

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

Pat McCrory Governor Aldona Z. Wos, M.D. Ambassador (Ret.) Secretary DHHS

> Drexdal Pratt Division Director

July 24, 2013

William R. Shenton, Partner Poyner Spruill, LLP 301 Fayetteville Street, Suite 1900 Raleigh, NC 27601

Exempt from Review - Replacement Equipment

Facility:

Sampson Radiation Oncology

Project Description:

Replace existing Varian 2100C linear accelerator with a Varian 21EX

County:

Sampson

FID#:

041657

Dear Mr. Shenton:

In response to your letter of June 21, 2013 and email letter of July 22, 2013, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Varian 21EX linear accelerator, serial number 1975 to replace the existing Varian 2100C linear accelerator, serial number 244. 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. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

It should be noted that this 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 Agency 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

Craig R. Smith, Chief Certificate of Need Section

cc:

Construction Section, DHSR



Certificate of Need Section

www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-733-8139
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

An Equal Opportunity/ Affirmative Action Employer

Poyner Spruill^{up}

William R. Shenton

wshenton@poynerspruill.com

Partner D: 919.783.2947 F: 919.783.1075

July 22, 2013

VIA E-MAIL

Greg Yakaboski
Project Analyst
Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Replacement of the Linear Accelerator in Clinton, NC

Dear Greg,

To follow up on our telephone calls last Thursday about the replacement of the linear accelerator in Clinton, which was the subject of my letter of June 21 to the CON Section, here is supplemental information to clarify the questions that you wanted to have more information about to complete the agency's response to the request:

- 1. The correct address is 215 Beaman Street in Clinton and the building located at that site is owned by Sampson Regional Cancer Center, LLC.
- 2. The CON Section confirmed by letter of April 2, 2012 (attached to my letter of June 21) that certain transactions could proceed without a certificate of need,. As a result of these transactions, North Carolina Radiation Therapy Management Services ("NCRTMS") became the owner and parent company of two entities: 1) Sampson Accelerator, LLC, which owns the linear accelerator at 215 Beamon Street; and 2) Sampson Simulator, LLC, which owns the simulator located there.
- 3. The business name that this facility operates under is Sampson Radiation Oncology, and the physician who provides the medical treatment is affiliated with a practice known as Radiation Therapy Associates of Western North Carolina, P.A., which was started in western North Carolina and which the Clinton physician has joined.
- Under a contract between NCRTMS and the physician practice, the two NCRTMS subsidiaries, Sampson Accelerator, LLC and Sampson Simulator, LLC provide the physician practice access to the equipment.

I think this addresses each of the points that you had questions on, but if I have missed anything, or if you need additional information of any kind, please let me know, and thanks for your time and attention on this request.

Very truly yours,

William R. Shenton

Partner

GH / CHARLOTTE /

ROCKY MOUNT / SOUTHERN PINES

Poyner Spruill

June 21, 2013

William R. Shenton Partner D: 919.783.2947 F: 919.783.1075 wshenton@poynerspruill.com

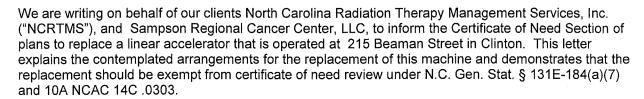
VIA HAND DELIVERY

Craig R. Smith
Chief
CON Section
809 Ruggles Drive
Raleigh, NC 27603

Martha Frisone Assistant Chief CON Section 809 Ruggles Drive Raleigh, NC 27603

RE: Replacement of Linear Accelerator at 215 Beaman Street in Clinton

Dear Mr. Smith and Ms. Frisone:



The Existing Linear Accelerator

The existing linear accelerator is a Varian 2100C machine (Serial Number 244). It has been operated by Sampson Regional Cancer Center, LLC since September of 2006. Thus, the linear accelerator has been operated for much more than the three years required under the CON Rule. Last year NCRTMS acquired the ownership interests in Sampson Regional Cancer Center, LLC in a transaction that was approved by the CON Section (See Exhibit A).

The Replacement Costs

The linear accelerator that is planned for installation at 215 Beaman Street is a used Varian 21EX (Serial Number 1975), which employs the same technology as the Varian 2100C machine, and will provide external beam radiation therapy, just as the 2100C machine has. Currently, the Varian 21EX is located in Naples Florida where it is operated by a company that is affiliated with NCRTMS. It has a book value of \$366,000, as documented in the attached Exhibit B, and this book value includes the operating software and a maintenance contract. However, based on the experience of NCRTMS, its fair market value is somewhat higher -- \$550,000, and so that is the value that has been used in presenting the details of this replacement proposal. Even if one adds Sampson County's seven percent sales tax (See http://www.dornc.com/taxes/sales/taxrates.html) to the Fair Market Value figure, that would raise the total cost of the Varian 21EX by only \$38,500, resulting in a total cost of \$588,500.

NCRTMS has identified the following specific costs that will be associated with the replacement:

- Installation of base frame at a cost of \$51,000 (See Exhibit C);
- Vault renovations costing \$275,000 (See Exhibit D); and
- Relocation and installation of Varian 21EX at a total cost of \$134,932 (See Exhibit E).

Craig R. Smith Martha Frisone June 21, 2013 Page 2

Finally there are other costs that have been calculated based on the experience of NCRTMS at other locations. These include the following components, presented as not to exceed figures based on NCRTMS experience:

- Other ancillary hardware/software and other costs, all of which will not exceed \$275,000.00;
- The cost of removing the Varian 2100C from North Carolina, which will not exceed \$15,000; and
- Salary and travel expense for the work of non-local staff who may be involved in the installation and commissioning which will not exceed \$25,000.00.

No other costs will be associated with the deployment of the Varian 21EX linear accelerator at the Beaman Street location. The result, combining these costs listed in the six bullet points with the linear accelerator cost of \$588,500, is a grand total of \$1,364,432.00 for all replacement costs.

As noted above, the Varian 2100C linear accelerator that had been operated at 215 Beaman Street will be moved out of state. Finally, NCRTMS also has instructed us to confirm that the acquisition of the Varian 21EX will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months of operation of the Varian 21EX linear accelerator.

Analysis of Provisions in CON Law and Rules

Based on this information the proposed replacement meets all requirements of 10A NCAC 14C .0303 (d) (3) to be exempt from review. The total cost of the replacement linear accelerator, with sales tax, falls far below the \$2 Million threshold and so this qualifies as "Replacement Equipment" under the Certificate of Need Law. The proposal also meets each of the requirements set out in 10A NCAC 14C .0303: The existing machine has been in operation for more than three years. The Varian 21EX has the same technology, is functionally similar, will be used for the same treatment purposes, and will not result in an increase in patient charges or per procedure operating costs.

Conclusion

We look forward to your confirmation that the proposed replacement of the linear accelerator at the Beaman Street location in Clinton is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7); and thank you in advance for your consideration of this request.

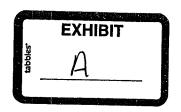
Very truly yours,

William R. Shenton

Jully N. Sherke

Partner





North Carolina Department of Health and Human Services Division of Health Service Regulation Certificate of Need Section

2704 Mail Service Center • Raleigh, North Carolina 27699-2704 http://www.ncdhbs.gov/dhsr/

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief Phone: (919) 855-3873 Fax: (919) 733-8139

April 2, 2012

William R. Shenton PoynerSpruill 301 Fayetteville Street Suite 1900 Raleigh, NC 27601

RE:

No Review

- Transfer By MV-Photon of its membership interest in Sampson Regional Cancer Center LLC to Sampson Regional Medical Center
- Transfer by Sampson Radiation Oncology, P.A. of its ownership interests in the Simulator currently located in the Sampson Regional Cancer Center LLC to a New LLC (a wholly owned subsidiary of Sampson Radiation Oncology, P.A.)
- Transfer by Sampson Regional Medical Center of its ownership interests in the Linac currently located in the Sampson Regional Cancer Center LLC to SRMC Sub (a wholly-owned subsidiary limited liability company)
- Acquisition of 100% of SRMC Sub by North Carolina Radiation Therapy Management Services, LLC
- Acquisition ob 100% of New LLC by North Carolina Radiation Therapy Management Services, LLC

Sampson County

Dear Mr. Shenton:

The Certificate of Need (CON) Section received your letters of February 29, 2012 and March 23, 2012 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

In addition, you should contact the Construction Section, DHSR to determine if they have any requirements for development of the proposed project. Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely

Gregory F. Yakaboski Project Analyst

Craig R. Splith, Chief Certificate of Need Section

Medical Facilities Planning Section, DHSR



Location: 809 Ruggles Drive, Dorothea Dix Hospital Campus, Raleigh, N.C. 27603

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May 30, 2013 at 10:10 AM

Book = internal

FYE Month = December

Class = CS

Co Asset No

21st Century Oncology Net Book Value Report

EXHIBIT

In Svc Date Med Depr Rem Life (+) Salvage Value Thru Date (-)
Current Accum
Depreciation

(=) Net Book Value

8 ₹

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											000 11072G	SUP. CONTR - SOFTWARE -VARIAN 01/01/13-12/31/13	000 11072F	SUP. CONTR - SOFTWARE - VARIAN 01/01/2012-12/31/2012	000 11072E	SUP. CONTR - SOFTWARE -VARIAN-01/01/2011-12/31/2011	000 11072D	VARIAN SOFTWARE EMR EXPANSION DESIGNATED SITE LICENSE	000 11072C	SUP. CONTR - SOFTWARE -VARIAN 07/07/2010-07/06/2011	000 110728	SUP. CONTR - SOFTWARE -VARIAN 01/01/10-12/31/10	Location = 10079
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Class = MC

Location = 10079

008077 MAINT/REP- VARIAN SN1975 000 11072A

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33.33%

Page 1

Book = Internal
FYE Month = December

May 30, 2013 at 10:10 AM			000 110725	# 8 %		Class = MC	Sys No Ext Co Asset No
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21st Century Oncology Net Book Value Report

Book = Internal

FYE Month = December

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Net Grand Total Count = 9

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56.01%

Report Assumptions

Report Name: Net Book Value Source Report <Standard Report>

Calculation Assumptions:

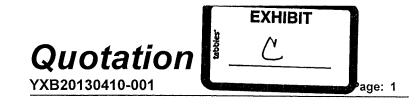
Include Sec 168 Allowance & Sec 179: No

Group/Sorting Criteria:

Group = <Selected Assets> from All Complete Assets Include Assets that meet the following conditions: <Selected Assets> from All Complete Assets Sorted by: Class (with subtotals), Location (with subtotals), System No, Extension

C





Quotation For:

Daniel Galmarini 21st Century Oncology - Corp. Headquarters & Administr. 2234 Colonial Blvd. Fort Myers, FL 33907 (239) 931 - 7333 FAX: (239) 931 - 7380 Please address inquiries and replies to:

Yoel Bakas Varian Medical Systems 2250 Newmarket Parkway Suite 120 Marietta, GA 30067 (770) 955 - 1367 FAX: (678) 255 - 3850 yoel.bakas@varian.com

Your Reference:	Quotation Firm Until: May 30, 2013
FOB Point: US2 FOB: Destination	Shipping Allocation: 90 DAYS ARO
Payment Terms: NET 30	Varian Terms and Conditions of Sale 1652U Attached

Clinton, NC Base Frame Stand Alone Accessories

21st Century Onc	ology - Corp. H	eadquarters &	Administr.	Varian Medical Systems			
Quotation Total o	of: USD \$51	1,000	Accepted by:				
Signature:				Submit	ted by:		
Name:					· · · · · · · · · · · · · · · · · · ·		
Title:					(Signature)		
				Name:	Yoel Bakas		
Date:							
For this purchase,				Title:	Director, Strategic Accounts		
Institution's Primar	•		on affiliation.				
Any change will be	e maicated belov	v.		Date:	April 10, 2013		
☐ AmeriNet ☐	Aptium	BJC	☐ Broadlane				
☐ CHW ☐	Consorta/HPG						
☐ Matrix ☐	MedAssets	☐ Novation	☐ Premier				
□ ROI □	uso	☐ VA Gov	☐ None				



Quotation

YXB20130410-001

Page: 2

21st Century Oncology - Corp. Headquarters & Administr., Fort

Section 1 Stand Alone Accessories

Offer Price

1.01 1 New Universal Baseframe 52" Fixed Floor

Quotation Total \$ 51,000.00

There may be radiological regulatory requirements applicable to possessing and/or operating radiation generating machines. Varian takes no responsibility regarding local radiation safety requirements.

These requirements are the customer's responsibility.

End of Support: Varian may terminate the Agreement at the end of support of the Product that is the object of the Support Services by giving twenty-four (24) months written notice to the Customer. However, Varian may shorten this notice period in its sole discretion if termination is required due to key component obsolescence issues or material product quality concerns.

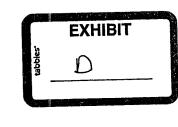
Terms & Conditions of Sale

This offer is subject to credit approval and is exclusive of any applicable sales taxes or duties.

If Customer chooses to pay by credit card, a four percent (4%) service fee will be added.

FINANCING AVAILABLE: For lease and finance plans, call Tony Susen, Director - Varian Customer Finance, at (508) 668-4609.

D



North Carolina Radiation Therapy Management Services, LLC
Project Cost Tracking Worksheet - Vault Construction
Project Location:
Clinton, NC
Project Description:
Replace Linear Accelerator

		Es P	Project Estimate	
Concrete Cutting & Grout In		↔	18,112	
Framing		€9	5,775	
HVAC		↔	3,158	
Electrical		↔	78,719	
Plumbing		€	5,253	
Casework		↔	37,524	
Flooring		↔	12,540	
Painting		₩	4,373	
Subtotal:		₩	165,452	
General Con Contingency Project Coor	General Conditions/Overhead/Profit Contingency Project Coordination	, , , , , , , , , , , , , , , , , , , 	25,673 12,375 16,500	
Total Construction Cost:	C	₩	228,250	
Architec Reimbu	Architectural & Engineering Reimbursable Travel, Mailing, etc.	₩ ₩	34,375 12,375	
Total Project Cost:		₩	275,000	

.



Maintenance Agreement

SAW20130607-004

Page: 1

Quotation Prepared For:

Don Lazarus 21st Century Oncology - Corp. Headquarters & Administr. 2234 Colonial Blvd. Fort Myers, FL 33907 (239) 931 - 7333 FAX: (239) 931 - 7380 Please address inquiries and replies to:

Scott A. Walker Varian Medical Systems Service 2250 Newmarket Parkway Suite 120 Marietta, GA 30067



(678) 255 - 3803 FAX: (678) 255 - 3801 scott.walker@varian.com

Your Reference:	Quotation Valid Until: December 4, 2013
Agreement Start Date: July 1, 2013	Agreement End Date: June 30, 2014
Comments:	Attachment 1 Service Level Specifications
	Attachment 2 Local Business Specifications
	Attachment 3 Legal Specifications

Relocation of Clinac EX #1975 from Lutgert Pavillion in Naples, Florida to 21st Century -Clinton, NC location. Baseframe to be provided seperately.

> Covered Equipment and Services Relocation of CL-EX #1975

Customer Rep	resentative:	Varian	Representative:
Signature:			
Name:		Name:	Scott A. Walker
Title:		Title:	National Accounts Manager
Date:		Date:	June 7, 2013



Attachment 1

SAW20130607-004

Page: 2

21st Century Oncology - Corp. Headquarters & Administr., Fort

Item

Support Description

Price

Section 1 Relocation of CL-EX #1975

1 Year Value Added Services

Relocation Services

This service includes relocation of the Low Energy Clinac (LE Clinac), High Energy Clinac (HE Clinac) or the TrueBeam system. The relocation service includes the different components that are shown in this section of the quotation.

The relocation service is provided to the customer under the standard Terms and Conditions of Sale included with this quotation. The following additional terms and conditions apply.

TITLE TO THE USED EQUIPMENT

CUSTOMER warrants and represents that CUSTOMER is the lawful owner of the Used Equipment and there are no restrictions preventing the removal of the Used Equipment such as security interests, liens, claims, UCC-1 financing statements, or encumbrances of any kind. Title shall remain with CUSTOMER at all times.

TRANSPORTATION AND RISK OF LOSS

All shipments are FOB CUSTOMER's site of origin (or Storage site in case of shipment from Storage) with all transportation and insurance at the expense of CUSTOMER. Risk of loss or damage to the Used Equipment shall remain with CUSTOMER.

REMOVAL AND STORAGE

Removal ("Removal") shall mean rigging the Used Equipment out of CUSTOMER's current site and transportation of the Used Equipment to CUSTOMER's new site or to Storage at a location mutually agreeable to both parties. VMS will be responsible for supervising the Removal and properly packaging the Used Equipment. Rigging amount listed on the VMS Quotation does not include special shoring of the floor to support the weight, room demolition for removal or if a crane is required to remove the Used Equipment. If the Used Equipment is transported to Storage, VMS is responsible for an inventory audit, using the list created in (1.) above. VMS shall provide CUSTOMER with a copy of the inventory list. CUSTOMER shall be responsible for all cost and expense of removal, freight and insurance for shipment, rigging and for any Storage fees as defined on VMS's Quotation.

NO VARIAN WARRANTIES

Notwithstanding VMS's possible Removal of the Used Equipment to Storage, if required, VMS disclaims (1) all warranties of title or warranties of right to transfer the Used Equipment; (2) all warranties that the Used Equipment will be free of any security interests, liens, claims, UCC-1 financing statements, or encumbrances of any kind, and (3) any warranty that possession of the Used Equipment will not be disturbed. These VMS disclaimers apply whether a warranty arises from Uniform Commercial Code section 2312 (1), from expressions of VMS, by implication, or from the common law.

- Relocation & Installation HE Clinac
- Equipment Inspection
- License Transfer



Attachment 1

SAW20130607-004

Page: 3

21st Century Oncology - Corp. Headquarters & Administr., Fort

Item	· S	Support Description		Price
	1	License Registration		
	-			
	-	Standard Equipment Rig-out/Supervision		
	-	Deinstall, Labor, Packaging for Shipping		
		New Site Coordination		
	-	Standard Equipment Rig-In/Supervision		
	-	Installation Services		
	•	Installation of Lasers		
	-	New Interconnect Cables		
		Agreeme	nt Total \$	134,932

End of Support:

Varian may terminate the Agreement at the end of support of the Product that is the object of the Support Services by giving twenty-four (24) months written notice to the Customer. However, Varian may shorten this notice period in its sole discretion if termination is required due to key component obsolescence issues or product quality concerns.

Attachment 1

SAW20130607-004

Page: 4

Payment Schedule

21st Century Oncology - Corp. Headquarters & Administr., Fort

Grand Total: \$134,932.00

Annually	Year 1
1. Relocation of CL-EX #1975	\$134,932.00
	\$134,932.00