



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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

September 19, 2018

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

Exempt from Review – Replacement Equipment

Record #: 2702
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace existing fixed MRI
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 September 18, 2018, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Siemens Magnetom Vida to replace the Siemens Magnestom Trio. 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 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.

Sincerely,

Bernetta Thorne-Williams
Project Analyst

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

cc: Construction Section, DHSR
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: 2701 Mail Service Center, Raleigh, NC 27699-2701
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3750 • FAX: 919-733-2757



Catharine W. Cummer
Regulatory Counsel, Strategic Planning



September 18, 2018

Via Electronic Mail

Ms. Martha Frisone
Ms. Bernetta Thorne-Williams
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 University Hospital

Dear Ms. Frisone:

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 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 an MRI existing located in Duke North, which is part of the main building of Duke University Hospital. The "main campus" of the facility is

Ms. Martha Frisone
Ms. Bernetta Thorne-Williams
September 18, 2017
Page 2

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 Medicine Pavilion, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the Hudson Building. A plan showing the site of this replacement within of Duke North is enclosed. The hospital's license and campus map have been previously provided to the CON Section.

(2) Previous Certificate of Need

The existing equipment was acquired and put into service in 2005, pursuant to the attached CON exemption.

(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).

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

Williams, Bernetta

From: Catharine Cummer <catharine.cummer@duke.edu>
Sent: Wednesday, September 19, 2018 7:47 AM
To: Williams, Bernetta
Subject: Re: [External] Equipment exemption notice

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to Report Spam.

I apologize that I did not include that confirmation in the original letter -- the existing MRI scanner will be disposed of and will not be used again in the state without first obtaining a CON if one is required. Thank you!

Catharine

Catharine W. Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd.
Suite 1300
Durham, NC 27707
(919) 668-0857 (office)
(919) 423-6928 (cell)
catharine.cummer@duke.edu

From: Williams, Bernetta <bernetta.williams@dhhs.nc.gov>
Sent: Wednesday, September 19, 2018 7:33 AM
To: Catharine Cummer
Subject: RE: [External] Equipment exemption notice

Good morning Catharine,

What will happen to the existing equipment? (i.e. 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).

Thanks

-----Original Message-----

From: Catharine Cummer [<mailto:catharine.cummer@duke.edu>]
Sent: Tuesday, September 18, 2018 1:17 PM
To: Frisone, Martha <martha.frisone@dhhs.nc.gov>; Williams, Bernetta <bernetta.williams@dhhs.nc.gov>; Gause, Cynthia <cynthia.gause@dhhs.nc.gov>
Subject: [External] Equipment exemption notice

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to Report Spam. <<mailto:report.spam@nc.gov>>

Ladies,

I sincerely hope that all of you and your homes have made it through our weather safely. Attached is an equipment replacement notice for DUH. Please let me know if you have any questions. Thanks!

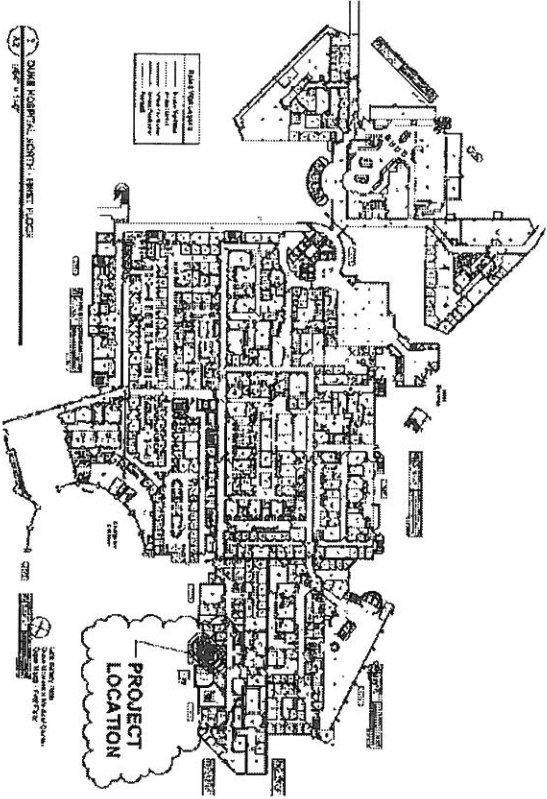
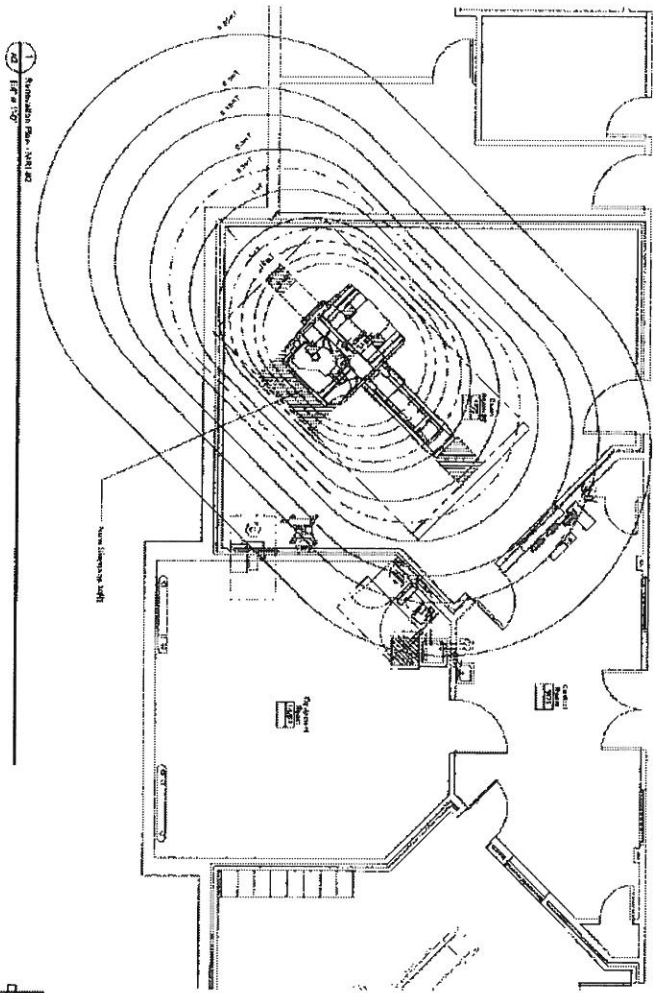
Catharine

Catharine Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd, Suite 1300
Durham NC 27707
(919) 668-0857 (office)
(919) 423-6928 (cell)

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EQUIPMENT COMPARISON

| Type of Equipment (List Each Component) | EXISTING EQUIPMENT | REPLACEMENT EQUIPMENT |
|--|---|--|
| Manufacturer of Equipment | Magnetic Resonance Imaging (MRI) Siemens | MRI Siemens |
| Tesla Rating for MRIs | 3.0 | 3.0 |
| Model Number | Magnetom Trio | Magnetom Vida |
| Serial Number | 35125 | TBD |
| Provider's Method of Identifying Equipment | MRI 2 Asset No. 138851 | MRI 2 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 | 11/01/2005 | 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 | TBD |
| Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form> | \$1,987,800 | \$3,387,000 |
| Total Cost of Equipment | \$1,919,551 | \$2,290,649 |
| Fair Market Value of Equipment | \$1,919,551 | \$2,290,649 |
| Net Purchase Price of Equipment | \$1,919,551 | \$2,290,649 |
| Locations Where Operated | Duke University Hospital Duke North | Duke University Hospital Duke North |
| 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 |



| WAD | |
|-----|--------------------|
| ✓ | Survey Complete |
| ✓ | Design/Construct |
| ✓ | Install/Commission |
| ✓ | Operational |
| ✓ | Post-Operational |
| ✓ | Final Report |
| ✓ | Final Invoice |

RCG Architects
 600 J. Robison, LLC
 Durham, North Carolina
 27705
 919.286.8800
 www.rcgarchitects.com

Duke University Medical Center
 4014 HSDC DUH Radiology Room 1625 3T MRI Scanner Installation
 and Upgrades
 2801 Erwin Road, Durham, NC 27705

| Project Information | |
|----------------------|---------------------------------------|
| Project No. | 18-175 |
| Client | Duke University |
| Contract No. | 18-175 |
| Contract Date | 04/22/18 |
| Contract Description | MRI Scanner Installation and Upgrades |
| Drawn By | J. Smith |
| Checked By | J. Smith |
| Scale | As Shown |



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

June 3, 2004

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 1.5 Tesla Signa Horizon LX magnetic resonance imaging (MRI) scanner with a Siemens 3.0 Tesla Magnetom Trio MRI scanner/Durham County
 FID # 943138

Dear Mr. Yaggy:

In response to your letter of May 10, 2004, 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 Siemens 3.0 Tesla Magnetom Trio MRI scanner to replace the existing GE 1.5 Tesla Signa Horizon LX [Serial # 01-34147]. 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. McKinnip, Project Analyst


 Lee B. Hoffman, Chief
 Certificate of Need Section

cc: Medical Facilities Planning Section, DFS





DUKE UNIVERSITY HEALTH SYSTEM

Duncan Yaggy
Chief Planning Officer

May 10, 2004

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 MRI Scanner #2 in Duke Hospital

Dear Mr. McKillip and Ms. Hoffman:

The purpose of this letter is to request your written confirmation that the replacement of MRI scanner #2 in Duke Hospital at a total capital cost of \$1,987,800 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 points 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 for the existing equipment and the replacement equipment 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.

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 vendor's quotation for the proposed replacement equipment, including a detailed description of all the components, is enclosed as Exhibit 5. Please note that the full purchase price (\$1,900,000) is listed on page 20 and that the items listed on the following pages are "Optional Items" whose price is "not included in contract total." We have not committed to purchase the optional items.

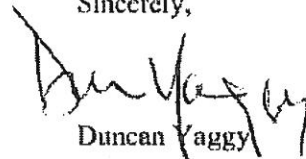
8. A letter from the person taking possession of the existing equipment is enclosed as Exhibit 6. Please note that the letter clearly states that the existing equipment will be taken out of clinical service and "permanently removed from the State of North Carolina."

9. A letter documenting that the existing equipment is currently 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.

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) | MRI System | MRI System |
| Manufacturer of Equipment | General Electric | Siemens |
| Tesla Rating for MRIs | 1.5 | 3 |
| Model Number | 1.5T Signa Horizon LX | Magneton Trio |
| Serial Number | 156733MR2 | To be determined |
| Provider's Method of Identifying Equipment (Duke Asset Number) | GE Identifier: 919631 MR2 | To be determined |
| Specify if Mobile or Fixed (on a rolling cart) | Fixed | Fixed |
| Mobile Trailer Serial Number/VIN# | NA | NA |
| Mobile Tractor Serial Number/VIN# | NA | NA |
| Date of Acquisition of Each Component | 28-Jun-85 | TBD |
| Does Provider Hold Title to Equipment of 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 | \$1,987,800 |
| Total Cost of Equipment | \$1,600,000 | \$1,900,000 |
| Fair Market Value of Equipment | NA | \$1,900,000 |
| Net Purchase Price of Equipment | NA | \$1,900,000 |
| Locations Where Operated (Duke Hospital DHN) | Durham, NC | Durham, NC |
| Number Days in Use To be Unused in N.C. Per Year | 365 | 365 |
| Percent of Change in Patient Charges (by Procedure) | N/A | No change |
| Percent of Change in Per Procedure Operating Expenses (by Procedure) | N/A | See below |
| Type of Procedures Currently Performed on Existing Equipment | Magnetic Resonance Imaging | NA |
| Type of Procedures New Equipment is Capable of Performing | N/A | Magnetic Resonance Imaging |

Note: Per procedure operating expenses of the Duke Hospital MR service will go down 0.54% during the remainder of FY2005 (when the maintenance of the new machine will be at no cost to Duke), increase 3.0% during FY2006 (during part of which the maintenance will be free), and increase 7.0% during FY2007. (These estimates assume no other changes to the MRI service at Duke Hospital.)

Effective January 01, 2018, this license is issued to
Duke University Health System, Inc.

to operate a hospital known as
Duke University 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: 943138
License Number: H0015

Bed Capacity: 957
General Acute 938, Psych 19,

Dedicated Inpatient Surgical Operating Rooms: 6
Dedicated Ambulatory Surgical Operating Rooms: 9
Shared Surgical Operating Rooms: 50
Dedicated Endoscopy Rooms: 11