



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

January 10, 2018

Robert A. Hamill
3015 Carrington Mill Boulevard, Suite 450
Morrisville, NC 27560

Exempt from Review – Replacement Equipment

Record #: 2468
Business Name: 2124
Business #: North Carolina Radiation Therapy Management Services, Inc.
Project Description: Replace existing CT simulator
County: Haywood

Dear Mr. Hamill:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of January 3, 2018, 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 GE LightSpeed QXI (Serial #233866CN3) to replace the GE ProSpeed (Serial #169725YM9). 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 and Radiation 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,

Julie M. Faenza
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

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



Robert A. Hamill
(919) 447-4970
rhamill@hallrender.com

January 3, 2018

VIA OVERNIGHT COURIER

Martha Frisone
Assistant Chief
North Carolina Division of Health Service Regulation
Health Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, NC 27603



RE: Notice of an Exempt Replacement of CT Simulator Pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

Dear Ms. Frisone:

We represent 21st Century Oncology, Inc. and its wholly-owned subsidiary, North Carolina Radiation Therapy Management Services, Inc. (collectively, "21C"). We are writing to inform the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Health Planning and Certificate of Need Section ("CON Section") of 21C's intention to replace its existing GE ProSpeed Simulator (Serial No. 169725YM9) ("**Existing Equipment**") that is currently in operation at the Haywood Cancer Center, located at 600 Hospital Drive, Clayton, NC 28721. For the reasons explained below, 21C's replacement of the Existing Equipment is exempt from certificate of need ("**CON**") review pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

1. **Description of Equipment.**

The Existing Equipment is a GE ProSpeed Simulator, that is used to simulate patients' radiation therapy treatment. The Existing Equipment was originally acquired by 21C on October 28, 2002. The Existing Equipment was used at a 21C location in Florida prior to being relocated to Haywood Cancer Center in 2007, pursuant to an exempt replacement that was confirmed by the CON Section in a July 10, 2007 letter, which is attached hereto as Exhibit A. The Existing

Equipment has been in operation at Haywood Cancer Center since 2007. Upon replacement, the Existing Equipment will be scrapped, so it will no longer be used in North Carolina.

21C intends to replace the Existing Equipment with a GE LightSpeed QXI Simulator (Serial No. 233866CN3) (“**Replacement Equipment**”). The Replacement Equipment is currently owned by 21C, and has been used by 21C at a facility in New Jersey. The Replacement Equipment has generally the same technology as the Existing Equipment, is functionally similar to the Existing Equipment, and will be used by 21C to provide the same radiation simulation services in support of treatment planning. The acquisition of the Replacement Equipment will not result in any increase in patient charges or per-procedure operating expenses within the first twelve months following acquisition. 21C’s total cost to acquire and relocate the Replacement Equipment to Haywood Cancer Center will be significantly less than \$2,000,000.

2. Overview of Applicable Law.

“Replacement equipment” is except from CON review. N.C. Gen. Stat. § 131E-184(a)(7). “Replacement equipment” is equipment that costs less than \$2,000,000 and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. N.C. Gen. Stat. § 131E-176(22a). The cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making the equipment operational shall be included when calculating the total cost of replacement equipment. *Id.*

Replacement equipment is comparable to the equipment being replaced if: (i) it has the same technology as the existing equipment, although it may possess expanded capabilities due to technological advancements; (ii) it is functionally similar and used for the same diagnostic or treatment purposes and is not used to provide a new health service; and (iii) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per-procedure operating expenses within the first twelve months after replacement. 10A N.C.A.C. 14C.0303(d).

Replacement equipment will be deemed not to be comparable if the replacement equipment is new or reconditioned, the existing equipment was purchased secondhand, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment. 10A N.C.A.C. 14C.0303(e)(1).

3. **Analysis.**

The Replacement Equipment constitutes “replacement equipment” as defined in N.C. Gen. Stat. § 131E-176(22a), satisfies the regulatory requirements set forth at 10A N.C.A.C. 14C.0303, and is therefore exempt from CON review, for the following reasons:

a. The total cost of the Replacement Equipment, inclusive of the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation and other activities essential to acquiring and making operational the Replacement Equipment will be significantly less than \$2,000,000. The current fair market value of the Replacement Equipment is estimated to be \$80,000. The costs to transport and install the Replacement Equipment, and to dismantle and scrap the Existing Equipment is \$13,500. A quote for such services, obtained by 21C from BC Technical, is attached as Exhibit B. The Replacement Equipment will be commissioned by a 21C employee, at an approximate cost of \$1,257.76 (8 hours at \$157.22 per hour). Construction will not be required in connection with installing the Replacement Equipment. Electrical work will be required in conjunction with installation of the Replacement Equipment, at a rate of \$1,680.98. No other activities that are essential to acquiring and making operational the Replacement Equipment will be required. The total cost of replacement, therefore, is approximately \$96,438.74.

b. The Existing Equipment will be scrapped, and will no longer be used in the State of North Carolina.

c. The Replacement Equipment has the same technology as the Existing Equipment, although it will have certain expanded capabilities due to technological advancements. Despite such technological advancements, the Replacement Equipment is functionally similar to the Existing Equipment, will be used for the same treatment purposes, and will not be used to provide any new health services. The Replacement Equipment is not capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the Existing Equipment. A chart comparing the Existing Equipment and Replacement Equipment is attached as Exhibit C.

d. The acquisition of the Replacement Equipment will not result in any increase in patient charges or per-procedure operating expenses within the first twelve months following installation.

e. The Replacement Equipment is being acquired more than three years after the acquisition of the Existing Equipment.

On behalf of 21C, we respectfully request that the CON Section provide written confirmation that 21C’s replacement of the Existing Equipment with the Replacement Equipment, as described herein, is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-

January 3, 2018

Page 4

184(a)(7). 21C desires to complete the replacement as soon as possible, and therefore requests expedited review of this matter.

Please do not hesitate to contact me if you have any questions or require additional information. Thank you for your review and consideration of this matter.

Sincerely,

HALL, RENDER, KILLIAN, HEATH & LYMAN, LLP

A handwritten signature in black ink that reads "Robert Hamill". The signature is written in a cursive, slightly slanted style.

Robert A. Hamill

Exhibit A



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

Michael F. Easley, Governor
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

July 10, 2007

Sean Timmons
Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, LLP
PO Box 2611
Raleigh, NC 27602

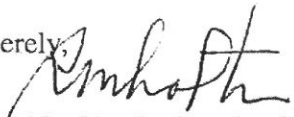
RE: Exempt from Review - Replacement Equipment/ Radiation Therapy Services, Inc., Haywood
Cancer Center/ Replace existing simulator/ Haywood County

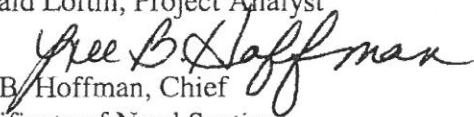
Dear Mr. Timmons:

In response to your letters of May 17, 2007, 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 G.E. ProSpeed CT simulator, serial number 169725YM9, to replace the existing Varian Ximatron simulator, serial number 607. 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,


Ronald Loftin, Project Analyst


Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DFS



Exhibit B

EQUIPMENT RELOCATION & INSTALLATION AGREEMENT

This Equipment Relocation & Installation Agreement dated, November, 2017 is offered by BC Technical, Inc. ("BC TECHNICAL"), a UTAH corporation, having its principal place of business at 7172 South Airport Road – West Jordan, UT 84084, to 21st Century Oncology, Inc. ("CUSTOMER") having its principal place of business at 2270 Colonial Boulevard, Ft. Myers, FL 33907.

Invoice To: Same as Above

Contact: Enrique Vaiani

BC TECHNICAL agrees to sell the services described below at the prices and deliveries stated to CUSTOMER, subject to the conditions stated in Scope of Work herein, and the Standard Terms and Conditions attached hereto.

SCOPE OF WORK:

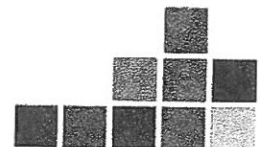
BC TECHNICAL will transport a certain GE LightSpeed OXI CT Scanner (#CT40195) ("Equipment") owned by CUSTOMER from the BC TECHNICAL warehouse to 21st Century Oncology, Inc. at the following location: 600 Hospital Drive, Clyde, NC 28721 ("Install Location") for installation. BC TECHNICAL will de- install their GE ProSpeed OJ CT Scanner (#CT40187) at the Install Location, and transport it to the BC TECHNICAL warehouse for scrapping. BC TECHNICAL will unload, rig-in, reconnect, and calibrate the Equipment to OEM specifications at the Install Location.

- TSD
- BC TECHNICAL shall transport the Equipment to the Install Location above, and rig into the room on November 13, 2017, at which time installation shall proceed.
 - Upon installation, Equipment shall be added to the 21st Century Master Service Agreement at the rate of \$3,115.00 per month.

SERVICES PRICE:

- Price and payments. The relocation & installation price is \$13,500.00 plus any applicable tax, and is due and payable upon acceptance of this Agreement.

CUSTOMER hereby agrees and acknowledges that, if the initiation and finalization of the relocation extends beyond January 1, 2018, due to circumstances resulting from CUSTOMER (i.e., lack of room preparation), the Services Price may require adjustment.



TERMS AND CONDITIONS ON FOLLOWING PAGES

BC Technical, Inc.

21st Century Oncology, Inc.

Approved:

CUSTOMER Acceptance

Authorized Signature:

BY: Todd Radtke

BY: 

Printed: TODD RADTKE

Printed: Doug Staut

Title: EVP

Title: Interim CFO

Date: 11 / 8 / 2017

Date: 11 / 8 / 17

CUSTOMER PO#: _____



TERMS AND CONDITIONS:

Customer Representations/Responsibilities:

- CUSTOMER represents that it owns the Equipment and that no liens are held against the Equipment. CUSTOMER holds BC TECHNICAL harmless from any liability concerning ownership, obligations and lien disputes.
- CUSTOMER is responsible for all removal, construction or modification to the current facility to allow the Equipment to be removed. Any costs for construction, demolition, permits, modifications and union labor are not included in this Agreement.

Project Timing/Installation:

- Unless otherwise agreed in writing, BC TECHNICAL will require three (3) weeks advance notice to schedule the deinstallation. While BC TECHNICAL shall endeavor to meet Customer expectations on project timing, actual project initiation dates shall be subject to the current BC TECHNICAL schedule.

Prices: The Prices quoted do not include local, state, federal, value-added or any other form of taxes, unless otherwise indicated. CUSTOMER will be responsible for any such taxes or obligations. Further, the prices of items quoted herein do not include: the cost of permits or fees relating to any equipment, installation work, construction, building additions or modifications and other activities, unless otherwise indicated. CUSTOMER will be responsible for any such fees or obligations.

Payment: Payment of undisputed invoices shall become due in accordance with the specific terms on the deposits made hereunder shall be nonrefundable. Failure to abide by the payment terms shall be considered a default of this Agreement. Upon default due to failure to abide by payment terms, BC TECHNICAL shall have option to terminate this Agreement.

Warranty/ Disclaimer: BC TECHNICAL REPRESENTS AND WARRANTS THAT SERVICES PERFORMED BY BC TECHNICAL OR BY A PERMITTED SUBCONTRACTOR, EMPLOYEE, OR AGENT OF BC TECHNICAL SHALL BE PERFORMED ON A PROFESSIONAL BASIS, CONSISTENT WITH THE BEST PRACTICES IN THE INDUSTRY AND IN A DILIGENT, WORKMANLIKE, AND EXPEDITIOUS MANNER AND IN COMPLIANCE WITH ALL APPLICABLE FEDERAL AND STATE LAWS, RULES, ORDINANCES AND REGULATIONS. UNLESS SPECIFICALLY STATED IN THIS AGREEMENT, BC TECHNICAL MAKES NO WARRANTIES HEREUNDER, AND EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Indemnification: Each party shall indemnify, defend, and hold harmless the other from and against any loss, damage, cost or expense (including reasonable attorneys' and experts' fees) that the indemnified party may incur by reason of or arising out of: (1) the indemnifying party or its personnel's, subcontractors', or agents' acts or omissions; (2) any personal injury (including death) or property damage caused by or arising from the negligence, acts or omissions of the indemnifying party or any employee or agent of such party to the extent not caused by the gross negligence or willful misconduct of the indemnified party; and (3) the indemnifying party's breach of any federal, state or local law, rule, regulation or ordinance.

Insurance: BC TECHNICAL shall maintain commercial general liability insurance against any claim or claims which might or could arise under the Agreement, including, but not limited to, replacement of the Equipment, which shall include CUSTOMER as an additional insured. The minimum limit of liability shall be \$1 million per occurrence and \$3 million in the annual aggregate for product and general commercial general liability. This may be accomplished through a combination of primary and excess insurance. In addition, BC TECHNICAL shall maintain insurance that will protect it from claims under workers' compensation acts and other employee benefit acts. BC TECHNICAL will provide CUSTOMER with a certificate of insurance, upon request by CUSTOMER, which shall set forth the insurance coverage carried by or on behalf of BC TECHNICAL with respect to the services provided hereunder. Each of the certificates shall provide that the coverage will not be canceled until at least thirty (30) days after written notice has been given to CUSTOMER.



Limitations of Liability: In no event, whether as a result of breach of contract, warranty, tort (including negligence and strict liability) or otherwise, shall either party be liable for any special, consequential, incidental or penal damages including, but not limited to, loss of profit or revenues, loss of use of the products or any associated equipment, damage to associated equipment, cost of capital, cost of substitute products, facilities, services or replacement power, down time costs, or claims of third parties for such damages alleged under this Agreement. In no event, whether as a result of breach of contract, warranty, tort (including negligence and strict liability) or otherwise, shall either party's liability to the other party for any loss or damage arising out of, or resulting from this Agreement, or from its performance or breach, or from the products or services furnished hereunder, exceed the price of the specific product or service which gives rise to the claim.

Termination: CUSTOMER may terminate this Agreement at any time prior to the commencement of services with prior notice to BC TECHNICAL. If BC TECHNICAL, however, has expended any costs associated with this Agreement prior to such notice of termination, CUSTOMER shall be liable for such costs, up to the price of the services offered hereunder, and such costs shall be billed to CUSTOMER.

General:

Assignment. This Agreement may not be assigned by either party without the prior written consent of the other party.

Notices. All notices pursuant to this Agreement shall be in writing, except as provided herein. Notices in writing shall be sufficient if hand delivered or mailed by first class mail, postage prepaid, or sent by telecommunications to the attention of the person listed below and to the party intended as the recipient thereof at the address listed in the Quotation, or at such other address or to the attention of such other person as such party shall have designated for such purpose in a written notice complying as to delivery with the terms of this Section.

No Waiver of Performance. Failure by either party at any time to require performance by the other party or to claim a breach of any provision of this Agreement will not be construed as a waiver of any right accruing under this Agreement, nor affect any subsequent breach, nor affect the effectiveness of this Agreement or any part hereof, nor prejudice either party as regards any subsequent action.

Entire Agreement; Conflicting Provisions. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and no representation or statement not contained in this Agreement shall be binding upon the parties as a warranty or otherwise.

Validity. The invalidity, in whole or part, of any of the foregoing paragraphs will not affect the remainder of such paragraph or any other paragraph in this section of this quotation.

Excluded Provider. BC TECHNICAL represents and warrants that neither it, nor any of its employees or other contracted staff has been or is about to be excluded from participation in any federal health care program.

Compliance with Laws. BC TECHNICAL represents and warrants that BC TECHNICAL and all services comply with the requirements of all applicable federal, state and local laws, ordinances, regulations.

Employee Conduct. BC TECHNICAL acknowledges CUSTOMER's obligations to comply with certain laws and regulations as well as the need for BC TECHNICAL's employees and agents to comply with reasonable requests, standard rules, and regulations of CUSTOMER regarding personal and professional conduct, including the use of an identification badge or personal protective equipment and the adherence to health care facility laws or regulations, including in some instances, criminal background checks, credit checks, health screening, vaccinations and testing, and general safety practices or procedures, generally applicable to such facilities.

Corporate Responsibility. CUSTOMER has in place a corporate responsibility program to ensure compliance with federal, state and local laws and regulations (the "Program"). The Program focuses on the risk management, the promotion of good corporate citizenship, the commitment to uphold a high standard of ethical and legal business practices, and the prevention of misconduct. BC TECHNICAL will conduct all business transactions pursuant to this Agreement in accordance with the Program.

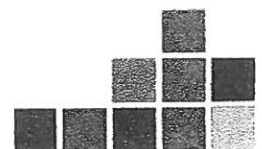


Exhibit C

21st Century Oncology

Comparison of Existing Simulator and Replacement Simulator

Equipment Comparison	Existing Equipment	Replacement Equipment
Type of Equipment	Simulator	Simulator
Manufacturer of Equipment	General Electric	General Electric
Model Name	ProSpeed	LightSpeed QXI
Serial Number	169725YM9	233866CN3
Provider's Method of Identifying Equipment	Serial number	Serial number
Specify if Mobile or Fixed	Fixed	Fixed
Date of Acquisition of Each Component	October 28, 2002 (relocated to North Carolina facility in 2007)	Acquired in 2005 (used at a 21C facility in New Jersey)
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	Refurbished	Refurbished
Total Capital Cost of Project (Including Construction, etc.)	\$236,857.16	\$96,438.74
Total Cost of Equipment When Originally Acquired by 21C	\$111,300.00 (Acquired in 2002 for use at a Florida facility)	\$344,500.00 (Acquired in 2005 for use at a New Jersey facility)
Current Fair Market Value of Equipment	Less than \$5,000.00	Approximately \$80,000.00
Locations Where Operated	Haywood Cancer Center 600 Hospital Drive, Clayton, NC 28721	Haywood Cancer Center 600 Hospital Drive, Clayton, NC 28721
Number Days in Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	No expected change in Patient charges by procedure
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	No expected change in per procedure operating expenses
Type of Procedures Currently Performed on Existing Equipment	Simulation of Radiation Therapy	Simulation of Radiation Therapy
Type of Procedures New Equipment is Capable of Performing	Simulation of Radiation Therapy	Simulation of Radiation Therapy