

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

March 19, 2014

Denise Gunter Nelson Mullins Riley & Scarborough LLP 380 Knollwood Street, Suite 530 Winston-Salem, NC 27103

No Review

Facility:

Novant Health Forsyth Medical Center

Project Description:

Install linear accelerator purchased in June 2005 in Vault 1

County:

Forsyth

FID #:

923174

Dear Ms. Gunter:

The Certificate of Need Section (CON Section) received your letters dated November 1, 2013, December 11, 2013, and December 20, 2013 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.

This decision is based on the following:

- 1. Pursuant to N.C. Gen Stat § 131E-178(a), "No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department...."
- 2. Pursuant to N.C. Gen Stat § 131E-176(16)f1, a "new institutional health service" includes "The acquisition by purchase, donation, lease, transfer, or comparable arrangement of any of the following equipment by or on behalf of any person...5a. linear accelerator. ..."
- 3. Pursuant to N.C. Gen Stat § 131E-176(16)p, "The acquisition by purchase, donation, lease, transfer, or comparable arrangement by any person of major medical equipment" is a "new institutional health service" which requires a certificate of need.



- 4. Pursuant to N.C. Gen Stat § 131E-176(140), "Major medical equipment means a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the cost of the equipment, studies, surveys, designs, plans, working drawings, specification, construction, installation, and other activities essential to acquiring and making operation the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. ..."
- 5. The letter dated November 1, 2013, and Exhibit A, indicates Novant Health Forsyth Medical Center (NHFMC) purchased three refurbished linear accelerators from RS&A, Inc. on June 3, 2005, before the certificate of need (CON) law changed effective August 26, 2005 to specifically regulate the acquisition of linear accelerators.
- 6. Therefore, since the linear accelerator listed in Exhibit A was purchased prior to August 26, 2005 for a capital cost less than \$750,000, the purchase of this linear accelerator in 2005 was not subject to CON review.
- 7. According to your letter dated November 1, 2013, and Exhibits A & C:
 - NHFMC proposes to install one of the three refurbished linear accelerators in Vault 1, which is currently vacant. The linear accelerator it is proposing to install is a Varian Clinac 2100-C linear accelerator, manufactured in 1991, serial number 318. According to the invoice provided in Exhibit A, the total capital cost of purchasing the refurbished linear accelerator in 2005 was \$176,380.00.
 - NHFMC did not install the linear accelerator at the time of purchase. The linear accelerator listed in Exhibit A has been in storage at RS&A, Inc. since 2005. The cost of storage is \$350 per month, after the first year of free storage.
 - NHFMC provides cost estimates in Exhibit C for the installation of the linear accelerator. The total capital cost of the project is \$338,553 which includes the following costs:

2005 Cost of linear accelerator	\$176,380
IT hardware and software	\$ 37,725
Storage (91 months @ \$350/month)	\$ 31,850
Equipment	\$ 28,080
Construction	\$ 43,800
Other - Testing	\$ 14,051
License transfer/state license	\$ 6,667
Total capital cost	\$338,553

Ms. Gunter March 19, 2014 Page 3

> 8. Since the total capital cost of the project does not cost more than \$750,000, the installation of this linear accelerator at NHFMC would not constitute the acquisition of "major medical equipment" as defined in N.C. Gen. Stat. § 131E-176(140).

Consequently, NHFMC may install the linear accelerator described in Exhibit A and purchased on June 3, 2005 without first obtaining 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. Moreover, you need to contact the Construction Section and the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

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.

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,

Kum Rundolph Kim Randolph, Project Analyst

Martha J. Frisoné, Interim Chief

Certificate of Need Section

Medical Facilities Planning Section, DHSR cc:

Construction Section, DHSR

Acute and Home Care Licensure and Certification Section, DHSR

June S. Ferrell, DOJ

Maureen Murray, Smith Moore Leatherwood LLP

Matthew Fisher, Bode Hemphill, LLP

Gary Qualls, K&L Gates

Nelson Mullins

Nelson Mullins Riley & Scarborough LLP

Attorneys and Counselors at Law 380 Knollwood Street / Suite 530 / Winston-Salem, NC 27103 Tel: 336.774.3300 Fax: 336.774.3372

www.nelsonmullins.com

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Denise M. Gunter Tel: 336.774.3322 Fax: 336.774.3372

denise.gunter@nelsonmullins.com

November 1, 2013

Hand Delivered

Craig R. Smith, Chief
Martha J. Frisone, Assistant Chief
Certificate of Need Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re:

Request for No Review Determination Novant Health Forsyth Medical Center Forsyth County Health Service Area II

Dear Mr. Smith and Ms. Frisone:

This letter requests a determination that the following proposal is not subject to the Certificate of Need ("CON") Law, N.C. Gen. Stat. § 131E-175 et seq. This letter replaces and supersedes the July 24, 2013 letter I sent you concerning the above-referenced subject; we are hereby withdrawing the July 24 letter. In this correspondence, we are revising the July 24 request to request only that Novant Health Forsyth Medical Center ("NHFMC") be allowed to install a Varian 2100-C refurbished linear accelerator that it purchased on June 3, 2005. We do not propose to substitute any equipment.

On June 3, 2005, NHFMC purchased three (3) refurbished linear accelerators. This was before the CON Law changed in July 2005 to specifically regulate the acquisition of linear accelerators. *See* N.C. Gen. Stat. § 131E-176(16) f1.5a. A copy of the invoice for the linear accelerator in question is attached as Exhibit A (the "Refurbished Linear Accelerator"). The purchase price was \$176,380.00, and included installation costs. The unit shown in Exhibit A is the unit NHFMC proposes to install.

All three refurbished linear accelerators, including the unit shown in Exhibit A, have been reported on NHFMC's annual Hospital License Renewal Applications ("HLRA") since the 2006 HLRA. However, none of the three has ever been installed at NHFMC because none of the four linear accelerator vaults at NHFMC has ever been available. The vendor of the refurbished linear accelerators, RS&A of Rural Hall, North Carolina, has been keeping them in storage since 2005. The four vaults at NHFMC have always been continuously occupied by other linear accelerators.

In December 2010, NHFMC received approval to relocate one of its previously-approved linear accelerators from NHFMC to Novant Health Kernersville Medical Center ("NHKMC"). See Exhibit B. This linear accelerator began delivering radiation therapy treatments for patients on September 16, 2013 and is located in the Medical Office Building on the NHKMC campus, in a building where Novant Health-affiliated Radiation Oncologists, Hematologist Oncologists, Surgical Oncologists, Nutritionists, and Oncology Nurse Navigators also have offices. Thus, for the first time, one of the four vaults at NHFMC ("Vault #1) is now available to be used by one of the refurbished linear accelerators (the "Vacated Vault").

The D.L. Davis Cancer Center at NHFMC is a major cancer treatment center for thousands of patients in northwest North Carolina. As radiation therapy sessions typically last for several weeks, and may entail lengthy travel for some patients and their family/friends, it is critical that NHFMC provide timely access to radiation therapy services. To ensure that cancer patients at NHFMC have timely access to radiation therapy services at NHFMC, NHFMC determined that it would make sense to install one of the three refurbished linear accelerators in the Vacated Vault. Specifically, NHFMC proposes to install the Refurbished Linear Accelerator shown in Exhibit A.

NHFMC Vault #1 is now empty because the linear accelerator that formerly occupied that vault has moved to Kernersville. Thus, NHFMC is able to access only three linear accelerators at its Cancer Center on the Winston-Salem hospital campus. On average, NHFMC is serving 97 radiation therapy patients per day on three linear accelerators. The NHFMC Radiation Therapy Director has indicated that this has required scheduling patients for radiation therapy treatments during evening hours and often the day's schedule of radiation therapy treatments is not completed until 9 pm to 10 pm. These three linear accelerators are operational Monday–Friday. One of those three linear accelerators is used primarily for specialized radiation therapy treatments such as Stereotactic Radiosurgery and SABR (stereotactic ablative body radiotherapy) cases which typically tie up that linear accelerator for two to six hours per case. Thus, NHFMC is eager to be able put the empty Vault #1 into productive use with a refurbished linear accelerator.

NHFMC has consistently been one of the five-busiest cancer treatment programs in North Carolina as measured by the annual ESTV-weighted radiation therapy treatment volumes reported in the NHFMC HLRAs and presented in the annual State Medical Facilities Plans ("SMFP"). ESTV-weighting factors account for the complexity of a variety of radiation

therapy treatments, the types of patients treated, and imaging that occurs concurrent with the radiation therapy treatments. For the past three years, the D.L. Davis Cancer Center at NHFMC has operated the 3rd or 4th busiest radiation therapy treatment program, of the 71 radiation therapy facilities in North Carolina. *See* the tables below.

In addition, the NHFMC linear accelerators have operated consistently at annual volumes well above the North Carolina statewide average annual ESTV-weighted linear accelerator radiation therapy treatments. For example, using FFY 2012 data, the North Carolina statewide annual average ESTV radiation therapy treatments per linear accelerator was 4,967 and NHFMC's annual average per (operational) linear accelerator was 6,181. *See* the tables below.

NHFMC, its physicians, and other highly-trained and expert clinical personnel are a very skilled team and high-quality operators of radiation therapy programs. The types of radiation therapy treatments offered include: external beam radiation therapy, intensity-modulated radiation therapy, and stereotactic radiosurgery. During FFY 2012, while statewide radiation therapy treatment volumes dropped by almost 15,000, NHFMC remained one of the top five busiest radiation therapy programs in North Carolina. This is a testament to the accessibility of the service and the quality of care and outcomes. For more information, *see* the following links:

www.facingcancerwithforsyth.com and

www.forsythmedicalcenter.org/home/services/cancer.aspx

FFY 2012 Radiation Therapy Treatment Data

Hospital	Annual FFY 2012 ESTV Weighted Radiation Therapy Volumes	# of Linear Accelerators	Avg ESTV- Weighted Radiation Therapy Treatments Per Linac*	Rank based on Total Annual ESTV- Weighted Radiation Therapy Treatments
Mission Hospital	19,161	3	6,387	7th
CMC	18,862	3	6,287	8th
NHFMC	24,723	4	6,181	4th
Cone Health	29,386	4	7,347	2nd
NCBH	18,670	4	4,667	9th
UNC	27,450	5	5,490	3rd
Duke	33,593	6	5,599	1st
First Health Moore Regional	18,276	3	6,092	10th
Cape Fear Valley Medical Center	20,967	5	4,193	5th
Rex Healthcare	19,401	4	4,850	6th
Total NC	601,061	121	4,967	

Source: Table 9G, Draft 2014 SMFP (with FFY 2012 data), available at

http://ncdhhs.gov/dhsr/ncsmfp/2014/proposed2014smfp.pdf

FFY 2011 Radiation Therapy Treatment Data

Hospital	Annual FFY 2011 ESTV Weighted Radiation Therapy Volumes	# of Linear Accelerators	Avg ESTV- Weighted Radiation Therapy Treatments Per Linac*	Rank based on Total Annual ESTV- Weighted Radiation Therapy Treatments
Mission Hospital	19,222	3	6,407	6th
CMC	19,612	3	6,537	5th
NHFMC	26,881	4	6,720	3rd
Cone Health	26,642	4	6,660	4th
NCBH	18,310	4	4,578	9th
UNC	30,387	6	5,065	2nd
Duke	35,177	5	7,035	1st
First Health Moore Regional	18,900	3	6,300	7th
Cape Fear Valley Medical Center	18,279	5	3,656	10th
Rex Healthcare	18,898	4	4,724	8th
Total NC	615,889	121	5,090	

Source: Table 9G, 2013 SMFP pages 145-146 (with FFY 2011 data)

FFY 2010 Radiation Therapy Treatment Data

Hospital	Annual FFY 2010 ESTV Weighted Radiation Therapy Volumes	# of Linear Accelerators	Avg ESTV- Weighted Radiation Therapy Treatments Per Linac*	Rank based on Total Annual ESTV- Weighted Radiation Therapy Treatments
Mission Hospital	20,415	3	6,805	5 th
CMC	16,393	3	5,464	10th
NHFMC	27,242	4	6,811	3rd
Cone Health	25,756	4	6,439	4th
NCBH	17,945	4	4,486	9th
UNC	30,238	6	5,040	2nd
Duke	34,771	8	4,346	1st
First Health Moore Regional	19,954	2	9,977	6th
Cape Fear Valley Medical Center	19,668	5	3,934	7th
Rex Healthcare	19,636	4	4,909	8th
Total NC	600,749	123	4,884	

Source: Table 9E, 2012 SMFP pages 138-139 (with FFY 2010 data)

Total costs to make the Refurbished Linear Accelerator operational are \$338,553.¹ This includes everything, including the Refurbished Linear Accelerator, hardware and

¹ These costs are lower than the costs stated in the July 24 letter because certain accessories/attachments are not needed with the linear accelerator shown in <u>Exhibit A</u>. Thus, NHFMC was able to reduce its capital cost.

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software, construction costs, the internal staff time for physics planning and commissioning, information technology services, storage fees paid to RS&A since 2005, and North Carolina licensing fees for linear accelerators, needed to make the Refurbished Linear Accelerator operational in the Vacated Vault. The certified cost estimate is included as Exhibit C. The back up for Exhibit C is found in Exhibits C-1 (a crosswalk), and C-2 through C-9. Exhibit C-10 is a memo from Curtis Whiddon, PhD, Chief Medical Physicist for Novant Health, explaining that no additional shielding is needed to comply with the appropriate radiation dose limits as defined in Chapter 11 of the North Carolina Regulations for Protection Against Radiation. A floor plan showing where the Refurbished Linear Accelerator will go is attached as Exhibit D.

Major medical equipment is defined in the CON Law as:

a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand In determining whether the major medical dollars (\$750,000). equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, working drawings. specifications, plans, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.

N.C. Gen. Stat. § 131E-176(14o).

As reflected in Exhibit C, the total cost to operationalize the Refurbished Linear Accelerator, \$338,553 is well below \$750,000. This proposal does not involve the acquisition of a linear accelerator since the Refurbished Linear Accelerator was purchased in June 2005 before the law changed.

² Exhibit C-3 is a Varian license transfer quote. Only the top part of the second page of Exhibit C-3 applies here (the license fee of \$5,167). Nothing else shown on Exhibit C-3 is being acquired. The license fee is included in the \$241,477 amount shown on Rows 13 and 14 of Exhibit C. The license fee was also broken out in line (13a) in the capital cost form, but it should not be double counted. As the crosswalk in Exhibit C-1 shows, the \$241,477 amount on Row 13 and 14 of Exhibit C includes the linear accelerator, the Varian license, the Sun Nuclear QA device and scanner, the storage fees and the Varian engineer expense.

I am aware that Cone Health, High Point Regional Health and North Carolina Baptist Hospital ("NCBH")³ opposed Novant's July 24 letter concerning the substitution of the Refurbished Linear Accelerator. Those comments are moot since we do not propose a substitution of equipment and the July 24 letter has been withdrawn.

To the extent that any of these providers suggests that the CON Law does not permit NHFMC to operationalize the Refurbished Linear Accelerator, their comments are incorrect. The CON Law governs only "[t]he acquisition by purchase, donation, lease, transfer, or comparable arrangement" of a linear accelerator. See N.C. Gen. Stat. § 131E-176(16)f1.5a. The law does not address installing or operating a linear accelerator that was purchased before the law changed in July 2005. The plain language of an unambiguous statute such as this must be applied as written. See Wiggs v. Edgecombe Cty., 361 N.C. 318, 322, 643 S.E.2d 904, 907 (2007). It is not permissible to add language to the statute that is not there. Sonopress, Inc. v. Town of Weaverville, 139 N.C. App. 378, 383, 533 S.E.2d 537, 539 (2000). Further, to the extent any of the commenters suggests that an acquisition of equipment is not complete until the equipment is in operation, such a suggestion is without basis. N.C. Gen. Stat. § 131E-176(16)f1.5a. only regulates acquisition; it does not regulate operation. See Evans v. Diaz, 333 N.C. 774, 779-80, 430 S.E.2d 244, 247 (1993) ("Under the doctrine of expression unius est exclusio alterius, when a statute lists the situations to which it applies, it implies the exclusion of situations not contained in the list."). Had the General Assembly wanted the law to regulate the operation of linear accelerators, it would have been a simple matter to include the word "operation" in subsection 5a. See In re Appeal of Bass Income Fund, 115 N.C. App. 703, 706, 446 S.E.2d 594, 596 (1994). But the General Assembly did not do so.

The Refurbished Linear Accelerator was acquired in June 2005 before the law changed. None of the providers submitting comments suggests otherwise. Indeed, NCBH states that "[i]t is undisputed that FMC obtained these Linacs prior to the August 2005 change in N.C. Gen. Stat. § 131E-176." See Letter of Matthew J. Fisher to Martha Frisone and Kim Randolph, September 13, 2013, p. 1.4

NCBH further states:

Arguably, FMC could place one of its three grandfathered Linacs into operation in the existing vault at FMC, so long as the total costs associated with making the Linac operational did not exceed

³ Of these providers, only NCBH operates linear accelerators in Linear Accelerator Service Area 10. Cone Health and its manager, the Charlotte Mecklenburg Hospital Authority, do not own, manage or operate any linear accelerators in Linear Accelerator Service Area 10. Likewise, High Point and its owner, UNC Healthcare, do not own, manage, or operate any linear accelerators in Linear Accelerator Service Area 10.

⁴ To the extent that the providers suggest that a need determination in the 2013 SMFP is required, such a suggestion is incorrect. The Refurbished Linear Accelerator was acquired in 2005; subsequent need determinations in the SMFP are irrelevant. Similarly, performance standards in 10A NCAC 14C .1903 are not relevant, since a CON application is not required for NHFMC's proposal.

\$750,000 threshold set forth in the N.C. Gen. Stat. § 131-176(140).

Id., p. 2.

As documented in <u>Exhibit C</u>, NHFMC's capital costs are well below the \$750,000 threshold and none of the providers who submitted comments suggests otherwise. *See Cape Fear Mem. Hospital v. N.C. Dep't of Human Resources*, 121 N.C. App. 492, 494, 466 S.E.2d 299, 301 (1996)("We believe the expansive interpretation proposed by the Department, thereby allowing micro-management over relatively minor capital expenditures, does not effectuate the overriding legislative intent behind the CON process, *i.e.*, regulation of major capital expenditures which may adversely impact the cost of health care services to the patient.").

Since none of the definitions of "new institutional health service" in the CON Law applies to this request, NHFMC respectfully requests a determination that a CON is not required for NHFMC to install the Refurbished Linear Accelerator in the Vacated Vault.

NHFMC thanks the CON Section for its prompt attention to this request. Please let me know if there are any questions.

Sincerely,

Mr. M. Durtter

Denise M. Gunter

Enclosures

Exhibit List

Exhibit A: June 2005 RS&A Quote for Varian 2011-C Linear Accelerator

Exhibit B: 1/4/2011 CON Section No Review Decision For Relocation of Existing NHFMC

Linear Accelerator to Kernersville

Exhibit C: Total Capital Cost Sheet

Exhibit C-1: Worksheet For Total Capital Cost Sheet

Exhibit C-2: Elekta Connectivity to Varian quote

Exhibit C-3: Varian License Transfer (note: only top part of second page is relevant; nothing else

shown on Ex. C-3 is being acquired)

Exhibit C-4: Physics Commissioning and testing

Exhibit C-5: Sun Nuclear Vendor Quote for Daily QA 3

Exhibit C-6: Sun Nuclear scanner

Exhibit C-7: Storage fees for linear accelerator shown in Exhibit A

Exhibit C-8: Architect's letter

Exhibit C-9: Varian engineer MQA expense

Exhibit C-10: Physicist's letter regarding shielding

Exhibit D: Line Drawing for NHFMC Linear Accelerator Vault #1

PAGE 02

06-03-05





Providing You With A Choice.

PRICE QUOTATION/SALES AGREEMENT

To Purchaser: Forsyth Medical Center

Date:

3333 Silas Creek Parkway Winston-Salem, NC 27103

This quote is firm for 60 days after above date. Quotation No: KW050603

Description One Refurbished Varian Clinac 2100-C Linear Accelerator

Price \$166,500.00

Specifications: Dual photon energies. 5 Electron energies Counterweighted gentry. 100cm target to isocenter distance,

Electron applicators. New Paint on accelerator fiberglass covers Photon wedges, ETR treatment couch,

This quotation includes the Base Frame, Delivery and Installation.

RS&A will provide standard site preparation drawings and a service representative to be available during the site planning meeting.

Purchaser is responsible for providing a clear path to the linear accelerator vault.

The purchaser is responsible for grouting the base frame in. RS&A will level the base frame and supervise grouting. Purchaser is responsible for site preparation; Electrical (including lasers, monitors and intercom), plumbing, mechanical,

This unit is warranted to operate at all manufacturers specifications at time of acceptance by Forsyth Medical Confer,

One Laser Package Includes: (3) Connaite DLL-2s Red Diede Cross Lasers,

\$ 8,625.00

(1) Contralite DLL-4 Red Diode Sagital Laser,

These lasers carry a two year parts warranty. The quoted price includes all shipping costs. Laser Installation will be included.

One Intercom System - Control Console to Treatment Vault Includes:

\$471.00

- Aiphone LEE-3 Muster intercom station.
- Aiphone Intercom substation LE-A,

12V Power Supply

The quoted price includes all shipping costs. Installation and wiring is the responsibility of the customer,

Video Observation System Includes: One

\$ 784.00

(7) Modifors and (6) cameras

. Plug and play cameras are powered by monitor

Includes six 60' Camera Connection Cables

The quoted price includes all shipping costs. Installation and wiring is the responsibility of the enstances

RS&A will include one year of free storage. Thereafter, there will be a storage fee of \$350.00 per month.

Subject to prior sale:

TOTAL PRICE

\$176,380,00

PAYMENT TERMS

35% (\$61,733.00) of purchase price at signing of contract. (ii)

45% (379,371.00) of purchase price on the earlier of; machine delivery or 12 months after contract signature.

20% (335,276,00) of purchase price on completion of the installation and acceptance testing by the castomer.

Accepted by Purchaser as quoted

Kenneth Wolff, President, RS&A, Inc.

RS&A Incorporated

465 FORUM PARKWAY * RURAL HALL. NC - 27045-8927

Voice: 336-969-0583 / 800-320-4332 FAX: 336-969-0584 - www.rss-inc.com



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

Beverly Eaves Perdue, Governor Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

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

January 4, 2011

Denise M. Gunter Nelson Mullins Riley & Scarborough LLP 380 Knollwood Street, Suite 530 Winston-Salem, NC 27103

RE: No Review / Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center / Relocation of a linear accelerator / Forsyth County

Dear Ms. Gunter:

The Certificate of Need (CON) Section received your letter of December 21, 2010 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 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,

Project Analyst

Litiary

Craig R. omith, Chief Certificate of Need Section

Construction Section, DHSR

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co;

Nelson Mullins

Nelson Mullins Riley & Scarborough LLP Attorneys and Counselors at Law 380 Knollwood Street / Suito 530 / Winston-Salem, NC 27103 Tel: 336,774,3300 Fax: 336,774,3372 www.nelsonmullins.com

Deniso M. Gunter
Tol: 336.774,3322
Fax: 336,774,3372
deniso.gunter@neisonmullins.com

December 21, 2010

VIA FEDEX

Craig Smith, Chief Martha Frisone, Assistant Chief Gebrette Miles, Project Analyst for Forsyth County Certificate of Need Section North Carolina Department of Health and Human Services 701 Barbour Drive Raleigh, North Carolina 27603

e: No Review Request for a Linear Accelerator on the Campus of Kernersville Medical Center

Dear Mr. Smith, Ms. Frisone and Ms. Miles:

On April 5, 2010, Forsyth Memorial Hospital d/b/a Forsyth Medical Center ("FMC") filed a declaratory ruling request (the "Original Declaratory Ruling Request") proposing to relocate one of its existing linear accelerators from FMC in Winston-Salem to a new medical office building in Kernersville on the campus of Kernersville Medical Center ("KMC"). A copy of the Original Declaratory Ruling Request is attached hereto as Exhibit A, and is incorporated by reference. On May 18, 2010, the Department denied the Original Declaratory Ruling Request. See Exhibit B.

There were two stated reasons for the denial: (1) relocating the linear accelerator to a medical office building on the campus of KMC prior to completion of KMC is a change in scope of the CON that was issued for KMC and is therefore a new institutional health service; and (2) the cost of the linear accelerator proposed to be relocated, plus the cost of relocating the linear accelerator, together exceed the \$2 million threshold in N.C. Gen. Stat. § 131B-176(16)b. in one year and therefore constitutes a new institutional health service.

FMC has since revised its proposal to resolve the issues raised by the Department. Ms. Brennan of the Attorney General's Office advised that we should submit our revised proposal to the CON Section in the form of no review request. We therefore request a no review

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With twelve office locations in the District of Columbia, Florida, Georgia, Massachusetts, North Carolina, South Carolina, and West Virginia

determination based on the facts set forth below.¹ Specifically, the linear accelerator will not treat patients in Kernersville until KMC has been open for a year and a day. Therefore, there will be no change in scope to KMC pursuant to N.C. Gen. Stat. § 131B-176(16)e. The linear accelerator at issue was purchased in 2009 and will not be relocated until sometime in 2012. Therefore, there will be no issue with spending more than \$2 million in the course of one year.

Since the time of the April 5, 2010 Declaratory Ruling Request, we have updated the capital costs. The capital cost to implement the project is \$1,104,570.20, which includes:

- Removing the linear accelerator from FMC (as stated in the Original Declaratory Ruling Request, the linear accelerator proposed to be relocated was installed at FMC as replacement equipment in 2009);
- Moving the linear accelerator to Kernersville;
- All construction needed to make the linear accelerator operational (including the
 vault, the control room, the exam room, the dressing room, the patient toilet, the
 staff's office space, the nursing station, the soiled utility room, the clean
 utility/supply room, and the physics work room);
- Calibration of the linear accelerator, the physics report, and physics acceptance and commissioning of the linear accelerator;
- Hardware and software, and MapCHECK, a dosage verification system;
- Regulatory fees, such as any fees that Licensure, the Construction Section and the Radiation Safety Protection Division of NC DENR may charge;
- Signage;
- Architecture and engineering fees; and
- Contingency,2

See Exhibit C.

¹Nothing in this letter is intended as an admission by FMC that the Department's May 2010 denial of the Original Declaratory Ruling Request was correct,

²If the linear accelerator is added to the costs, the total is \$1,863,565.20. FMC does not believe, however, that it is appropriate to add the costs of the linear accelerator to the total because that cost has already been incurred at the time the linear accelerator (a replacement unit) was purchased and installed at FMC's Cancer Center in 2009.

-##811-9135-2928 v.l.

All other facts set forth in Exhibit A remain the same.

ANALYSIS

The CON law would require a full review of FMC's proposal if it involved: (1) a change in scope of KMC; (2) a capital expenditure of greater than \$2 million; or (3) an acquisition of a linear accelerator. See N.C. Gen. Stat. §§ 131E-176(16)b., e. and f1.5a. None of these circumstances exists here.

A. No Change in Scope of KMC

N.C. Gen. Stat. § 131E-176(16)e., defines "new institutional health service" as:

A change in a project that was subject to certificate of need review and for which a certificate of need was issued, if the change is proposed during the development of the project or within one year after the project was completed. For purposes of this subdivision, a change in a project is change of more than fifteen percent (15%) of the approved capital expenditure amount or the addition of a health service that is to be located in the facility or portion thereof, that was constructed or developed in the project.

KMC will open in the Spring of 2011. The linear accelerator will not begin treating patients until KMC has been open for 366 days, which is greater than one year. Therefore, there will be no change in scope in the KMC project.³

So that the radiation therapy services can be offered in Kernersville on Day 366, FMC will need to construct the vault and move the linear accelerator from Winston-Salem to Kernersville prior to Day 366. These actions do not implicate N.C. Gen. Stat. § 131E-176(16)e, because no health service will be offered until Day 366.

B. No capital expenditure greater than \$2 million

The cost to build the vault, relocate the linear accelerator and obtain other items essential to the operation of the linear accelerator is \$1,104,570,20. Even if one "double counts" the cost of the linear accelerator itself (which was purchased in 2009), the project does

³Based on Exhibit B, FMC understands that the Department views the "campus" of KMC to include the medical office building and that the radiation therapy services provided in the medical office building should be viewed as part of KMC since both KMC and the radiation therapy services in the medical office building will be licensed under FMC. While FMC does not agree with the Department's position on this issue, the Issue is most since the radiation therapy services will not be offered until Day 366 of KMC's operations.

-/#481-9135-2328 v.1~

not exceed \$2 million. As noted above, so that the linear accelerator can treat patients on Day 366 of KMC's operations, construction of the vault and the relocation of the linear accelerator will take place prior to Day 366. However, construction and relocation will not occur until sometime 2011, so there is no issue with spending more than \$2 million in one year.⁴

C. Not Acquiring a Linear Accelerator

FMC will not be acquiring a linear accelerator as part of this project; rather, the project involves the relocation of an existing linear accelerator. Thus, there is no issue with N.C. Gen. Stat. § 131E-176(16)f1.5a, which requires a CON for the acquisition of a linear accelerator.

Further, there is no CON with which the linear accelerator is required to comply. In Kernersville, FMC will continue to offer the same service on the linear accelerator that it now offers in Winston-Salem: radiation therapy services. The relocation will occur within Forsyth County, so there will be no change in the inventory of linear accelerators within Forsyth County as part of this project. Additionally, the Department has previously approved a linear accelerator relocation in Mecklenburg County that involved comparable distances. See Exhibit D.

Accordingly, the proposed relocation is not a "new institutional health service" that is regulated by the CON Law.

⁴Based on Exhibit B, FMC understands that the Department aggregates the costs incurred over a one year period to determine if a proposal crosses the \$2 million threshold in N.C. Gen. Stat. § 131E-176(16)b. While FMC disagrees with this interpretation, the issue is most because the costs for the vault construction and linear accelerator relocation (CY 2011) will not be incurred in the same year (CY 2009) as the cost for acquiring the linear accelerator.

-##811-9135-2228 \(\)_1-

CONCLUSION

Based on the facts set forth in this letter, FMC respectfully requests that the CON Section determine that the proposal described in this letter is not subject to CON review.

Sincerely,

Denise M. Gunter

Enclosures

cc: Stephanie Brennan (via FedEx)(with enclosures)

PROJECT CAPITAL COST: Novant Health Forsyth Medical Center Linear Accelerator Vault #1 Equipment Backfill (Stored Linac Unit)-Revised October 2013

A. Site Costs		ed October 2013	
(1) Full purchase price of lar	nd	\$0	
(2) Closing costs		\$0	
(3) Site Inspection and Surve	ey .	\$0	
(4) Legal fees and subsoil in	vestigation	\$0	
	Include: Soil Borings, Clearing and Grading,		
<u>-</u>	Water and Sewer, Excavation and Backfill,		
Termite Treatment		\$0	
Sub-Total Site Preparation	on Costs	\$0	
(6) Other (N/A)		\$0	
(7) Sub-Total Site Costs –R	ows (1)-(6)	\$0	
B. Construction Contract			
Concrete/Masonry, Wo	aterials Include: General Requirements, bods/Doors & Windows/Finishes, Thermal & ipment/Specialty Items, Mechanical/Electrical	•	
Sub-Total Cost of Materi		\$12,000	
(9) Cost of Labor		\$18,000	
(10) Other (N/A)		\$0	
(11) Sub-Total Con	struction Contract –Rows (8)-(11)	\$30,000	
C. Miscellaneous Project C	Costs		
(12) Building Purcha	ise	N/A	T.
` ' ` '	vable Equipment Purchase (Equipment,		
Equipment Components,		\$241,477	
(13a) Other Equip-Relate Software for Linac Contr	ed Components (Varian License, Hardware &	\$ 5.163	e Conte tin
	hnology (Software, Hardware)	\$32,725	: (note: this license fee is included
(15) Furniture	miology (bottware, rimaware)	\$0	is in cluded
(16) Landscaping		\$0	in He \$241 47
(17) Consultant & O	ther Fees	Ψΰ	in the \$241,47 in Row 13-14
	eering Fees (+ Reimbursables)	\$10,000	, , , , ,
DHSR Review		\$1,800	
	r Accelerator License	\$1,500	
******	ussioning & Testing	\$14,051	•
SubTotal Consultant Fee		\$27,351	
	(e.g. Bond, Loan, etc.)	7	
(19) Interest During		\$0	
(20) Other: Project		\$2,000	
	cellaneous-Rows (12)-(20)	\$308,553	À
	Sum A-C above-Rows (7), (11), & (21)	\$338,553	hatvally equal
Zotal Cupital Cost of Froject (D		4000,000	1323,553

I certify that, to the best of my knowledge, the above construction related costs of the proposed project are complete and correct.

Welson Charges 10/23/13 (Signature of Licensed Architect or Engineer)

I assure that to the best of my knowledge, the above capital costs for the proposed projects are complete and correct and that it is my intent to carry out the proposed project as described.

(Signature of Officer Authorized to Represent (Provider/Company)

File: Projected Capital Cost FormFMCRefurbLinac 10 22 2013.doc

Backfill Empty Vault #1 at FMC with Refurbished Varian Linear Accelerator Model 2100C Capital Cost Worksheet-Revised Oct 2013

			e	M 20 20			•										,	
				20 C C C C C C C C C C C C C C C C C C C	or second page applies nere	tion Physicist	Document of the second of the			à.	ties Planning				ties Planning)	Novant IT	
	COST Exhibit #	\$176,380 Exhibit A	✓ \$32,725 Exhibit C-2 ৮ ্ব তথ্য			\$1,500 Estimate by Novant Radiation Physicist	√\$14,051 Exibit C-4 (\$\s\colon\colo	√\$8,250 Exhibit C-5 4×6 6 € 25 3	1 54,250 Exhibit C-6 € × 61185 € 30113	~\$31,850 Exhibit C-7 Vatil 12 30 3	\$1,800 Estimate by Novant Facilities Planning	\$12,000 Exhibit C-8	√ \$18,000 Exhibit C-8	√\$10,000 Exhibit C-8	\$2,000 Estimate by Novant Facilities Planning	\$15,580 Exhibit C-9	\$5,000 PCs & Printer ordered thru Novant IT	\$338,553
	Cost Category	Equipment	E	Sacot I botolog aims	בלמוסם דוכפווסם	License	Other .	Equipment	Equipment	Refurb Linac	Construction	Construction	Construction	Construction	Construction	Equipment	<u></u>	Total
Row	Number Description	5 Cost of Linac (includes installation)	6 Elekta Connectivity to Varian	7 Varian: License Transfer	variant: Electrical Harrister	8 NC State Linear Accelerator Licensure	9 Physics commissioning & testing	10 Sun Nuclear Daily QA device	11 Sun Nuclear scanner	12 Storage Fees Linac (SN#318) - RS&A	13 DHSR review fee	14 Materials	15 Labor	16 A&E fee	16A Project Contingency	17 Varian Engineer MQA expense	18 Computer Hardware for Linac Control Room	

		 7 subtotal on Row 13 &14	
Found on State's Capital Cost Form \$37,725 Row 14	\$ 1,500 Row 17	\$241,477 Rows 13 and 14; Varian License of \$5,167 is included in the 241,477 subtotal on Row 13 &14	\$ 43,800 Rows 8-11; 17-20 \$ 14,051 Row 17 \$338,553
Row #s on This Worksheet Rows 6 & 18 IT Subtotal	Row 8 NC Linac License	Rows 5, 7, 10, 11, 12, 17 Equipment Subtotal	Rows 12, 13, 14, 15, 16, 16A Construction Subtotal \$ 43,800 Rows 8-11; 17-20 Row 9 Other \$ 14,051 Row 17 Total Capital Cost \$338,553 File: CON Cost Worksheet Linac backfill BF KD 10222013.xls



EXHIBIT

Quotation Number: 2013-26117-OB Version Number: 2

Quotation Date: May 28, 2013

Valid Unill: August 1, 2013

Prepared For:

Novant Health ACCOUNTS PAYABLE PO BOX 25686 WINSTON SALEM, North Carolina 27114-5686 บร

(f) +1 910-718-9257 Currency: USD

(1)+1-336-277-1075---

Prepared By: Chris Broyles North Carolina Sales Client Manager Elekta Inc.

400 Perimeter Center Terrance, Sulte 50 Allania, GA 30348

(1) 704;322;3493 (c) +1 7046998788

chris.broyles@elekta.com

Elekta is pleased to submit the following Quotation for the products, softwere licenses, and/or services described herein at the prices and terms. stated.

MOSAIQ®

Offer Price:

The price under this Quotation reflects a discount of \$5,776.00 USD. If customer is an entity that reports its costs on a cost report required by the Department of Health and Human Services of a state healthcare program, the customer must fully and accurately report any discount that has been provided by Elekia under the final agreement between the parties in the applicable cost report and provide information upon request by the Secretary of Health and Human Services or a state agency:

Subject to Elekla, Inc. Terms & Conditions or those previously negotiated.

State, local and other taxes, and import/export licenses are not included in this Quotation.



Quotation Number: 2013-26117-CB Version Number: 2

Quolallon Date: May 28, 2013

Valid Until: August 1, 2013

Scope of Supply

Part Number Name Qly Extended List License Term

450 10001000IQRO Connectivity to Varian Linac (TBD) 1 \$38,500.00 Perpetual Interface to Varian Linac Treatment Machine Connectivity connects the MOSAIQ radiation oncology EMR directly to a linear accelerator to verify that the machine is set up according to plan and electronically records actual setup parameters.

Elekta, Inc., 400 Perimeter Center Terrace, Sulte 50, Atlanta, GA 30346. Phone: 770 300 9725 | Fax: 770 448 6338 | www.elekta.com

Page 2 of 3

All terms, conditions, pricing, product, and service information must remain confidential and should not be disclosed to any other party especially consultant firms such as MDB, ECRI, etc.



Quotation Number: 2013-26117-CB Version Number: 2

Quotation Date: May 28, 2013

Valld Until: August 1, 2013

Elekta, Inc., 400 Perimeter Center Terrace, Sulte 50, Atlanta, GA 30346 Phone: 770 300 9725 | Fax: 770 448 6338 | www.elekta.com

Page 3 of 3

All terms, conditions, pricing, product, and service information must remain confidential and should not be disclosed to any other party espacially consultant firms such as MDB, ECRI, etc.

EXHIBIT

Quotatic

MNM20090827-004A

Page: 1

Quotation For:

K.D. Lanning Radiation Oncology Forsyth Regional Cancer Center 3333 Silas Creek Pkwy Winston Salem, NC 27103 (336) 718 - 8699 FAX: (336)277-7689

medical systems

Please address inquiries and replies to:

Susan Thomas Varian Medical Systems 2250 Newmarket Parkway Sulte 120 Marietta, GA 30067 (770) 955 - 1367 FAX: (678) 255 - 3850

Your Reference:	Quotation Firm Until: December 31, 2013
FOB Point: U\$2 FOB; Destination	Shipping Allocation: 90 DAYS ARO
Payment Terms: See Terms and Conditions	Varian Terms and Conditions of Sale 1652T Attached

Forsyth Regional Cancer Center
License Transfer for Clinac 2100C
s/n TBD
PV Workstation Upgrade for CL
2100C s/nTBD
MLC Workstation Upgrade for CL
2100C s/nTBD

Forsyth Regional Cancer Center Quotation Total of: USD \$19,706 Accepted by:	Varian Medical Systems
Signature:	Submitted by:
Name:	
Title:	(Signature)
Date:	Name: Susan Thomas
For this purchase, we designate NOVATION as our institution's Primary Group Purchasing Organization affiliation. Any change will be indicated below:	Title: District Manager

This document is confidential and intended solely for the information and benefit of the immediate recipient and Varian



1.01

3.01

Quotation

MNM20130607'005A

Page; 2

	oya cama	Forsyth Regional Cancer Center, Winston Salem, NC	
LTS-CARLEAG			the street of the state of
	Product Description	•	Offer Pr
 A STATE OF THE REAL PROPERTY.	THE RESIDENCE AND PARTY OF THE		

Section 1 License Transfer for CL 21000

License Transfer for C'Series Clinac
When ownership of a C-Series Clinac occurs, the new owner is liable to Varian for
the transfer of Clinac software (firmware) ownership. The license transfer is in
addition to the required Quality Audit for non-Varian serviced machines.

5,167.00

Section Total \$

6,167.00

Section 2 PV Workstation Upgrade for CL 2100C

PortalVision Workstation Upgrade
 Upgrade PortalVision Workstation hardware with latest manufacturing released hardware. Software upgrade must be purchased separately.

5,167.00

2.02 1 PortalVision Software App Upg Standalone

Upgrade includes latest software release of the PortalVision Application for Version

6,200.00

7. Applies to Standalone environments.

LICENSE:

PortalVision software license for ONE (1) PortalVision connected to C-Series

FEATURES:

- 1. 'Next field' bulton verses manual selection of next field name to be imaged.
- 2. Ability to acquire IMRT integrated images.
- 3. Digital graticule.
- 4. Enhanced filters for selection of images to be reviewed.
- 5. More robust Field Edge Detection.
- 6. Improved automated matching with 'mutual information algoritm'.
- 7. New Image review display filters.
- 8: Pre-requisite software for Portal Dosimetry capability (separate purchasable option).

Section Total \$

11,367,00

Section 3 MLC Workstation Upgrade for CL 2100C

1 MLC Workstation Hardware Upgrade Upgrade MLC Workstallon hardware with latest manufacturing released hardware, Software upgrade must be purchased separately, For CR or Millennium MLC

3,172.00

Section Total \$

3,172,00



Quotation

MNW20130607'005A

Page: 3

Forsyth Regional Cancer Center, Winston Salem, NC

ltem

ity Product Description

Offer Price

Quotation Total \$

19.708.00

Terms & Conditions of Sale

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

Unless otherwise provided in this Quotation, Varian warrants that for a period of ninety (90) days after completion of installation, any upgrade for Varian Hardware shall operate in conformity with its applicable Specifications.

Varian shall be entitled to perform a system performance audit prior to installation of any upgrade Products. If the audit reveals that the system is not operating to Varian specifications, the Customer is responsible for bringing the system to the Varian specifications at its own cost as a prerequisite condition to Varian's installation of the upgrade Products.

- ' Freight and insurance for upgrade products is included unless otherwise specified.
- ' Installation is included in the upgrade price.
- ' Hardware is not included unless specified in the product description.

NOVATION payment terms are as follows: 10% with purchase order 85% upon shipment to hospital 5% upon installation

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

SHIPPING Terms: Destination

FINANCING AVAILABLE: For lease and finance plans, call Tony Susen, Director Varian Gustomer Finance, at (508) 658'4609.

EXHIBIT C-4



June 10, 2013

Re: CON Exemption request to install Linac at FMC C/O; Denise Gunter

-To Whom It May Concern: --

Included in the cost estimate to implement a Varian 2100C Linear accelerator at Novant Health Forsyth Medical Center is the salary cost for acceptance testing and commissioning. The work for acceptance and commissioning of a Linear Accelerator will be done by Novant Health employed medical physics staff. The average hourly rate of a Medical Physicist at Forsyth Medical Center; based on 2013 salary information is \$78.06/hr. The average amount of time to perform this testing and commissioning is about 170 hours, or 4 ½ work weeks.

\$78.06 * 180 hours = \$14,050.80

Thank you,
Katherine D. Lanning
Katherine D. Lanning RN, MSN, OCN
Director, Radiation Oncology

Novant Health

EXHIBIT C-5



425-A Pineda Court Melbourne, FL 32940 Phone: +1 321-269-6862 Fax: +1 321-757-0066

Quotation

Questions? Contact: Andrea Matarazzo x331 AndreaMatarazzo@s unnuclear.com

SHIP

Forsyth Regional Cancer Center
Katherine Lanning
3333 Silas Creek Parkway
Winston-Salem, NC 27103

Forsylh Regional Cancer Center Katherine Lanning 3333 Silas Creek Parkway Winston-Salem, NC 27103

For Purchase Order processing, please email orders to Orders@sunnuclear.com

1 1093000-0 Dally QA 3 13 total ion chambers for dally output, flatness and symmetry, electron & photon energy trending (no buildup or additional attenuation required). 12 total diode detectors for Light: Radiation field coincidence. Real-time air density correction with results displayed on PC Windows software. Includes advanced comprehensive database manager for graphical data presentation and dally therapist guide, 25 meter power-data cable, USB power-data interface, USB cable. 1 year warranty included. See product datasheet for minimum PC requirements.	Unit Price	Extended Price:
presentation and daily therapist guide, 25 meter power-data cable, USB power-data interface, USB cable, 1 year warranty included, See	\$ 8,250.00	\$ 8,250.00
	vestment;.	\$ 8,250,00

Quote # 00331636 Prepared by Andrea Matarazzo



425-A Pineda Court Melbourne, FL 32940 Phone: +1 321-259-6862 Fax: +1 321-767-0066

Quotation

Questions? Contact: Andrea Matarazzo x331 AndreaMatarazzo@s-unnuclear.com

Sun Nüclear Corporation

- 1. All purchases approved for Nel terms are due 30 days from the shipping date or services,
- 2. Shipping terms are FOB Shipping Point
- Payment with credit cards is restricted to SNC products and services of less than \$2,500. A 3% convenience charge will be added to any payment processed for special order products (resale items) and any SNC product of service with a sales price greater than \$2,500
- 4. Prices do not include applicable taxes. SNC will collect and remit the appropriate taxes for some U.S. states. If applicable taxes are not on Customer Purchase Order, Customer is responsible for remittance of appropriate taxes.
- Undisputed past due accounts are subject to a late service fee charge of 18% per annum (1.6% per month), or the maximum allowed by law.
- Any payment made in respect of credit transactions shall first be applied to the accumulated service charge, if any, and thereafter
 to the principal amount of the cutstanding debt.
- 7. SNGWIII assess handling charges in the amount of \$100.00 for any dishonoured check received from the Customer.
- All products shipped are subject to recourse by SNC until paid in full, Upon request from SNC, Customer agrees to immediately
 relinquish and return all unpakt equipment in its original condition to the SNC, subject to a 20% restock fee or costs required to
 return equipment to its original condition, whichever is higher.
- 9. The parties agree that the Customer's sole and exclusive remedy for defective products shall be limited to the stated warranty provided by SNC for its manufactured products, or the warranty assigned by SNC to the extent provided by the manufacturer (resale items) of the particular component or system. The Customer agrees that no other remedy (including, but not limited to, incidental or consequential damages for lost profile, lost sales, injury to person or properly, transportation charges or other incidental or consequential loss) shall be available.
- 10. Customers who cancel or postpone scheduled training/education/installation services are subject to cancellation fees (minimum of \$500 not to exceed \$3,000) for resource allocations and non-recoverable scheduling costs (i.e., hotels, alifare, reservations, etc.).
- 11. Customer agrees to advise SNC of any defective product(s) and/or any disputed invoice(s) in writing within 10 days of receipt. Failure to properly notify SNC of any dispute and /or defective goods constitutes a waiver of any and at such disputes, provided, however, that this provision shall in noway affect or limit customer's rights under SNC warranty, or where such is limited by taw.
- 12. Subject to SNO approval, Customer may return unused product within 30 days from the shipping date subject to a 20% restocking fee and Customer must pay for the return shipping charges. Generally, returns after 30 days will not be considered. All approved returns must have an RMA (Return Materials Authorization) number issued by SNO, Special order products (Reseale items) cannot be returned without the express written consent of the manufacturer. Customer must pay for the return shipping charges. Unauthorized returns i.e., those without an RMA # provided) will be rejected and returned at Customer's expense.
- 13. SNC Support Contracts and Maintenance Agreements are non-refundable or transferable. Multi-year SNC Support Contracts may not be cancelled for current coverage period amounts that have been billed to the customer by SNC. Remaining Multi-year SNC Support Contract coverage periods that have not been billed to the customer by SNC may be cancelled if the customer no longer offers Radiation Oncology Services or should SNC no longer be able to provide services associated with the Agreement, SNC at its discretion may prorate the charges should one of these circumstances arise.
- 14. Customer, hereby agrees to Indemnify SNC for all collection fees, legal fees and all other fees and expenses which SNC incurs should Customer's account be in arrears.
- 15. SNC software is only licensed to the original purchaser and the license is not transferable.
- 16. SNC requires that when (I) the standard warranty has ended and lapsed by more than 365 days, (II) a previously purchased context has expired and lapsed by more than 366 days or (III) there has been a transfer of product ownership, the equipment must be inspected and a reinstatement fee paid before placing such equipment under a new support services contract. The inspection and reinstatement fee is non-refundable and does not apply to the purchase of the support services contract. Equipment which has had a transfer of ownership and has not been inspected by SNC is eligible for standard repair pricing.
- 17. SNC reserves the right to modify these terms, require advance payment, and cancel any order.
- 18. SNC sales representatives do not have the authority to bind SNC or make any representation in respect of credit or any other matter which deviates from standard policy. All special arrangements or requirements must be confirmed in writing with an authorized person from SNC.

Rev. 10/13/2012



425-A Pineda Court Melbourne, FL 32940 Phone: +1 321-259-6862 Fax: +1 321-757-0066

Quotation

Questions? Contact: Ahdrea Matarazzo x331 AndreaMatarazzo@s unnuclear.com

Customer's Acceptant (ONLY, (o.be) completed in I	oe eu of a hard copy purchase order)	
Ву:		
Printed Name:		
	-	111111111111111111111111111111111111111
Date:	PO#:	
After completion, plea	ise scan and email to <u>Orders@</u>	sunnuclear.com or

EXHIBIT C-6

Oustation



425-A Plineda Court Melbourne, FL 32940 Phone: +1 321-259-6862 Fax: +1 321-757-0066

Quotation

Questions? Contact: Andrea Matarazzo x331 AndreaMatarazzo@s unnuclear.com

Porsyth Regional Cancer Center Katherine Lanning 3333 Silas Creek Parkway Winston-Salem, NC 27103

Forsyth Regional Cancer Center Katherine Lanning 3333 Silas Creek Parkway Winston-Salem, NC 27103

Date # 00331637
Quote # 00331637
Date Exx. 106/30/33111111
Terms Net 30
Shiping Point
FOB Shipping Point

For Purchase Order processing, please email orders to Orders@sunnuclear.com

iltem	(Part#i, ::::	Description	<u>::Qiy</u>	ių:Unit:Price	LExtended Price.
1	1233000-0	1D Scanner 1D Scanner positions detectors for calibration measurements with depths up to 300 mm (with 0.1 mm accuracy). Features include automatic positioning of the physical center of the detector to water surface and support for all common electron cones. Optional scanning software module is also available to enable full PDD functionality (1230-1DS), Control is through a local control display or through a single cable connection to a PC using included software, includes universal detector holder and vertical holder. Optional leveling platform is available (1080000-0).	1	\$ 4,250.00	\$ 4,250.00
			Tota	I Investment:	\$ 4,250.00



425-A Pineda Court Melbourne, FL 32940 Phone: +1 321-259-6862 Fax: +1 321-757-0066

Quotation

Questions? Contact: Andrea Matarazzo x331 AndreaMatarazzo@s unnuclear,com

This quotation is a confidential document containing privileged information that is not to be disclosed to parties, outside of quotee and Sun Nuclear Corporation. Disclosure of this information to third parties voids terms outlined in the quotation.

Sun Nuclear Corporation Terms & Condition s

- All purchases approved for Net terms are due 30 days from the shipping date or services;
- Shipping terms are FOB Shipping Point
- Payment with credit cards is restricted to SNC products and services of less than \$2,500. A 3% convenience charge will be
 added to any payment processed for special order products (resalls items) and any SNC product of service with a sales price
 greater than \$2,500
- 4. Prices do not include applicable taxes, SNO will collect and remit the appropriate taxes for some U.S. states. If applicable taxes are not on Customer Purchase Order, Customer is responsible for remittance of appropriate taxes.
- Undisputed past due accounts are subject to a late service fee charge, of 18% per annum (1.5% per month), or the maximum allowed by law:
- Any payment made in respect of credit transactions shall that be applied to the accumulated service charge, if any, and thereafter to the principal amount of the culstanding debt
- 7. SNCw | assess handling charges in the amount of \$100,00 for any dishonoured check received from the Customer.
- All products shipped are subject to recourse by SNC until paid in full. Upon request from SNC, Customer agrees to inmediately
 relinquish and return all unpaid equipment in its original condition to the SNC, subject to a 20% restock fee or costs, required to
 return equipment to its original condition, whichever is higher.
- 9. The parties agree that the Customer's sole and exclusive remedy for defective products shall be limited to the stated warranty provided by SNC for its manufactured products, or the warranty assigned by SNC to the extent provided by the manufacturer (resale items) of the particular component or system. The Customer agrees that no other remedy (including, but not limited to, incidental or consequential damages for test profits, lost sales, injury to person or property, transportation charges or other incidental or consequential loss) shall be available.
- Customers who cancel or pospone scheduled training/education/installation services are subject to cancellation fees (minimum of \$500 not to exceed \$3,000) for resource allocations and non-recoverable scheduling costs (i.e., hotels, airfare, reservations, etc.).
- 11. Qustomer agrees to advise SNC of any defective product(s) and/or any disputed invoice(s) in writing within 10 days of receipt. Fallure to properly notify SNC of any dispute and /or defective goods constitutes a waiver of any and all stoch disputes, provided, however, that this provision shall in no way affect or limit Customer's rights under SNC warranty, or where such is limited by law.
- 12. Subject to SNG approval, Quistomer may return unused product within 30 days from the shipping date subject to a 20% restocking fee and Customer must pay for the return shipping charges. Generally, returns after 30 days will not be considered. All approved returns must have an RMA (Return Materials Authorization) number issued by SNC. Special order products (Resale items) cannot be returned without the express written consent of the manufacturer. Customer must pay for the return shipping charges. Unauthorized returns i.e., those without an RMA # provided) will be rejected and returned at Quetomer's expense.
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- .14. Customer hereby agrees to Indemnify. SNO for all collection fees, legal fees and all other fees and expenses which SNO incurs ... should Customer's account be in errears.
- 15. SNC software is only licensed to the original purchaser and the license is not transferable.
- 16. SNC requires that when (i) the standard warranty has ended and lapsed by more than 365 days, (ii) a previously purchased contact has expired and lapsed by more than 365 days or (iii) there has been a transfer of product ownership, the equipment must be inspected and a reinstatement fee paid before placing such equipment under a new support services contract. The inspection and reinstatement fee is non-refundable and does not apply to the purchase of the support services contract. Equipment which has had a transfer of ownership and has not been inspected by SNC is eligible for standard repair pricing.
- 17. SNO reserves the right to modify these terms, require advance payment, and cancel any order.
- 18. SNC sales representatives do not have the authority to bind SNC or make any representation in respect of credit or any other matter which deviates from standard policy. All special arrangements or requirements must be confirmed in writing with an authorized person from SNC.

Rev. 10/13/2012



425-A Pineda Court Melbourne, FL 32940 Phone: +1 321-259-6862 Fax: +1 321-757-0068

Quotation

Questions? Contact: Andrea Matarazzo x331 AndreaMatarazzo@s unnuclear.com

Зу:	of a hard copy purchase order	
Printed Name;		
Title:		f
Date:	PO#:	

Storage Cost for FMC Refurbished Linear Accelerator

VARIAN Clinac 2100C (Serial #318) Vendor Quote Signed 6/3/2005

Time Period

	31,850	€9		Total Storage Cost
4,200 = 12 Months X \$350/Month per vendor Quote (Exhibit A)	4,200	∨	Year Nine	1/1 - 12/31, 2013
4,200 = 12 Months X \$350/Month per vendor Quote (Exhibit A)	4,200	€	Year Eight	1/1 - 12/31, 2012
4,200 = 12 Months X \$350/Month per vendor Quote (Exhibit A)	4,200	5	Year Seven	1/1 - 12/31, 2011
4,200 = 12 Months X \$350/Month per vendor Quote (Exhibit A)	4,200	€9	Year Six	1/1 - 12/31, 2010
4,200 = 12 Months X \$350/Month per vendor Quote (Exhibit A)	4,200	€9	Year Five	1/1 - 12/31, 2009
4,200 = 12 Months X \$350/Month per vendor Quote (Exhibit A)	4,200	⇔	Year Four	1/1 - 12/31, 2008
4,200 = 12 Months X \$350/Month per vendor Quote (Exhibit A)	4,200	5/3	Year Three	1/1 - 12/31, 2007
2,450 = 7 Months X \$350/Month per vendor quote (Exhibit A)	2,450	⇔	Partial Year Two	6/3/2006- 12/31/2006 Partial Year Two
\$0 First Year Storage Free per Vendor Quote (Exhibit A).	\$0		Year One	6/3/2005-6/2/2006

XHIBIT C-7

October 23, 2013



architecture

engineering

interior design

planning

Mr. Barry Harper Novant Health

3600 Country Club Road, Suite 102

Winston-Salem, NC 27104

Re:

Forsyth Medical Center

Linear Accelerator #1 Replacement

Dear Barry:

As required for the Certificate of Need application to be submitted by Peterson Associates, we have prepared a project construction cost estimate and do certify the following:

Construction Cost

Labor:

\$18,000.00

Material:

\$12,000.00

Total CERTIFIED COST:

\$30,000.00

Related Cost (A/E Fees, other)

\$10,000.00

Total Cost:

\$40,000.00

The costs as projected are based on the work required to install a replacement linear accelerator in the existing Vault #1 at FMC. To the best of our knowledge and based upon our experience with similar projects, we concur that these costs are reasonable, accurate, and complete.

Please note that this certification does not include other miscellaneous costs, which may be included in the total project costs.

Sincerely,

PETERSON ASSOCIATES, p.a.

Nelson C. Soggs, AIA, LEED AP, Associate

Sr. Project Manager

NCS/pfm

2115 Rexford Road

Suite 500

Charlotte NC 28271

P704.364.3400

F704.364.7080

www.peterson-ae.com

Varian Medical Systems
2250 Newmarket Pkwy, Suite 120
Matletta, Georgia 30067
tel 770.955.1775
fax 770.984.6249
www.varian.com

Date:	June 2013	
To:	K.D. Lanning, Forsyth Medical Center	
From: Dan	n Spurgeon, Varlan Medical Systems	
Pages:	1	
Re; Mali	aintenance Quality Audit (MQA) for 2100C SN TBD (华12.87)	
Regional M improve re for a service associated	an estimation of the costs associated with MQA on a 2100C for Forsyth Medical Center. The MQA will identify areas of refurbishment in order to reliability and performance, extend the life of the Clinac, and make it eligible rice contract. Below is a breakdown of the estimated time and cost and with a MQA. The quote below is for a Senior Service Rep and a local tep, invoice will reflect actual hours. Please let me know if you have any	
Travel to si	site, 4.0 hrs @ \$240.00 / hr\$960.00	
Overnight	nt charge, 2 nights @ \$230.00 \$460.00	
. 16 hours o	of labor for Senior Field Service Engineer @300/hr\$4,800.00	
	f OT labor for Senior Field Service Engineer @\$450/hr\$1,800.00	
16 hours o	of labor for Local Service Rep @ \$300/hr\$4,800,00	
4 hours of	f OT labor for Local Service Rep @\$450/hr\$1,800,00	
Return Trav	avel, 4.0 hrs @ \$240.00 / hr\$960.00	
Total estim	mate for the MQA on 2100C, s/n TBD \$15,580.00	
NOTI a sepa	TE: Any parts that need replacing or additional work requested will be added to the invoice or billed to parate purchase order. Applicable sales tax will be applied to invoice.	•
Customer A	AcceptanceDate:	
Pürchase O	Order Number:	

EXHIBIT C-10



June 10, 2013 Re: Radiation Vault Shielding Evaluation C/O; Denise Gunter

To Whom It May Concern:

The linear accelerator area designated as Vault 1 at Novant Health Forsyth Medical Center is currently shielded and approved by the State of North Carolina's Department of Health and Human Services for radiation treatments with a maximum photon energy of 15MV. No additional shielding modifications will be necessary to comply with the appropriate radiation dose limits as defined in Chapter II of the North Carolina Regulations for Protection Against Radiation for the installation of a 6MV Varian 2100C linear accelerator.

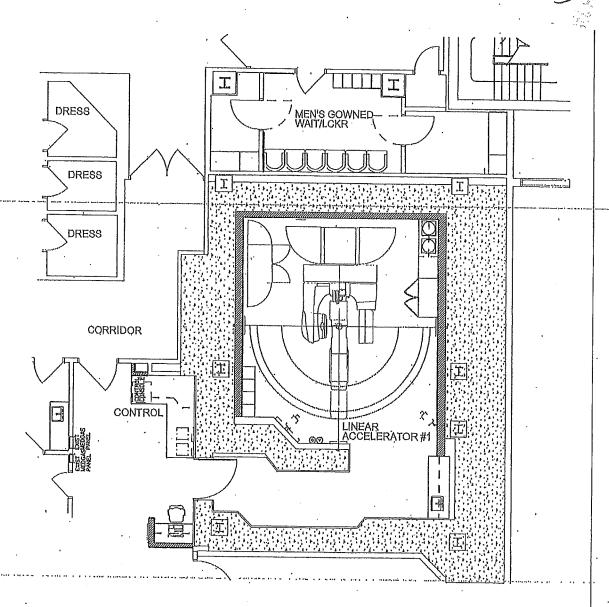
As a board-certified medical physicist by the American Board of Medical Physics, I am qualified to perform radiation shielding calculations for Novant Health.

Thank you,

Curtis Whiddon, PhD

Chief Medical Physicist

ABMP Certified Physicist



PARTIAL LOWER LEVEL FLOOR PLAN LINEAR ACCELERATOR VAULT #1



FORSYTH MEDICAL CENTER WINSTON-SALEM, NC