

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

Pat McCrory Governor Richard O. Brajer Secretary DHHS

Mark Payne Assistant Secretary for Audit and Health Service Regulation

June 2, 2016

Denise Gunter 380 Knollwood Street, Suite 530 Winston-Salem, NC 27103

Exempt from Review – Replacement Equipment

Record #:

1952

Facility Name:

New Hanover Regional Medical Center

FID #:

943372

Business Name:

New Hanover Regional Medical Center

Business #:

1308

Project Description:

Replace existing linear accelerator

County:

New Hanover

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of May 27, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Varian 2100 Clinac C/D Linear Accelerator, serial number 1827. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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



Healthcare Planning and Certificate of Need Section

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

Sincerely,

Tanya S. Rupp Project Analyst Martha J. Frisone

Assistant Chief, Certificate of Need

cc:

Construction Section, DHSR

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

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.nelsonnullins.com



May 27, 2016

VIA HAND DELIVERY

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

FID 943372

Re:

Notice of Replacement and Relocation of Linear Accelerator

New Hanover Regional Medical Center Business id 1308

HSA V

NR12 1952

New Hanover County/Linear Accelerator Service Area 19

Dear Ms. Frisone:

On behalf of New Hanover Regional Medical Center ("NHRMC") and in accordance with N.C. Gen. Stat. § 131E-184(a)(7), I am writing to notify the CON Section of NHRMC's intention to replace and relocate an existing linear accelerator currently in use at NHRMC.

Background

Linear Accelerator Service Area 19 ("Service Area 19") is comprised of Brunswick, Columbus, New Hanover and Pender Counties. There are four linear accelerators in Service Area 19. Three of Service Area 19's linear accelerators are located in New Hanover County. See Exhibit A. NHRMC, located at 2131 S. 17th Street in Wilmington, owns one of the three linear accelerators in New Hanover County. NHRMC's linear accelerator, an Elekta unit, is currently in use at NHRMC's Zimmer Cancer Center.

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Coastal Carolina Radiation Oncology, P.A. ("CCRO") is a radiation oncology practice located at 1988 S. 16th Street in Wilmington (the "CCRO Site"). The CCRO Site is less than one mile from NHRMC. CCRO owns the other two linear accelerators in New Hanover County. There are three linear accelerator vaults at CCRO's Site, but only two of these vaults are occupied. One of the vaults is empty.

CCRO and NHRMC have a long-standing, collaborative relationship. CCRO's radiation oncologists are on the medical staff at NHRMC. CCRO physicians prescribe radiation therapy on NHRMC's linear accelerator. NHRMC patients have been treated on CCRO's linear accelerators.

All three linear accelerators in New Hanover County are extremely busy. According to the 2016 SMFP, CCRO's two machines averaged 6,938 procedures per unit in FFY 2014. This makes the CCRO Site the seventh busiest radiation therapy site in North Carolina. According to Table 9G in the 2016 SMFP, NHRMC's linear accelerator performed 6,027 procedures in FFY 2014, making its linear accelerator the fourteenth busiest linear accelerator in North Carolina. See Exhibit A.

NHRMC and CCRO are part of a joint venture, South Atlantic Radiation Oncology, which operates the linear accelerator in Brunswick County. Sharing resources through SARO has allowed NHRMC and CCRO to provide radiation oncology services more efficiently and at a reduced cost. For some time, NHRMC and CCRO have been discussing how they can work together in New Hanover County to improve access to radiation oncology services and make the process more efficient. Most radiation oncology treatments are delivered on an outpatient basis over the course of many weeks. NHRMC's only linear accelerator is inside the hospital at Zimmer Cancer Center. The CCRO Site is exclusively outpatient and it offers convenient surface parking.

The parties have concluded that patients will be served best by consolidating radiation therapy services at CCRO's Site.¹ For NHRMC's patients, access will be improved by locating radiation oncology away from a busy hospital setting. Having all three linear accelerators under one roof also provides greater flexibility when machines are taken out of service for repairs or maintenance. Patient records will be consolidated so patients can flow seamlessly between locations. Staffing will also be consolidated, thereby allowing clinical staff to meet demand without excess staffing.

¹ The parties propose to consolidate only radiation oncology services at the CCRO Site; NHRMC's Zimmer Cancer Center will continue to provide the other services it has historically provided.

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Replacement Equipment Exemption Request

NHRMC's linear accelerator is almost 16 years old and nearing the end of its useful life. NHRMC proposes to replace its Elekta unit (the "Existing Linear Accelerator") with one of CCRO's machines, a Varian 2100 Clinac C/D (the "Replacement Linear Accelerator"), which is already in operation at CCRO. The proposed cost for this replacement is \$187,500. See capital cost sheet attached as Exhibit B and the equipment comparison form attached as Exhibit C. The Replacement Linear Accelerator is already located in a yault, so there will be no construction costs associated with this project. Since the parties propose to consolidate radiation oncology services at CCRO, the replacement will take place at CCRO and use the existing vault. Thus, while NHRMC will be relocating its radiation oncology service to CCRO, the Existing Linear Accelerator will not move to CCRO. Upon completion of the replacement described in this letter, NHRMC will shut down the Existing Linear Accelerator and arrange for the de-installation and disposal of the Existing Linear Accelerator. The deinstallation and disposal cost of \$12,500 is included in the capital cost form. See Exhibit D.

In a separate replacement equipment exemption request, CCRO will propose to replace the Varian 2100 Clinac C/D that NHRMC will acquire through this replacement equipment exemption request. The end result is that there will be three linear accelerators at the CCRO Site. At no time pertinent to the transaction described in this request will there be more than three linear accelerators operating in New Hanover County or more than four linear accelerators operating in Service Area 19. Thus, the transaction described in this request will not increase the number of linear accelerators in New Hanover County or in Service Area 19. Except for the Varian 2100 Clinac C/D linear accelerator that NHRMC proposes to acquire through this replacement equipment exemption request, the consolidation of radiation oncology services at the CCRO Site does not involve "[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. At all times pertinent to the transaction described in this request, NHRMC will continue to own one linear accelerator, and CCRO will continue to own two linear accelerators.

Reasons Why Project Is Exempt from CON Review

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

1. The cost of the equipment and the cost of all activities essential to acquiring and making operational the replacement equipment are less than \$2 million; and

Martha J. Frisone May 27, 2016 Page 4

2. The sole purpose of this proposal is to replace comparable medical equipment currently in use, which will be sold or otherwise disposed of when replaced.

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

- The Replacement Linear Accelerator has the same technology as the Existing Linear Accelerator although it may possess expanded capabilities due to technological improvements; and
- The Replacement Linear Accelerator is functionally similar and is used for the same diagnostic or treatment purposes as the Existing Linear Accelerator and is not used to provide a new health service; and
- The acquisition of the Replacement Linear Accelerator will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the Replacement Linear Accelerator is acquired.

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

Based on the foregoing, NHRMC respectfully requests that the CON Section confirm in writing that the above-referenced proposal is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7). As NHRMC would like to replace its Existing Linear Accelerator in the near future, we would appreciate receiving your written reply at your earliest opportunity.

Thank you for your time and attention.

Enclosures

STATE HEALTH COORDINATING COUNCIL

STATE MEDICAL FACILITIES PLAN

DESTINATION OF Health Service Regulation

North Carolina Department of Health and Human Services



Table 9G: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2013- 9/30/2014	Average Number of Procedures per Unit
Harris Regional Hospital	1	Jackson	1	4,583	4,583
NC Radiation Therapy - Franklin	1	Macon	1	2,093	2,093
Mission Hospital	2	Buncombe	3	18,146	6,049
NC Radiation Therapy - Asheville	2	Buncombe	2	6,338	3,169
NC Radiation Therapy - Clyde	2	Haywood	1 .	3,698	3,698
NC Radiation Therapy - Marion	2	McDowell	1	4,274	4,274
Watauga Medical Center	3	Watauga	1	4,871	4,871
Margaret R. Pardee Memorial Hospital	4	Henderson	1	4,539	4,539
NC Radiation Therapy - Hendersonville	4	Henderson	1	1,894	1,894
NC Radiation Therapy - Brevard	4	Transylvania	1	2,627	2,627
Carolinas HealthCare System Blue Ridge	5	Burke	2	4,902	2,451
Caldwell Memorial Hospital	5	Caldwell	1	1,845	1,845
Catawba Valley Medical Center	5	Catawba	2	12,035	6,017
Frye Regional Medical Center	5	Catawba	1	5,229	5,229
Carolinas HealthCare System Cleveland	6	Cleveland	1	7,961	7,961
Caromont Regional Medical Center	6	Gaston	3	16,656	5,552
NC Radiation Therapy - Forest City	6	Rutherford	1	5,088	5,088
Carolinas Medical Center	7	Mecklenburg	3	21,410	7,137
Matthews Radiation Oncology Center	7	Mecklenburg	1	9,298	9,298
Novant Health Presbyterian Medical Center	7	Mecklenburg	4	11,300	2,825
Pineville Radiation Therapy Center	7	Mecklenburg	1	2,480	2,480
University Radiation Therapy Center	7	Mecklenburg	i	6,723	6,723
Carolinas Medical Center-Union	7	Union	1	6,933	6,933
Iredell Memorial Hospital	8	Iredell	2	5,253	2,627
Lake Norman Radiation Oncology Center	8	Iredell	1	10,039	10,039
Novant Health Rowan Medical Center	8	Rowan	1	6,366	6,366
Carolinas Medical Center - NorthEast	9	Cabarrus	2	10,960	5,480
Stanly Regional Medical Center	9	Stanly	1	3,548	3,548
North Carolina Baptist Hospital	10	Forsyth	4	23,188	5,797
Novant Health Forsyth Medical Center	10	Forsyth	5	29,369	5,874
Hugh Chatham Memorial Hospital	10	Surry	1	3,729	3,729
Lexington Medical Center	11	Davidson	1	2,820	2,820
Cone Health	12	Guilford	4	23,177	5,794
High Point Regional Health	12	Guilford	2	7,707	3,854
Morehead Memorial Hospital	12	Rockingham	1	4,368	4,368
Randolph Hospital	13	Randolph	1	4,436	4,436
University of North Carolina Hospitals	14	Orange	5	31,514	6,303
Alamance Regional Medical Center	15	Alamance	2	8,611	4,306
Duke Regional Hospital	16	Durham	1	5,851	5,851

Table 9G: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2013- 9/30/2014	Average Number of Procedures per Unit
Duke University Hospital	16	Durham	8	37,984	4,748
Maria Parham Medical Center	16	Vance	1	4,960	4,960
FirstHealth Moore Regional Hospital	17	Moore	3	15,609	5,203
Scotland Memorial Hospital	17	Scotland	1	4,027	4,027
Cape Fear Valley Medical Center	18	Cumberland	5	18,540	3,708
Southeastern Regional Medical Center	18	Robeson	1	7,475	7,475
NC Radiation Therapy - Sampson	18	Sampson	1	2,359	2,359
South Atlantic Radiation Oncology	19	Brunswick	1	5,869	5,869
Coastal Carolina Radiation Oncology	19	New Hanover	2	13,876	6,938
New Hanover Regional Medical Center	19	New Hanover	1	6,027	6,027
Franklin County Cancer Center	20	Franklin	1	19	19
2014 SMFP Need Determination	20	Wake	1		
Cancer Centers of North Carolina	20	Wake	3	6,705	2,235
Duke Raleigh Hospital	20	Wake	1	9,474	9,474
Rex Hospital	20	Wake	4	20,079	5,020
2015 SMFP Need Determination	21	Hamett	1		
Clayton Radiology Oncology	22	Johnston	1	3,668	3,668
Smithfield Radiation Oncology	22	Johnston	1	3,399	3,399
Lenoir Memorial Hospital	23	Lenoir	1	6,562	6,562
NC Radiation Therapy - Goldsboro	23	Wayne	1	5,852	5,852
Carteret General Hospital	24	Carteret	1	4,220	4,220
CarolinaEast Medical Center	24	Craven	2	7,911	3,955
Onslow Radiation Oncology	25	Onslow	1	3,235	3,235
NC Radiation Therapy - Roanoke Rapids	26	Halifax	1	2,037	2,037
Nash General Hospital	26	Nash	2	7,585	3,792
Wilson Medical Center	26	Wilson	1	5,099	5,099
Vidant Beaufort Hospital	27	Beaufort	1	1,881	1,881
Vidant Roanoke-Chowan Hospital	27	Hertford	1	2,596	2,596
Leo Jenkins Cancer Center	27	Pitt	2	10,773	5,386
NC Radiation Therapy - Greenville	27	Pitt	2	10,916	5,458
Vidant Medical Center	27	Pitt	1	2,053	2,053
The Outer Banks Hospital	28	Dare	1	2,990	2,990
Sentara Albemarle Medical Center	28	Pasquotank	1	5,007	5,007
Totals (70 Facilities)			125	584,630	4,677

PROPOSED CAPITAL COSTS

Project Name: Repla Proponent: New Har	nover Regio	onal Medical Center	
A.	Site Costs (1)	Full purchase price of land	\$
	(2)	Acres Price per Acre \$	
	(3)	Closing costs	S. C.
	(4) (5)	Site Inspection and Survey Legal feet and subsoil investigation	
	(+)	Site Preparation Costs	
		Soil Borings	\$
		Clearing-Earthwork	
		Roads-Paving	\$
		Concrete Sidewalks	
		Fooling Excavation.	
		Footing Backfill	\$
		Termite Treatment	
		Other (Specify) Sub-Total Site Preparation Costs	
	(6)	Other (Specify)	\$
ъ	(7)	Sub-Total Site Costs	\$
В.	(8)	ion Contract Cost of Materials	
	(-7	General Requirements	
		Concrete/Masonry	
		Woods/Doors & Windows/Finishes Thermal & Moisture Protection	
		Equipment/Specialty Items	
		Mechanical/Électrical	
		Other (Specify) Sub-Total Cost of Materials	\$
	(9)	Cost of Labor	S
	(10)	Other (Specify) Sub-Total Construction Contract	\$
C,	(11) Miscellan	Sub-Total Construction Contract	
	(12)	Building Purchase.	
	(13)	Fixed Equipment Purchase/Lease \$175,000 Moyable Equipment Purchase/Lease \$	
	(14) (15)	Furniture	
	(16)	Landsceping	
	(17)	Consultant Fees Architect and Engineering Fees	
		Architect and Engineering Fees \$	
		Market Analysis	
•		Other (Specify) Sub-Total Consultant Fees. S	
	(18)	Financing Costs (e.g. Bond, Loan, etc.)	\$
	(19)	Interest During Construction	5
	(20) (21)	Other (Specify) Disposal of Elekta Unit \$12,500 Sub-Total Miscellaneous	\$
	(22)	Total Capital Cost of Project (Sum A-C above)	\$ 187,500
Tomaticostina analogit			a rus of
I certify that, to the f	est of my k	mowledge, the above construction related costs of the proposed project named above are complete and c	orrect.
			•
(Signature of Licens	ed Architec	t or Engineer)	
, -			
I assure that, to the b	iest of my k	nowledge, the above capital costs for the proposed project are complete and correct and that it is my into	ent to carry out the proposed
project as accorded	T et et	Be 10 M. There	MI
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(Proponent signatu	ire of office	r) (Vide of officer)	11
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EQUIPMENT COMPARISON

New Hanover Regional Medical Center Linear Accelerator Replacement

	Clarence	THE PARTY OF THE P
	FOITIDMENT	FOITIPMENT
Type of Equipment (List Each Component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Elekta	Varian 2100 Clinac C/D
Tesla Rating for MRIs	N/A	N/A
Model Number	Precise	Clinac 2100 C/D
Serial Number	5568	1827
Provider's Method of Identifying Equipment	Elekta Accelerator	Manufacturer's Serial #
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	10/2000	12/21/2001
Dues Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <use attached="" form=""></use>		\$187,500 (includes
Total Cost of Equipment (Linear Accelerator only)		C175 000
Fair Market Value of Foundment	03	\$175,000
Net Directore Of Banisment	\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	\$175,000
TYCL I UCIESC FILE OF EQUIPMENT	W/WI	\$1/3,000
Locations Where Operated	Zimmer Cancer Center	Coastal Carolina
	of New Hanover	Radiation Oncology,
	Regional Medical	PA, 1988 S. 16 th Street,
	Street Wilminoton NC	Wilmington, NC
Number Days In Use/To Be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	N/A	%0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	. N/A	%0 ·
Type of Procedures Currently Performed on Existing Equipment	External Beam Radiotherapy	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	External Beam Radiotherapy



Client Contact

RS&A Contact

Michelle Hoadley Elekta 400 Perimeter Center Terrace, Suite 50 Atlanta, GA 30346 David Stith | <u>dstith@rsainc.net</u> 465 Forum Parkway Rural Hall, NC 27045 P: (800) 320-4332

Statement of Work

Objective:

Inspect, remove, dispose of Zimmer Cancer Center's radiation therapy equipment

(listed below).

Equipment:

Elekta Precise

Location:

Zimmer Cancer Center | 2131 S 17th St. | Wilmington, NC 28401

Approach:

As part of this project, RS&A will:

- Assign a dedicated project coordinator to oversee all activities.
- Assign a qualified engineer team to perform all activities.
- Coordinate all activities with facility staff.
- Provide all equipment needed to complete the work.
- Perform a pre-job site walk down and machine inspections prior to beginning removal activities.

Start Date:

TBD / 2016

Reference #:

OP-005530

Pricing

Below is a pricing breakdown by activity - these may vary and are provided for budgeting purposes only.

Lir	ne Item	An	nount
1	Complete pre-inspection of facility.	\$	Included
2	De-install and remove existing machine.	\$	12,500
3	Travel and expenses	\$	Included

Total \$ 12,500

Note: Does not include applicable taxes.



Acceptance of Agreement

By signing below, the Client hereby agrees to the pricing, terms, and conditions of this agreement:

Client:	Elekta ("Client") 400 Perimeter Center Terrace, Suite 50 Atlanta, GA 30346	
Authorized Signature:		Date:
Printed Name:	·	
Contract PO #:		
Tax Number (if exempt):		
Provider:	RS&A, Inc. (" RS&A") 465 Forum Parkway Rural Hall, NC 27045	
Authorized by:	Kenneth C. Wolff RS&A President and CEO	Date:

Attachments:

Terms and Conditions



Client and RS&A (collectively, the "Parties") enter into this Equipment Services ("Contract" or "Agreement") and agree as follows. Additional qualifications or adjustments are to be included by addendum only.

- 1. PLAN RS&A will work with the Client to best define their objectives, desired outcomes and key considerations throughout the project. RS&A will utilize its discovery questionnaire to determine the following information:
- 1.1 Determine the facility's future plans and needs as they relate to desired upgrades of existing equipment or additional equipment procurement. This includes, but is not limited to, machine and financial specifications (e.g., budget).
- 1.2 Evaluate existing machine(s) at Facility. For Facilities that have existing machines, RS&A will complete a machine evaluation to determine current operating condition, useful remaining life, and estimated market value (bank, third party acquisition, and trade-in).
- 1.3 Inspect Facility to assess any physical considerations, constraints, or limitations. This inspection includes, but is not limited to, room dimensions, shielding requirements, electrical requirements, base frame needs, and other construction related needs.
- 1.4 RS&A will provide a site planning summary to the Client (the "Site Evaluation") in which RS&A outlines its findings and recommendations. This will include, but is not limited to, any construction or facility infrastructure related items necessary to install the desired Equipment.
- 1.5 Client shall review the Site Evaluation. If Client elects not to proceed with RS&A's recommendations, then it shall provide RS&A with written notice within thirty (30) days of the date on the Site Evaluation that it elects to terminate this Agreement. If Client fails to give written notice to terminate, then it shall be presumed that Client elects to proceed with RS&A's recommendations.
- 2. **PROCURE** If applicable, RS&A will monitor the equipment market and provide Client with notices of machine options that meet the necessary specifications provided in the Site Evaluation. Upon identification of a machine that meets the desired specifications (the "Equipment"), RS&A agrees to the following:
- 2.1 RS&A will conduct an on-site inspection of the Equipment in alignment with its Quality Assurance program (the "Inspection Report"). The Inspection Report will include, without limitation, (i) the Equipment's operational and visual functionality and (ii) RS&A's recommendation regarding whether to accept or reject the Equipment. RS&A will provide a copy of its Inspection Report to the Client.
- 2.2 If Client desires to accept the Equipment, it must notify RS&A in writing within forty-eight (48) hours of RS&A's delivery of the Inspection Report to Client. If Client does not respond within 48 hours, then it is presumed that Client rejects the Equipment.
- 2.3 Upon acceptance of the Equipment by Client, RS&A will contract with the seller of the Equipment ("Seller") to purchase the Equipment on behalf of the Client. RS&A will provide the necessary funds to hold the Equipment, which may include a required down-payment or escrow amount. RS&A will coordinate the purchase and acquisition of the Equipment, including without limitation, machine acquisition and removal, title transfer, software licensing and registration fees, and relocation or temporary storage. This Agreement with then be amended to include the machine specifications of the Equipment purchased (see Attachment B).
- 3. **INSTALL** Once the Equipment is identified and under contract with the Seller, the Parties shall move forward with the plans for installing the Equipment as outlined in this Section.
- 3.1 **Project Coordinator.** RS&A will appoint a project coordinator (the "Project Coordinator") to work with the Client and manage the installation of the Equipment. The Project Coordinator will be the main contact for Client and is charged with overseeing the project which may include: (i) Coordinating project activities, (ii) Developing an Installation Schedule, (iii) Attending project meetings and preparing meeting summaries (progress to date, next steps, issues log), (iv) Establishing a project contact list, (v) Supporting the Client with change management exercises (e.g., communications plan), (vi) Executing installation procedures to perform and verify the work, and (vii) Issuing project milestone acceptance letters.



- 3.2 **Installation Schedule.** The Parties will meet and prepare an installation schedule (the "Installation Schedule"). Both Parties shall use commercially reasonable efforts to comply with the Installation Schedule.
- 3.3 **Site Preparation.** RS&A will work with the Client to prepare the Site ("Site Preparation") to install the Equipment. The Site Preparation may include, but is not limited to, the following:
- 3.3.1 Removal of Existing Equipment. If a machine is currently installed at the Facility and is being replaced (the "Existing Equipment"), RS&A will remove and disposition the Existing Equipment as it deems appropriate. RS&A will manage any disposal requirements for radiative material associated with the removal of the Existing Equipment. Accessories such as photon wedges, accessory trays, electron cones, couch top panels and treatment accessories will be removed with the Existing Equipment. Unless otherwise noted, RS&A will take possession (in full) of any removed equipment and accessories as part of this agreement.
- 3.3.2 **Disconnection of Utilities.** Client is responsible for disconnecting the electrical, air, and plumbing systems from the Existing Equipment prior to removal of the Existing Equipment and Installation of the Equipment.
- 3.3.3 **Construction Activities.** Client is responsible for any activities required to configure the Facility to install the Equipment at the Facility. Such items may include without limitation (i) electrical, plumbing or other utility requirements, (ii) vault preparation and requirements, (iii) additional shielding, (iv) floor or wall repairs, (vi) any code compliance requirements, (vi) chiller installations, (vii) IT requirements and configurations or (viii) any other infrastructure/construction requirements to install the selected Equipment. See Attachment C for a breakdown of roles/responsibilities (Note: This may be altered to meet the needs of this Agreement and should be included by addendum).
- 3.3.4 **Permits.** Client is responsible for (i) obtaining any required permits to possess and install the Equipment and (ii) complying with all state, federal and local regulations in connection with Equipment.
- 3.3.5 **Radiation Controls.** The radiation control regulations in several regions prohibit RS&A from delivering equipment until the Client can provide evidence of meeting certain requirements. This may include verifying that the Client has licensed or registered their equipment and/or registered their facility. Client shall obtain their license or file their registration in a timely manner to avoid delivery and installation delays, which may occur if these requirements have not been met.
- 3.3.6 Facility Plan. Certain regions require that RS&A must verify the Client has had their facility plan review approved by the regional radiation control agency before the delivery of equipment can be authorized.
- 3.4 **Delivery and Install of Equipment.** Once the Site Preparation is complete (including permitting), RS&A will finalize the acquisition, removal and delivery of the Equipment to the Facility. RS&A will install the Equipment to operate within manufacturer specifications. Upon completion of the mechanical and electrical installation process, RS&A will be present with the Facility's designated staff (e.g., Physics) to administer manufacturer acceptance testing procedures. The completion of the installation process is defined as when acceptance testing is done and signed off by the Client (acceptance letter).
- 4. **OPERATE** RS&A will support the Facility's transition to the new Equipment as appropriate. This includes, but is not limited to, the following:
- 4.1 **Train Personnel.** Prior to operations, RS&A will train Facility personnel on the new equipment. This will be scheduled and coordinated with the Client in advance of completing Equipment installation. As part of one-year service agreement, RS&A will provide technical support to the Client to ensure a seamless transition to the new Equipment.
- 4.2 Treat Patients (i.e., Equipment Operations). Client shall properly operate all Equipment and related controls in accordance with the applicable operating manuals and recommended procedures and ensure that qualified personnel are provided for such operations, including any product calibration. Client shall operate the Equipment continuously in environmental and electrical conditions that meet or exceed the manufacturer's specifications for the Equipment. Client shall be responsible to perform the daily care of the Equipment. In any instances where the Equipment is not operated within the defined product specifications and operating procedures supplied by the



equipment manufacturer, any repairs necessitated thereby shall be conclusively presumed the result of Client's negligence, and will be invoiced on a time and material basis.

5. PRICING AND PAYMENT TERMS

- 5.1 The price for the services rendered under this Agreement shall be equal to the "Pricing" as outlined on summary page (the "Fee").
- 5.2 All payments are net due upon completion of the Client acceptance testing document. Past due balances are subject to a service charge of the maximum amount permitted by law. If collection action is required to collect any amount due under this Agreement, then Client agrees to be responsible for the payment of all past dues, late fees, accrued interest and reasonable attorneys' fees by RS&A to collect such sums. Payments shall be made by certified check payable to RS&A. Inc. or by wire transfer.
- 5.3 **Exclusions.** Pricing does <u>not</u> include (i) any construction related costs in the vault (e.g., additional shielding or floor repair), (ii) compliance issues, utility services, chiller installs, IT requirements, etc., (iii) local, state, and federal taxes or (iv) any construction, demolition, or repair work that might be required.
- 5.4 **Licensure.** Client may be subject to re-licensing fees associated with the transfer of ownership on used equipment. The Original Equipment Manufacturers (OEM) regulates license transfer policies and only the OEM can supply license transfers. RS&A shall not be responsible for any license fees subsequently charged by the Original Manufacturer, unless specifically agreed upon.

5.5 Refund Policy.

5.5.1 Client may elect to terminate this Agreement by providing written notice to RS&A. Once RS&A has entered into a binding contract with the Seller, all funds paid under this Agreement shall be non-refundable.

6. REPRESENTATIONS AND WARRANTIES

- 6.1 **RS&A Representations and Warranties.** RS&A represents and warrants as follows:
- 6.1.1 The services will conform to the Equipment manufacturer's specifications and applicable laws and regulations.
 - 6.1.2 RS&A has full power and authority to enter into and to perform its obligations hereunder.
- 6.1.3 The execution, delivery and performance of this Contract by RS&A have been duly authorized by all necessary action. This Contract and all other documents delivered to Client will be, duly executed and delivered on behalf of RS&A by duly authorized agents of RS&A, and the legal, valid and binding obligations of RS&A enforceable in accordance with their respective terms.
 - 6.2 Client Representations and Warranties. Client represents and warrants as follows:
- 6.2.1 By entering into this Contract, Client shall not be in violation of any contract with another party, including without limitation, any exclusive right by the manufacturer to service the Equipment.
 - 6.2.2 Client has full power and authority to enter into and to perform its obligations hereunder.
- 6.2.3 The execution, delivery and performance of this Contract by Client have been duly authorized by all necessary action. This Contract and all other documents delivered to RS&A will be, duly executed and delivered on behalf of Client, and the legal, valid and binding obligations of Client enforceable in accordance with their respective terms.

7. MISCELLANEOUS

7.1 Disclaimer of Warranties.

7.1.1 THE WARRANTY FOR MATERIALS AND EQUIPMENT IS A MANUFACTURER'S WARRANTY ONLY, AND RS&A PROVIDES NO OTHER WARRANTIES WHATSOEVER, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY, ANY IMPLIED

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WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE AND ANY IMPLIED WARRANTIES OTHERWISE ARISING FROM COURSE OF DEALING OR TRADE.

7.2 Limitation of Liability.

- 7.2.1 Notwithstanding anything in this Agreement to the contrary, RS&A shall have no responsibility or liability for delays however caused. In no event shall RS&A be liable for any indirect, special, incidental, consequential or punitive damages, losses or expenses including, but not limited to, loss of use, loss of profits, or loss of goodwill. Any liability of RS&A is expressly limited to payments actually received by RS&A under this Contract.
- 7.2.2 Client hereby agrees to hold harmless RS&A and its respective officers, employees, agents, representatives, and their respective successors and assigns from and against any and all loss, liability, damages, claims, causes of action, costs, and expenses, including but not limited to attorney's fees and other types of liability, whether accrued, absolute, contingent or otherwise, arising out of or related to use of any of the Equipment at any time. Client alone is responsible for costs required to comply with all requirements imposed by law or regulation relating in any way to personal safety prior to use or operation of Equipment.
- 7.3 Computer Software. Computer software (including, without limitation, source code, object code, application software, server and Client software, operating system software, and software implemented as firmware) provided with the Equipment remains the property of the original equipment manufacturer (the "OEM") or the OEM's licensors. All software licensing and registration fees, including machine licensing and portal imaging licensing must be addressed with the OEM. RS&A agrees to work with the Client to obtain all necessary software for the Equipment.
- 7.4 **Third Party Beneficiary.** Nothing in this Agreement is intended or should be construed to give any third person, including a patient of Client, any legal or equitable rights under this Agreement.
- 7.5 **Entire Agreement.** This Agreement, including any schedules, price lists and exhibits that may be attached hereto, constitutes the entire understanding and agreement between the parties and supersedes any and all prior and contemporaneous oral or written representations, communications, understandings and agreements between the parties with respect to the subject matter contained herein and in the schedules, price lists and exhibits attached hereto. A modification of the terms and conditions hereof by any separate terms and conditions offered by Client must be signed by RS&A in order to become binding on RS&A and enforceable by Client. The parties acknowledge and agree that neither party is entering into this Agreement on the basis of any representation, understanding, agreement or promise not expressly set forth in this Agreement.
- 7.6 Confidential Information. Each Party agrees not to use any Confidential Information of the other party for any purpose except for performing their respective obligations pursuant to this Agreement. Each Party agrees to limit disclosure of any Confidential Information of the other party to those agents, business consultants, representatives or employees of the receiving party who are required to have the information in order to evaluate or engage in discussions concerning the contemplated business relationship. Neither Party shall reverse engineer, disassemble or decompile any software or other tangible objects which are provided as the other party's Confidential Information. "Confidential Information" means any information relating to, available to, or disclosed pursuant to this Agreement, including, but not limited to, information relating to either party's products, services and/or service plans, trade secrets, inventions, data, designs, reports, analyses, costs, prices and names, patients, patient information, customer lists, finances, marketing plans, business plans, strategic plans or business opportunities.
- 7.7 **Attorney's Fees.** If any legal action is brought for the enforcement of this Agreement or because of an alleged dispute, breach, default, or misrepresentation in connection with any of the provisions of this Agreement, the prevailing party or parties shall be entitled to recover their reasonable attorney's fees and other costs incurred in that action or proceeding, in addition to any other relief to which they may be entitled.
- 7.8 **Counterparts and Facsimile Signatures.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same Agreement. For purposes of this Agreement, signatures sent via facsimile shall be deemed originals and shall have the same force and effect as if they were originals.
- 7.9 Force Majeure. Neither party shall be liable in damages or have the right to terminate this Agreement for any delay or default in performing hereunder if such delay or default is caused by conditions beyond its

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control including, but not limited to Acts of God, government restrictions (including the denial or cancellation of any export or other necessary license), wars, adverse weather conditions, insurrections and/or any other cause beyond the reasonable control of the party whose performance is affected.

7.10 **Governing Law.** This Contract shall be governed by and construed in accordance with the laws of the state of North Carolina. Client hereby irrevocably consents to the venue and jurisdiction of the courts in Forsyth County, North Carolina.

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