



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor  
MANDY COHEN, MD, MPH • Secretary  
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

June 26, 2020

Michael Papagikos  
[mpapagikos@nhroc.com](mailto:mpapagikos@nhroc.com)

**Exempt from Review – Replacement Equipment**

**Record #:** 3304  
**Facility Name:** Coastal Carolina Radiation Oncology  
**FID #:** 160260  
**Business Name:** Coastal Carolina Radiation Oncology, PA  
**Business #:** 2403  
**Project Description:** Replace existing linear accelerator  
**County:** New Hanover

Dear Dr. Papagikos:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 17, 2020, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Halcyon Varian Medical Systems fixed linear accelerator to replace the existing Clinac iX Varian Medical Systems SN H294095 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.

Moreover, you need to contact the Agency's Construction, Radiation Protection 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.

Sincerely,

Tanya M. Saporito  
Project Analyst

Martha J. Frisone  
Chief

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

June 17, 2020

Via Electronic Mail Only

Ms. Marth Frisone  
Ms. Tanya Saporito  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
NC Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, North Carolina 27699-2704

RE: Request for Exemption to Certificate of Need Review for Acquisition of a Replacement Linear Accelerator in New Hanover County

Dear Ms. Frisone and Ms. Saporito,

Coastal Carolina Radiation Oncology, P.A. requests a no review determination regarding the proposed purchase of a Varian Halcyon Linear Accelerator (Halcyon) to replace an existing Varian Clinac 21iX Linear Accelerator (iX). The total capital cost of the replacement accelerator is less than \$2.0M, thus meeting the “replacement equipment” requirements as defined in NCGS 131E-176(22a).

#### **Scope of Proposed Project**

It is the intention of CCRO to purchase a Halcyon linear accelerator to replace our iX accelerator. The Halcyon will be housed in the same vault at the same address that is currently occupied by the iX. The iX was new medical equipment when placed into service in 2008. NHRO will up fit the vault and console area to accommodate the Halcyon in accordance with Varian specifications as well as all regulatory requirements. There will not be change in the floor space required for this project. The iX is owned by CCRO and operated by New Hanover Regional Medical Center (NHRMC) as described in “Letter of Exemption re: Replace existing Linear accelerator and consolidate radiation therapy services at Coastal Carolina Radiation Oncology” submitted by NHRMC 5/27/16. The Halcyon will be operated by NHRMC in an identical fashion to the iX.

#### **Reason for Project**

We have seen significant growth in our patient volumes in Linac Service Area 19 and our per machine utilization is one of the highest in North Carolina according to NC SMFP Reports. We often must run multiple shifts and extended hours to be able to accommodate all our patients. This places tremendous stress on our equipment as the availability of the accelerators to our service engineers is limited and we have seen increasing downtime. When one machine is placed temporarily out of service, the entire system experiences significant operational strain. The Halcyon, by virtue of its engineering and modern design allows for faster delivery of the most common types of treatments that we offer: Intensity Modulated Radiation Therapy (IMRT), Image Guided Radiation Therapy (IGRT), and 3D-Conformal Radiation Therapy (3D-CRT). All these techniques are available on the iX, but at a slower and less efficient pace.

#### **Capital Cost of the Replacement Accelerator**

The cost of the Halcyon, including power conditioner and all necessary hardware and software is \$1,763,210. The cost to up fit the vault and console area to accommodate the Halcyon including contingency will be \$55,000. Our in-house

physics group will provide the physics acceptance and commissioning services, resulting in no additional cost for these services. Sales tax on the Halcyon is estimated to be \$123,425. The project's total estimated capital cost for the replacement accelerator is \$1,943,635. Please see **Appendix A** for detailed Halcyon quote and **Appendix B** for the Projected Capital Cost Form.

**Other Review Issues**

The iX will be removed and retained by Varian and either refurbished and sold or salvaged for parts. The cost of removal, shipping, rigging, and installation are included in the Varian quote. No new institutional health services are being created because of this replacement. The number of linear accelerators in the Linac Service Area will not change due to this replacement project. The Halcyon is functionally similar to the iX and will be used for the same purpose. Please see **Appendix C** for an equipment comparison table. The replacement equipment will not result in an increase in patient charges.

**Determination Requested**

I ask you to please review this letter and attached supporting documentation and confirm that CCRO's acquisition of a replacement accelerator does not require a certificate of need review.

Thank you for your consideration in this matter and if you have any questions, please feel free to contact me at 910-251-1839 or via email at mpapagikos@ccradonc.com.

Sincerely,



Michael A. Papagikos, M.D.

Vice President

Coastal Carolina Radiation Oncology

**Attachments**

Appendix A

Attach Varian Quote

Appendix B

Projected Capital Costs Form

Appendix C

Equipment Comparison Table

**Appendix A**

**Varian Halcyon Quote 2020-258539**

# varian

Custom System Proposal

Quotation Number - 2020-258536

Pricing of \$1,763,210

Looking further



## Coastal Carolina Radiation Oncology Center ("Customer")

Michael Papagikos  
1988 S 16TH ST  
WILMINGTON, North Carolina 28401-6647 United States  
Tel : 910-251-1839  
Fax : 910-251-8286  
Email : mpapagikos@nhroc.com

## VMS Inc, Oncology Systems

Jeffrey Boone  
US District Sales Manager  
Work from home  
Atlanta, GA 30327 US  
Tel : 704-737-9395  
Email : jeffrey.boone@varian.com

\*\*\* Confidential - Proposal is intended for Recipient and Recipient's Site Representatives Only \*\*\*

### Quote Information

Quotation Number :	2020-258536	Sales PO Required :	No
Quotation Valid Until :	July 01, 2020	Customer Procurement Contact	Needed
Customer Requested Delivery Date :	August 28, 2020	Name :	
Quotation Date :	May 12, 2020		

### Sales

Incoterms :	DPU Site Insured
Payment Terms :	30 days net
Shipment :	80.00%
Acceptance :	20.00%

For orders equal or less than \$75K, 100% upon shipment, net 30.

Finance support available: For lease and finance plans, call Toby Wann, Director Varian Customer Finance - 408.221.4294 / Toby.Wann@varian.com

### Terms and Conditions

**Products and Services:** Customer's access to and use of the Products, Support Services and Services (except Software-as-a-Service or Subscription Services) as indicated in this Quotation are subject to and governed by: (a) the Varian Terms and Conditions of Sale (Form RAD 1652) at: [https://www.varian.com/1652V\\_OCT\\_2018](https://www.varian.com/1652V_OCT_2018) and (b) any Schedules, Exhibits and/or additional terms (including third party terms) contained, attached, referenced or otherwise indicated in this Quotation. All terms and conditions provided in the website link listed in item (a) above are incorporated by reference and form part of the contract between Varian and Customer. If there is a separate written agreement (e.g. master agreement) in effect between the parties that expressly provides for and governs the purchase and sale of the specific Products, Support Services, Services, Software-as-a-Service and/or SubscriptionService set forth in this Quotation, such written agreement shall govern. Hard copies of the referenced terms and conditions and any additional terms indicated will be provided to Customer upon request.

### For and on behalf of Customer

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Authorized Representative : Michael Papagikos  
Title : Medical Director  
Date : May 12, 2020

### For and on behalf of Varian Medical Systems

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Authorized Representative : Jeffrey Boone  
Title : US District Sales Manager  
Date : May 12, 2020

Offered Products (Sales)

Halcyon, Mobius S/N: 9999

Trade-In and Removal and Disposal for Clinac iX SN H294095

Draft Only

Item	Description	Qty
<b>Section 1</b>	<b>Halcyon, Mobius S/N: 9999</b>	
1.1	<p><b>Halcyon kV System v3.0</b></p> <p>Medical linear accelerator designed to provide radiotherapy using a 6 megavoltage (MV), flattening filter free (FFF) mode beam with Image Guided Radiation Therapy (IGRT) to align the patient as specified by the treatment plan before treatment begins.</p> <p>Features:</p> <ul style="list-style-type: none"> <li>• Patient identity and bolus verification</li> <li>• Daily machine performance check</li> <li>• Integrated lasers and patient monitoring</li> <li>• Integrated beam shielding</li> </ul> <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> <li>• Complete the required facility preparations per the Product Planning Guide (PPG). For detailed information, contact your Regional Planner.</li> </ul>	1
1.2	<p><b>Halcyon Elite v3.0</b></p> <p>Features:</p> <ul style="list-style-type: none"> <li>• Three-dimensional (3D) Image Guided Radiation Therapy (IGRT) with kilovoltage cone beam computed tomography (kV CBCT)</li> <li>• Iterative CBCT reconstruction for kV</li> <li>• 3D IGRT with megavoltage (MV) radiograph pair</li> <li>• 3D IGRT with MV cone beam computed tomography (MV CBCT)</li> <li>• Field-in-Field and dynamically flattened 3D conformal treatment</li> <li>• RapidArc® Volumetric Modulated Arc Therapy (VMAT) treatment</li> <li>• Intensity Modulated Radiation Therapy (IMRT) treatment</li> <li>• Extended treatment field</li> <li>• One step setup</li> <li>• 5.0 mm leaf definition</li> <li>• Up to 800 cGy/minute dose rate</li> <li>• Up to 5.0 cm/second multileaf collimator leaf speed at isocenter</li> <li>• Up to 4 revolution/minute gantry speed</li> <li>• Online access to a marketing kit that contains a broad range of advertising, educational, promotional, and public relations materials targeted to referring physicians, patients, and the media</li> </ul> <p>Prerequisites:</p> <ul style="list-style-type: none"> <li>• Eclipse™ treatment planning system v15.6 or higher with Advanced Planner Desktop</li> <li>• ARIA® oncology information system for radiation oncology v15.1 or higher</li> </ul> <p>Notes:</p> <ul style="list-style-type: none"> <li>• Halcyon is designed and validated to be used only with a Varian treatment planning system and oncology information system.</li> </ul>	1
1.3	<p><b>Patient Motion Monitoring</b></p> <p>Using the existing Halcyon™ patient monitoring system, patient motion monitoring provides an indication if the patient is moving while they are in treatment position.</p> <p>Prerequisites:</p> <ul style="list-style-type: none"> <li>• Halcyon MV System v3.0 or higher or Halcyon kV System v3.0 or higher</li> </ul>	1
1.4	<p><b>Extended Length CBCT Imaging</b></p> <p>Provides the ability to acquire two three-dimensional (3D) Image Guided Radiation Therapy (IGRT) with kilovoltage cone beam computed tomography (kV CBCT) datasets then merge them together so the entire length of the treatment area can be imaged.</p> <p>Prerequisites:</p> <ul style="list-style-type: none"> <li>• Halcyon™ kV System v3.0 or higher</li> </ul>	1
1.5	<p><b>Transtector Power Cond., OBI</b></p> <p>Transtector Power Conditioner for OBI or Halcyon, internal TVSS and input breaker.</p> <p>Features:</p> <ul style="list-style-type: none"> <li>• Input: 208V, 480V and 600V</li> <li>• Output: 480/277V</li> </ul> <p>Notes:</p>	1



Item	Description	Qty
	<ul style="list-style-type: none"> <li>Available in all voltage configurations from 208V to 600V in 50Hz or 60 Hz models for US and ROW applications.</li> </ul>	
1.6	<p><b>Isolation Transformer</b></p> <p>An isolation transformer is used to transfer electrical power from a source and is required for sites with 3-phase 380VAC power.</p> <p>Prerequisites:</p> <ul style="list-style-type: none"> <li>Halcyon system v1.0 or higher or Adaptive therapy solution v1.0 or higher</li> </ul>	1
1.7	<p><b>STD TRNG: Halcyon Training</b></p> <p>Halcyon™ system training to be provided at the customer facility to ensure that staff members can operate the system in a safe and effective manner. Training plan details will be provided by the training management team as part of the product implementation process. Recommended audience includes: Configuration administrator, policy administrator, treatment provider, quality provider, and maintenance technician.</p> <p>Features:</p> <ul style="list-style-type: none"> <li>Hands-on training including: Introduction to the system and system safety, system configuration, policy review, treatment delivery workflows, quality assurance tasks, and technical support overview</li> <li>Go-Live support where the trainer will observe your actions during the first clinical treatment day</li> <li>Duration: 2 days on-site</li> </ul> <p>Prerequisites:</p> <ul style="list-style-type: none"> <li>Halcyon system installed and accepted</li> </ul> <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> <li>Schedule on-site training to coincide with delivery of radiation treatment to your first patient. It is highly suggested to limit the number of scheduled patients on the first clinical day to allow the treatment provider and trainer to discuss specific scenarios that may not have been addressed during the hands-on session</li> </ul> <p>Notes:</p> <ul style="list-style-type: none"> <li>Offer is valid for up to 18 months after installation</li> <li>Training is non-refundable and non-transferable</li> </ul>	1
1.8	<p><b>INCL ED: HA201 Halcyon Physics</b></p> <p>This course provides training for medical physicists responsible for commissioning and administration of the Halcyon™ system. This course will provide the clinical physicist the knowledge and understanding required to use the Halcyon accelerator in a safe and effective manner. This class will examine the various parts of the linac, beam production, imaging, and MLC. Emphasis will be placed on the standard physics tasks, including absolute dose calibration and imaging mode calibrations.</p> <p>Features:</p> <ul style="list-style-type: none"> <li>Instruction of the basic delivery components, basic imaging components and a general overview of system components</li> <li>The course subject matter is presented from a clinical use perspective. The primary emphasis is on the overall commissioning, calibration, and QA of the Halcyon system and its components.</li> <li>Extensive hands-on laboratory exercises</li> <li>Training Type and Location: 2.5 days classroom training at the nearest Varian Education Center offering this course</li> </ul> <p>Prerequisites:</p> <ul style="list-style-type: none"> <li>Halcyon system installed and accepted</li> </ul> <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> <li>All travel expenses (airfare, hotel, rental car, meals and travel incidentals)</li> </ul> <p>Notes:</p> <ul style="list-style-type: none"> <li>Includes tuition and materials for one person</li> <li>Offer is valid for up to 18 months after installation</li> <li>Training is non-refundable and non-transferable</li> </ul>	1
1.9	<p><b>NLS: English</b></p>	1
<b>Section 2</b>	<b>Trade-In and Removal and Disposal for Clinac iX SN H294095</b>	
2.1	<p><b>Trade-In Discount</b></p> <p>Trade-In for Clinac iX SN H294095</p>	1

Item	Description	Qty
2.2	Remove/Dispose Existing Equipment	1
	Remove/Dispose for Clinac iX SN H294095	

Draft Only

Quotation Total

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Quotation Total

US \$1,763,210.00

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Draft Only

**Appendix B Projected Capital Cost Form**

Building Purchase Price	N/A
Purchase Price of Land	N/A
Closing Costs	N/A
Site Preparation	N/A
Construction Renovation Contract(s)	\$50,000
Landscaping	N/A
Architect/Engineering Fees	\$2000
Medical Equipment	\$1,763,210
Non-Medical Equipment	N/A
Furniture	N/A
Consultant Fees (specify)	N/A
Financing Costs	N/A
Interest during Construction	N/A
Other (Taxes)	\$123,425
Other (10% Construction contingency)	\$5000
<b>Total Capital Cost</b>	<b>\$1,943,635</b>

Appendix C Equipment Comparison Form

NHRO iX Linac Replacement with Halcyon		Existing Equipment	Replacement Equipment
Type (e.g., Cardiac Catheterization, Gamma Knife, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, MRI Scanner, Other Major Medical Equipment)		Linear Accelerator	Linear Accelerator
Manufacturer		Varian Medical Systems	Varian Medical Systems
Model Number		Clinac iX	Halcyon
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)		SN H294095	TBD
Is the equipment mobile or fixed?		Fixed	Fixed
Date of acquisition		2008	2020
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>		\$1,846,154	\$1,943,635
Total cost of the equipment		\$1,672,182	\$1,763,210
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>		1988 South 16 <sup>th</sup> St, Wilmington, NC 28401	1988 South 16 <sup>th</sup> St, Wilmington, NC 28401
Document that the existing equipment is currently in use		Yes	NA
Will the replacement equipment result in any increase in the average charge per procedure?		NA	No
If so, provide the increase as a percent of the current average charge per procedure		NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure?		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>		External Beam Radiotherapy	NA
Type of procedures performed on the replacement equipment <Attach a separate sheet if necessary>		NA	External Beam Radiotherapy

**From:** [Michael Papagikos](#)  
**To:** [Waller, Martha K](#)  
**Cc:** [Tanya Saporito](#)  
**Subject:** [External] Letter of Request for No Review Determination  
**Date:** Wednesday, June 17, 2020 4:25:04 PM  
**Attachments:** [CCRO Letter of No Review 2020-06-17.pdf](#)

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Ms. Waller,

Please find attached a letter with supporting documentation a request for Coastal Carolina Radiation Oncology to replace one of our current linear accelerators.

Please let me know if you have any questions or if there is anything else I can provide.

Thanks!

Mike

Michael A. Papagikos, M.D.

T 910-251-1839

F 910-251-8286

<https://www.nhrmc.org/services/cancer/cancer-treatments/radiation-oncology>

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