



North Carolina Department of Health and Human Services
Division of Health Service Regulation

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Governor

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Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

June 2, 2016

Thomas S. Stukes
300 North Greene Street, Suite 1900
Greensboro, NC 27401

Exempt from Review – Replacement Equipment

Record #: 1957
Facility Name: Coastal Carolina Radiation Oncology, P.A.
FID #: 160260
Business Name: Coastal Carolina Radiation Oncology, P.A.
Business #: 2403
Project Description: Replace existing grandfathered linear accelerator
County: New Hanover

Dear Mr. Stukes:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter dated May 27 and received in our office on May 31, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Varian Clinac iX Silhouette Linear Accelerator to replace the grandfathered unit currently in operation. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

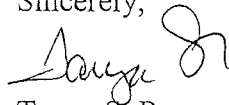
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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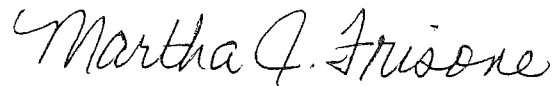


It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,



Tanya S. Rupp
Project Analyst



Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

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May 27, 2016

VIA FEDERAL EXPRESS

Ms. Martha Frisone
Assistant Chief
Healthcare Planning and Certificate of Need Section
DHHS Division of Facility Services
809 Ruggles Drive
Raleigh, North Carolina 27603

*FID # 160260 Type-DxClr
CCRO Bus. Id 2403
NR id 1957*

RE: No Review Request to Acquire One Replacement Linear Accelerator by Coastal Carolina Radiation Oncology, P.A.

Dear Martha:

This firm represents Coastal Carolina Radiation Oncology, P.A., a freestanding radiation oncology treatment center located at 1988 S. 16th Street, Wilmington, North Carolina (CCRO). CCRO requests a no review determination regarding the proposed purchase of a linear accelerator to replace an existing accelerator. The total capital cost of the replacement linear accelerator will be less than \$2,000,000, 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 Varian Clinac iX Silhouette linear accelerator (CL iX) to replace CCRO's Clinac 2100CD linear accelerator (CL 2100CD). The CL iX will be housed in an empty vault that is in CCRO's High Dose Rate Brachytherapy suite. CCRO will up-fit the vault and console area to accommodate the CL iX in accordance with Varian specifications. The floor space will not need to be increased.

As discussed at our in-person meeting with you and representatives from New Hanover Regional Medical Center (NHRMC) on 3/31/16, the 2100CD will be sold to New Hanover Regional Medical Center as a replacement for their current Elekta accelerator. Please see the Notice of Replacement and Relocation of Linear Accelerator to be submitted by NHRMC today for a further description of these inter-related requests.

Reason for Project

Today's technology advances have progressed such that the need for Stereotactic Radiosurgery (SRS), Stereotactic Body Radiation Therapy (SBRT) and Volumetric Arc Therapy (aka RapidArc) are growing at a significant rate. CCRO has only one machine that is capable of delivering these forms of modern radiotherapy; however, CCRO's patient volume is such that two linear accelerators with those capabilities are needed.

The 2100CD is more than capable of providing regular External Beam Radiotherapy (EBRT) and Intensity Modulated Radiotherapy (IMRT) treatments with curative intent for simple cancers. It is also a capable machine for treating a significant portion of palliative cases that are encountered in a busy radiation oncology clinic. However it lacks the updated technology needed for SRS, SBRT, and RapidArc. Thus CCRO desires to replace it with a new CL iX.

Capital Cost of the Replacement Accelerator

The cost of the CL iX, including treatment room accessories and power conditioner is \$1,700,000.00. The cost to up-fit the vault and console area to accommodate the CL iX and its controls will be \$59,100.00. CCRO's in-house physicist(s) will provide the physics acceptance and commissioning services, therefore no additional costs will be incurred in this area. Other costs associated with fees and permits are estimated at \$2,000.00. Sales tax on the CL iX and other equipment is estimated at \$120,000.00. The project's total estimated capital cost for the replacement linear accelerator is \$1,881,100.00. See Exhibit A for the certified Project Capital Cost.

Other Review Considerations

This proposal meets the definition of "replacement equipment" as set forth in N.C. Gen. Stat. § 131E-176(22a) because:

1. The cost of the equipment and the cost of all activities essential to acquiring and making operational the replacement equipment are less than \$2 million; and
2. The sole purpose of this proposal is to replace comparable medical equipment currently in use, which will be sold or otherwise disposed of when replaced.

Further, this proposal meets the requirements of 10A NCAC 14C .0303(d) because:

- The CL iX has the same technology as the 2100CD although it may possess expanded capabilities due to technological improvements; and
- The CL iX is functionally similar and is used for the same diagnostic or treatment purposes as the 2100CD and is not used to provide a new health service; and

- The acquisition of the CL iX will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

None of the exclusions in 10A NCAC 14C .0303(e) applies here.

Determination Requested

Please review this letter and the attached documentation and confirm that CCRO's acquisition of a new linear accelerator for replacement purposes does not require a certificate of need review.

Very truly yours,

WOMBLE CARLYLE SANDRIDGE & RICE
A Limited Liability Partnership



Thomas S. Stukes

TSS:jac
Enclosures

Exhibit A

Certified Project Cost

PROJECT CAPITAL COST

Site Costs

(1) Full purchase price of land	\$ _____	
Acres _____ Price per Acre	\$ _____	
(2) Closing costs	\$ _____	
(3) Site Inspection and Survey	\$ _____	
(4) Legal fees and subsoil investigation	\$ _____	
(5) Site Preparation Costs [Include]		
Soil Borings		
Clearing and Grading		
Roads, Parking, & Sidewalks		
Water and Sewer		
Excavation and Backfill		
Termite Treatment		
Sub-Total Site Preparation Costs		\$ _____
(6) Other (Specify)	\$ _____	
(7) Sub-Total Site Costs		\$ _____

Construction Contract

(8) Cost of Materials [Include]		
General Requirements		
Concrete/Masonry		
Woods/Doors & Windows/Finishes		
Thermal & Moisture Protection		
Equipment/Specialty Items		
Mechanical/Electrical		
Sub-Total Cost of Materials		\$ _____
(9) Cost of Labor	\$ _____	
(10) Other (Specify)	\$ _____	
(11) Sub-Total Construction Contract		\$ <u>59,100.00</u>

Miscellaneous Project Costs

(12) Building Purchase	\$ _____	
(13) Fixed Equipment Purchase/Lease	\$ <u>1,700,000.00</u>	
(14) Movable Equipment Purchase/Lease	\$ _____	
(15) Furniture	\$ _____	
(16) Landscaping	\$ _____	
(17) Consultant Fees		
Architect and Engineering Fees	\$ <u>2,000.00</u>	
Legal Fees & Market Analysis	\$ _____	
Other (Specify)	\$ _____	
Sub-Total Consultant Fees		\$ <u>2,000.00</u>
(18) Financing Costs (e.g. Bond, Loan, etc.)	\$ _____	
(19) Interest During Construction	\$ _____	
(20) Other (Specify) Sales Tax	\$ <u>120,000.00</u>	
(21) Sub-Total Miscellaneous		\$ <u>1,822,000.00</u>
(22) Total Capital Cost of Project (Sum A-C above)		\$ <u>1,881,100.00</u>

I hereby certify that the foregoing Project Capital Cost is true and correct.

This the 27 day of May, 2016.



Julie Blundo
Administrative Director
Coastal Carolina Radiation Oncology, P.A.

Table 8L. Freestanding Oncology Center Procedures
1993 - 1995

Facility Name	County	LIN ACC	PROCEDURES		
			1993	1994	1995
Greensboro Radiation Oncology Center	Guilford	1	6,130	5,208	3,346
Western Regional Cancer Center	Haywood	1	537	4,315	3,884
Mountain Regional Cancer Center	Jackson	2	0	2,991	9,000
Charlotte Radiation Care	Mecklenburg	1	7,037	3,089	1,143
Matthews Radiation Oncology	Mecklenburg	1	7,695	7,644	8,007
University Place Radiation Care	Mecklenburg	1	0	1,167	1,124
New Hanover Radiation Oncology Center *	New Hanover	2	NA	16,559	14,665
Albemarle Regional Cancer Center	Pasquotank	1	5,479	4,129	4,476
Salisbury Oncology Center	Rowan	1	NA	3,666	4,495
Sandhills Oncology Treatment Center	Scotland	1	NA	1,847	1,042
Wayne Radiation Oncology Center	Wayne	1	1,462	6,435	5,700
Roanoke Valley Cancer Center **	Halifax	1	2,609	3,045	3,245
TOTALS		14	30,949	60,095	60,127

* Two Accelerators

** Cobalt Only