

MARK PAYNE • Director, Division of Health Service Regulation

#### VIA EMAIL ONLY

October 3, 2024

**Dorsey Tobias** 

Dorsey.tobias@unchealth.unc.edu

**Exempt from Review – Replacement Equipment** 

Record #: 4592

Date of Request: September 24, 2024 Facility Name: Nash General Hospital

FID #: 933368

Business Name: Nash Hospitals, Inc.

Business #:

Project Description: Replace two units of linear accelerator equipment

County: Nash

Dear Ms. Tobais:

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 TrueBeam fixed linear accelerator to replace the Varian Clinic 23EX Platinum fixed linear accelerator Serial #H296084 and to acquire without a certificate of need another Varian TrueBeam fixed linear accelerator to replace the Varian 21iX fixed linear accelerator Serial #SN-H140835. This determination is based on your representations that the existing units 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,

Gregory F. Yakaboski

Project Analyst

Micheala Mitchell Chief

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

Radiation Protection Section, DHSR

Construction Section, DHSR

Micheala Mitthell

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



#### **UNC Health Nash**

2460 Curtis Ellis Drive Rocky Mount, NC 27804 www.unchealthnash.org O 252-962-8000

September 20, 2024

### VIA ELECTRONIC MAIL

Ms. Micheala Mitchell, Chief
Mr. Greg Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704
Micheala.Mitchell@dhhs.nc.gov
Greg.Yakaboski@dhhs.nc.gov

RE: Main Campus Exemption Request

Facility:

Nash General Hospital

FID #:

933368

County:

Nash

Dear Ms. Mitchell and Mr. Yakaboski:

Please accept this letter as notification of Nash Hospitals, Inc. d/b/a UNC Health Nash (hereinafter referred to as UNC Health Nash) intends to replace two existing units of linear accelerator equipment, for a total cost greater than \$3,000,000 pursuant to N.C. Gen. Stat. § 131E-184(f) and 10A NCAC 14C .0303.

Under N.C. Gen. Stat. § 131E-184(f), the CON law provides that an applicant's proposal for "the purchase of any replacement equipment" that exceeds the \$3 million threshold is exempt from Certificate of Need review 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.

Replacement equipment is defined in the CON law under N.C. Gen. Stat. § 131E-176(22a)<sup>1</sup> as:

"Equipment that costs less than three million dollars (\$3,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will

Please note that the text cited below is as amended by Session Law 2023-7, which was enacted March 27, 2023, with the cited portion effective immediately.

Ms. Micheala Mitchell, Chief Mr. Greg Yakaboski, Project Analyst Page Two

be sold or otherwise disposed of when replaced. In determining whether the replacement equipment costs less than three million dollars (\$3,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Beginning September 30, 2023, and on September 30 each year thereafter, the cost threshold amount in this subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1."

UNC Health Nash is aware that the most recent annual update has changed the replacement equipment cost threshold to \$2,971,200. In any case, UNC Health Nash's proposed replacement equipment exceeds this threshold and therefore qualifies for replacement under N.C. Gen. Stat. § 131E-184(f). Specifically, as set forth below, UNC Health Nash's proposed equipment replacement meets the definition of replacement equipment that is located on the main campus and is therefore exempt from Certificate of Need review.

UNC Health Nash seeks to acquire two Varian TrueBeam linear accelerators (Replacement Equipment) to replace two of UNC Health Nash's existing linear accelerators (Existing Equipment), one of which was acquired in 2005 pursuant to CON Project ID #L-7078-04, and the other is a grandfathered linear accelerator, originally acquired prior to the CON requirement for linear accelerators, and then replaced most recently in 2008. The proposed replacements are needed as the Existing Equipment is beyond its useful life. A completed Equipment Comparison Form for each unit of Existing Equipment is included in Attachment 1. The Replacement Equipment is functionally similar to the Existing Equipment and will be used for the same treatment purposes, although the Replacement Equipment will possess expanded capabilities given technological advancements. The proposed Replacement Equipment will not be used to provide a new health service and will not result in more than a 10 percent increase in patient charges or per procedure operating expenses within the first 12 months after it is acquired. Further, as documented in Attachment 2, once the Replacement Equipment has been installed and is operational, the Existing Equipment will be sold or otherwise disposed of and will not be otherwise utilized in the state without permission.

The total proposed capital cost for the proposed equipment replacement, including all costs associated with equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making the Replacement Equipment operational is \$7,408,266. Attachment 3 contains a projected capital cost form for the project and all associated construction and engineering fees as well as a vendor quote for the proposed Replacement Equipment and all associated systems and tools. As documented in Attachment 2, the Existing Equipment will be removed from North Carolina by the vendor and will not be used again without Agency approval.

Main campus is defined in the CON law under N.C. Gen. Stat. § 131E-176(14n) as:

Ms. Micheala Mitchell, Chief Mr. Greg Yakaboski, Project Analyst Page Three

- 1) The 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 building and grounds adjacent to that main building.
- 2) Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The Existing Equipment is located at the Nash Day Hospital at 2460 Curtis Ellis Dr, Rocky Mount, NC, the same address, and physical site of the main building of UNC Health Nash, a licensed acute care hospital (License Number H0228) where clinical patient services are provided, and financial and administrative control are exercised over the entire facility. Attachment 4 provides a map of UNC Health Nash main campus, illustrating the distance of Nash Day Hospital from the main building; however, pursuant to 131E-176(14n)(2), Nash Day Hospital is fully contiguous to Nash General Hospital and is operated as part of the UNC Health Nash license.

As outlined above and illustrated in the Attachments, the proposed Replacement Equipment qualifies as replacement equipment located on the main campus pursuant to regulatory and statutory definitions (N.C. Gen. Stat. § 131E-176(14n) (22a) and 10A NCAC 14C .0303). As such, the proposed project is exempt from Certificate of Need review pursuant to N.C. Gen. Stat. § 131E-184(f).

If you could, please confirm that you agree with our understanding that the proposed Replacement Equipment is exempt from Certificate of Need review. Please do not hesitate to contact me if any additional information is needed.

Sincerely,

**Dorsey Tobias** 

Vice President of Strategy & Communications

**UNC Health Nash** 

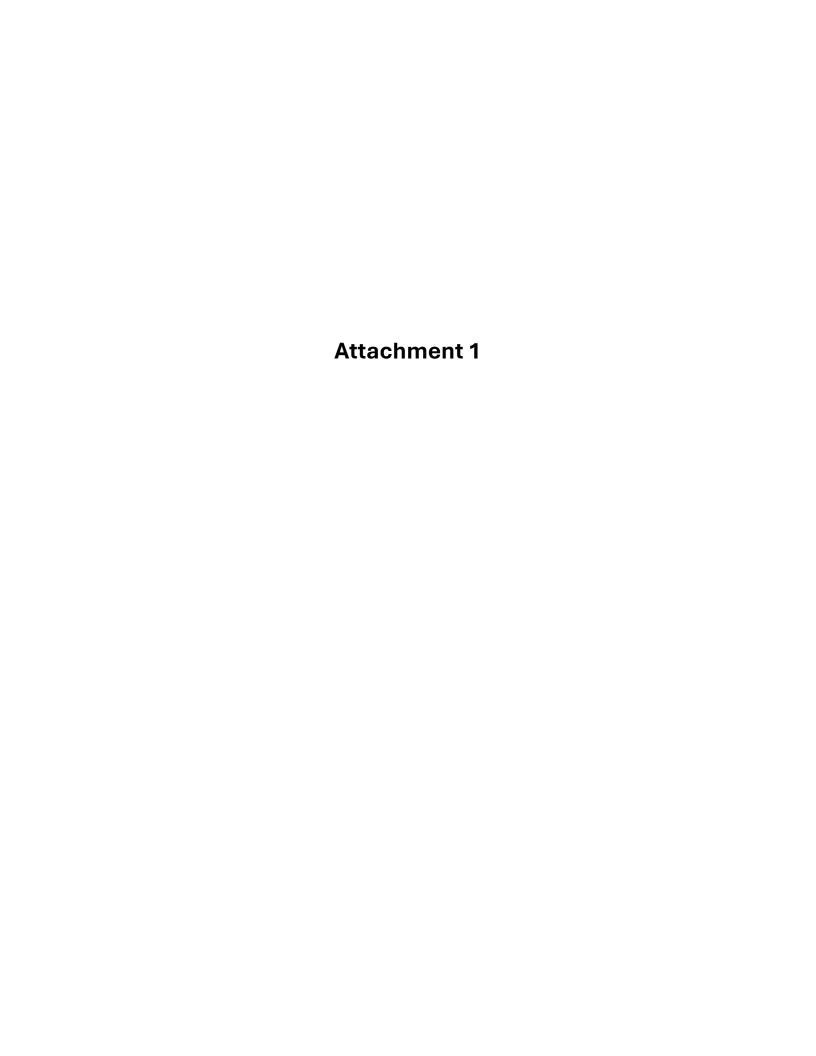
Worsey Cobias

Attachment 1 - Equipment Comparison Forms

Attachment 2 - Letter Re: Continuous Historical Use and Future Disposition of Existing Equipment

Attachment 3 - Projected Capital Cost and Replacement Equipment Quote

Attachment 4 - Main Campus Map

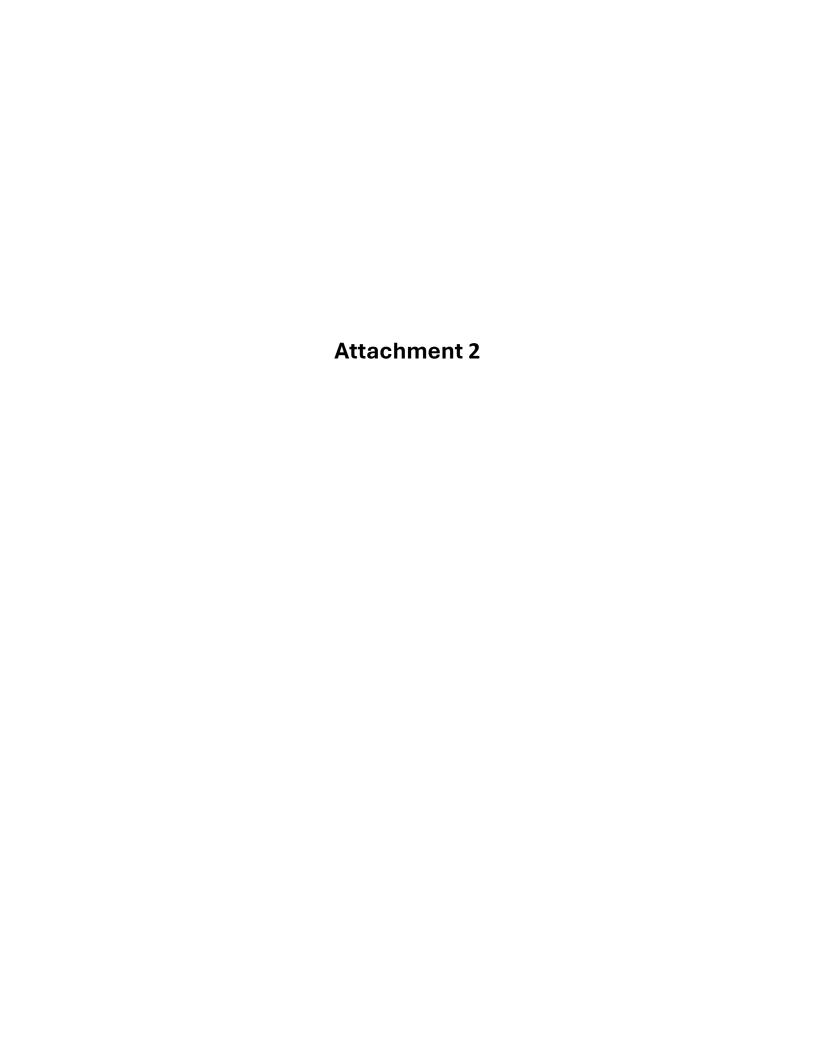


# **EQUIPMENT COMPARISON**

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Varian	Varian
Model Number	Clinic 23EX Platinum	TrueBeam
Serial Number	H296084	TBD
Specify if Mobile or Fixed	Fixed	Fixed
Date of Acquisition	2005	~9/30/2024
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	N/A	\$ 3,704,133
Total Cost of Equipment	N/A	\$3,029,880
Fair Market Value of Equipment	N/A	\$3,029,880
Net Purchase Price of Equipment	N/A	\$3,029,880
Locations Where Operated	Nash Day Hospital	Nash Day Hospital
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	N/A	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	<10%
Type of Procedures Currently Performed on Existing Equipment	Radiation treatment	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Radiation treatment

# **EQUIPMENT COMPARISON**

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Varian	Varian
Model Number	21iX	TrueBeam
Serial Number	SN-H140835	TBD
Specify if Mobile or Fixed	Fixed	Fixed
Date of Acquisition	2005	~2025 or 2026
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	N/A	\$ 3,704,133
Total Cost of Equipment	N/A	\$3,029,880
Fair Market Value of Equipment	N/A	\$3,029,880
Net Purchase Price of Equipment	N/A	\$3,029,880
Locations Where Operated	Nash Day Hospital	Nash Day Hospital
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	N/A	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	<10%
Type of Procedures Currently Performed on Existing Equipment	Radiation treatment	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Radiation treatment





## **UNC Health Nash**

2460 Curtis Ellis Drive Rocky Mount, NC 27804 www.unchealthnash.org O 252-962-8000

September 20, 2024

Ms. Micheala Mitchell, Chief
Greg Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation, NC DHHS
2704 Mail Service Center
Raleigh, NC 27699-2704
Micheala.Mitchell@dhhs.nc.gov
Greg.Yakaboski@dhhs.nc.gov

Dear Ms. Mitchell and Mr. Yakaboski:

UNC Health Nash currently owns and operates two Varian linear accelerators (Existing Equipment) that have been in operation continuously at Nash Day Hospital on the main campus of Nash General Hospital since acquired in 2005 and 2008. The Existing Equipment has not been taken out of service since originally acquired, except on a temporary basis as needed for updates or repairs. Additionally, the linear accelerators (Existing Equipment) has been used at least 10 times in the past 12 months.

UNC Health Nash proposes to replace the Existing Equipment with new Varian TrueBeam linear accelerators to be located in the same space as the Existing Equipment. UNC Health Nash understands that the Existing Equipment will be removed from North Carolina by the vendor. UNC Health Nash will not own or use the Existing Equipment after its replacement.

Please contact me with any questions regarding this matter.

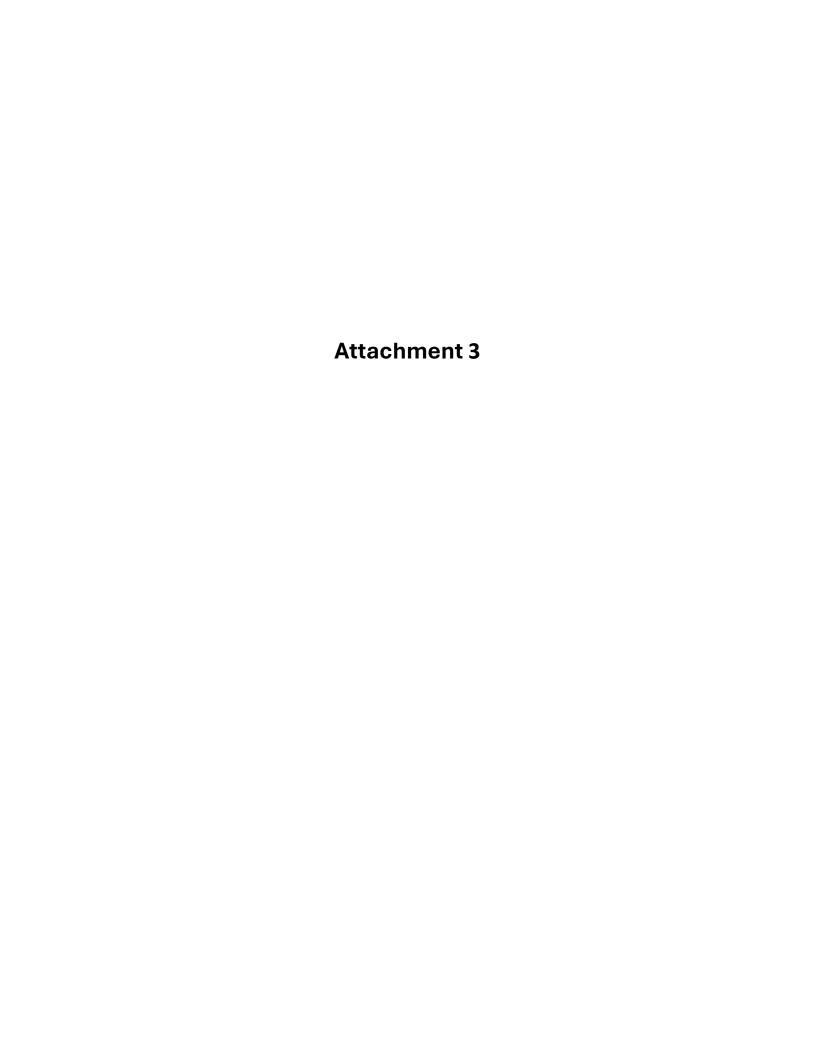
Sincerely,

**Dorsey Tobias** 

Vice President of Strategy & Communications

**UNC Health Nash** 

Dosey Cobras





#### **UNC Health Nash**

2460 Curtis Ellis Drive Rocky Mount, NC 27804 www.unchealthnash.org O 252-962-8000

## **Projected Capital Cost Form**

Building Purchase Price	\$0
Purchase Price of Land	\$0
Closing Costs	\$0
Site Preparation	\$0
Construction/Renovation Contract(s)	\$1,348,506
Landscaping	\$0
Architect / Engineering Fees	\$0
Medical Equipment	\$6,059,760
Non-Medical Equipment	\$0
Furniture	\$0
Financing Costs	\$0
Interest during Construction	\$0
Other (specify)	\$0
Total Capital Cost	\$7,408,266

### **CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT**

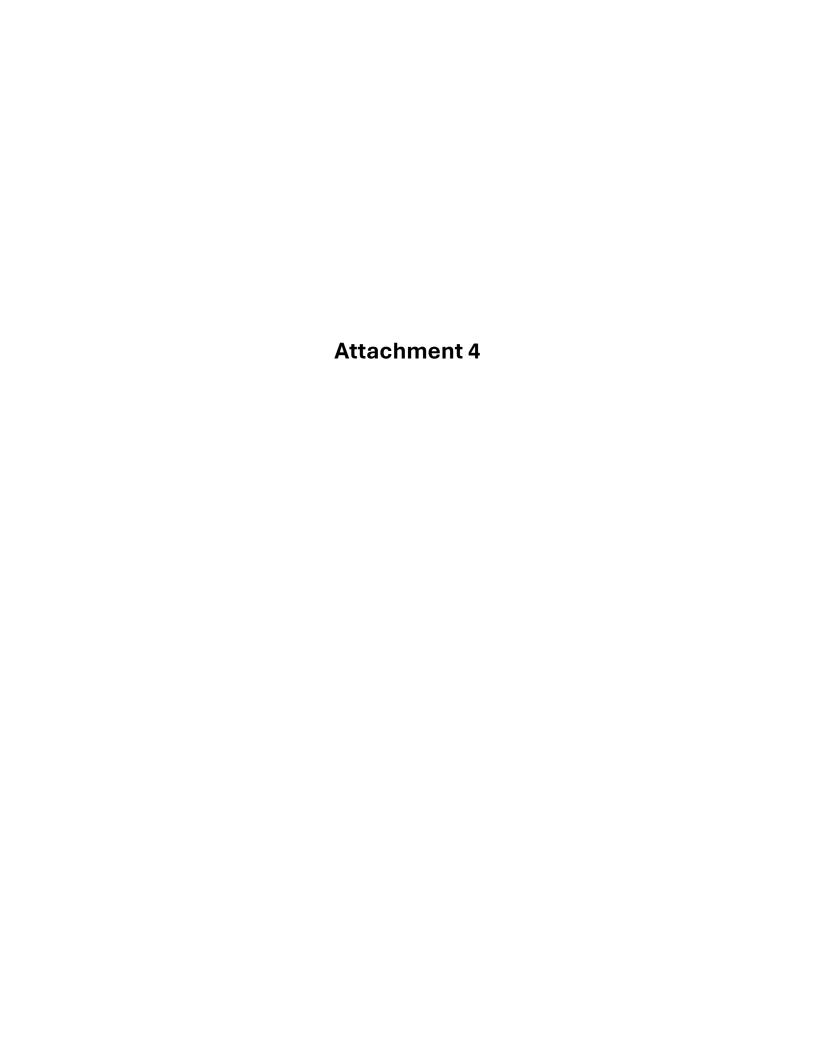
I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that it is our intent to carry out the proposed project as described.

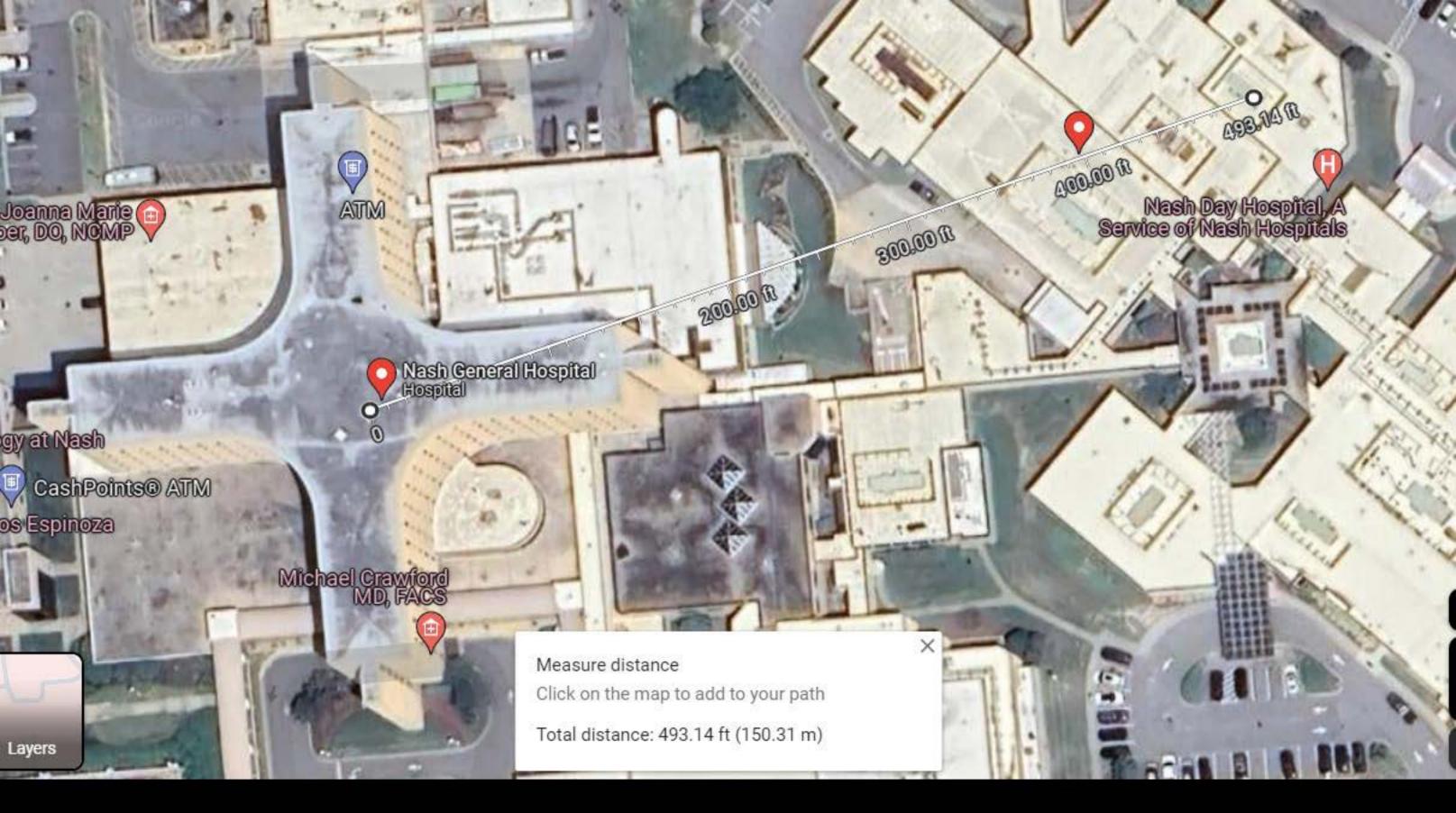
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Signature of Officer/Agent

Vice President, Strategy: Communication

Title of Officer/Agent





From: Mitchell, Micheala L

To: Stancil, Tiffany C

Cc: <u>Yakaboski, Greg; Waller, Martha K</u>

Subject: FW: [External] UNC Health Nash Linac Exemption

Date: Tuesday, September 24, 2024 1:07:15 PM

Attachments: <u>image001.png</u>

UNC Health Nash LINAC FINAL.pdf

Tiffany,

Would you mind logging this and assigning to Greg?

Thanks,

Micheala Mitchell, JD

NC Department of Health and Human Services

Division of Health Service Regulation

Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center

Raleigh, NC 27699-2704

Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov

From: Kim Meymandi < KimMeymandi@ascendient.com>

Sent: Tuesday, September 24, 2024 12:49 PM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>; Yakaboski, Greg

<greg.yakaboski@dhhs.nc.gov>

**Cc:** Waller, Martha K <martha.waller@dhhs.nc.gov> **Subject:** [External] UNC Health Nash Linac Exemption

**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.

Hi Micheala and Greg-

I hope you are both doing well. Please see attached for an exemption request submitted on behalf of UNC Health Nash.

If you would please confirm receipt at your earliest convenience.

Thanks so much,

Kim

Kim Meymandi | Senior consultant

kimmeymandi@ascendient.com | 919.226.1712 | linkedin | www.ascendient.com



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