



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

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Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

July 24, 2015

Catharine W. Cummer, Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd, Suite 1300
Durham NC 27707

Exempt from Review – Proposed Research Activity

Record #: 1660
Facility Name: Duke University Hospital
Type of Facility: Hospital
FID #: 943138
Business Name: Duke University Health System
Business #: 639
Project Description: Acquire CT scanner for a research trial
County: Durham

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that based on your letter of July 14, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-179. Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project. 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,

Michael J. McKillip
Project Analyst

Martha J. Frisone
Assistant Chief, Certificate of Need

cc: Construction Section, DHHS
Acute and Home Care Licensure and Certification Section, DHHS
Assistant Chief, Healthcare Planning



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

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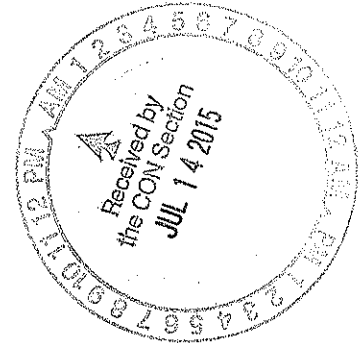
Duke University Health System

Catharine W. Cummer
Regulatory Counsel, Strategic Planning

July 14, 2015

Via Electronic Mail

Ms. Martha Frisone
Assistant Chief
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704



Re: Exempt research project at Duke University Hospital

Dear Ms. Frisone:

I am writing to notify you of the acquisition of a CT scanner at the Duke University Hospital and to seek confirmation that this acquisition is exempt from CON requirements.

Duke University Hospital (DUH) intends to acquire a newly developed state-of-the-art CT scanner, General Electric's (GE) Revolution CT and install it into an existing bay in the hospital's Cancer Center. It would use the scanner for research purposes only for approximately 4 months. We then plan to transition it to clinical use at the end of the proposed research trial, taking an existing 10-year-old CT scanner out of service at that time.

Research use

We understand that the initial acquisition is exempt from certificate of need requirements under NCGS § 131E-179. Duke will be acquiring for research use a GE Revolution CT with Gemstone Spectral Imaging (GSI), which be installed in the hospital's Cancer Center.

This project will not:

- (1) 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;
- (2) Change the bed capacity of the facility; or
- (3) Substantially change the medical or other patient care services of the facility.

While it is designated as a research-only scanner, Duke will not bill patients or payors for services on this equipment.

Conversion to clinical use/replacement of existing clinical scanner

At the end of the research trial, Duke intends to replace an existing clinical CT scanner with this GE Revolution CT and begin using the new equipment as a clinical scanner, taking the existing scanner out of service. As the net effect is no increase in the number of clinical CT scanners operated by Duke University Hospital, we understand that this conversion from research to clinical use would be exempt as the acquisition of replacement equipment under N.C.G.S. 131E-184(f). That exemption requires the following:

- (1) The equipment being replaced is located on the main campus.
- (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
- (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

As set forth below, we believe that this replacement is exempt from certificate of need review.

(1) Main Campus

The purpose of this project is to replace a CT scanner that, after replacement, will be located in the part of Duke University Hospital identified as the Cancer Center, which is located on the main campus of Duke University Hospital. The "main campus" of the facility is defined in N.C.G.S. 131E-176(14n) to include both "[t]he site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building" and "[o]ther areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building."

In this case, Duke University Hospital is a licensed health service facility and the main hospital building from which Duke University Hospital provides its clinical services and exercises financial and administrative control is the physically contiguous structure that includes Duke South, Duke North, the Duke Children's Hospital, the Duke Medical Pavilion, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the Hudson Building. The existing equipment to be replaced is currently located in Duke North. We would note that a different existing scanner will be relocated from the Cancer Center into that location in Duke North when the equipment to be replaced is removed from service. The new scanner will remain

Ms. Martha Frisone
July 14, 2015
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in the Cancer Center. Thus, the total number of clinical CT scanners to be operated in the Cancer Center (and in the hospital overall) will remain the same.

(2) Previous Certificate of Need

As set forth in the correspondence attached as Exhibit A, Duke received confirmation in 2005 that the acquisition of the existing equipment did not require certificate of need review.

(3) Replacement Equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions. A completed Equipment Comparison Form is enclosed as Exhibit B. Both the existing equipment and the replacement equipment provide CT procedures. The total project cost exceeds \$2,000,000 reflecting equipment and installation expenses. A copy of the equipment quotation is available upon request. Duke will not acquire any other major medical equipment or develop any other new institutional health services other than those described in Section 131E-176(16)(b). The planned replacement is anticipated to occur on or before March 1, 2016.

Conclusion

We would appreciate your confirmation that both phases of the project – the initial acquisition for research use and the subsequent conversion to clinical use – are exempt from CON review. Please let me know if you have any questions or if we can provide you any further information.

Very truly yours,



Catharine W. Cummer

Enclosures

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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 28, 2005

Duncan Yaggy, Chief Planning Officer
Duke University Health System
3100 Tower Boulevard
Suite 600, Box 80
Durham, NC 27707

RE: Exempt from Review/Duke University Health System/Replace existing GE QX/1 Lightspeed computed tomography (CT) scanner with a GE Lightspeed VCT CT scanner/Durham County FID # 943138

Dear Mr. Yaggy:

In response to your letter of January 20, 2005, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the GE Lightspeed VCT CT scanner to replace the existing GE QX/1 Lightspeed CT scanner [Serial # 346669CNS]. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

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,

Michael J. McKillip, Project Analyst

for
Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DFS



Exhibit A



DUKE UNIVERSITY HEALTH SYSTEM

Duncan Yaggy
Chief Planning Officer

January 20, 2005

Mr. Michael McKillip, Project Analyst
Ms. Lee Hoffman, Chief
Certificate of Need Section
Division of Facility Services
Department of Health & Human Services
2704 Mail Services Center
Raleigh, NC 27699-2704

Re: Replacement of CT Scanner in Room J3 of Duke Hospital (North)

Dear Mr. McKillip and Ms. Hoffman:

The purpose of this letter is to request your written confirmation that the replacement of the CT scanner in Room J3 of Duke Hospital North at a total capital cost of \$726,789.82 will not require certificate of need review.

To facilitate your consideration of this request we provide below and in the exhibits enclosed with this letter our responses to the issues listed in the Section's standard letter requesting additional information from those proposing equipment replacement projects. The numbering below follows the numbering in the Section's letter:

1. A comparison of the existing and replacement equipment, using the prescribed format, is enclosed as Exhibit 1.
2. A description of the basic technology and functions of the existing equipment and the replacement equipment, including the diagnostic and treatment purposes for which the equipment is used or capable of being used, is provided in the brochures enclosed as Exhibits 2 and 3.
3. A brochure describing the capabilities of the existing equipment is enclosed as Exhibit 2. A brochure describing the capabilities of the replacement equipment is enclosed as Exhibit 3.

Page Two

4. A copy of the purchase order for the existing equipment, including all components and the original purchase price, is enclosed as Exhibit 4.

5. Not applicable. The existing equipment was purchased by Duke University, and it is owned by Duke University Health System, but no title was issued.

6. Not applicable. The replacement equipment will not be leased.

7. A copy of the quotation for the replacement equipment from General Electric is enclosed as Exhibit 5. The quotation shows the list price (\$1,363,873.02), the selling price after discount (\$761,782.82), the amount General Electric is allowing for the trade-in of the existing equipment (\$45,000), and the amount Duke will pay net (\$716,789.82).

8. A letter from the person taking possession of the existing equipment is enclosed as Exhibit 6. Please note that the letter conforms with the Section's requirements.

9. A letter documenting that the existing equipment is still in use and has not been taken out of service is enclosed as Exhibit 7.

Also enclosed, as Exhibits 8 and 9, are completed Proposed Total Capital Cost of Project and attestation forms. Please note that there is no attestation by an architect or engineer on Exhibit 9 because this project involves no "construction related costs."

Thank you for your consideration of this request. If you have questions or need further information, please let me know.

Sincerely,



Duncan Yaggy

DY:dw

Enclosures

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	CT scanner	CT scanner
Manufacturer of Equipment	General Electric	General Electric
Tesla Rating for MRIs	NA	NA
Model Number	CT/i	Lightspeed 16
Serial Number	277521CN1	TBD
Provider's Method of Identifying Equipment	GE Identifier: 919684J3	TBD
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/MIN #	NA	NA
Mobile Tractor Serial Number/Min #	NA	NA
Date of Acquisition of Each Component	19-Sep-95	Mar-05
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	NA	\$ 726,789.82
Total Cost of Equipment	\$ 677,625.00	\$ 716,789.82
Fair Market Value of Equipment	NA	\$ 716,789.82
Net Purchase Price of Equipment	NA	\$ 716,789.82
Locations Where Operated	Durham, NC	Durham, NC
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	No Change
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	1.9%
Type of Procedures Currently Performed on Existing Equipment	Computerized Tomography	NA
Type of Procedures New Equipment is Capable of Performing	NA	Computerized Tomography

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name:

Provider/Company:

A. Site Costs

(1) Full purchase price of land		\$ _____	
Acres _____ Price per Acre \$ _____			
(2) Closing costs	\$ _____		
(3) Site Inspection and Survey		\$ _____	
(4) Legal fees and subsoil investigation		\$ _____	
(5) Site Preparation Costs			
Soil Borings.....	\$ _____		
Clearing-Earthwork...	\$ _____		
Fine Grade For Slab...	\$ _____		
Roads-Paving.....	\$ _____		
Concrete Sidewalks....	\$ _____		
Water and Sewer.....	\$ _____		
Footing Excavation....	\$ _____		
Footing Backfill.....	\$ _____		
Termite Treatment....	\$ _____		
Other (Specify).....	\$ _____		
Sub-Total Site Preparation Costs		\$ _____	
(6) Other (Specify)		\$ _____	
(7) Sub-Total Site Costs			\$ 0

B. Construction Contract

(8) Cost of Materials			
General Requirements	\$ _____		
Concrete/Masonry	\$ _____		
Woods/Doors & Windows/Finishes	\$ _____		
Thermal & Moisture Protection	\$ _____		
Equipment/Specialty Items	\$ _____		
Mechanical/Electrical	\$ _____		
Other (Specify)	\$ _____		
Sub-Total Cost of Materials.....		\$ 143,698	
(9) Cost of Labor.....		\$ 95,798	
(10) Other (Specify).....		\$ _____	
(11) Sub-Total Construction Contract			\$239496

C. Miscellaneous Project Costs

(12) Building Purchase.....		\$ _____	
(13) Fixed Equipment Purchase/Lease		\$1,805,358	
(14) Movable Equipment Purchase/Lease		\$ _____	
(15) Furniture		\$ 550	
(16) Landscaping		\$ _____	
(17) Consultant Fees			
Architect and Engineering Fees	\$ 17,450		
Legal Fees.....	\$ _____		
Market Analysis.....	\$ _____		
Other (Specify).....	\$ _____		
Other (Specify).....	\$ _____		
Sub-Total Consultant Fees.....		\$ 17,450	
(18) Financing Costs (e.g. Bond, Loan, etc.).		\$ _____	
(19) Interest During Construction.		\$ _____	
(20) Other (Specify)		\$ _____	
(21) Sub-Total Miscellaneous..			\$ 1,823,358
(22) Total Capital Cost of Project (Sum A-C above)			\$ 2,062,854

I certify that, to the best of my knowledge, the costs of the proposed project named above are complete and correct.

Paul Grogan _____ Date Certified: 7-9-15
 (Signature of Licensed Architect or Engineer)

I assure that, to the best of my knowledge, the above costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

_____ Date Signed: _____
 (Signature and Title of Officer Authorized to Represent Provider/Company)

EQUIPMENT COMPARISON
DUH CT J3 Replacement

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	CT	CT
Manufacturer of Equipment	GE Medical Systems	GE Medical Systems
Tesla Rating for MRIs	n/a	n/a
Model Number	GE LightSpeed	GE Revolution CT
Serial Number	370891CN44	To be determined
Provider's Method of Identifying Equipment	Asset #140866	To be determined
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	n/a	n/a
Mobile Tractor Serial Number/VIN #	n/a	n/a
Date of Acquisition of Each Component	2005	To be determined - 2015
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$ 716,789.82	\$ 2,062,854
Total Cost of Equipment	\$ 716,789.82	\$ 1,763,385
Fair Market Value of Equipment	\$ 50,000.00	\$ 2,020,680
Net Purchase Price of Equipment	\$ 716,789.82	\$ 1,713,385
Locations Where Operated	Duke University Hospital Duke North	Duke University Hospital Cancer Center
Number Days In Use/To be Used in N.C. Per Year	365	250
Percent of Change in Patient Charges (by Procedure)	NA	0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0
Type of Procedures Currently Performed on Existing Equipment	CT procedures	NA
Type of Procedures New Equipment is Capable of Performing	NA	CT procedures

*Total Cpt Cost = FPDC 1,999,954 + Training 62,900 = \$2,062,854

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name:
 Provider/Company:

A. Site Costs

- (1) Full purchase price of land
 Acres _____ Price per Acre \$ _____
- (2) Closing costs \$ _____
- (3) Site Inspection and Survey \$ _____
- (4) Legal fees and subsoil investigation \$ _____
- (5) Site Preparation Costs
 - Soil Borings..... \$ _____
 - Clearing-Earthwork... \$ _____
 - Fine Grade For Slab... \$ _____
 - Roads-Paving..... \$ _____
 - Concrete Sidewalks.... \$ _____
 - Water and Sewer..... \$ _____
 - Footing Excavation.... \$ _____
 - Footing Backfill..... \$ _____
 - Termite Treatment.... \$ _____
 - Other (Specify)..... \$ _____
- Sub-Total Site Preparation Costs \$ _____
- (6) Other (Specify) \$ _____
- (7) Sub-Total Site Costs \$ _____

B. Construction Contract

- (8) Cost of Materials
 - General Requirements \$ _____
 - Concrete/Masonry \$ _____
 - Woods/Doors & Windows/Finishes \$ _____
 - Thermal & Moisture Protection \$ _____
 - Equipment/Specialty Items \$ _____
 - Mechanical/Electrical \$ _____
 - Other (Specify) \$ _____
- Sub-Total Cost of Materials..... \$ 143,698
- (9) Cost of Labor..... \$ 95,798
- (10) Other (Specify)..... \$ _____
- (11) Sub-Total Construction Contract \$ 239,496

C. Miscellaneous Project Costs

- (12) Building Purchase..... \$ _____
- (13) Fixed Equipment Purchase/Lease \$ 1,805,358
- (14) Movable Equipment Purchase/Lease \$ _____
- (15) Furniture \$ 550
- (16) Landscaping \$ _____
- (17) Consultant Fees
 - Architect and Engineering Fees \$ 17,450
 - Legal Fees..... \$ _____
 - Market Analysis..... \$ _____
 - Other (Specify)..... \$ _____
 - Other (Specify)..... \$ _____
- Sub-Total Consultant Fees..... \$ 17,450
- (18) Financing Costs (e.g. Bond, Loan, etc.). \$ _____
- (19) Interest During Construction. \$ _____
- (20) Other (Specify) \$ _____
- (21) Sub-Total Miscellaneous.. \$ 1,823,358
- (22) Total Capital Cost of Project (Sum A-C above) \$ 2,062,854

I certify that, to the best of my knowledge, the costs of the proposed project named above are complete and correct.

Paul Grogan
 (Signature of Licensed Architect or Engineer)

Date Certified: 7-9-15

I assure that, to the best of my knowledge, the above costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

[Signature]
 (Signature and Title of Officer Authorized to Represent Provider/Company)

Date Signed: 7/12/15