



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

JOSH STEIN • Governor

DEV DUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

July 16, 2025

Catherine Cumber

catharine.cumber@duke.edu

Exempt from Review – Replacement Equipment

Record #: 4835

Date of Request: July 3, 2025

Facility Name: Duke University Hospital

FID #: 943138

Business Name: Duke University Health System, Inc.

Business #: 640

Project Description: Replace a linear accelerator

County: Durham

Dear Ms. Cumber:

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 existing Varian Clinac linear accelerator. 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: Construction 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



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

July 3, 2025

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 monetary threshold set forth in G.S. 131E-176(22a), 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.

(2) Previous Certificate of Need

The existing equipment was acquired and put into service in 2011 pursuant to a CON for Project J-8560-10.

(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. 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 (List Each Component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Varian	Varian
Tesla Rating for MRIs	NA	NA
Model Number	Clinac iX Silhouette	Ethos
Serial Number	940	NA
Provider's Method of Identifying Equipment	SN	SN
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	April 2011	
Does Provider Hold Title to Equipment or Have a Capital Lease?	Owned	
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	1,347,469	7,219,000
Total Cost of Equipment	999,000	3,552,051
Fair Market Value of Equipment		
Net Purchase Price of Equipment		
Locations Where Operated	Morris Bldg Rm 005139	Morris Bldg Rm 005139
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	See attached	NA
Type of Procedures New Equipment is Capable of Performing	NA	See attached

Type of procedures performed on the existing equipment

77385	IMRT Treatment, Simple
77386	IMRT Treatment, Complex
77402	Radiation Treatment Delivery, Simple
77407	Radiation Treatment Delivery, Intermediate
77412	Radiation Treatment Delivery, Complex

Type of procedures the replacement equipment will perform

77385	IMRT Treatment, Simple
77386	IMRT Treatment, Complex
77402	Radiation Treatment Delivery, Simple
77407	Radiation Treatment Delivery, Intermediate
77412	Radiation Treatment Delivery, Complex

From: [Catharine Cummer](#)
To: [Stancil, Tiffany C](#); [Bradford, Cynthia L](#)
Cc: [Lara Orgain](#)
Subject: [External] Exemption notice - Duke University Hospital
Date: Thursday, July 3, 2025 11:31:49 AM
Attachments: [To State Exemption Notice DUH Tan Linac replacement.pdf](#)

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 and Cindy,
Attached please find an equipment replacement exemption notice for Duke University Hospital. If you need any additional information, please let me know. Thank you and I hope you have a great holiday weekend!
Catharine

Catharine W. Cummer
Associate General Counsel
Duke University | Duke University Health System, Inc.
Office 919-668-0857
Cell 919-423-6928