



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

September 13, 2022

Anna Post Mickleberry  
[apost@wakehealth.edu](mailto:apost@wakehealth.edu)

**Exempt from Review – Replacement Equipment**

**Record #:** 4015  
**Date of Request:** August 2, 2022  
**Facility Name:** North Carolina Baptist Hospital  
**FID #:** 943495  
**Business Name:** North Carolina Baptist Hospital  
**Business #:** 1819  
**Project Description:** Replace LINAC on main campus  
**County:** Forsyth

Dear Ms. Mickleberry:

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 Elekta Versa-HD LINAC to replace the Varian 23 SCX #H272315 LINAC. 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,

Gregory F. Yakaboski  
Project Analyst

Micheala Mitchell  
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR  
Radiation Protection Section, DHSR  
Construction 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

July 21, 2022

Ms. Micheala Mitchell, Chief  
Mr. Greg Yakaboski, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
809 Ruggles Drive  
Raleigh, NC 27603

**Re: Request for Confirmation of Exemption for North Carolina Baptist Hospital (FID # 943495; Lic # H0011), Replacement Linear Accelerator**

Dear Ms. Mitchell and Mr. Yakaboski,

Pursuant to NC G.S. § 131E-184 (f), Exemptions Review, I am writing to request confirmation that the project described below for North Carolina Baptist Hospital (“NCBH”) is exempt from review.

NCBH plans to replace the existing Varian 21EX linear accelerator (“LINAC”) with a new Elekta Versa-HD. The total capital cost of the project is \$2,300,000. NCBH’s project meets the requirements set forth in N.C. Gen. Stat. 131E-184(f) for “replacement equipment” that exceeds two million (\$2,000,000) threshold in the following ways:

(1) Main Campus

The “main campus” of the facility is defined in NC G.S. 131E-176(14n) as “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 buildings and grounds adjacent to that main building.” The purpose of this project is to replace an existing LINAC currently in service in the Radiation Oncology department, which is located in the main building of NCBH, a licensed health service facility, located at 1 Medical Center Boulevard, Winston-Salem, NC 27157 from which NCBH provides clinical patient services and exercises financial and administrative control over the entire facility.

(2) Replacement Equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions. The existing LINAC has reached the end of its useful life. Both the existing equipment and the replacement equipment provide radiation oncology procedures that are functionally similar. The existing equipment will be removed from service upon its replacement.

NCBH respectfully requests that the facts stated above, as well as the information included in the Attachments, serve as prior written notification to the Department that the replacement of the LINAC at NCBH meets all of the exemption criteria in N.C.G.S. 131E-184(f).

Please let me know if you have any questions or if additional information is needed.

Sincerely,

*Anna Post Mickleberry*

Anna Mickleberry  
AVP, Strategy, Regulatory Planning, and Business Development  
Telephone Number 336-608-7460  
Email address [apost@wakehealth.edu](mailto:apost@wakehealth.edu)

## EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	X	X
Manufacturer	Varian	Elekta
Model number	21EX	Versa-HD
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	# H272315	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2003	8/1/2022
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	NA	NA
Total cost of the equipment	\$850,000	\$ 2,300,000
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	WFBMC	WFBMC
Document that the existing equipment is currently in use	Yes	NA
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?	NA	Yes
If so, provide the increase as a percent of the current average charge per procedure	NA	15%
Will the replacement equipment result in any increase in the <b>average operating expense per procedure</b> ?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	Radiation Therapy	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Radiation Therapy

Date of last revision: 5/17/19

**From:** [Nicole Moore](#)  
**To:** [Yakaboski, Greg](#)  
**Cc:** [Anna Post Mickleberry](#)  
**Subject:** [External] RE: RE: RE: NCBH Request Confirmation on LINAC CON Exemption  
**Date:** Wednesday, August 31, 2022 4:13:42 PM

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Hi Greg,

In follow up to your inquiry below, I wanted to confirm that NCBH has 4 LINACs located on the main campus of which 3 are grandfathered and 1 is associated with Project ID #G-8038-08. The requested LINAC replacement in our letter is to replace one of the grandfathered LINACs (Varian linear accelerator, Model Number 23 SCX). The existing equipment will be removed from service upon its replacement and will not be used again within the state without first receiving approval.

Please advise if further details are needed. Thank you in advance for your review!

Warm Regards,

Nicole

**Nicole Moore, MBA**

Strategy & Planning Manger

*Growth, Strategy, and Business Development*

Medical Center Boulevard | Winston-Salem | NC | 27157

Office: 336-716-6968 | Cell: 469-831-6587

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**From:** Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

**Sent:** Wednesday, August 31, 2022 7:06 AM

**To:** Nicole Moore <nsmoore@wakehealth.edu>

**Subject:** RE: [External] RE: RE: NCBH Request Confirmation on LINAC CON Exemption

**WARNING:** This email originated from outside of Atrium Health ([greg.yakaboski@dhhs.nc.gov](mailto:greg.yakaboski@dhhs.nc.gov)). **DO NOT** click links or open attachments unless you know and trust the sender. **NEVER** provide your password to anyone, and use the Squish the Phish button to report any suspicious email.

Morning Nicole,

Thank you... the document opened "no problem" this time.

Question- Your team is seeking to replace a LINAC pursuant to the exemption listed in Section 131E-184(f) ... there are 3 criteria:

#1) Equipment being replaced is located on the main campus.

#2) A CON was previously issued for the LINAC being replaced.

#3) Prior written notice is provided.

Need your help re: Condition #2: Do you know if a CON was previously issued for the LINAC that your team is seeking to replace? How many LINAC's are located at North Carolina Baptist Hospital? I did find that we issued a CON for a replacement LINAC back in 2008 (Project ID #G-8038-08).... If there is only one LINAC at the hospital that we are all set.

Thanks,

Greg

Sincerely,

*Gregory F. Yakaboski*

**Gregory F. Yakaboski**

Project Analyst

[Division of Health Service Regulation \[ncdhhs.gov\]](https://ncdhhs.gov), Certificate of Need

[NC Department of Health and Human Services \[ncdhhs.gov\]](https://ncdhhs.gov)

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Office: 919-855-3873

[Greg.Yakaboski@dhhs.nc.gov](mailto:Greg.Yakaboski@dhhs.nc.gov)

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Raleigh, NC 27699-2704

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**From:** Nicole Moore <[nsmoore@wakehealth.edu](mailto:nsmoore@wakehealth.edu)>

**Sent:** Friday, August 26, 2022 9:33 AM

**To:** Yakaboski, Greg <[greg.yakaboski@dhhs.nc.gov](mailto:greg.yakaboski@dhhs.nc.gov)>

**Subject:** [External] RE: RE: NCBH Request Confirmation on LINAC CON Exemption

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Hi Greg,

Please find the attached letter. Please advise if this cannot be opened.

Warm Regards,

Nicole

**Nicole Moore, MBA**

Strategy & Planning Manger

*Growth, Strategy, and Business Development*

*Medical Center Boulevard | Winston-Salem | NC | 27157*

Office: 336-716-6968 | Cell: 469-831-6587

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**From:** Yakaboski, Greg <[greg.yakaboski@dhhs.nc.gov](mailto:greg.yakaboski@dhhs.nc.gov)>

**Sent:** Thursday, August 25, 2022 3:16 PM

**To:** Nicole Moore <[nsmoore@wakehealth.edu](mailto:nsmoore@wakehealth.edu)>

**Subject:** RE: [External] RE: NCBH Request Confirmation on LINAC CON Exemption

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Could you resend your request..... for some reason the letter is not opening for me.

Thanks,

Greg

Sincerely,

*Gregory F. Yakaboski*

**Gregory F. Yakaboski**

Project Analyst

[Division of Health Service Regulation \[ncdhhs.gov\]](https://ncdhhs.gov), Certificate of Need

[NC Department of Health and Human Services \[ncdhhs.gov\]](https://ncdhhs.gov)

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#StayStrongNC and get the latest at [nc.gov/covid19 \[nc.gov\]](https://nc.gov/covid19)

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[Greg.Yakaboski@dhhs.nc.gov](mailto:Greg.Yakaboski@dhhs.nc.gov)

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Raleigh, NC 27699-2704

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**From:** Nicole Moore <[nsmoore@wakehealth.edu](mailto:nsmoore@wakehealth.edu)>

**Sent:** Tuesday, August 23, 2022 7:59 AM

**To:** Yakaboski, Greg <[greg.yakaboski@dhhs.nc.gov](mailto:greg.yakaboski@dhhs.nc.gov)>

**Cc:** Anna Post Mickleberry <[apost@wakehealth.edu](mailto:apost@wakehealth.edu)>

**Subject:** [External] RE: NCBH Request Confirmation on LINAC CON Exemption

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Hi Greg,

I hope this email finds you well. I wanted to follow up on the email below regarding NCBH's request for a LINAC replacement. I look forward to your reply.

Warm regards,

Nicole

**Nicole Moore, MBA**

Strategy & Planning Manger

*Growth, Strategy, and Business Development*

Medical Center Boulevard | Winston-Salem | NC | 27157

Office: 336-716-6968 | Cell: 469-831-6587

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**From:** Nicole Moore

**Sent:** Tuesday, August 2, 2022 11:45 AM

**To:** [greg.yakaboski@dhhs.nc.gov](mailto:greg.yakaboski@dhhs.nc.gov)

**Cc:** Anna Post Mickleberry <[apost@wakehealth.edu](mailto:apost@wakehealth.edu)>

**Subject:** NCBH Request Confirmation on LINAC CON Exemption

Hi Greg,

Please find the attached letter for NCBH requesting confirmation of exemption for LINAC replacement. Please let us know if you need anything else. Thank you!

Warm regards,

Nicole

**Nicole Moore, MBA**

Strategy & Planning Manger

*Growth, Strategy, and Business Development*

Medical Center Boulevard | Winston-Salem | NC | 27157

Office: 336-716-6968 | Cell: 469-831-6587

## **Atrium Health**

***Wake Forest Baptist Health is now  
Atrium Health Wake Forest Baptist***

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## EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	X	X
Manufacturer	Varian	Elekta
Model number	23 SCX	Versa-HD
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	# H272315	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2003	8/1/2022
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Date of last revision: 5/17/19