



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

January 14, 2019

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

Exempt from Review – Replacement Equipment

Record #: 2839
Facility Name: Duke Raleigh Hospital
FID #: 923421
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace an existing MRI scanner
County: Wake

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of January 11, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184f. Therefore, you may proceed to acquire without a certificate of need the Siemens Magnetom Vida to replace the existing GE HDX. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Acute and Home Care Licensure and Certification Section, DHSR 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.

Sincerely,

[Handwritten signature of Fatimah Wilson]

Fatimah Wilson
Team Leader

[Handwritten signature of Martha J. Frisone]

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR
Melinda Boyette, Administrative Assistant, Healthcare Planning, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr • TEL: 919-855-3873

Bus # 640
FID # 923421
Record # 2839



Catharine W. Cummer
Regulatory Counsel, Strategic Planning



January 11, 2019

Via Electronic Mail

Ms. Martha Frisone
Mr. Michael McKillip
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Exempt MRI Replacement Project at Duke Raleigh Hospital

Dear Ms. Frisone and Mr. McKillip:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of replacement MRI equipment 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 Raleigh Hospital's project meets these requirements and is exempt from certificate of need review.

(1) Main Campus

Duke Raleigh Hospital is a licensed hospital and is therefore an existing licensed health service facility, and this project will be implemented in the main building from the hospital

Ms. Martha Frisone
Mr. Michael McKillip
January 11, 2019
Page 2

provides clinical patient services and exercises financial and administrative control over the entire facility.

(2) Previous Certificate of Need

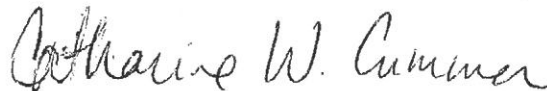
The existing equipment was acquired pursuant to an exemption request dated July 12, 1999, and then upgraded pursuant to another exemption in 2008 (please see attached correspondence).

(3) Replacement equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions. A completed Equipment Comparison form is enclosed. Both the existing equipment and the replacement equipment provide MRI procedures. The total project cost exceeds \$2,000,000 reflecting major medical equipment, related equipment, and renovation/installation expenses. Copies of the equipment quotations are 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), and the existing equipment will be removed by the vendor.

Thank you for your attention to this request. If you have questions about this information, please let me know.

Very truly yours,



Catharine W. Cummer

Enclosures



File

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

Michael F. Easley, Governor
Dempsey Benton, Secretary

www.ncdhrs.gov/dhsr

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

February 4, 2008

Catharine Cummer
149 Cedar Hills Cir.
Chapel Hill NC 27514

RE: No Review/Duke University Health System d/b/a Duke Raleigh Hospital/Upgrade MRI scanner and renovate MRI suite on the first floor of the hospital/Wake County
FID # 912421

Dear Ms. Cummer:

The Certificate of Need (CON) Section received your letter of January 22, 2008 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

In addition, you should contact the Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project. Please contact the CON Section if you have any questions.

Sincerely,

Michael J. McKillip
Project Analyst

Lee B. Hoffman, Chief
Certificate of Need Section

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR





DUKE UNIVERSITY HEALTH SYSTEM

Duncan Yaggy
Chief Planning Officer

July 12, 1999

Ms. Lee B. Hoffman
Chief
Certificate of Need Section
Department of Health & Human Services
Division of Facility Services
P. O. Box 29530
Raleigh, NC 27626-0530

Dear Ms. Hoffman:

The purpose of this letter is to request your confirmation that the proposed replacement of the magnetic resonance imaging (MRI) scanner at Raleigh Community Hospital (RCH) at a total capital cost of \$1,989,886 will not require certificate of need review.

The existing MRI scanner at RCH was acquired in 1987 at a cost of \$1,654,574. The scanner was installed in a medical office building on the RCH campus. It has been upgraded since, most recently in March of this year, and continues in active use.

Replacing the existing scanner with a new scanner of the same field strength (1.5 Tesla) will allow us to take advantage of the advances in MRI technology since 1987, and it will also give us an opportunity to relocate the Hospital's MRI service from the medical office building to the Hospital. As outlined in the enclosed "Rationale of Proposed Location Site," transferring the service to the Hospital will allow us to improve the quality, efficiency, and cost-effectiveness of MRI scanning at RCH.

The total capital cost of the replacement will be \$1,989,886. Components of the project include:

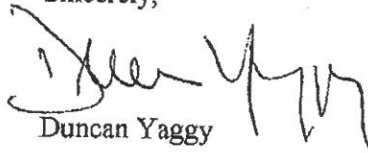
1. New MRI Scanner	\$1,496,586
2. 3/99 Upgrade Transferred from Existing Machine to New Machine	183,300
3. Renovation Costs (inc. A&E)	<u>310,000</u>
Total	\$1,989,886

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Inasmuch as acquisition of the new MRI scanner will not result in an increase of more than 10% in patient charges, and the total cost of the replacement project will be less than \$2 million, we believe that this project qualifies for an exemption from review under Section 131E-184(a)(7), and we would appreciate your letter confirming that.

As always, we would be happy to meet with you or your designee to share copies of the purchase order, the contracts for architecture and engineering and construction and other relevant documents. Please let me know if that would be helpful.

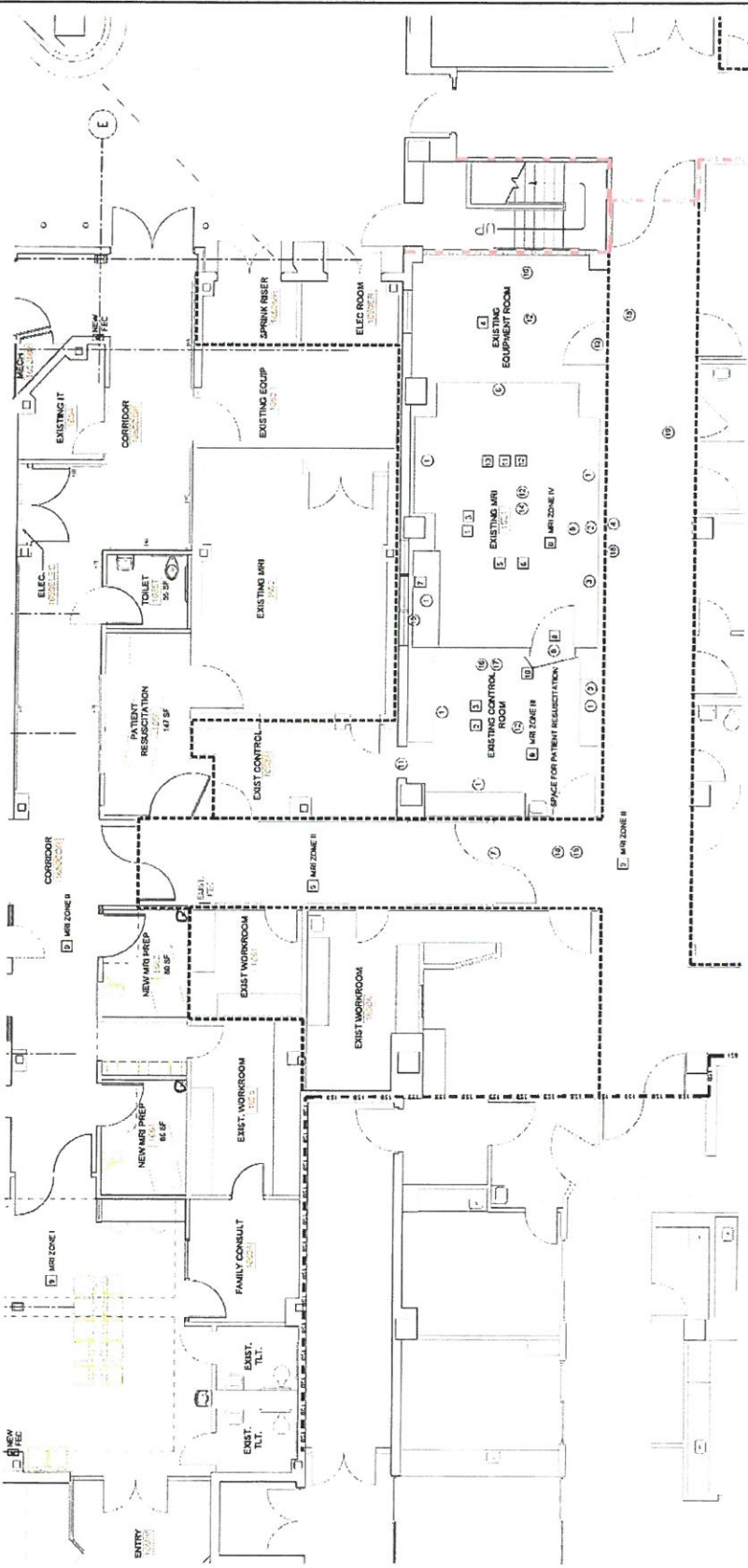
Sincerely,

A handwritten signature in black ink, appearing to read "Duncan Yaggy", written over a printed name.

Duncan Yaggy

DY:dw

cc: Paul Lindia
Mary Ann Ecksteine

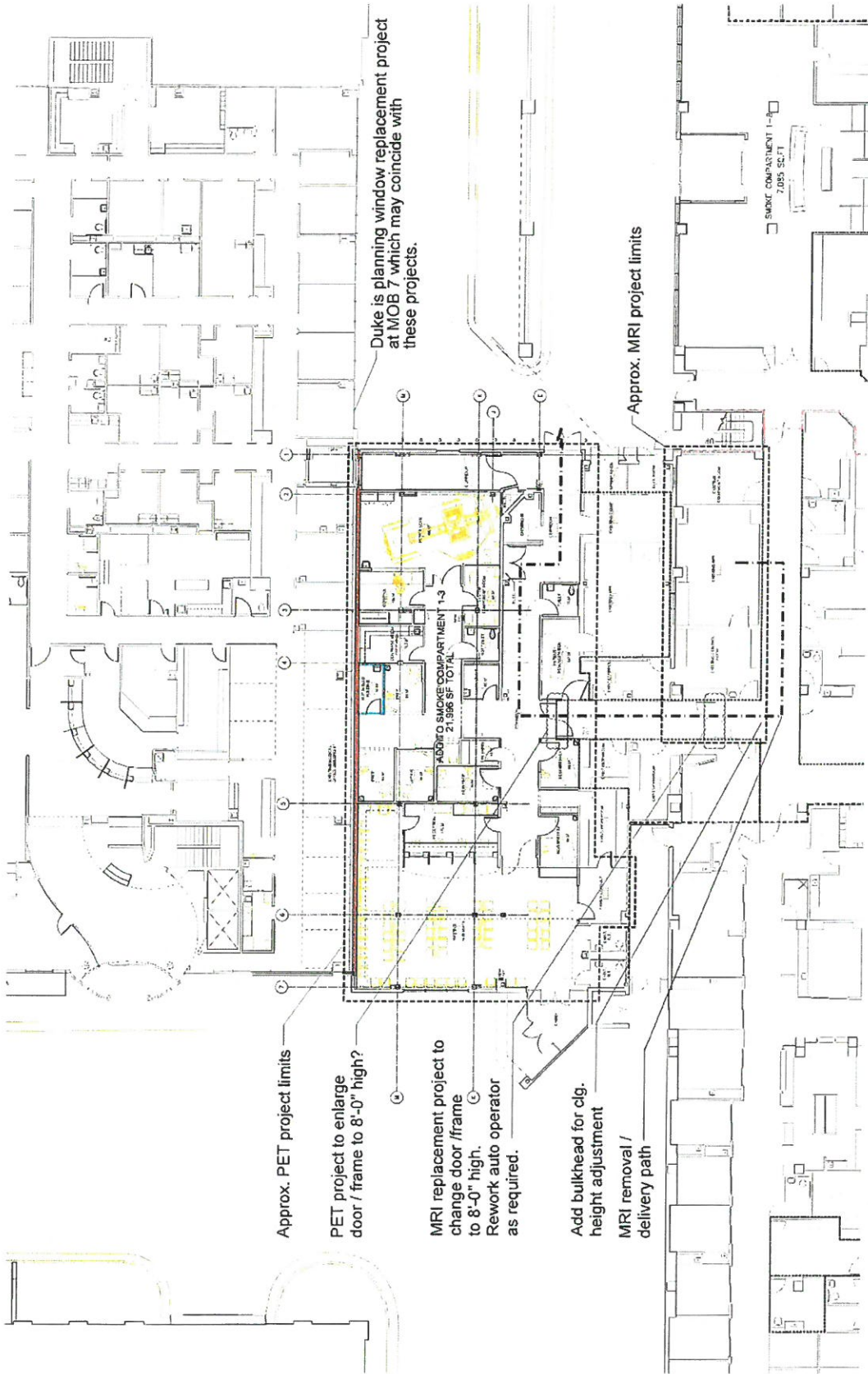


- RENOVATION KEYNOTES**
- 1 NEW CABINETRY - REFER TO CABING SITE / ASCENSION INFO
 - 2 NEW CONTROL ROOM CABINETRY
 - 3 NEW SEAMLESS FLOORING / RUBBER BASE PAINT WALLS
 - 4 NEW WALL FLOORING / RUBBER BASE PAINT WALLS
 - 5 NEW VCT FLOORING / RUBBER BASE PAINT WALLS
 - 6 INSTALL NEW EZE BAY FACTORY LIGHT TUBES
 - 7 REFER TO SEIBERS FINAL SITE SPECIFIC DRAWINGS
 - 8 REFER TO SEIBERS FINAL SITE SPECIFIC DRAWINGS
 - 9 REFER TO SEIBERS FINAL SITE SPECIFIC DRAWINGS
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 - 18 REFER TO SEIBERS FINAL SITE SPECIFIC DRAWINGS

- DEMOLITION KEYNOTES**
- 1 REPLACE EXISTING CABINETRY
 - 2 REMOVE NEW RADIATION PANEL TO REMOVE MRI
 - 3 RELOCATE MEDICAL CHAIRS
 - 4 REMOVE CORRIDOR HANDRAIL / PUMPER RAIL TO ADJACENT
 - 5 REMOVE CORRIDOR HANDRAIL / PUMPER RAIL TO ADJACENT
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NOTE: REFER TO ARCHITECT'S DEMOLITION SCHEDULE FOR DEMOLITION SEQUENCE AND PROTECTION OF EXISTING ROOM FEATURES. PROVIDE WITH PRELIMINARY PRICING DOCUMENTS.

1 DEMOLITION / RENOVATION P_LAN
 MRI ROOM 1621
 1/4" = 1'-0"



Approx. PET project limits

PET project to enlarge door / frame to 8'-0" high?

MRI replacement project to change door / frame to 8'-0" high. Rework auto operator as required.

Add bulkhead for ckg. height adjustment
MRI removal / delivery path

Approx. MRI project limits

Duke is planning window replacement project at MOB 7 which may coincide with these projects.

SMOKE COMPARTMENT 1-3
21,996 SF TOTAL

SMOKE COMPARTMENT 1-4
7,855 SF TI

1 PROJECT CONTEXT PLAN
MRI ROOM 1621
1/8" = 1'-0"

EQUIPMENT COMPARISON – Duke Raleigh Hospital MRI Replacement

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Magnetic Resonance Imaging (MRI)	MRI
Manufacturer of Equipment	GE	Siemens
Tesla Rating for MRIs	1.5	3.0
Model Number	HDX	Magnetom Vida
Serial Number	89223	TBD
Provider's Method of Identifying Equipment	MRI 1/Asset # 150830	TBD
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	May 2008	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Holds Title	TBD
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$956,753	\$3,381,565
Total Cost of Equipment	\$928,866	\$2,083,332 (after trade in allowance)
Fair Market Value of Equipment	\$928,866	\$2,123,332
Net Purchase Price of Equipment	\$928,866	\$2,123,332
Locations Where Operated	Raleigh, NC	Raleigh, NC
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	NA
Type of Procedures New Equipment is Capable of Performing	NA	MRI

Effective January 01, 2018, this license is issued to

Duke University Health System, Inc.

to operate a hospital known as

Duke Raleigh Hospital

located in Raleigh, North Carolina, Wake 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: 923421

License Number: H0238

Bed Capacity: 186

General Acute 186

Dedicated Inpatient Surgical Operating Rooms: 0

Dedicated Ambulatory Surgical Operating Rooms: 0

Shared Surgical Operating Rooms: 15

Dedicated Endoscopy Rooms: 3