



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

Pat McCrory  
Governor

Richard O. Brajer  
Secretary DHHS

Mark Payne  
Assistant Secretary for Audit and  
Health Service Regulation

June 17, 2016

Catharine W. Cummer  
3100 Tower Blvd  
Suite 1300  
Durham, NC 27707

**Exempt from Review – Replacement Equipment**

**Record #:** 1963  
**Facility Name:** Duke University Hospital  
**FID #:** 943138  
**Business Name:** Duke University Health System  
**Business #:** 639  
**Project Description:** Replace existing MRI scanner in the Morris Clinic and the temporary utilization of an existing dedicated research MRI scanner to be used for radiation oncology treatment planning until the replacement MRI scanner is installed  
**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 June 14, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(f). Therefore, you may proceed to acquire, without a certificate of need, a Siemens Skyra fixed MRI scanner and to temporarily utilize the existing dedicated research MRI scanner located in Duke North for planning radiation oncology treatment until the replacement MRI scanner is installed in the Morris Clinic. 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.

Moreover, 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 the 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 office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.



**Healthcare Planning and Certificate of Need Section**

[www.ncdhhs.gov](http://www.ncdhhs.gov)

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

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

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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Ms. Catharine W. Cummer  
June 17, 2016  
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Sincerely,



Bernetta Thorne-Williams  
Project Analyst

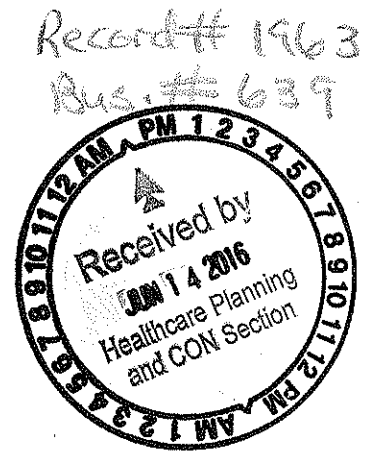


Martha J. Frisone,  
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR  
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR

# Duke University Health System

Catharine W. Cummer  
Regulatory Counsel, Strategic Planning



June 14, 2016

Via Electronic Mail

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

Re: Exempt Replacement Project at Duke University Hospital

Dear Ms. Frisone:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of an MRI scanner used for radiation oncology treatment planning at Duke University Hospital satisfies the requirements under N.C.G.S. 131E-184(f) for "replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:

- (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 Duke University Hospital's project meets these requirements and is exempt from certificate of need review.

(1) Main Campus

The purpose of this project is to replace existing MRI equipment operated in the Morris Clinic 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.

(2) Previous Certificate of Need

The Certificate of Need for the existing equipment is attached as Exhibit A.

(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 MRI procedures for planning radiation oncology treatments. 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).

Temporary use of research scanner as replacement

In addition, we would request your confirmation that during the period when the radiation oncology MRI equipment is out of service due to the construction and replacement of the equipment, Duke University Hospital may use an existing dedicated research MRI scanner located in Duke North for these clinical procedures, for which it would seek reimbursement from payors as appropriate during this period. When the new equipment is installed and operational, Duke would discontinue the use of the research scanner for clinical procedures and return it to dedicated research use. At no time would Duke operate more than its approved complement of MRI scanners for clinical use. It is our understanding that this temporary replacement would be exempt from review under N.C.G.S. 131E-184(a)(7) and/or 184(f), and we would appreciate your confirmation of this understanding.

Martha Frisone  
June 14, 2016  
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Thank you for your attention to this request. We currently plan to start the replacement project on July 5, 2016. If you have questions about this information, please let me know.

Very truly yours,



Catharine W. Cummer

Enclosures

# STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services

## CERTIFICATE OF NEED

for

Project Identification Number J-6295-00

FID #943138

ISSUED TO: Duke University Health System  
3100 Tower Boulevard, Box 80  
University Tower, Suite 1300  
Durham, NC 27707

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)c. 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: Duke University Health System shall acquire one MRI scanner to be used in planning radiation oncology treatments and as a device to treat patients undergoing hyperthermia treatment Durham County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Duke University Hospital  
3000 Erwin Road  
Durham, NC 27710

MAXIMUM CAPITAL EXPENDITURE: \$5,799,900

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: September 1, 2001

This certificate is effective as of the 21<sup>st</sup> day of May, 2001.

*Yee D. Hoffman*  
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Chief, Certificate of Need Section  
Division of Facility Services

EXHIBIT A

## CONDITIONS

1. Duke University Health System shall not acquire, as part of this project, equipment that is not included in the capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.
2. Duke University Health System, Inc., shall materially comply with all representations made in the certificate of need application and the supplemental information submitted to the Agency Dated March 22, 2001. In those instances in which any of these representations conflict, Duke University Health System shall materially comply with the last-made representation.

## TIMETABLE

Completion of final drawings and specifications	July 1, 2001
Approval of final drawings and specifications by Construction Section, DFS	August 1, 2001
Approval of Site by Construction Section, DFS	August 1, 2001
Contract Award	August 1, 2001
25% completion of construction	December 1, 2001
50% completion of construction	April 1, 2002
75% completion of construction	September 1, 2002
Ordering equipment	September 1, 2002
Completion of construction	March 3, 2003
Arrival of equipment	July 1, 2003
Occupancy/offering of service(s)	July 1, 2003

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	GE	Siemens
Tesla Rating for MRIs	1.5	3
Model Number	Signa	Skyra
Serial Number	1261WH7	To Be Determined
Provider's Method of Identifying Equipment	Serial number	Serial number
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #		
Date of Acquisition of Each Component	FY2004	FY2017
Does Provider Hold Title to Equipment or Have a Capital Lease?	New	Will be new
Specify if Equipment Was/Is New or Used When Acquired		
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$1,600,000	\$2,096,824
Total Cost of Equipment		
Fair Market Value of Equipment		
Net Purchase Price of Equipment		
Locations Where Operated	Duke Hosp, Radiation Oncology	Duke Hosp, Radiation Oncology
Number Days In Use/To be Used in N.C. Per Year	365	365
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	MRI imaging	NA
Type of Procedures New Equipment is Capable of Performing	NA	M&I Imaging