



**North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director**

2701 Mail Service Center • Raleigh, North Carolina 27699-2701
<http://www.ncdhhs.gov/dhsr/>

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Phone: 919-855-3750
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January 22, 2013

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

Exempt from Review - Replacement Equipment


Facility: Duke University Health System d/b/a Duke University Hospital
Project Description: Replace MRI scanner
County: Durham
FID #: 943138

Dear Ms. Cumber:

In response to your letter of January 16, 2013, 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 1.5T Discovery MRI scanner to replace the existing GE 3T MRI scanner [Serial # 51110607-2]. 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,

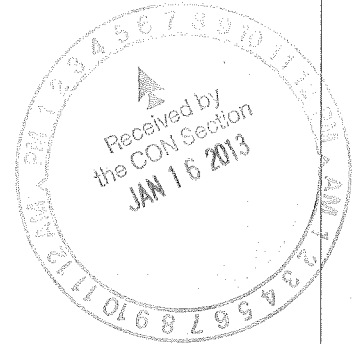

Michael J. McKillip
Project Analyst


Craig R. Smith, Chief
Certificate of Need Section



 **Duke University Health System**

Catharine W. Cummer
Regulatory Counsel, Strategic Planning



January 16, 2013

Via Electronic Mail

Michael J. McKillip, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Equipment Replacement Project at Duke University Hospital – MRI

Dear Mr. McKillip:

I am writing to notify you of the acquisition of a replacement MRI scanner at Duke University Hospital. The existing and replacement equipment both can provide MRI scanning services. A completed equipment comparison form, a capital cost form, and a quote for the new equipment are all enclosed. The total extended selling price reflecting the fair market value of the equipment is \$1,436,636. The installation of the replacement equipment in the new DUH Duke Medical Pavilion building (for which a CON was already issued) will require rigging costs of approximately \$24,000, for a total project cost of \$1,460,636. The existing equipment is currently in use at Duke, but will be removed from service in the state upon placement of the replacement equipment into service.

It is our understanding that this replacement is exempt from certificate of need review as the exempt acquisition of replacement equipment pursuant to N.C.G.S. Section 131E-184. We would appreciate your confirmation of this understanding. Thank you for your attention to this request. Should you have any questions, please let me know.

Very truly yours,

A handwritten signature in cursive script that reads "Catharine W. Cummer".

Catharine W. Cummer

Enclosures

cc: Monte Brown
Britt Crewse

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI Scanner	MRI Scanner
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	3T	1.5T
Model Number	51110607-2	Discovery MR 450w
Serial Number	267373MR9	N/A
Provider's Method of Identifying Equipment	MR 3	N/A
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #		
Date of Acquisition of Each Component	2004	2013
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>		
Total Cost of Equipment	\$1,624,832	\$1,460,636
Fair Market Value of Equipment		\$1,436,636
Net Purchase Price of Equipment	\$1,624,832	\$1,436,636
Locations Where Operated	DUH - Duke North	DUH - DMP
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	MR Imaging	NA
Type of Procedures New Equipment is Capable of Performing	NA	MR Imaging

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: Acquisition of MRI Scanner
 Provider/Company: Duke University Health System d/b/a Duke University Hospital

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.....		\$ _____	
(9) Cost of Labor.....		\$ _____	
(10) Other (Specify).....		\$ _____	
(11) Sub-Total Construction Contract			\$ _____

C. Miscellaneous Project Costs

(12) Building Purchase.....		\$ _____	
(13) Fixed Equipment Purchase/Lease		\$ 1,436,636	
(14) Movable Equipment Purchase/Lease		\$ _____	
(15) Furniture		\$ _____	
(16) Landscaping		\$ _____	
(17) Consultant Fees			
Architect and Engineering Fees	\$ _____		
Legal Fees.....	\$ _____		
Market Analysis.....	\$ _____		
Other (Specify).....	\$ _____		
Other (Specify).....	\$ _____		
Sub-Total Consultant Fees.....		\$ _____	
(18) Financing Costs (e.g. Bond, Loan, etc.).		\$ _____	
(19) Interest During Construction.		\$ _____	
(20) Other (Specify) RIGGING		\$ 24,000	
(21) Sub-Total Miscellaneous..			\$ _____
(22) Total Capital Cost of Project (Sum A-C above)			\$ 1,460,636

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

 (Signature of Licensed Architect or Engineer) Date Certified: _____

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 and Title of Officer Authorized to Represent Provider/Company) Date Signed: 1/14/13

Quotation Number: P8-C152260 V 25

Duke University Hospital
2301 Erwin Rd
Durham NC 27705-4699

Attn: Thomas Boehringer
Radiology Technical Admin.
Erwin Rd
Durham NC 27710

Date: 12-31-2012

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

- 1) This Quotation that identifies the Product offerings purchased or licensed by Customer;
- 2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation. The parties agree that they have not relied on any oral or written terms, conditions, representations or warranties outside those expressly stated or incorporated by reference in this Agreement in making their decisions to enter into this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products, shall constitute an agreement by either party to any such terms.

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

- Terms of Delivery: FOB Destination
- Quotation Expiration Date: 12-31-2012
- Billing Terms: 80% delivery / 20% Installation
- Payment Terms: NET 30
- Governing Agreement: Duke University Health System

Each party has caused this agreement to be signed by an authorized representative on the date set forth below. Please submit purchase orders to GE Healthcare
3200 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GE HEALTHCARE

Scott Ramsey Date
Product Sales Specialist

CUSTOMER

Authorized Customer Date

Print Name and Title

PO #

Desired Equipment First Use Date

GE Healthcare will use reasonable efforts to meet Customer's desired equipment first use date. The actual delivery date will be mutually agreed upon by the parties.

INDICATE FORM OF PAYMENT:

(If there is potential to finance with a lease transaction, GE HFS or otherwise, select lease.)

___ Cash * ___ Lease ___ HFS Loan

If financing please provide name of finance company below*:

*Selecting Cash or not identifying GE HFS as the finance company declines option for GE HFS financing.



Quotation Number: P8-C152260 V 25

Item No.	Qty	Catalog No.	Description	Contract Price	Ext Sell Price
	1		Optima MR450w 1.5T with GEM		
1	1	S4500YP	<p>Optima MR450w with GEM 1.5T MR System - 44/200</p> <p>Patient expectations of MR have shifted in recent years, as patients have begun to demand a better, more comfortable scanning experience. Increasing the size of the bore is a good first step, but it's only the beginning. The right system should overcome traditional limitations of wide-bore MR, offering both excellent images and a user-friendly experience. Patients should be more comfortable during their scan, and clinicians more comfortable in making a diagnosis. All the while, organizations should expect their MR system to help them deliver solid financial returns, maintain a high standard of patient safety, and increase the quality of their care.</p> <p>The Optima MR450w with GEM 1.5T MRI scanner from GE Healthcare offers a range of new functionality, provides a more patient-friendly environment and is a clinical workhorse system for practices of all sizes and specialties.</p> <p>OpTix RF Receive Chain: GE's innovative Optical RF receive technology improves signal detection while simultaneously reducing electrical noise. By locating the receiver electronics on the side of the magnet and close to the origin of the MR signal, interference from external noise sources is reduced thus improving image quality and SNR. The result is a 27% SNR improvement over previous generation, non-optical systems for volumetric scanning.</p> <p>The use of optical transmission reduces the cabling footprint over conventional copper cable designs and enables high channel count configurations without requiring additional space. The OpTix technology can seamlessly route signals from any coil port to the receiver using a dynamic switching RF hub. To enable the simultaneous use of multiple coils, there are multiple high-density coil connections ports conveniently located where the detachable table</p>	\$1,266,000.00	\$435,362.34



Quotation Number: P8-C152260 V 25

Item No.	Qty	Catalog No.	Description	Contract Price	Ext Sell Price
			straps are included.		
32	1	M3335EW	1.5T Unified Coil Phantom Kit Set of phantoms for the 1.5T system that is used on various surface coils to conduct quality assurance testing.	\$3,000.00	\$1,077.60
	1		Optima MR450w 1.5T IB Options		
33	1	M7001FB	Optima MR450w 23.1 Software and Technical Publications	Incl.	Incl.
34	1	M7001DA	Label Collector Kit - English	\$3,000.00	\$1,077.60
35	1	M7000PF	MAVRIC SL MAVRIC SL is a new advanced magnetic resonance imaging technique for imaging soft tissue and bone near MR conditional metallic devices. MAVRIC SL is designed to greatly reduce susceptibility artifacts, compared to conventional fast spin echo techniques, and is suitable for use on all patients cleared for MR exams.	\$65,000.00	\$23,348.03

Quote Summary:

Total Contract List Price:	\$4,171,449.00
Total Discount: (65.56%)	(\$2,734,813.78)
Total Extended Selling Price:	\$1,436,635.22
Total Quote Net Selling Price	\$1,436,635.22

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)

