



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

November 15, 2023

Catherine W. Cummer

Catherine.cummer@duke.edu

Exempt from Review – Replacement Equipment

Record #: 4313
Date of Request: November 8, 2023
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace a linear accelerator on the main campus
County: Durham

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project 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 Varian Ethos linear accelerator to replace the Varian Clinac 600C linear accelerator (Serial # H180806). 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.

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,

Cynthia Bradford,
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, 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
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

From: [Catharine Cumber](#)
To: [Stancil, Tiffany C](#)
Cc: [Lara Orgain](#)
Subject: [External] Exemption Notice DUH Yellow Linac replacement
Date: Wednesday, November 8, 2023 11:37:16 AM
Attachments: [To State Exemption Notice DUH Yellow Linac replacement.docx](#)
[Replacement Equipment Comparison Form for Yellow Linac \(FY24\).docx](#)

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Tiffany,

I hope you're doing well. I am attaching an exemption notice for replacement equipment. Please let me know if you have any questions. Thank you!

Catharine

Catharine W. Cumber
Regulatory Counsel, Strategic Planning, Duke University Health System
Office 919-668-0857 | Cell 919-423-6928



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

November 8, 2023

Via Electronic Mail

Ms. Micheala Mitchell
Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Exempt Linear Accelerator Replacement Project at Duke University Hospital

Dear Ms. Mitchell:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of replacement linear accelerator 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 existing linear accelerator currently in service in the Morris Clinic, which is part of the main building 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 Medicine Pavilion, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the Hudson Building. The hospital’s license and campus map have been previously provided to the CON Section. The construction plans showing the location of the project within the Morris Clinic are enclosed.

(2) Previous Certificate of Need

The existing equipment was acquired and put into service in 2004. As set forth in Project J-6294-00, as of 2000, Duke operated three linear accelerators (originally grandfathered), and was approved to acquire two additional linacs and to replace two existing linacs. The replacement of the third grandfathered linac was approved pursuant to an exemption granted in 2000. The equipment to be replaced now was one of the five linear accelerators approved in 2000 for acquisition and/or replacement.

(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 radiation oncology procedures. The total project cost exceeds \$2,000,000 reflecting major medical equipment, related equipment, and renovation/installation expenses. Copies of the equipment quotation and construction plans are available upon request. This replacement will not affect the gross charges or governmental or contractual reimbursement rates for the services provided on this equipment. 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). The existing equipment will be removed from service in the state upon its replacement.

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

Catharine W. Cummer

Enclosures

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment	Linear accelerator	Linear accelerator
Manufacturer of Equipment	Varian	Varian
Tesla Rating for MRIs	Not applicable	Not applicable
Model Number	Clinac 600C	Ethos
Serial Number	H180806	To be determined
Provider's Method of Identifying Equipment	Serial number	Serial number
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	Not applicable	Not applicable
Mobile Tractor Serial Number/VIN #	Not applicable	Not applicable
Date Acquired	March 2004	
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	614,102	7,700,000
Total Cost of Equipment	572,000	4,020,000
Fair Market Value of Equipment		
Net Purchase Price of Equipment		
Locations Where Operated	Duke Univ Hosp	Duke Univ Hosp
Number of Times Existing Equipment was Used to Provide a Health Service during the 12 months prior to the Date of the Written Notice	74	
Type of Procedures Currently Performed on Existing Equipment	Radiation Therapy	
Type of Procedures New Equipment is Capable of Performing		Radiation Therapy

Date of last revision: 12/4/2020