



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

Pat McCrory  
Governor

Aldona Z. Wos, M.D.  
Ambassador (Ret.)  
Secretary DHHS

Drexdal Pratt  
Division Director

January 15, 2014

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

**Exempt from Review - Replacement Equipment**

Facility: Duke Regional Hospital  
Project Description: Temporarily replace MRI scanner with a mobile MRI scanner  
County: Durham  
FID #: 923142

Dear Ms. Cummer:

In response to your letter of January 13, 2014, the above referenced proposal is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may lease, without a certificate of need, the Alliance Imaging, Inc. mobile MRI scanner to temporarily replace the existing MRI scanner prior to the installation of a permanent replacement MRI scanner. 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 Branch with the serial number of the new equipment to update the inventory, if not already provided.

Moreover, you need to contact the Construction Section 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, Interim Chief  
Certificate of Need Section

cc: Construction Section, DHSR  
Medical Facilities Planning Branch, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR



**Certificate of Need Section**

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

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

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

An Equal Opportunity/ Affirmative Action Employer



# Duke University Health System

*Duke*

Catharine W. Cummer  
Regulatory Counsel, Strategic Planning

January 13, 2014

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: Temporary MRI replacement at Duke Regional Hospital

Dear Mr. McKillip:

On behalf of the Duke University Health System, I am writing to seek confirmation that Duke Regional Hospital may proceed with a proposed arrangement with Alliance Imaging for the temporary use of a mobile MRI scanner without certificate of need review. As background, Duke Regional Hospital received an exemption for the replacement of an existing MRI scanner on its hospital campus by letter dated December 10, 2013. The renovation of the space for the new equipment will take several months during which time the existing scanner must be taken out of operation. In order to ensure continuity of care for patients during the renovation, Duke now proposes to enter into an operating lease with Alliance Imaging for the use of a mobile MRI scanner while the renovation necessary to accommodate the new scanner is underway.

Duke's existing scanner will be removed some time in February 2014. Construction is estimated to last three months. During that time, Alliance will lease Duke a GE MRI 1.5T (with a fair market value of less than \$2 million), which will be staffed by Duke Regional staff. Alliance will remove the equipment upon installation of the permanent replacement scanner, and will not operate it in North Carolina thereafter without approval of the Certificate of Need Section. At no time will Duke operate more than two MRI scanners (Duke has a second scanner that will be unaffected by this project).

Michael J. McKillip  
January 13, 2014

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. If you have questions or need any further information, please let me know.

Very truly yours,



Catharine W. Cummer



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

Pat McCrory  
Governor

Aldona Z. Wos, M.D.  
Ambassador (Ret.)  
Secretary DHHS

Drexdal Pratt  
Division Director

December 10, 2013

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

**Exempt from Review - Replacement Equipment**

Facility: Duke Regional Hospital  
Project Description: Replace MRI scanner  
County: Durham  
FID #: 923142

Dear Ms. Cummer:

In response to your letter of September 16, 2013, 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, the GE 1.5T MRI scanner to replace the existing GE 1.5T MRI scanner [Serial # R0428]. 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 Branch with the serial number of the new equipment to update the inventory, if not already provided.

Moreover, you need to contact the Construction Section 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,

*Martha J. Trisone for*

Michael J. McKillip  
Project Analyst

*Craig R. Smith*  
Craig R. Smith, Chief  
Certificate of Need Section

cc: Construction Section, DHSR  
Medical Facilities Planning Branch, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR



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923142  
9/27/13



# Duke University Health System

**Catharine W. Cummer**  
Regulatory Counsel, Strategic Planning

September 16, 2013

Via Electronic Mail

SEP 18 2013  
Received by  
the CON Section

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 Regional Hospital

Dear Mr. McKillip:

On behalf of the Duke University Health System, I am writing to provide prior written notice of an equipment replacement project and to request the Section's written confirmation that the project is exempt from certificate of need review. The project involves the replacement of an MRI scanner installed in 1999 at Duke Regional Hospital that is out of date and, due to its age, has experienced increasing downtimes.

This project 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."

### Main campus

The existing and replacement MRI scanner are/will be located in the main Duke Regional Hospital building. This is on the "main campus" of the facility, as defined in 131E-176(14n), as "[t]he site of the main building from which a licensed health service facility provides clinical

Michael J. McKillip  
September 16, 2013

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.”

Duke Regional Hospital is a licensed health service facility (see License attached as Exhibit A), and the main hospital building from which Duke Regional Hospital provides its inpatient clinical services and exercises financial and administrative control over all Duke Regional Hospital services is located at 3643 North Roxboro Road in Durham. (As it happens, Duke Regional Hospital’s chief executive office and chief financial officer also have their offices within this same building, in the annex labeled on the hospital map as “Watts.”) Maps showing the campus and identifying the site of the proposed construction are attached as Exhibit B.

#### Previous Certificate of Need

The existing MRI scanner was acquired pursuant to a certificate of need issued for Project J-5589-97, attached as Exhibit C.

#### Replacement Equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definition. A completed Equipment Comparison form enclosed as Exhibit D. Both the existing equipment and the replacement equipment are magnetic resonance imaging scanners used for diagnostic imaging procedures. The existing machine is currently in service and will remain so until the replacement equipment is operational, at which time it will be removed from service within the state unless the Certificate of Need Section otherwise approves its continued use in the state.

In addition to the cost of the equipment, project costs include the construction necessary to install it, renovations to support the provision of general anesthesia to MRI patients, and minor renovation of the existing prep, storage and waiting areas to improve patient comfort, safety and access control. The construction floor plan is attached as Exhibit E. The total project cost is approximately \$2,722,000, of which approximately \$1,353,543 reflects the net purchase price of the new scanner. A copy of the equipment quotation for the proposed GE Optima MR450w 1.5T GEM MR is available upon request. Total construction costs associated with this project are \$787,656.<sup>1</sup> A capital cost form is attached as Exhibit F. 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).

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<sup>1</sup> We would note that even if the renovations were undertaken separately, they would not require a certificate of need as the cost is well under \$2 million, and would presumably be exempt from CON review in any event pursuant to Section 131E-184(g).

Michael J. McKillip  
September 16, 2013

We would appreciate your confirmation that this project is exempt from CON review. Thank you for your attention to this request. If you have questions, please let me know.

Very truly yours,

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

Catharine W. Cummer

Enclosures

# State of North Carolina

Department of Health and Human Services  
Division of Health Service Regulation

*Effective July 01, 2013, this license is issued to*

*Duke University Health System, Inc.*

*to operate a hospital known as*

*Duke Regional Hospital*

*located in Durham, North Carolina, Durham County.*

*This license is issued subject to the statutes of the  
State of North Carolina, is not transferable and shall remain  
in effect until amended by the issuing agency.*

*Facility ID: 923142*

*License Number: H0233*

**Bed Capacity: 369**

*General Acute 316, Rehabilitation 30, Psych 23,*

**Dedicated Inpatient Surgical Operating Rooms: 2**

**Dedicated Ambulatory Surgical Operating Rooms: 0**

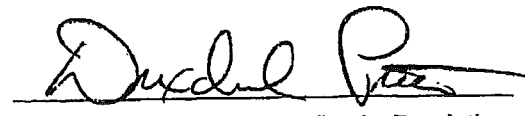
**Shared Surgical Operating Rooms: 13**

**Dedicated Endoscopy Rooms: 4**

Authorized by:



Secretary, N.C. Department of Health and  
Human Services



Director, Division of Health Service Regulation

EXHIBIT A



**CONDITIONS:**

**J-5589-97**

1. CH/Durham Limited Partnership by CHF Washington, Inc. (General Partner) (Lessor) and Duke University (Lessee) shall materially comply with all representations made in the certificate of need application.
2. Duke University shall not increase patient charges as a result of this project.
3. Duke University shall license and certify the Satellite Imaging Center as part of the hospital and shall bill Medicare and Medicaid reimbursement for services provided in the center under Duke University Hospital's provider number.
4. CH/Durham Limited Partnership by CHF Washington, Inc. (General Partner) (Lessor) and Duke University (Lessee) shall acknowledge acceptance and compliance with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

A letter acknowledging acceptance and compliance with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on October 6, 1997.

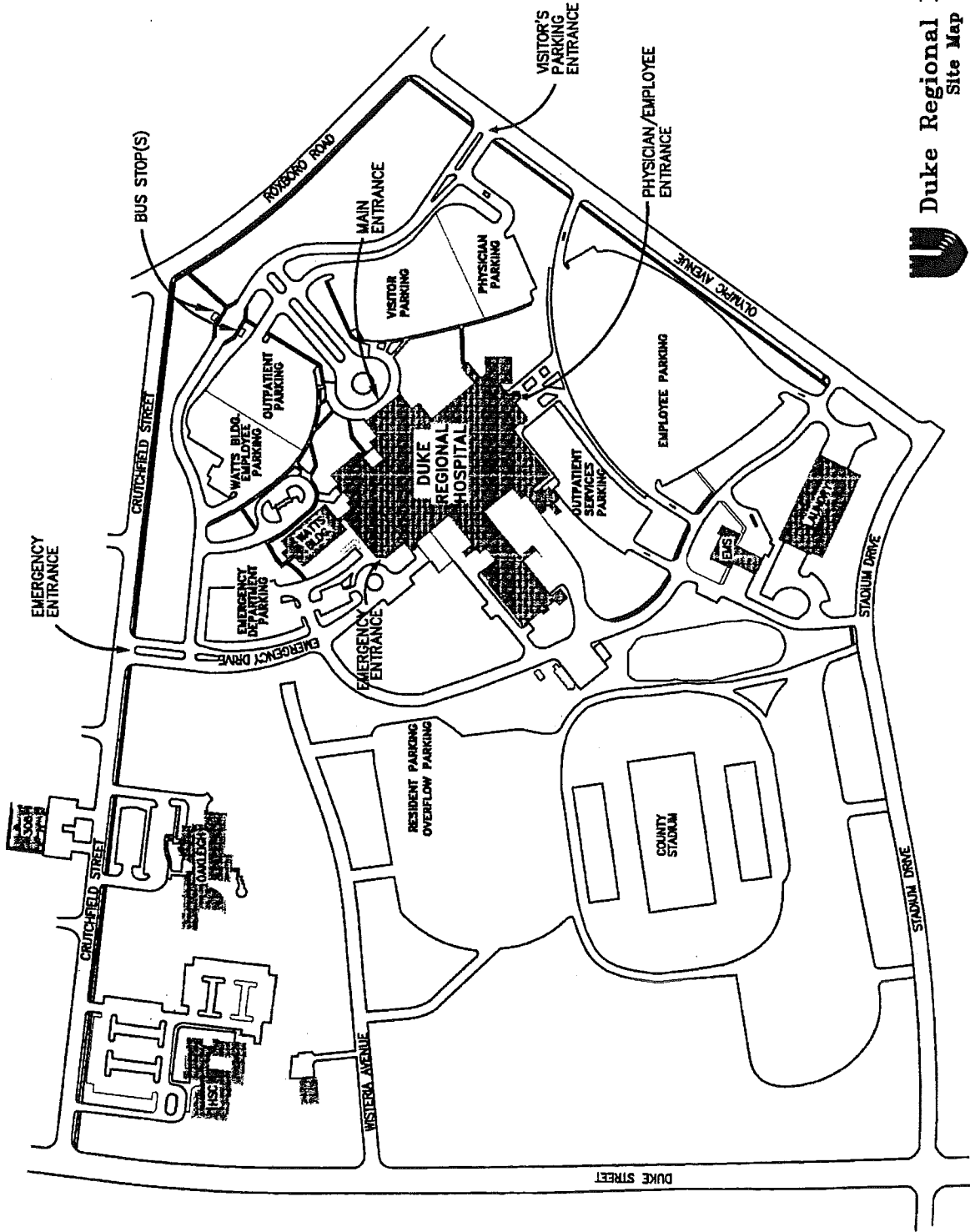
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**TIMETABLE:**

Obtaining construction financing _____	November 1, 1997
Obtaining permanent financing _____	November 1, 1997
Obtaining funds necessary to undertake project _____	November 1, 1997
Completion of preliminary drawings _____	June 1, 1997
Completion of final drawings and specifications _____	October 1, 1997
Approval of final drawings and specifications by Construction Section, DFS _____	November 1, 1997
Approval of Site by Construction Section, DFS _____	November 1, 1997
Contract Award _____	November 15, 1997
25% completion of construction _____	January 15, 1998
50% completion of construction _____	March 15, 1998
75% completion of construction _____	May 15, 1998
Completion of construction _____	July 15, 1998
Occupancy/offering of service _____	August 15, 1998
Ordering equipment _____	November 15, 1997
Arrival of equipment _____	April 15, 1998
Operation of equipment _____	August 15, 1998



**Duke Regional Hospital**  
Site Map



# State of North Carolina

## Department Of Health and Human Services Division Of Facility Services Certificate Of Need

Project Identification Number J-5589-97 Effective Date October 28, 1997

Issued to: Durham Limited Partnership by CHE Washington, Inc. (General Partner) (Lessor)  
University Tower, 3100 Tower Blvd., Box 80 Duke University (Lessee)  
Durham, NC 27707

The North Carolina Department of Health and Human Services, pursuant to the North Carolina Health Planning and Resource Development Act of 1978, G.S. § 131-175, et seq., as amended and recodified, G.S. § 131E-175, et seq., hereby finds and certifies that the new institutional health service proposed by the person listed above is consistent with, or as conditioned is consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. The findings of the Department are attached hereto and incorporated by reference.

This Certificate affords the person listed above the opportunity to proceed with development of the proposed new institutional health service in a manner consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. This Certificate includes and is limited to:

SCOPE: Durham Limited Partnership by CHE Washington, Inc. (General Partner) (Lessor) shall construct space to be added to primary care center and Duke University (Lessee) shall purchase one MRI scanner, one CT scanner and other diagnostic radiological equipment.

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: 6300 Herndon Road  
Durham, NC 27713

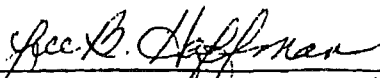
MAXIMUM CAPITAL EXPENDITURE: \$6,136,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: December 15, 1997

This Certificate is limited to the person listed above and is not transferable or assignable. This Certificate may be withdrawn as provided in G.S. § 131E-189, and the rules and regulations promulgated thereunder.

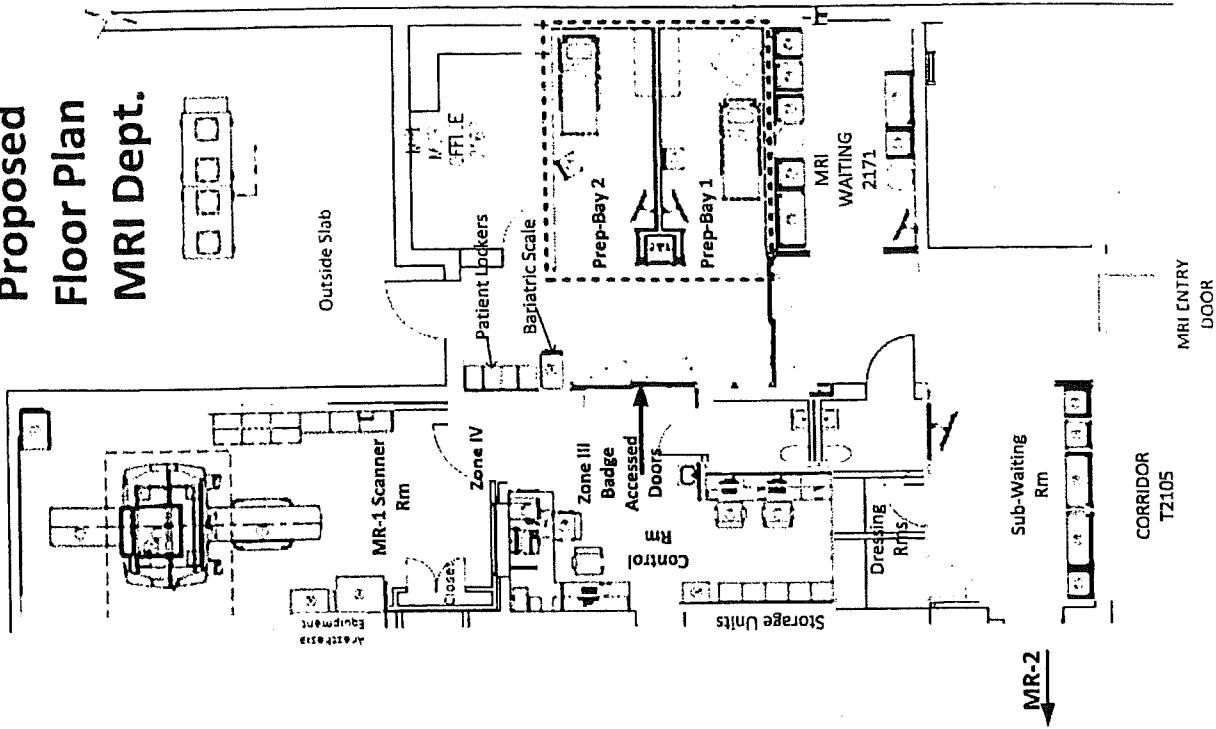
Issuance of this Certificate does not supplant provisions or requirements embodied in codes, ordinances, statutes other than G.S. § 131E-175, et seq., rules regulations or guidelines administered or enforced by municipal, state or federal agencies or the agent thereof.

  
\_\_\_\_\_  
Chief, Certificate of Need Section  
Division of Facility Services

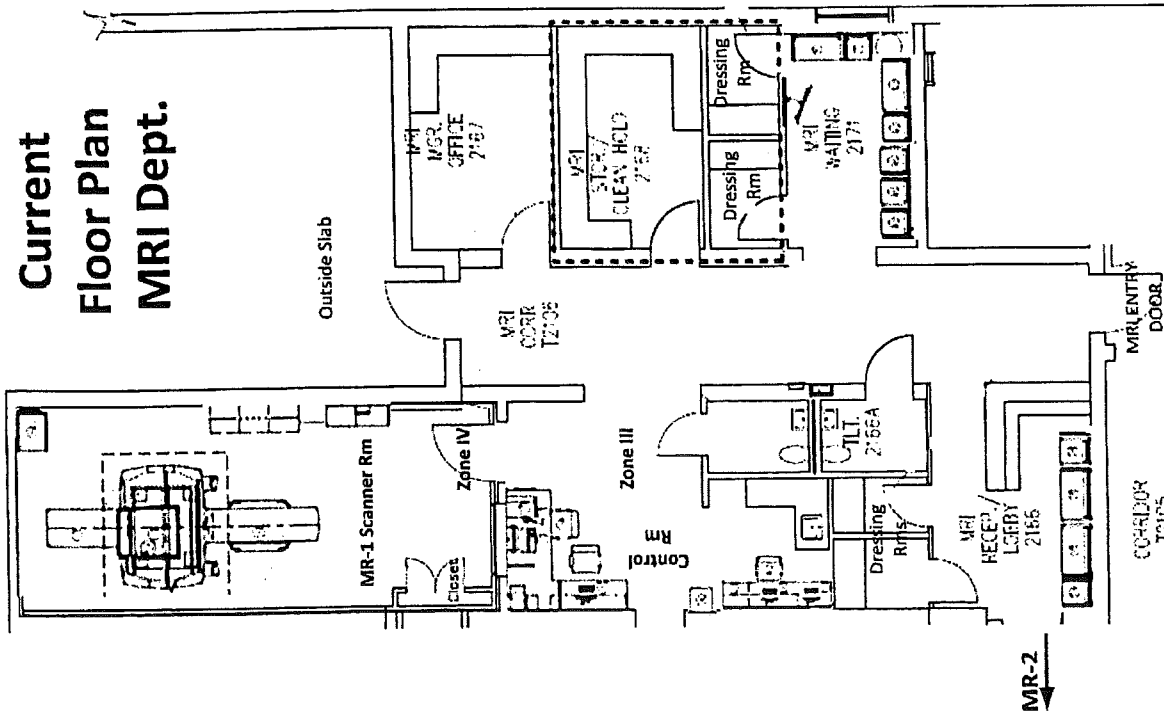
EQUIPMENT COMPARISON - DRH MRI SCANNER

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	1.5T	1.5T
Model Number	HDX	450w
R0428	R0428	NA
Provider's Method of Identifying Equipment	MR-1	Mr-1
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	8/15/99 (software upgrade 2008)	NA
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title (software subject to capital lease)	NA
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	NA	\$2,722,000
Total Cost of Equipment	\$1,979,219 + software upgrade (\$713,810)	\$1,493,543 (includes trade-in allowance)
Fair Market Value of Equipment	\$140,000	\$1,493,543 (includes trade-in allowance)
Net Purchase Price of Equipment	\$1,979,219 + software upgrade (\$713,810)	\$1,353,543 (cost less trade-in)
Locations Where Operated	Duke Regional Hospital	Duke Regional Hospital
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 scanning	NA
Type of Procedures New Equipment is Capable of Performing	NA	MR scanning

# Proposed Floor Plan MRI Dept.



# Current Floor Plan MRI Dept.



**PROJECTED CAPITAL COST**

Project Name: 3422 HSDR DHR MRI 1 Replacement and Renovation

Proponent: \_\_\_\_\_

<b>A. Site Costs</b>			
(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		\$ <u>787,656</u>
<b>B. Construction Contract</b>			
(8)	Cost of Materials		
	General Requirements	\$ _____	
	Concrete/Masonry	\$ _____	
	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		\$ <u>787,656</u>
<b>C. Miscellaneous Project Costs</b>			
(12)	Building Purchase		\$ _____
(13)	Fixed Equipment Purchase/Lease		\$ <u>1,421,529</u>
(14)	Movable Equipment Purchase/Lease		\$ _____
(15)	Furniture		\$ <u>37,490</u>
(16)	Landscaping		\$ _____
(17)	Consultant Fees		
	Architect and Engineering Fees	\$ <u>158,524</u>	
	Legal Fees	\$ _____	
	Market Analysis	\$ _____	
	Other (Permits, Inspection, MR Rent)	\$ <u>196,210</u>	
	Sub-Total Consultant Fees		\$ <u>354,734</u>
(18)	Financing Costs (e.g. Bond, Loan, etc.)		\$ _____
(19)	Interest During Construction		\$ _____
(20)	Other (contingency)		\$ <u>120,591</u>
(21)	Sub-Total Miscellaneous		\$ <u>1,934,344</u>
D.	<b>Total Capital Cost of Project</b>		\$ <u>2,722,000</u>

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

Paul Croonen  
 (Signature of Licensed Architect or Engineer)

Date Certified: 9-10-13

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.

\_\_\_\_\_  
 (Proponent - Signature of Officer) (Title of Officer) Date Signed: \_\_\_\_\_

Effective: 5/16/06