBH Radiation Therapy Program has performed annual volumes or ESTV-weighted radiation therapy treatments that are lower than the NC average number of radiation therapy treatments per linear accelerator. For example, in FFY 2012 NCBH reported an average of 4,667 ESTV-weighted radiation therapy treatments per linear accelerator compared to the NC state average of ESTV-weighted radiation therapy treatments per linear accelerator of 4,967. See the table directly below.

**Three-Year Comparison of
Radiation Therapy Treatment Program Annual Volumes
Novant Health FMC & NCBH**

	FFY 2012	FFY 2011	FFY 2010
Annual Radiation Therapy Treatments*			
NCBH	18,670	18,310	17,945
NHFMC	24,723	26,881	27,242
Radiation Therapy Treatments/Linear Accelerator*			
NCBH	4,667	4,578	4,667
NHFMC	6,181	6,720	6,811
<i>State Avg Radiation Treatments*/Linear Accelerator</i>	4,967	5,090	4,884
Rank of Radiation Therapy Program*			
NCBH	9th	9th	9th
NHFMC	4th	3rd	3rd

*Note: Based on ESTV-Weighted Radiation Therapy Treatments

FFY 2012 Radiation Therapy Treatment Data

Hospital	Annual FFY 2012 ESTV Weighted Radiation Therapy Volumes	# of Linear Accelerators	Avg ESTV- Wted Rad Therapy Treatments Per Linac*	Rank based on Total Annual ESTV-Weighted Radiation Therapy Treatments
Memorial Mission	19,401	2	6,387	7th
CMC	18,862	3	6,287	8th
FMC	24,723	4	6,181	4th
Cone Health	29,386	4	7,347	2nd
NCBH	18,670	4	4,667	9th
UNC	27,450	6	4,575	3rd
Duke	33,593	5	6,719	1st
First Health Moore Regional	18,276	3	6,092	10th
Cape Fear Valley Medical Center	20,967	5	4,193	5th
Rex Healthcare	19,401	4	4,850	6th
Total NC	601,061	121	4,967	

Source: Table 9G Draft (as of 5/17/13) for 2014 SMFP as presented at 5/29/13 SHCC Meeting

FFY 2011 Radiation Therapy Treatment Data

Hospital	Annual FFY 2011 ESTV Weighted Radiation Therapy Volumes	# of Linear Accelerators	Avg ESTV- Wted Rad Therapy Treatments Per Linac*	Rank based on Total Annual ESTV- Weighted Radiation Therapy Treatments
Memorial Mission	19,222	3	6,407	6th
CMC	19,612			5th
FMC	26,881	4	6,720	3rd
Cone Health	26,642	4	6,660	4th
NCBH	18,310	4	4,578	9th
UNC	30,387	6	5,065	2nd
Duke	35,177	5	7,085	1st
First Health Moore Regional	18,900	3	6,300	7th
Cape Fear Valley Medical Center	18,279	5	3,656	10th
Rex Healthcare	18,898	4	4,724	8th
Total NC	615,889	121	5,090	

Source: Table 9G 2013 SMFP pages 145-146 (with FFY 2011 data)

FFY 2010 Radiation Therapy Treatment Data

Hospital	Annual FFY 2010 ESTV Weighted Radiation Therapy Volumes	# of Linear Accelerators	Avg ESTV- Wted Rad Therapy Treatments Per Linac*	Rank based on Total Annual ESTV- Weighted Radiation Therapy Treatments
Memorial Mission	20,415	3	6,805	5 th
CMC	16,393	3		10th
FMC	27,242	4	6,811	3rd
Cone Health	25,756	4	6,439	4th
NCBH	17,945	4	4,486	9th
UNC	30,238	6	5,040	2nd
Duke	34,771	8	4,346	1st
First Health Moore Regional	19,954	2	9,997	6th
Cape Fear Valley Medical Center	19,668	5	3,934	7th
Rex Healthcare	19,636	4	4,909	8th
Total NC	600,749	123	4,884	

Source: Table 9G 2012 SMFP pages 138-139 (with FFY 2010 data)

LIST OF EXHIBITS

- EXHIBIT A** NCBH Declaratory Ruling Request to Use AC-3 PET/CT Scanner for Clinical PET/CT Scans
- EXHIBIT B** July 2004 Certificate of Need for NCBH AC-3 PET/CT Scanner
- EXHIBIT C** NCBH Annual Hospital Licensure Renewal Application Pages for PET/CT Scan Reporting (For LRA Years 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012)
- EXHIBIT D** Certificate of Need for NCBH Clinical PET/CT Scanner Replacement
- EXHIBIT E** January 2004 Exemption Request & Decision for NCBH Research Positron Emission Mammography Technology

**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

**IN RE: REQUEST FOR DECLARATORY)
RULING BY NORTH CAROLINA BAPTIST) DECLARATORY RULING
HOSPITAL)
Project I.D. No. F-943495)**

I, Jeff Horton, as Acting Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services (“Department” or “Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

North Carolina Baptist Hospital (hereinafter “NCBH”) has requested a declaratory ruling to allow it to temporarily replace the clinical PET/CT scanner it currently uses for diagnostic and clinical purposes with another, separate, PET/CT that it operates in its Radiation Oncology Department for treatment planning and research purposes.

This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. S. Todd Hemphill of Bode, Call & Stroupe, LLP has requested this ruling on behalf of NCBH and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

NCBH received a certificate of need for and operates a clinical PET/CT scanner, which is used for diagnostic and clinical purposes (“Clinical PET/CT”). NCBH also received a certificate of

need pursuant to Policy AC-3 in the State Medical Facilities Plan for a separate PET/CT scanner in the Radiation Oncology Department ("AC-3 PET/CT"), for treatment planning only (i.e., simulation). The Clinical PET/CT is being relocated from the PET Center to the Radiology Department, located in Reynolds Tower. This declaratory ruling requests approval to temporarily replace the Clinical PET/CT with the AC-3 PET/CT for approximately 6 weeks in the Spring of 2010, while the Clinical PET/CT is moved from the PET Center to Reynolds Tower. Once the Clinical PET/CT has been installed in Reynolds Tower, it will once again be used for diagnostic and clinical purposes and the AC-3 PET/CT will be used only for treatment planning.

ANALYSIS

N.C. Gen. Stat. §131E-181 (a) states "*A certificate of need shall be valid only for the defined scope, physical location, and person named in the application.*" However, the Agency has allowed approved applicants to change the physical location named in their application where convenience dictates or the objectives of the CON law are otherwise advanced. This request to approve the temporary replacement of the Clinical PET/CT with the AC-3 PET/CT does not constitute a new institutional health service for the reasons set forth below.

NCBH proposes to use the AC-3 PET/CT as a temporary replacement for the Clinical PET/CT for a limited 6-week period of time, while the Clinical PET/CT is de-installed from the PET Center and relocated to Reynolds Tower. NCBH does not intend to use the AC-3 PET/CT for non-research clinical purposes on a permanent basis. Once the relocation is complete and the Clinical PET/CT is operational again, the AC-3 PET/CT will cease to provide clinical scans and will return to the sole use of treatment planning and research, pursuant to the Policy AC-3 in the SMFP and the original certificate of need.

"Replacement equipment," is defined in G.S. 131E-176 (22a) as:

"equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced."

NCBH projects that the total cost associated with moving the Clinical PET/CT will be \$114,900, which is substantially less than \$2,000,000. The Clinical PET/CT and the AC-3 PET/CT are comparable. The issue is whether the equipment will be "disposed of." In this instance, the proposal will not result in an increase in the inventory of PET/CT scanners, which is the intent of the "disposed of" language.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request are true, I conclude that NCBH is not required to first obtain a Certificate of Need in order to temporarily use the AC-3 PET/CT in place of the Clinical PET/CT for a period of six weeks, to occur approximately between February 1, 2010 and March 15, 2010, while the Clinical PET/CT is being relocated from the PET Center to the Reynolds Tower.

This the _____ day of February, 2010.

Jeff Horton, Acting Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

S. Todd Hemphill
Bode, Call & Stroupe, LLP
3105 Glenwood Avenue, Suite 300
Raleigh NC 27612

This the _____ day of February, 2010.

Jesse Goodman
Acting Chief Operating Officer

BODE, CALL & STROUPE, L.L.P.

ATTORNEYS AT LAW

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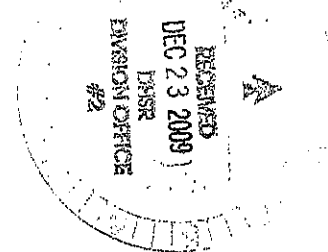
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December 23, 2009



Jeff Horton
Acting Director
NC DEPT OF HEALTH AND HUMAN SERVICES,
DIVISION OF HEALTH SERVICE REGULATION,
701 Barbour Drive
Raleigh, North Carolina 27603

VIA HAND DELIVERY

Re: Request for Declaratory Ruling re: North Carolina Baptist Hospital Temporary Replacement of PET/CT Scanner
FID No: 943495

Dear Mr. Horton:

North Carolina Baptist Hospital ("NCBH") holds a certificate of need ("CON") for and operates a clinical PET/CT scanner, which is used for diagnostic and clinical purposes (the "Clinical PET/CT").¹ NCBH also owns and operates a separate PET/CT in the Radiation Oncology Department, which was approved for a CON pursuant to Policy AC-3 of the SMFP, for treatment planning and research purposes only (the "AC-3 PET/CT").² The purpose of this letter is to obtain a declaratory ruling from the Division of Health Service Regulation ("DHSR"), that NCBH may temporarily replace the Clinical PET/CT by utilizing the AC-3 PET/CT for approximately six weeks, in February and March 2010, without first obtaining a CON. NCBH patients would receive their scans at the existing site of the AC-3 PET/CT in the Radiation Oncology Department.

The reason for this request is that the Clinical PET/CT is being relocated from the PET Center to the Radiology Department located in Reynolds Tower. The NCBH Facilities Planning Department estimates that the de-installation of the Clinical PET/CT from the Radiology Department will occur on approximately February 1, 2010, and it will be re-installed at Reynolds Tower on approximately March 15, 2010. This option of using the AC-3 PET/CT during this time period is the most cost effective alternative for the hospital to ensure that NCBH's patients continue to receive the PET/CT scans that they need without delay, and that no disruption of service occurs.

The capital costs associated with renovation of the new space in Reynolds Tower and the costs associated with moving the existing Clinical PET/CT scanner are expected to be approximately \$114,900. See letter from Bill Tutt, Construction Manager, and attached cost estimate, *Exhibit C* hereto. Once that

¹ A copy of NCBH's CON for its clinical PET/CT, issued effective June 30, 2005, is attached as *Exhibit A*. It replaced a previously-approved PET scanner.

² A copy of NCBH's CON for the AC-3 PET/CT, issued effective July 8, 2004, is attached as *Exhibit B*.

relocation is complete, and the Clinical PET/CT is operational, the AC-3 PET/CT would cease to provide clinical scans and would return solely to its treatment planning and research role.

I. ANALYSIS

There are two questions at issue in your analysis of this request:

1. May NCBH temporarily replace the Clinical PET/CT with the AC-3 PET/CT while the Clinical PET/CT is being relocated?
2. Once the Clinical PET/CT is relocated and reinstalled, does it constitute "replacement equipment" which will replace equipment which will be sold or otherwise disposed of when replaced, within the meaning of G.S. 131E-176(22a) and 131E-184(a)(7)?

These questions will be addressed in turn.

A. Temporary Replacement of Clinical PET/CT

The facts and analysis related to this issue are virtually the same as those in DHSR's Declaratory Ruling approving NCBH's use of an interim helicopter, a copy of which is attached as *Exhibit D*. NCBH is simply using the AC-3 PET/CT as a temporary replacement for the Clinical PET/CT during a limited period of time that the Clinical PET/CT is out of service. The lack of an available clinical PET/CT would impact the health and safety of numerous NCBH patients, and the AC-3 PET/CT is necessary to continue NCBH's clinical PET/CT service for which a need has previously been established. By this ruling, NCBH is not seeking to use the AC-3 PET/CT for non-research clinical purposes on a permanent basis or even indefinitely, because it intends to bring the Clinical PET/CT back on line as soon as it is installed in its new location in Reynolds Tower.

B. Permanent Replacement of AC-3 PET/CT

The second issue before you is, once the Clinical PET/CT has been temporarily taken off line, whether NCBH must file a CON application or obtain a CON to relocate that PET/CT and replace the temporary AC-3 PET/CT. NCBH contends that it does not, because the relocation of the Clinical PET/CT is exempt from CON review as replacement equipment, pursuant to G.S. 131E-184(a)(7). That statute provides, in pertinent part, that:

[T]he Department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, which notice includes an explanation of why the new institutional health service is required, ... [t]o provide replacement equipment.

Replacement equipment is defined as

...equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In determining whether the replacement

equipment costs less than two million dollars (\$2,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

G.S. 131E-176(22a).

The relocated Clinical PET/CT properly qualifies as "replacement equipment" within the meaning of the statute because (1) it costs less than \$2,000,000; (2) its sole purpose is to replace the comparable AC-3 PET/CT; and (3) the AC-3 PET/CT will be "disposed of" when replaced.

The first two points are self-evident. The cost to relocate and reinstall the Clinical PET/CT will be only \$114,900. It will replace the AC-3 PET-CT for purposes of providing clinical scans.

We also believe that the AC-3 PET/CT will be "disposed of," within the meaning of the statute, once it no longer is providing clinical PET/CT scans. In defining "disposed of," the CON law gives only the example of a sale of equipment. The Agency's rule defining replacement equipment, 10A N.C.A.C. 14C.0303 (copy attached as *Exhibit E*), also provides no guidance. However, the clear intent of the replacement equipment statute is to maintain the status quo of approved new institutional health services, and to ensure that once an item of covered equipment is replaced, the provider does not attempt to use it for an unapproved purpose. Here, both the Clinical PET/CT and the AC-3 PET/CT currently are approved services, the Clinical PET/CT for clinical diagnostic purposes pursuant to its CON, and the AC-3 PET/CT for treatment planning and research purposes pursuant to its separate CON. NCBH proposes in this request to use the AC-3 PET/CT for both clinical and research purposes for only a short period of time. After the Clinical PET/CT is relocated and operational, the AC-3 PET/CT will return to use solely for treatment planning/research purposes under its own CON, and therefore, it will be "disposed of," as far as terminating its future use as a clinical PET/CT scanner.

II. CONCLUSION

The only means by which NCBH can readily continue to provide this life-saving health service is if it is permitted to temporarily replace the Clinical PET/CT with the AC-3 PET/CT, until such time as NCBH can complete the relocation and reinstallation of the Clinical PET/CT. NCBH would not make this request, were it not an absolute necessity for the continued operation of its PET/CT service, and of such great importance to the patients NCBH serves. Accordingly, NCBH respectfully requests that DHSR enter a Declaratory Ruling (1) permitting NCBH to temporarily replace the Clinical PET/CT with the AC-3 PET/CT, pending relocation and installation of the Clinical PET/CT; and (2) finding that once the Clinical PET/CT is relocated and operational, NCBH may once again replace the AC-3 PET/CT with the relocated Clinical PET/CT for the provision of clinical PET/CT scans, at which time NCBH will return the AC-3 PET/CT solely to its treatment planning/research status.

Mr. Horton
December 23, 2009
Page 4

For your convenience, a proposed Declaratory Ruling is attached hereto as *Exhibit F*. Should you require an electronic version of this proposed ruling, we would be happy to provide one. In the meantime, should you have any questions or concerns, do not hesitate to contact us.

Thank you very much for your consideration of this request.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.



S. Todd Hemphill

STH/sh

Enclosures

cc w/enc.:

Martha Frisone, Team Leader (hand delivery)
Jennifer Houlihan (via e-mail only)

— Exhibits —

Exhibit	Description
A	NCBH CON for Clinical PET/CT Scanner
B	NCBH CON for AC-3 PET/CT
C	Letter regarding Relocation Costs for the Clinical PET/CT
D	<u>In re: Request for Declaratory Ruling Request by North Carolina Baptist Hospital</u> (February 6, 2008)
E	10A N.C.A.C. 14C-0303
F	Proposed Declaratory Ruling

STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services

CERTIFICATE OF NEED

for

Project Identification Number G-7082-04

FID#943495

ISSUED TO: North Carolina Baptist Hospital
Medical Center Boulevard
Winston-Salem, NC 27157

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16). The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: North Carolina Baptist Hospital shall acquire no more than one PET/CT scanner to replace the existing PET scanner, Serial Number 46311925P21, which will be disposed of when the replacement PET/CT scanner begins operating.

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: North Carolina Baptist Hospital
Medical Center Boulevard
Winston-Salem, NC 27157

MAXIMUM CAPITAL EXPENDITURE: \$1,963,770

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: June 30, 2005

This certificate is effective as of the 4th day of April, 2005.

Lee B. Hoffman

Chief, Certificate of Need Section
Division of Facility Services



CONDITIONS

1. North Carolina Baptist Hospital shall materially comply with all representations made in Project ID #G-7082-04, and the supplemental documents supplied on March 29, 2005, except as such representations reference utilization and financial projections for operation of two diagnostic PET scanners for clinical purposes. In those instances in which the representations in the supplemental documents differ from those in the application, Baptist shall materially comply with the representations in the supplemental documents.
2. As part of this project, North Carolina Baptist Hospital shall replace and dispose of its existing PET scanner, Serial Number 46-311925P21.
3. Upon completion of this project, North Carolina Baptist Hospital shall acquire and operate no more than one diagnostic PET/CT scanner for clinical purposes.

TIMETABLE

Ordering equipment	April 6, 2005
Contract award	April 6, 2005
50% completion of construction	May 4, 2005
Completion of construction	May 18, 2005
Offering of services on replacement equipment	July 1, 2005
Termination of services on PET/CT simulator and Research PET scanner	July 1, 2005

STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services

CORRECTED 7/13/04

CERTIFICATE OF NEED

for

Project Identification Number G-6816-03

FD #948495

ISSUED TO: North Carolina Baptist Hospital
Medical Center Boulevard
Winston-Salem, NC 27157

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16). The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: North Carolina Baptist Hospital shall acquire no more than one 3.0T MRI simulator and no more than one PET/CT simulator pursuant to Policy AC-3 in the 2003 SMFP/Forsyth County.

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: North Carolina Baptist Hospital
Medical Center Boulevard
Winston-Salem, NC 27157

MAXIMUM CAPITAL EXPENDITURE: \$6,491 —

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: December 31, 2004

This certificate is effective as of the 8 day of July, 2004.

Lee B. Hoffman
Chief, Certificate of Need Section
Division of Facility Services



CONDITIONS

1. North Carolina Baptist Hospital shall materially comply with all representations made in Project ID #G-6816-03 and the supplemental documents provided to the Agency on March 15, 2004, May 7, 2004 and June 7, 2004. In those instances in which representations conflict, North Carolina Baptist Hospital shall materially comply with the last-made representation.
2. North Carolina Baptist Hospital shall not use the MRI or PET/CT simulators for diagnostic procedures unrelated to cancer treatment planning and follow-up, except as necessary to handle emergency cases in which the procedure is essential within three hours of the time it is ordered by the physician and is needed in order to treat an "Emergency Medical Condition," as that term is defined by N.C.G.S. 58-3-130(g)(1), and cannot be performed on existing equipment because it is unavailable for use.
3. North Carolina Baptist Hospital 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.

TIMETABLE

Contract award	September 1, 2004
50% completion of construction	November 1, 2004
Completion of construction	December 1, 2004
Occupancy/offering of service(s)	January 1, 2005



Facilities Planning

December 14, 2009

Jeff Horton
Acting Director
NC DEPT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
701 Barbour Drive
Raleigh, North Carolina 27603

Dear Mr. Horton:

The attached estimate is for the relocation of the PET/CT from the MRI facility to the Nuclear Medicine Dept. on the Main floor of Reynolds Tower.

The attached estimate includes engineering fees for mechanical, electrical and plumbing and architectural fees for millwork and ceiling layouts. The total anticipated capital cost is \$114,900, of which \$92,300 is for General Contractor work. The General Contractor pricing includes new electrical feeders to serve the GE unit, new mechanical ductwork to accommodate the equipment heat load, millwork designed around the equipment layout, dimmable canister lighting in the ceiling and wiring for telecom and data ports. The cost of moving and installing the equipment will be funded by GE.

Provisions to utilize the NCBH owned PET/CT equipment in the NCBH Radiation Oncology Dept. have been arranged for the duration of the moving and installation period. The relocated PET/CT equipment should be operational in its new location in Reynolds Tower in early spring 2010.

Sincerely,

Bill Tutt

A handwritten signature in black ink that reads 'Bill Tutt'.

Construction Manager
Facilities Planning and Construction Dept.



BUDGET ESTIMATE

Project# 2010.016

PET/CT RELOCATION TO NUCLEAR MEDICINE

Design/Engineering	\$	12,600.00
General Contractor	\$	92,300.00
Data Wiring/Telecom	\$	3,500.00
Support Equipment	\$	5,000.00
Moving Costs	\$	1,500.00
Total Project Estimate	\$	114,900.00

General Contractor Summary

GC/Field/OH&P	\$34,300.00
Mechanical	\$18,000.00
Electrical	\$28,000.00
Plumbing]	\$ 4,000.00
Millwork/Finishes	\$ 8,000.00
Total GC Estm	\$92,300.00

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY)
RULING BY NORTH CAROLINA) DECLARATORY RULING
BAPTIST HOSPITAL)
Project I.D. No. G-2861-87)

I, Robert J. Fitzgerald, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A.0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

North Carolina Baptist Hospital ("NCBH") has requested a declaratory ruling allowing it to operate its air ambulance service, Project I.D. No. G-2861-87, on a temporary basis with a backup aircraft pending its application and receipt of a Certificate of Need ("CON") for a permanent replacement aircraft. For the reasons stated below, I approve the request.

This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. S. Todd Hemphill of Bode, Call & Stroupe, L.L.P. has requested this ruling on behalf of NCBH and has provided the material facts upon which this ruling is based. Wallace C. Hollowell, III, of Nelson Mullins Riley & Scarborough, L.L.P., has submitted comments opposing the NCBH request on behalf of Med-Trans Corporation ("MTC").



STATEMENT OF THE FACTS

Effective 7 April 1987, the CON Section issued a CON to NCBH for Project I.D. No. G-2861-87, pursuant to which NCBH replaced its air ambulance unit with a Bell-412 twin engine aircraft (the "Existing Helicopter"). NCBH operated the Existing Helicopter under lease with Air Methods Corporation. NCBH states that on 26 July 2007, the Existing Helicopter was being transported by tractor trailer for maintenance when the main rotor mast struck a highway bridge. NCBH represents that the Existing Helicopter sustained irreparable damage and is a total loss.

NCBH has worked with the lessor of the Existing Helicopter, Air Methods, to provide a backup aircraft (the "Interim Helicopter") to continue its air ambulance service. The Interim Helicopter is being provided under the terms of the current lease for the Existing Helicopter.

By letter dated 9 October 2007, NCBH requested a declaratory ruling that it could acquire a permanent replacement aircraft without first obtaining a CON. On 5 December 2007, I issued a declaratory ruling that the proposed replacement aircraft was not exempt from CON review, and denied NCBH's request.

NCBH now represents that it anticipates being prepared to file its CON application for the replacement aircraft on or before 15 May 2008. It states that its current lease with Air Methods is scheduled to expire on 31 December 2008. NCBH intends to enter into a new lease with Air Methods upon approval of its CON.

ANALYSIS

If NCBH were offering or developing a new institutional health service, it would be required to obtain a CON. N.C.G.S. § 131E-178(a). On the narrow facts of this case, the use of the Interim Helicopter as a temporary replacement for the Existing Helicopter does not constitute

a new institutional health service, because NCBH has no ownership or property interest in the Interim Helicopter, and it is simply using it as a temporary replacement for an out-of-service aircraft during a limited period of time while it undertakes to acquire a new aircraft for its air ambulance service. The Existing Helicopter was damaged beyond repair, and the Interim Helicopter is necessary to continue NCBH's air ambulance service for which a need has previously been established.

This ruling does not permit NCBH to use the Interim Helicopter on a permanent basis or even indefinitely. NCBH has represented that it intends to submit an application for a CON authorizing its proposed permanent replacement aircraft not later than 15 May 2008. If NCBH does not submit an application by the designated date, NCBH shall be required to seek an additional or a revised ruling to extend the period of time it uses the Interim Helicopter based on the facts and circumstances at the time.

The comments submitted on behalf of MTC argue that the Interim Helicopter should require a CON just as a replacement aircraft should. (The comments also note MTC's basic position that the CON requirement for air ambulance services is preempted by federal law. That position is currently the subject of litigation in federal court.) As noted above, if the Interim Helicopter constituted a new institutional health service, it would require a CON. Here, however, the Interim Helicopter is a temporary measure to allow the continuation of a health service for which a need has been identified and a CON issued, while NCBH addresses the exceptional circumstance of a replacing an aircraft damaged beyond repair.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that NCBH's use of the Interim Helicopter as a temporary replacement for the Existing

Helicopter does not violate its CON. If NCBH does not submit its application for a CON before 16 May 2008, NCBH shall be required to seek an additional or a revised ruling extending the time for using the Interim Helicopter based on the facts and circumstances at the time.

This the 6th day of February, 2008.



Robert J. Fitzgerald, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:


CERTIFIED MAIL

S. Todd Hemphill
Bode, Call & Stroupe, L.L.P.
3105 Glenwood Avenue, Suite 300
Raleigh, NC 27612

With a courtesy copy to:

Wallace C. Hollowell, III
Nelson Mullins Riley & Scarborough, LLP
GlenLake One, Suite 200
4140 Parklake Avenue
Raleigh, NC 27612

This the 6th day of February, 2008.



Jeff Horton
Chief Operating Officer

10A NCAC 14C .0303 REPLACEMENT EQUIPMENT

(a) The purpose of this Rule is to define the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a).

(b) "Activities essential to acquiring and making operational the replacement equipment" means those activities which are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.

(c) "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

(d) Replacement equipment is comparable to the equipment being replaced if:

- (1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

(e) Replacement equipment is not comparable to the equipment being replaced if:

- (1) the replacement equipment is new or reconditioned, the existing equipment was purchased second-hand, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or
- (2) the replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or
- (3) the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment; or
- (4) the replacement equipment is purchased and the existing equipment is leased, unless the lease is a capital lease; or
- (5) the replacement equipment is a dedicated PET scanner and the existing equipment is:
 - (A) a gamma camera with coincidence capability; or
 - (B) nuclear medicine equipment that was designed, built, or modified to detect only the single photon emitted from nuclear events other than positron annihilation.

*History Note: Authority G.S. 131E-177(1);
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. January 4, 1994;
Amended Eff. April 1, 1999; November 1, 1996;
Temporary Amendment Eff. June 3, 2002;
Amended Eff. April 1, 2003.*



NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY)
RULING BY NORTH CAROLINA BAPTIST)
HOSPITAL)

DECLARATORY RULING

I, Jeff Horton, Acting Director of the North Carolina Department of Health and Human Services, Division of Health Service Regulation (hereinafter the "Department"), hereby issue this declaratory ruling to North Carolina Baptist Hospital (hereinafter "NCBH"), pursuant to N.C. Gen. Stat. § 150B-4, 10A N.C.A.C. 14A .0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. NCBH has filed a Declaratory Ruling Request (hereinafter the "Request") asking the Department to issue a ruling: (1) permitting NCBH to temporarily replace the its CON-approved clinical diagnostic PET/CT scanner (the "Clinical PET/CT"), with a separate PET/CT owned by NCBH and operated for research purposes pursuant to Policy AC-3 of the State Medical Facilities Plan (the "AC-3 PET/CT"), pending relocation and installation of the Clinical PET/CT; and (2) finding that once the Clinical PET/CT is relocated and operational, NCBH may once again replace the AC-3 PET/CT with the relocated Clinical PET/CT for the provision of clinical diagnostic PET/CT scans, without a certificate of need. For the reasons given below, I conclude that the Request should be granted, subject to the conditions stated below.

This ruling is binding on the Department and the person(s) requesting it only to the extent that the material facts stated in the Request are accurate and no material facts have been omitted from the Request. Except as provided by N.C. Gen. Stat. § 150B-4, the Department reserves the right to change the conclusion which are contained in this ruling. S. Todd Hemphill of the law



firm Bode, Call and Stroupe, L.L.P., has requested this ruling on behalf of NCBH and has provided the statement of facts upon which this ruling is based. The material facts as provided by NCBH are set out below.

STATEMENT OF FACTS

NCBH owns the Clinical PET/CT scanner pursuant to a certificate of need issued effective June 30, 2005. The Clinical PET/CT is located at the PET Center on the NCBH campus. The Clinical PET/CT is being relocated from the PET Center to the Radiology Department located in Reynolds Tower in the Spring of 2010. The NCBH Facilities Planning Department estimates that the de-installation of the Clinical PET/CT from the Radiology Department will occur on approximately March 1, 2010, and it will be re-installed at Reynolds Tower on approximately April 15, 2010. The capital costs associated with renovation of the new space in Reynolds Tower and with moving the existing Clinical PET/CT are expected to be approximately \$114,900.

NCBH also owns and operates a separate PET/CT in the Radiation Oncology Department, which was approved for a CON effective July 8, 2004, pursuant to Policy AC-3 of the SMFP, for treatment planning and research purposes only. NCBH proposes that during the time when the NCBH PET/CT is being relocated from the PET Center to Reynolds Tower, NCBH be permitted to operate the AC-3 PET/CT for clinical diagnostic purposes. The AC-3 PET/CT also would continue to be operated by NCBH for treatment planning and research purposes. Once the Clinical PET/CT is operational in its new location, NCBH would cease to use the AC-3 PET/CT for clinical diagnostic purposes.

ANALYSIS

If NCBH were offering or developing a new institutional health service, it would be required to obtain a CON. N.C. Gen. Stat. § 131E-178(a). On the narrow facts of this case, the use of the AC-3 PET/CT as a temporary replacement for the Clinical PET/CT does not constitute a new institutional health service, because NCBH is simply using it as temporary replacement during a limited period of time while it relocates its existing approved Clinical PET/CT. The Clinical PET/CT will be non-operational for approximately six weeks, which impacts the health and safety of NCBH's patients, and the AC-3 PET/CT is necessary to continue NCBH's clinical diagnostic PET/CT service for which a need has previously been established.

Further, once the Clinical PET/CT has been relocated and is ready for operation in the Radiology Department, NCBH will not be required to file a CON application or obtain a CON to replace the AC-3 PET/CT with the Clinical PET/CT. The relocation of the Clinical PET/CT is exempt from CON review as replacement equipment, pursuant to G.S. 131E-184(a)(7). The relocated Clinical PET/CT properly qualifies as "replacement equipment" within the meaning of G.S. 131E-176(22a), because (1) the cost to relocate and install the Clinical PET/CT is \$114,900, less than the \$2,000,000 statutory threshold; (2) its sole purpose is to replace the comparable AC-3 PET/CT; and (3) the AC-3 PET/CT will be "disposed of" when it is replaced.

With regard to my last conclusion, neither the CON law nor the Agency's rules give a definition of "disposed of," other than as it relates to the sale of equipment. G.S. 131E-176(22a); 10A N.C.A.C. 14C.0303. However, the clear intent of the replacement equipment statute is to maintain the status quo of approved new institutional health services, and to ensure that once an item of covered equipment is replaced, the provider does not attempt to use it for an unapproved purpose. Here, both the Clinical PET/CT and the AC-3 PET/CT currently are approved services, the NCBH PET/CT pursuant to its CON for clinical diagnostic purposes, and the AC-3 PET/CT

pursuant to its separate CON for treatment planning/research purposes. NCBH proposes in this request to use the AC-3 PET/CT for both purposes for only a short period of time. After the Clinical PET/CT is relocated and operational, the AC-3 PET/CT will return to use solely for treatment planning/research purposes under its own CON, and therefore, it will be "disposed of," as far as terminating its future use as a clinical diagnostic PET/CT scanner.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that NCBH's use of the AC-3 PET/CT as a temporary replacement for the Clinical PET/CT does not violate the CONs issued for either PET/CT scanner. Further, once the Clinical PET/CT is relocated and operational, NCBH may once again use the Clinical PET/CT without filing a CON application or obtaining a new CON.

This the ____ day of _____, 2010.

By: _____
JEFF HORTON
Acting Director
NORTH CAROLINA DEPARTMENT OF HEALTH
AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

EXHIBIT
B

STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services

CORRECTED 7/13/04

CERTIFICATE OF NEED

for

Project Identification Number G-6816-03

FD#943495

ISSUED TO: North Carolina Baptist Hospital
Medical Center Boulevard
Winston-Salem, NC 27157

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16). The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: North Carolina Baptist Hospital shall acquire no more than one 3.0T MRI simulator and no more than one PET/CT simulator pursuant to Policy AC-3 in the 2003 SMFP Forsyth County.

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: North Carolina Baptist Hospital
Medical Center Boulevard
Winston-Salem, NC 27157

MAXIMUM CAPITAL EXPENDITURE: \$6,491 —

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: December 31, 2004

This certificate is effective as of the 8 day of July, 2004.

Lee B. Hoffman
Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS

1. North Carolina Baptist Hospital shall materially comply with all representations made in Project ID #G-5816-03 and the supplemental documents provided to the Agency on March 15, 2004, May 7, 2004 and June 7, 2004. In those instances in which representations conflict, North Carolina Baptist Hospital shall materially comply with the last-made representation.
2. North Carolina Baptist Hospital shall not use the MRI or PET/CT simulators for diagnostic procedures unrelated to cancer treatment planning and follow-up, except as necessary to handle emergency cases in which the procedure is essential within three hours of the time it is ordered by the physician and is needed in order to treat an "Emergency Medical Condition," as that term is defined by N.C.G.S. 58-3-130(g)(1), and cannot be performed on existing equipment because it is unavailable for use.
3. North Carolina Baptist Hospital 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.

TIMETABLE

Contract award	September 1, 2004
50% completion of construction	November 1, 2004
Completion of construction	December 1, 2004
Occupancy/offering of service(s)	January 1, 2005

EXHIBIT C

NCBH Hospital
LRAs

2005-2013

PET Scanner Pages

Responses should pertain to October 1, 2011 through September 30, 2012.

Scans Performed on Mobile CT Scanners (Multiply # scans by Conversion Factor to get HECT Units)

	Type of CT Scan	# of Scans		Conversion Factor	=	HECT Units
1	Head without contrast		X	1.00	=	
2	Head with contrast		X	1.25	=	
3	Head without and with contrast		X	1.75	=	
4	Body without contrast		X	1.50	=	
5	Body with contrast		X	1.75	=	
6	Body without contrast and with contrast		X	2.75	=	
7	Biopsy in addition to body scan with or without contrast		X	2.75	=	
8	Abscess drainage in addition to body scan with or without contrast		X	4.00	=	

10d. Other Imaging Equipment

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	1	279	2,111	2,390
Mobile PET Scanner				
PET pursuant to Policy AC-3	1			
Other Human Research PET Scanner				
Ultrasound equipment	9	6,706	17,995	24,701
Mammography equipment	4	20	10,963	10,983
Bone Density Equipment				
Fixed X-ray Equipment (excluding fluoroscopic)	22	27,892	101,655	129,547
Fixed Fluoroscopic X-ray Equipment	5	3,659	5,614	9,273
Special Procedures/ Angiography Equipment (neuro & vascular, but not including cardiac cath.)	5	15,196	9,874	25,070
Coincidence Camera				
Mobile Coincidence Camera				
Vendor:				
SPECT	4	209	564	773
Mobile SPECT				
Vendor:				
Gamma Camera	3	684	3,073	3,757
Mobile Gamma Camera				
Vendor:				

* PET procedure means a single discrete study of one patient involving one or more PET scans. PET scan means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 27.

10e. Lithotripsy

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Fixed				
Mobile	X		5	5

Lithotripsy Vendor/Owner:
SIEMENS/PIEDMONT STONE

All responses should pertain to October 1, 2010 through September 30, 2011.

Scans Performed on Mobile CT Scanners (Multiply # scans by Conversion Factor to get HECT Units)

Type of CT Scan	# of Scans	Conversion Factor	HECT Units
1 Head without contrast	X	1.00	=
2 Head with contrast	X	1.25	=
3 Head without and with contrast	X	1.75	=
4 Body without contrast	X	1.50	=
5 Body with contrast	X	1.75	=
6 Body without contrast and with contrast	X	2.75	=
7 Biopsy in addition to body scan with or without contrast	X	2.75	=
8 Abscess drainage in addition to body scan with or without contrast	X	4.00	=

10d. Other Imaging Equipment

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	1	277	2,294	2,571
Mobile PET Scanner	-	-	-	-
PET pursuant to Policy AC-3	-	-	-	-
Other Human Research PET Scanner	-	-	-	-
Ultrasound equipment	9	6,501	75,483	21,984
Mammography equipment	4	31	11,333	11,364
Bone Density Equipment	-	-	-	-
Fixed X-ray Equipment (excluding fluoroscopic)	24	29,824	106,796	136,620
Fixed Fluoroscopic X-ray Equipment	8	3,182	6,197	9,379
Special Procedures/ Angiography Equipment (neuro & vascular, but not including cardiac cath.)	5	13,330	8,439	21,769
Coincidence Camera	-	-	-	-
Mobile Coincidence Camera	-	-	-	-
Vendor:				
SPECT	4	256	515	771
Mobile SPECT	-	-	-	-
Vendor:				
Gamma Camera	3	634	3,138	3,772
Mobile Gamma Camera	-	-	-	-
Vendor:				

* PET procedure means a single discrete study of one patient involving one or more PET scans. PET scan means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 27.

10e. Lithotripsy

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Fixed				
Mobile	1	0	38	38

Lithotripsy Vendor/Owner:
 Siemens / Piedmont Stone

All responses should pertain to October 1, 2009 through September 30, 2010.

Scans Performed on Mobile CT Scanners (Multiply # scans by Conversion Factor to get HECT Units)

	Type of CT Scan	# of Scans		Conversion Factor		HECT Units
1	Head without contrast		X	1.00	=	
2	Head with contrast		X	1.25	=	
3	Head without and with contrast		X	1.75	=	
4	Body without contrast		X	1.50	=	
5	Body with contrast		X	1.75	=	
6	Body without contrast and with contrast		X	2.75	=	
7	Biopsy in addition to body scan with or without contrast		X	2.75	=	
8	Abscess drainage in addition to body scan with or without contrast		X	4.00	=	

10d. Other Imaging Equipment

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	1	215	2122	2337
Mobile PET Scanner	-			
PET pursuant to Policy AC-3	-			
Other Human Research PET Scanner	-			
Ultrasound equipment	22	5276	14226	19502
Mammography equipment	4	6	11642	11648
Bone Density Equipment	-			
Fixed X-ray Equipment (excluding fluoroscopic)	8	27831	704503	131884
Fixed Fluoroscopic X-ray Equipment	24	2995	6355	9348
Special Procedures/ Angiography Equipment (neuro & vascular, but not including cardiac cath.)	5	11111	7001	18112
Coincidence Camera	-			
Mobile Coincidence Camera	-			
Vendor:	-			
SPECT	4	166	432	598
Mobile SPECT	-			
Vendor:	-			
Gamma Camera	3	645	2921	3566
Mobile Gamma Camera	-			
Vendor:	-			

* PET procedure means a single discrete study of one patient involving one or more PET scans. PET scan means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 27.

10e. Lithotripsy

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Fixed				
Mobile	1	0	47	47

Lithotripsy Vendor/Owner:
Siemens / Piedmont Star

All responses should pertain to October 1, 2008 through September 30, 2009.

Scans Performed on Mobile CT Scanners (Multiply # scans by Conversion Factor to get HECT Units)

	Type of CT Scan	# of Scans		Conversion Factor	=	HECT Units
1	Head without contrast	—	X	1.00	=	
2	Head with contrast	—	X	1.25	=	
3	Head without and with contrast	—	X	1.75	=	
4	Body without contrast	—	X	1.50	=	
5	Body with contrast	—	X	1.75	=	
6	Body without contrast and with contrast	—	X	2.75	=	
7	Biopsy in addition to body scan with or without contrast	—	X	2.75	=	
8	Abscess drainage in addition to body scan with or without contrast	—	X	4.00	=	

10d. Other Imaging Equipment

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	1	255	1,896	2,151
Mobile PET Scanner	—			
PET pursuant to Policy AC-3	—			
Other Human Research PET Scanner	—			
Ultrasound equipment	13	5,064	14,146	19,210
Mammography equipment	5	29	13,205	13,234
Bone Density Equipment	—			
Fixed X-ray Equipment (excluding fluoroscopic)	24	17,089	107,014	124,103
Fixed Fluoroscopic X-ray Equipment	7	2,401	4,878	7,279
Special Procedures/ Angiography (neuro & vascular, but not including cardiac cath.)	5	11,064	6,874	17,938
Coincidence Camera	—			
Mobile Coincidence Camera	—			
Vendor:	—			
SPECT	4	141	395	536
Mobile SPECT	—			
Vendor:	—			
Gamma Camera	3	801	3,782	4,583
Mobile Gamma Camera	—			
Vendor:	—			

* PET procedure means a single discrete study of one patient involving one or more PET scans. PET scan means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 27.

10e. Lithotripsy

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Fixed	—			
Mobile	1	0	40	40

Lithotripsy Vendor/Owner:
Siemens/Piedmont Stone

All responses should pertain to October 1, 2007 through September 30, 2008.

Scans Performed on Mobile CT Scanners (Multiply # scans by Conversion Factor to get HECT Units)

	Type of CT Scan	# of Scans		Conversion Factor		HECT Units
1	Head without contrast		X	1.00	=	
2	Head with contrast		X	1.25	=	
3	Head without and with contrast		X	1.75	=	
4	Body without contrast		X	1.50	=	
5	Body with contrast		X	1.75	=	
6	Body without contrast and with contrast		X	2.75	=	
7	Biopsy in addition to body scan with or without contrast		X	2.75	=	
8	Abscess drainage in addition to body scan with or without contrast		X	4.00	=	

10d. Other Imaging Equipment

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	1	250	1,761	2,011
Mobile PET Scanner	-			
PET pursuant to Policy AC-3	-			
Other Human Research PET Scanner	-			
Ultrasound equipment	13	10,105	13,375	19,480
Bone Density Equipment	-			
Fixed X-ray Equipment (excluding fluoroscopic)	24	37,028	105,860	142,888
Fixed Fluoroscopic X-ray Equipment	7	3,640	4,249	7,889
Special Procedures/ Angiography (neuro & vascular, but not including cardiac cath.)	5	11,298	6,327	17,625
Coincidence Camera				
Mobile Coincidence Camera				
Vendor:				
SPECT	4	197	408	605
Mobile SPECT				
Vendor:				
Gamma Camera	3	1,257	4,614	5,871
Mobile Gamma Camera				
Vendor:				

* PET procedure means a single discrete study of one patient involving one or more PET scans. PET scan means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 27.

10e. Lithotripsy

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Fixed	-			-
Mobile.*	1	2	18	20

Lithotripsy Vendor/Owner:
Siemens Piedmont Stone

* Started in June 2007, Numbers low last year due to later beginning date

All responses should pertain to October 1, 2006 through September 30, 2007.

10a. Diagnostic Imaging and Lithotripsy Data

Indicate the number of machines/instruments and the number of the following types of procedures performed during the 12-month reporting period at your facility. For Hospitals that operate medical equipment at multiple sites, please provide a separate page for each site.

Imaging	Number of Units	No. of Procedures			No. of MRI Procedures *					
		Inpatient	Outpatient	Total	With Contrast or Sedation	Without Contrast or Sedation	Total			
Magnetic Resonance Imaging										
Fixed MRI Scanners	6	5799	14912	20711	14919	5792	20711			
Open MRI Scanners included in row above	-									
MRI pursuant to Policy AC-3:	1	-	791	791	706	85	791			
Other Human Research MRI Scanner	-									
MRI Mobile Equipment										
Identify Vendor/Owner in space () below:	Number of Units	No. of Procedures			With Contrast or Sedation	Without Contrast or Sedation	Total			
MRI #1 ()		Inpatient	Outpatient	Total						
MRI #2 ()										
CT Scanner (Fixed or Mobile)	9	34306	51634	85940	Note: * Totals of MRI inpatients and and without contrast or sedation.					
CT Scanner HECT Units										
Mammogram	5	-	13317	13317						
Fixed Other Radiographic&Fluoroscopic	79	119391	100835	220226						
Nuclear Medicine										
PET Scanners										
Dedicated Fixed PET Scanner	1	212	1707	1919						
Mobile PET Scanner Vendor ()										
PET pursuant to Policy AC-3	1		98	98						
Other Human Research PET Scanner										
Other Nuclear Medicine										
Coincidence Camera										
Mobile Coincidence Camera Vendor ()										
SPECT	4	194	464	658						
Mobile SPECT Vendor ()										
Gamma Camera	3	1032	3876	4908						
Mobile Gamma Camera Vendor ()										
Lithotripsy										
[Identify Vendor/Owner in space () below:]	Number of Units	No. of Procedures								
Fixed		Inpatient	Outpatient	Total						
Mobile (Siemens/PiedmontStone)	1		6	6						

MRI procedure is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. **NOTE:** Please Report ALL Angiography procedures on page 10, in Table 9 under Special Procedures/Angiography Rooms.

PET procedure is defined as a single discrete PET scan of a patient (single CPT coded procedure), not counting other radiopharmaceutical or supply charge codes.

All responses should pertain to October 1, 2005 through September 30, 2006. If otherwise, indicate the actual reporting period used on Page 3 of this document.

10a. Diagnostic Imaging and Lithotripsy Data

Indicate the number of machines/instruments and the number of the following types of procedures performed during the 12-month reporting period at your facility. For Hospitals that operate medical equipment at multiple sites, please provide a separate page for each site.

Imaging							
Fixed Equipment (Exclude Research & Policy AC-3 Units)	Number of Units	No. of Procedures			No. of MRI Procedures *		
		Inpatient	Outpatient	Total	With Contrast or Sedation	Without Contrast or Sedation	Total
CT Scanner	9	31,946	45,365	77,311			
MRI	6	5,237	14,160	19,397	13,406	5,991	19,397
Open MRI Scanners included in row above	-						
Mammogram	5	-	11,870	11,870			
Other radiographic & fluoroscopic (See Note Below)	71	113,762	95,744	209,504			
Mobile Equipment	Number of Units	No. of Procedures			No. of MRI Procedures		
Identify Vendor/Owner in space () below:		Inpatient	Outpatient	Total	With Contrast or Sedation	Without Contrast or Sedation	Total
MRI #1 ()	-						
MRI #2 ()	-						
CT Scan ()	-						
Nuclear Medicine							
Fixed Equipment	Number of Units	No. of Procedures			No. of Procedures **		
Dedicated PET Scanner	1	190	1,287	1,477	Clinical	Research	Total
Coincidence Camera	-	-	-	-			
SPECT	4	214	538	752			
Gamma Camera	3	832	3,523	4,355			
Mobile Equipment	Number of Units	No. of Procedures			No. of Procedures **		
Identify Vendor/Owner in space () below:		Inpatient	Outpatient	Total	Clinical	Research	Total
Dedicated PET Scanner ()	-						
Coincidence Camera ()	-						
SPECT ()	-						
Gamma Camera ()	-						
Policy AC-3 or Research Equipment	Number of Units	No. of Procedures			No. of Procedures **		
MRI pursuant to Policy AC-3:	1	0	543	543	543	-	543
Other Human Research MRI Scanner *	1	-	-	-			
PET pursuant to Policy AC-3	1	-	48	48	15	33	48
Other Human Research PET Scanner *	1	-	-	-			
Lithotripsy							
[Identify Vendor/Owner in space () below:]	Number of Units	No. of Procedures			No. of Procedures **		
Fixed (A)	-	0	0	0			
Mobile ()	-						

Note: Totals of MRI inpatients and outpatients should equal MRI totals with and without contrast or sedation

Note: Totals of MRI inpatients and outpatients should equal MRI totals for clinical and research procedures

MRI procedure is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. **NOTE:** Please Report ALL Angiography procedures on page 10, in Table 9 under Special Procedures/Angiography Rooms.

PET procedure is defined as a single discrete PET scan of a patient (single CPT coded procedure), not counting other radiopharmaceutical or supply charge codes.

* Other human research scanners are not owned by NCBH. The scanners are owned by Wake Forest University Health Sciences.

A NCBH divested its fixed lithotripsy pursuant to G-7462-06.

All responses should pertain to October 1, 2004 through September 30, 2005. If otherwise, indicate the actual reporting period used on Page 3 of this document.

10a. Diagnostic Imaging and Lithotripsy Data

Indicate the number of machines/instruments and the number of the following types of procedures performed during the 12-month reporting period at your facility. For Hospitals that operate medical equipment at multiple sites, please provide a separate page for each site.

Imaging							
Fixed Equipment							
(Exclude Research & Policy AC-3 Units)							
	Number of Units	No. of Procedures		Total	No. of MRI Procedures *		
		Inpatient	Outpatient		With Contrast or Sedation	Without Contrast or Sedation	Total
CT Scanner	9	28,548	42,633	71,181			
MRI	5	5,090	14,339	19,429	12,568	6,861	19,429
Mammogram	4	0	14,371	14,371			
Other radiographic & fluoroscopic (See Note Below)	72	112,429	91,842	204,271			
Mobile Equipment							
Identify Vendor/Owner in space () below:							
MRI #1 ()							
MRI #2 ()							
CT Scan ()							
Nuclear Medicine							
Fixed Equipment							
	Number of Units	No. of Procedures		Total	Note: Totals of MRI inpatients and outpatients should equal MRI totals with and without contrast or sedation		
		Inpatient	Outpatient				
Dedicated PET Scanner	1	171	1,095	1,266			
Coincidence Camera	0	0	0	0			
SPECT	6	1574	4,478	6,052			
Gamma Camera	2	85	250	335			
Mobile Equipment							
Identify Vendor/Owner in space () below:							
Dedicated PET Scanner ()							
Coincidence Camera ()							
SPECT ()							
Gamma Camera ()							
Policy AC-3 or Research Equipment							
	Number of Units	No. of Procedures		Total	No. of Procedures **		
		Inpatient	Outpatient		Clinical	Research	Total
MRI pursuant to Policy AC-3: *	1	0	0	0			
Other Human Research MRI Scanner ^							
PET pursuant to Policy AC-3*	1	0	0	0			
Other Human Research PET Scanner ^							
Lithotripsy							
[Identify Vendor/Owner in space () below:]							
Fixed (Dornier)	1		96	96	Note: Totals of MRI inpatients and outpatients should equal MRI totals for clinical and research procedures		
Mobile ()							

* NCBH was awarded MRI and PET/CT simulators pursuant to Policy AC-3, CON 6-618-03. These scanners were not operational during the current reporting period.
 ^ Other Human Research Scanners are not owned by NCBH. The Research Scanners are owned by Wake Forest University
 MRI procedure is defined as a single discrete MRI study of one patient (single CPT coded procedure). An Health MRI study means one or more scans relative to a single diagnosis or symptom. **NOTE:** Please Report ALL sciences - Angiography procedures on page 10, in Table 9 under Special Procedures/Angiography Rooms.

PET procedure is defined as a single discrete PET scan of a patient (single CPT coded procedure), not counting other radiopharmaceutical or supply charge codes.

All responses should pertain to **October 1, 2003** through **September 30, 2004**. If otherwise, indicate the actual reporting period used on Page 3 of this document.

10a. Diagnostic Imaging and Lithotripsy Data

Indicate the number of machines/instruments and the number of the following types of procedures performed during the 12-month reporting period at your facility. For Hospitals that operate medical equipment at multiple sites, please provide a separate page for each site.

Imaging								
Fixed Equipment (Exclude Research & Policy AC-3 Units)		Number of Units	No. of Procedures		Total	No. of MRI Procedures *		Total
	Inpatient		Outpatient	With Contrast or Sedation		Without Contrast or Sedation		
CT Scanner	9	29,525	41,853	71,378	10,735	8,055	18,790	
MRI	5	4,870	13,920	18,790				
Mammogram	4	1	14,916	14,917				
Other radiographic & fluoroscopic (See Note Below)	72	119,920	92,086	212,006				
Mobile Equipment		Number of Units	No. of Procedures		Total	No. of MRI Procedures		Total
Identify Vendor/Owner in space () below:			Inpatient	Outpatient		With Contrast or Sedation	Without Contrast or Sedation	
MRI #1 ()								
MRI #2 ()								
CT Scan ()								
Nuclear Medicine		Number of Units	No. of Procedures		Total	Note: Totals of MRI inpatients and outpatients should equal MRI totals with and without contrast or sedation		
Fixed Equipment			Inpatient	Outpatient				
Dedicated PET Scanner	1	111	1,686	1,797				
Coincidence Camera	0	0	0	0				
SPECT	4	347	533	880				
Gamma Camera	4	839	3,849	4,688				
Mobile Equipment		Number of Units	No. of Procedures		Total			
Identify Vendor/Owner in space () below:			Inpatient	Outpatient				
Dedicated PET Scanner ()								
Coincidence Camera ()								
SPECT ()								
Gamma Camera ()								
Policy AC-3 or Research Equipment		Number of Units	No. of Procedures		Total	No. of Procedures **		Total
	Inpatient		Outpatient	Clinical		Research		
MRI pursuant to Policy AC-3*	1	0	0	0	N/A	0	0	
Other Human Research MRI Scanner^	0	N/A	N/A	N/A	N/A	N/A	N/A	
PET pursuant to Policy AC-3*	1	0	0	0	N/A	0	0	
Other Human Research PET Scanner^	0	N/A	N/A	N/A	N/A	N/A	N/A	
Lithotripsy		Number of Units	No. of Procedures		Total	Note: Totals of MRI inpatients and outpatients should equal MRI totals for clinical and research procedures		
[Identify Vendor/Owner in space () below:]			Inpatient	Outpatient				
Fixed (Dornier)		1	1	92				
Mobile ()		N/A	N/A	N/A				

*NCBH was awarded MRI and PET/CT simulators pursuant to Policy AC-3, CON G-618-03. These scanners were not operational during the current reporting period.
 ^Other Human Research scanners are not owned by NCBH. The research scanners are owned by Wake Forest University Health Sciences.

MRI procedure is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. **NOTE:** Please Report ALL Angiography procedures on page 10, in Table 9 under Special Procedures/Angiography Rooms.

PET procedure is defined as a single discrete PET scan of a patient (single CPT coded procedure), not counting other radiopharmaceutical or supply charge codes.

STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services

CERTIFICATE OF NEED

for

Project Identification Number G-7082-04

FID#943495

ISSUED TO: North Carolina Baptist Hospital
Medical Center Boulevard
Winston-Salem, NC 27157

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(d). The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: North Carolina Baptist Hospital shall acquire no more than one PET/CT scanner to replace the existing PET scanner, Serial Number 46311925E21, which will be disposed of when the replacement PET/CT scanner begins operating.

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: North Carolina Baptist Hospital
Medical Center Boulevard
Winston-Salem, NC 27157

MAXIMUM CAPITAL EXPENDITURE: \$1,963,770

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: June 30, 2005

This certificate is effective as of the 4th day of April, 2005.

Geek B. Hoffman

Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS

1. North Carolina Baptist Hospital shall materially comply with all representations made in Project ID #G-7082-04, and the supplemental documents supplied on March 29, 2005, except as such representations reference utilization and financial projections for operation of two diagnostic PET scanners for clinical purposes. In those instances in which the representations in the supplemental documents differ from those in the application, Baptist shall materially comply with the representations in the supplemental documents.
2. As part of this project, North Carolina Baptist Hospital shall replace and dispose of its existing PET scanner, Serial Number 46-311925P21.
3. Upon completion of this project, North Carolina Baptist Hospital shall acquire and operate no more than one diagnostic PET/CT scanner for clinical purposes.

TIMETABLE

Ordering equipment	April 6, 2005
Contract award	April 6, 2005
50% completion of construction	May 4, 2005
Completion of construction	May 18, 2005
Offering of services on replacement equipment	July 1, 2005
Termination of services on PET/CT simulator and Research PET scanner	July 1, 2005



EXHIBIT
E

North Carolina Department of Health and Human Services
Division of Facility Services
Certificate of Need Section
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

January 16, 2004

~~Michael L. Freeman~~
Vice President, Strategic Planning
Wake Forest University Baptist Medical Center
Medical Center Boulevard
Winston-Salem, NC 27157-1196

RE: Research Exemption/ Wake Forest University Health Sciences/ Acquire a Naviscan PET Systems, Inc. PEM Flex™ device exclusively for research/ Forsyth County

Dear Mr. Freeman:

In response to your letter of January 6, 2004, the above-referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-179. Therefore, Wake Forest University Health Sciences (WFUHS) may proceed to acquire the Naviscan PET Systems, Inc. PEM Flex™ device. This determination is based on your representations that:

- 1) the Naviscan PEM Flex™ device will not be used for any clinical purposes;
- 2) use of this equipment by WFUSM for research purposes only will not affect patient charges;
- 3) there will be no change in bed capacity or the provision of services; and
- 4) patients will not be charged for use of the Naviscan PEM Flex™ device.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

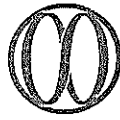
Sincerely,

Martha J. Frisone, Project Analyst

Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DFS





Wake Forest University Baptist
MEDICAL CENTER

RECEIVED

JAN 20 2004

Certificate Of Need Section

January 16, 2004

Strategic Planning

Telephone: (336) 716-5092

Fax: (336) 716-2879

Lee B. Hoffman, Chief
Martha J. Frisone, Project Analyst
Certificate of Need Section
Division of Facility Services
North Carolina Department of Human Resources
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RE: Intent to Evaluate Positron Emission Mammography (PEM) technology/ Wake Forest University Health Sciences/Forsyth County

Dear Ms. Hoffman and Ms. Frisone,

The purpose of this letter is to provide clarifying information regarding the intent of Wake Forest University Health Sciences (WFUHS) to evaluate Positron Emission Mammography (PEM) technology through an agreement with Naviscan PET Systems. In addition to the attestations of statutory compliance provided in the letter dated January 6, 2004, WFUHS would like to clarify that it will not "charge patients for the use of the service for which an exemption has been granted (N.C. General Statute §131E-179(b))." The use of the proposed equipment will be limited to research only and patients will not be charged for the service.

As stated in the letter dated January 6, 2004, WFUHS will be utilizing this technology solely for research and therefore respectfully requests an exemption from CON review pursuant to N.C. General Statute §131E-179 and Administrative Rule 10A NCAC 14C.0301. Please provide written documentation that the proposed loan of PEM technology for the purposes of research evaluation as described in this letter is exempt from CON law as defined in N.C. General Statute §131E-179 and Administrative Rule 10A NCAC 14C.0301. If you have any questions or need additional information, please do not hesitate to call me at (336) 716-5097. On behalf of WFUHS, I appreciate your attention to this important matter.

Sincerely,

Lynn S. Pitman
Director, Strategic Planning
Wake Forest University Baptist Medical Center

Wake Forest University Health Sciences
North Carolina Baptist Hospital

**Wake Forest University Baptist**

January 16, 2004

Strategic Planning

Telephone: (336) 716-5092

Fax: (336) 716-2879

Lee B. Hoffman, Chief
Martha J. Frisone, Project Analyst
Certificate of Need Section
Division of Facility Services
North Carolina Department of Human Resources
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RE: Intent to Evaluate Positron Emission Mammography (PEM) technology/ Wake Forest University Health Sciences/Forsyth County

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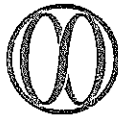
As stated in the letter dated January 6, 2004, WFUHS will be utilizing this technology solely for research and therefore respectfully requests an exemption from CON review pursuant to N.C. General Statute §131E-179 and Administrative Rule 10A NCAC 14C.0301. Please provide written documentation that the proposed loan of PEM technology for the purposes of research evaluation as described in this letter is exempt from CON law as defined in N.C. General Statute §131E-179 and Administrative Rule 10A NCAC 14C.0301. If you have any questions or need additional information, please do not hesitate to call me at (336) 716-5097. On behalf of WFUHS, I appreciate your attention to this important matter.

Sincerely,

Lynn S. Pitman
Director, Strategic Planning
Wake Forest University Baptist Medical Center

*Wake Forest University Health Sciences
North Carolina Baptist Hospital*

Medical Center Boulevard • Winston-Salem, North Carolina 27157



Wake Forest University Baptist
MEDICAL CENTER

January 6, 2004

Strategic Planning

Telephone: (336) 716-5092
Fax: (336) 716-2879

Lee B. Hoffman, Chief
Martha J. Frisone, Project Analyst
Certificate of Need Section
Division of Facility Services
North Carolina Department of Human Resources
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RECEIVED

JAN 08 2004

Certificate Of Need Section

RE: Intent to Evaluate Positron Emission Mammography (PEM) technology/ Wake Forest University Health Sciences/Forsyth County

Dear Ms. Hoffman and Ms. Frisone,

The purpose of this letter is to inform you of the intent of Wake Forest University Health Sciences (WFUHS) to evaluate Positron Emission Mammography (PEM) technology through an agreement with Naviscan PET Systems. WFUHS will be utilizing this technology solely for research and therefore respectfully requests an exemption from CON review pursuant to N.C. General Statute §131E-179 and Administrative Rule 10A NCAC 14C.0301. These technologies will not affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research, will not change the bed capacity of the facility and will not substantially change the medical or other patient health services of the facility.

The Department of Radiology, Section of Mammography has reached an agreement with the provider of the PEM equipment, Naviscan PET Systems, to evaluate this technology. The terms of the agreement include a loan of this equipment to WFUHS in exchange for WFUHS commitment to conduct research regarding the efficiency and efficacy of the equipment. Please see Exhibit 1 for a letter documenting the terms of the proposed agreement. WFUHS will not perform any clinical care with the equipment. The equipment will initially be provided for 12 months. At the end of the 12 months, both WFUHS and Naviscan PET Systems will determine whether the research should continue. This loan is without remuneration from WFUHS to Naviscan PET Systems; therefore it should not be construed as a lease or acquisition. As a point of information, WFUHS has determined that the fair market value of the equipment is \$590,000 (lease or purchase price). The list price of the equipment is \$750,000. Please see Exhibit 2 for documentation of the fair market value and list price. This technology will not affect the charges of the health service facility for the provision of medical or other patient care services other than services which are

Wake Forest University Health Sciences
North Carolina Baptist Hospital

included in the research, will not change the bed capacity of the facility and will not substantially change the medical or other patient health services of the facility.

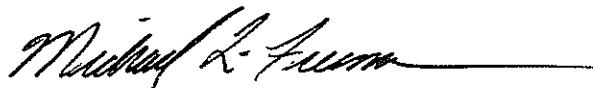
The PEM equipment applies PET technology to mammography. Similar to the process used in conventional PET scanning, PEM uses injected radioactively "tagged" sugar-like molecules (FDG) to mark or make visible tissue which is more likely to be cancerous. The cancer tumors accumulate more of the radioactive tracer thus allowing them to appear in the PEM images. PEM equipment is designed to photograph the entire breast, which has the potential to eliminate the need for multiple films of the breast in order to make a clinical assessment of the presence of cancerous tissue. The technology has the potential to reduce the number scans for the patient, thereby reducing the amount of time the patient has to spend in a painful position and reducing the costs of scanning for both the patient and the hospital.

While this equipment will be present purely for research purposes, WFUHS recognizes that the PEM will employ "radioactive substances to examine the metabolic activity of various body structures" as defined by §131E-176(14e). However, due to the complete dedication of the technology to research, WFUHS humbly suggests that this technology is more appropriately addressed by the research exemption Statute and Administrative Rule. WFUHS does not intend to use his equipment to offer a new institutional health service as defined by §131E-176(16).

The PEM equipment that will be loaned under this agreement is the PEM Flex™ PET Scanner. Please see Exhibit 3 for detailed specifications. The proposed PEM equipment will be housed in the Ardmore Plaza Outpatient Radiology Department until such time as the department moves to the Outpatient Comprehensive Cancer Center. The equipment is portable and there are no expenses associated with moving the equipment within the Medical Center.

Please provide written documentation that the proposed loan of PEM technology for the purposes of research evaluation as described in this letter is exempt from CON law as defined in N.C. General Statute §131E-179 and Administrative Rule 10A NCAC 14C.0301. If you have any questions or need additional information, please do not hesitate to call me at (336) 716-5097. On behalf of WFUHS, I appreciate your attention to this important matter.

Sincerely,



Michael L. Freeman
Vice President, Strategic Planning
Wake Forest University Baptist Medical Center

Exhibits

Exhibits

Exhibit 1

NOV 24 2003

November 21, 2003

Michael Freeman
Vice President, Strategic Planning
Wake Forest University Health Sciences
Medical Center Boulevard
Winston Salem, NC 27157

Dear Mr. Freeman:

This letter sets forth the terms on which Naviscan PET Systems, Inc. is providing its PEM Flex device to Wake Forest University Health Sciences.

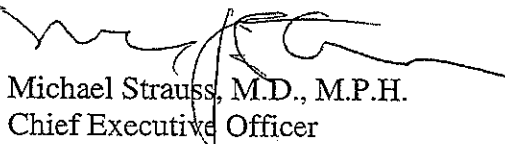
The PEM Flex device is to be used solely for research purposes. Naviscan will work with Wake Forest University Health Sciences to establish the protocols to be used in the research.

Naviscan will provide the PEM Flex device to Wake Forest University Health Sciences at no cost to Wake Forest University Health Sciences.

The PEM Flex device is a mobile device. As such, Naviscan reserves the right to remove the device at any time for a period of days or weeks, given the understanding that we will return the device to Wake Forest University Health Sciences for completion of the research. No costs will be charged to Wake Forest University Health Sciences in the event of removal.

Naviscan will provide the device to Wake Forest University Health Sciences on a temporary basis, for a period of 12 months, which is the term we have agreed, is required to collect the data from the protocols. At the end of 12 months, we can determine if the research should continue. If continued, the parameters set forth above will apply to the continuation. The 12 month period may be shortened in the event of a change in circumstances with respect to the research.

Sincerely,



Michael Strauss, M.D., M.P.H.
Chief Executive Officer

Exhibit 2



Naviscan PET Systems, Inc.
7617 Standish Place
Rockville, MD 20855
301-315-2001 fax 301-315-2081

PEM Flex™ PET Scanner

September 2003

List Price: \$750,000

Fair Market Value: \$590,000

Exhibit 3

Product Data Sheet PEM Flex™ PET Scanner

The PEM Flex™ PET Scanner is a dedicated, high resolution PET scanner specifically designed for imaging small body parts (e.g., breast, hand, brain).

- PET Design: • Partial-ring
- Detectors: • Lutetium-based
• Detector heads move to accommodate prescribed field-of-view and provide access for procedures
• Self-calibrating
• 2.0 mm FWHM intrinsic spatial resolution
- Configuration: • Can be configured as stand-alone unit, or can be placed on the MultiCare™ Stereotactic Table for anatomic correlation.
• Accepts video outputs for anatomic co-registration with other imaging modalities.
- Resolution: • High spatial resolution
 - 2.5 mm FWHM in-plane spatial resolution
 - 5 mm FWHM between-plane resolution
- Scan Times: • Variable. Typical scan time 10-minutes.
- Field-of-View: • 175 x up to 235 mm.
- Count-Rate Capability: • Peak true rate of 10.1 kcps is reached at activity concentration 9.25 kBq/mL. Peak NEC rate of 6.2 kcps is reached at activity concentration 7.5 kBq/mL
- Uniformity: • 12% RMS
- Spatial Linearity: • < 0.5mm over 12 cm length
- Energy Resolution: • Typical 14.3% FWHM maximum at 511 keV

- System Sensitivity: • 566 counts/sec/MBq, using sleeve NEMA NU-2 2001 Phantom
- Coincident Timing Window: • 10 ns.
- Power Requirements: • 120 VAC +/-10%; single phase 60 Hz +/-5%;
2.1A type, 4 Amax
- UPS/Battery Back-Up: • Run time 15 minutes
• Power conditioning
- Operating Environment: • Temperature: 15 to 30C, stable within +/-5C/hour
Humidity: 30 to 75%
- Storage Environment: • Temperature: -20 to 70C
Relative humidity: 10 to 95% non-condensing
- Workstation: • LINUX operating system, SCSI Harddrive 37.5 GB, 3 ¼ floppy drive, DVD, Video digitizer, 16 MB graphics adapter, dual Pentium processor.
- Quality Control: • Point Source Q/C Phantom

Size & Weights

- Workstation • Dimensions (in): 13(W) x 15(H) x 9(D)
• Weight: 21lbs.
- Display Monitor • Dimensions with stand (cm): 40(W) x 40-50(H) x 20(D)
• Weight: 28lbs
• Viewable Size: 18.1"
• Video Input: DVI
• Resolution: 1280 x 1024
• Keyboard/mouse: Co-mark 8280 combo, NEMA 12 sealed
- Compression-side Assembly • Includes Detector Stage & PEM Compression Tray
• Overall Dimensions (cm): 26(W) x 22(H) x 8(D)
• Weight: 12lbs
- Support-side Assembly • Includes Detector Stage & PEM Compression Tray
• Overall Dimensions (cm): 32(W) x 31(H) x 10(D)
• Weight: 13lbs

Stand-Alone Base	<ul style="list-style-type: none"> • Includes Compression & Support Side Assemblies • Overall Dimensions (cm): 320(W) x 15(H) x 54(D)
Cart	<ul style="list-style-type: none"> • Includes locking casters and storage bin for paddles • Dimensions: H 40", D 25", W 28.5" • Weight: 40lbs
Standard Components	<ul style="list-style-type: none"> • 18x24 detector support/patient support • 18x24 compression paddle detector support w/access window • Stand-Alone Support Base <hr/> <ul style="list-style-type: none"> • Operator Console w/cart • Software for Image Acquisition, Image Correlation, Archiving and ROI Analysis • DICOM 3.0 print • Splitter Cable for Digital Image Correlation • Operator's Manual • Service Manual • Tool Kit
Optional Accessories	<ul style="list-style-type: none"> • DICOM 3.0 Storage, Query, Retrieve, Modality Worklist, Bolsters for Stand-Alone Use