



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

January 15, 2016

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

**Exempt from Review – Replacement Equipment**

**Record #:** 1834  
**Facility Name:** Duke University Hospital  
**FID #:** 943138  
**Business Name:** Duke University Health System  
**Business #:** 639  
**Project Description:** Replace existing vascular equipment  
**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 December 23, 2015, 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 Philips Allura Xper FD20/15 fixed vascular equipment. This determination is based on your representations that the 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

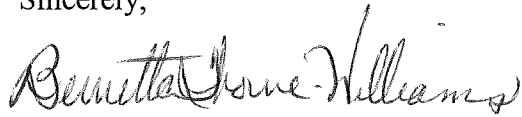
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

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

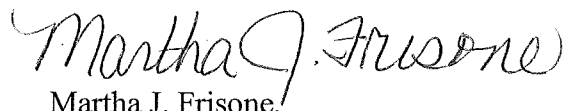
An Equal Opportunity/ Affirmative Action Employer



Sincerely,



Bernetta Thorne-Williams  
Project Analyst



Martha J. Frisone,  
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR  
Kelli Fisk, Program Assistant, Healthcare Planning, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR

# Duke University Health System

Catharine W. Cummer  
Regulatory Counsel, Strategic Planning

December 23, 2015

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 vascular interventional radiology equipment 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 is now exempt from certificate of need review.

(1) Main Campus

The purpose of this project is to replace existing biplane vascular equipment operated in Duke North at Duke University Hospital, which is located 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 new Hudson Building.

(2) Previous Certificate of Need

As set forth in the documentation attached as Exhibit A, the acquisition of the existing equipment that will be replaced was exempt from certificate of need review.

(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 vascular interventional radiology procedures. 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).

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



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 14, 2004

Duncan Yaggy, Chief Planning Officer  
Duke University Health System  
3100 Tower Boulevard  
Suite 600, Box 80  
Durham, NC 27707

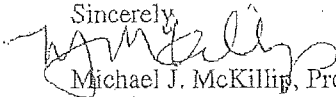
RE: Exempt from Review/Duke University Health System/Replace existing Phillips Integris V3000 bi-plane vascular system with a Phillips Integris Allura bi-plane vascular system/Durham County FID # 943138


Dear Mr. Yaggy:

In response to your letter of June 7, 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 Phillips Integris Allura bi-plane vascular system to replace the existing Phillips Integris V3000 bi-plane vascular system [Serial # 2955280]. 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

  
Lee B. Hoffman, Chief  
Certificate of Need Section

cc: Medical Facilities Planning Section, DFS



Location: 701 Barbour Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603  
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Exhibit A



## DUKE UNIVERSITY HEALTH SYSTEM

Duncan Yaggy  
Chief Planning Officer

June 7, 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 Vascular Radiology Laboratory at Duke Hospital

Dear Mr. McKillip and Ms. Hoffman:

I am writing on behalf of Duke University Health System, Inc. ("DUHS") with regard to the replacement of an existing vascular radiology laboratory at Duke University Hospital ("DUH"). DUHS proposes to remove the existing lab from Room 1548K5 on the first floor of DUH and to install the replacement equipment in Room 1548K in the same suite at a total capital cost of \$1,187,000. By this letter, DUHS provides notice to the Certificate of Need Section (the "Agency") of DUHS' exempt acquisition of replacement vascular radiology laboratory equipment pursuant to N.C.G.S. § 131E-184, and requests your confirmation that the acquisition of this replacement equipment will not require a certificate of need ("CON").

DUHS proposes to replace its existing vascular radiology equipment which is described in the enclosed Exhibit 2 ("existing equipment") with vascular radiology equipment which is described in the enclosed Exhibit 3 ("replacement equipment"). The existing equipment is currently located in Room 1548K5 at Duke University Hospital and the replacement equipment will be located to Room 1548K in the same suite. DUHS' capital expenditure related to this acquisition will not exceed \$2,000,000. DUHS' acquisition of the replacement equipment is exempt from certificate of need review under N.C.G.S. 131E-184(a)(7) because it is "replacement equipment." The certificate of need law defines "replacement equipment" as:

[E]quipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

N.C.G.S. § 131E-176(22a).

DUHS' proposed purchase of a new vascular radiology laboratory to replace its existing unit, serial number 2955280, fits within this statutory definition. The replacement equipment DUHS proposes to purchase costs less than \$2,000,000, including all activities essential to making the equipment operational. A copy of the vendor's quotation for the proposed replacement equipment, including a detailed description of all the components, is attached as Exhibit 5. The existing equipment will be taken out of service in North Carolina as confirmed by a letter for the person taking possession of the existing equipment and attached as Exhibit 6. Furthermore, the replacement equipment is "comparable" to the existing equipment. A comparison of the specifications of the two machines is attached as Exhibit 1.

DUHS' proposed purchase constitutes "replacement equipment" under N.C.G.S. § 131E-176(22a), as that statute has been interpreted in 10 N.C.A.C. 3R.0214 (the "Rule"). Pursuant to N.C.G.S. § 131E-176(22a), all "activities essential to acquiring and making operational the replacement equipment" must be included in the calculation of the cost of the replacement equipment, which cost must be less than \$2,000,000. Subsection (b) of the Rule defines these essential activities as "those activities which are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational." The attached Exhibit 7 explains that the existing equipment is currently in use and has not been taken out of service. Because the equipment is currently operational, the only relevant cost pursuant to these provisions is the purchase price of the equipment. However, DUHS estimates that its total expenditures related to this equipment--including not only the purchase of the equipment, but also the remanufacturing costs and the cost of additional equipment--will be only \$1,187,000. Therefore, subsection (b) of the Rule is clearly not implicated.

Subsection (c) of the Rule defines "comparable medical equipment" as "equipment which is functionally similar and which is used for the same diagnostic or treatment purposes." The replacement equipment DUHS plans to purchase performs the same functions and will be used for the same purposes as the existing equipment. *See Exhibits 1, 2, 3, 4 and 5.* The replacement equipment, therefore, is "comparable" to the existing equipment as defined in subsection (c).

Subsection (d) of the Rule provides that replacement equipment is comparable to the equipment being replaced if:

- (1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and

- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The proposed acquisition satisfies subsection (d)(1) because the replacement equipment has the same core technology as the equipment currently in use. *See* Exhibits 1 through 5. The proposed acquisition satisfies subsection (d)(2) for the reasons discussed above with respect to subsection (c). With respect to subsection (d)(3), DUHS will not change its pricing as a result of this acquisition. Furthermore, due to the similar technology involved, the acquisition of the replacement equipment will not result in a 10% increase in per procedure operating expenses within the first twelve months after the new machine is acquired.

Finally, DUHS' planned acquisition does not fall within any of the four definitions of equipment which is "not comparable" under subsection (e). Subsections (e)(1) and (e)(2) apply only if the existing equipment was purchased second-hand or as reconditioned equipment less than three years prior to replacement. Because DUHS' existing equipment was purchased new in 1996, subsections (e)(1) and (e)(2) are inapplicable. Subsection (e)(3) is inapplicable because the replacement equipment is not capable of performing procedures that the existing equipment could not perform, and DUHS will not use the replacement equipment to perform procedures that were not performed with the existing equipment. Finally, subsection (e)(4) is inapplicable because the existing equipment was purchased, not leased. Thus, none of the parts of subsection (e) of the Rule apply to the replacement equipment DUHS plans to purchase.

Based on the foregoing information, DUHS hereby requests the Agency to confirm as soon as possible that replacing its existing vascular radiology laboratory unit, serial number 2955280, with a new unit as described herein is exempt from certificate of need review under N.C.G.S. § 131E-184(a)(7).

To facilitate your consideration of this request, we have responded below and in the enclosed exhibits to the questions that the Section asks about proposals to replace equipment. The numbering of the paragraphs below follows the numbering employed in the Section's letter requesting additional information:

1. A table comparing the existing equipment and replacement equipment using the standard format is enclosed as Exhibit 1.



2. The basic technology and functions of the existing and replacement equipment, including the diagnostic and treatment purposes for which the equipment is used or is capable of being used, are described in the brochures enclosed as Exhibit 2 and Exhibit 3.

3. A brochure describing the existing equipment is enclosed as Exhibit 2. A brochure describing the replacement equipment is enclosed as Exhibit 3.

4. A copy of the purchase order for the existing equipment, including all components and the purchase price, is enclosed as Exhibit 4.

5. The existing equipment is owned and the replacement equipment will be owned, not leased, but we do not have a formal title to the existing equipment and do not anticipate receiving a formal title to the replacement equipment.

6. Not applicable. The replacement equipment will not be leased.

7. A copy of the vendor's quotation for the replacement equipment is enclosed as Exhibit 5. Payment terms are detailed on the second page. As noted below, the vendor will remove the existing equipment, but no trade-in allowance will be provided.

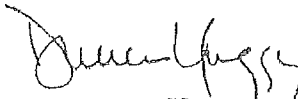
8. A letter from the person taking possession of the existing equipment that acknowledges that the existing equipment will be removed from services and will not be reutilized within the State of North Carolina is enclosed as Exhibit 6.

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 are a completed Proposed Total Capital Cost of Project form (Exhibit 8) and an executed attestation form (Exhibit 9).

Thank you for your consideration of this request. If you have questions or need further information, please let me know. I look forward to hearing from you soon.

Sincerely,

  
Duncan Yaggy

DY:dw

Enclosures

no review vascular lab letter\_v3

EQUIPMENT COMPARISON  
DUH Vascular Interventional Radiology

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Vascular	Vascular
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs	n/a	n/a
Model Number	INTEGRIS Allura 15/12	Allura Xper FD20/15
Serial Number	1019	To be determined
Provider's Method of Identifying Equipment	Asset # 138413	To be determined
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	2005	2016
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>	n/a	\$ 3,598,000
Total Cost of Equipment	\$950,000	\$ 2,409,326
Fair Market Value of Equipment	\$10,600	\$ 2,409,326
Net Purchase Price of Equipment	\$950,000	\$ 2,399,326 (with trade-in allowance)
Locations Where Operated	Duke University Hospital	Duke University Hospital
Number Days In Use/To be Used in N.C. Per Year	250	250
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	Vascular Interventional Radiology Procedures	NA
Type of Procedures New Equipment is Capable of Performing	NA	Vascular Interventional Radiology Procedures

Exhibit B