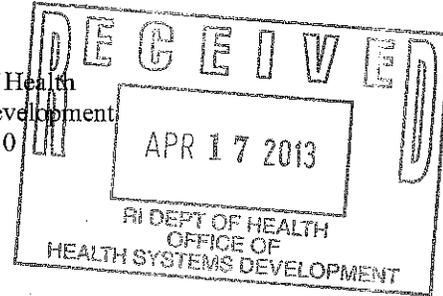




Rhode Island Department of Health  
Office of Health Systems Development  
Three Capitol Hill, Room 410  
Providence, RI 02908-5097

Phone: (401) 222-2788  
Fax: (401) 222-3017



[www.health.ri.gov/hsr/healthsystems/index.php](http://www.health.ri.gov/hsr/healthsystems/index.php)

### One-for-one Replacement Form (April 2007)

1. Name and address of the Applicant:

Name:	Radiation Oncology Associates, Inc. / dba NorthMain Radiation Oncology
Address:	825 North Main Street Providence, RI 02904

2. Contact Information for the Chief Executive Officer:

Name:	Nicklas B. E. Oldenburg, MD	Telephone:	(401) 521-9700
Address:	825 North Main Street Providence, RI 02904		
E-mail:	noldenburg@nmrad.com	Fax number:	(401) 331-6718

3. Information for the person to contact regarding this proposal:

Name:	Nicklas B. E. Oldenburg, MD	Telephone:	(401) 521-9700
Address:	825 North Main Street Providence, RI 02904		
E-mail:	noldenburg@nmrad.com	Fax number:	(401) 331-6718

4. Please provide a copy of the state agency's decision letter granting approval to acquire the currently operating equipment which is proposed to be replaced.

Please see the attached letter from Michael K. Dexter dated 07/20/2007.

5. Please identify all conditions of approval required as part of the state agency's decision granting approval to acquire the currently operating equipment which is proposed to be replaced and whether the applicant is in compliance with all such conditions of approval.

There were no conditions associated with the prior one for one replacement in 2007.

6. Please complete the table below comparing the current equipment to the proposed equipment:

	Current Equipment (to be replaced)	Proposed Equipment (New Health Care Equipment)
a. Name of Equipment Owner(s)	Providence Radiation Oncology Partners, LLC	Same
b. Type of Equipment	Medical Linear Accelerator	Same
c. Manufacturer	Varian Medical Systems	Elekta
d. Model Name & Number*	Clinac 600 CD	Infinity
e. Capital cost of equipment	N/A	\$1.9M
f. Other costs	N/A	\$0.4M construction \$0.1M test equipment
g. Total costs (e+f)	N/A	\$2.4M
h. Financing Mix (Debt/Equity/Lease (%))	N/A	80% Lease Financing 20% Equity
i. Date of Acquisition	2007	09/2013, Pending 1:1 replacement approval
j. Physical location of the equipment	825 North Main Street Concrete Vault	Same

\*for CT scanners please also identify the number of slices;

for MRI scanners please also identify the tesla strength and whether the unit is open or closed;

7. Please identify any additional costs (ex. Enhancements) that will be required within a one-year period.

None Anticipated

8. Please identify all the purposes, functions and clinical applications for the current and proposed equipment. Please clearly distinguish any purposes, functions or clinical applications (ex. CT angiography) which cannot be performed on the currently operating equipment which is to be replaced but can be performed on the proposed equipment.

(1)	Current Equipment (to be replaced) (2)	Proposed Equipment (3)
<b>Purpose</b>	External Beam Radiation Therapy	Same See further explanation Below
<b>Function</b>	External Beam Radiation Therapy	Same See further explanation Below
<b>Clinical Applications</b>	Treatment of malignancies and some benign conditions at all body sites	Same See further explanation Below

9. Please provide a detailed discussion of any differences identified in the information provided in columns (2) and (3) in response to question #7 above.

Clinical linear accelerators are used under the direction of a radiation oncologist physician to treat malignancies and some benign conditions at all body sites. These provide high energy radiation in the form of x-rays and electrons which are focused on tumors. Our current machine has 6 MV (Mega Voltage) treatment energy, image guidance (IGRT), multileaf collimation (MLC) for shaping the beam, and the ability to deliver Intensity-Modulated Radiation Therapy (IMRT). Our replacement machine will have all of these features and in addition 10 MV energy and the ability to deliver electron beam therapy. The new machine does allow us to update and modernize certain features. We will describe those differences below:

#### Imaging Capabilities:

Modern, state of the art linear accelerators are equipped with enhancements which improve treatment accuracy and safety for the patient. Among the most important of these features is the ability to image the tumor. Imaging permits the tumor area to be identified and the treatment field to be adjusted before the patient is treated. Our new machine will offer state of the art imaging capabilities. For example, the new Elekta Linear Accelerator will be equipped with kV (low energy diagnostic imaging x-rays) imaging in addition to MV (high energy treatment x-rays) imaging we currently have on our machine. This will permit better imaging of the patient's tumor, improving accuracy of the delivered beam and minimizing dose to normal tissues. The kV imager will also permit cone-beam imaging which provides CT images over a short (26 centimeter) distance. CT quality images permit better visualization in certain parts of the body than regular x-ray images. The CT images obtained from this machine are not used for diagnostic CT scans.

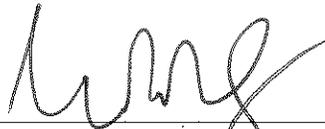
Beam Shaping:

Radiation machines have beam shaping devices called multileaf collimators (MLC). These have replaced "blocks", which were customized static devices poured from hot liquid metal which cooled to a certain shape. Our current machine has an 80 leaf MLC (each 1 cm wide). The new machine will have a 160 MLC (each 0.5 cm wide), permitting finer shaping of the treatment fields. The presence of 160 microleaf collimation and cone-beam CT imaging will permit stereotactic cranial and stereotactic body radiation therapy to be delivered when appropriate.

Intensity-Modulated Radiation Therapy (IMRT):

IMRT is a treatment planning and delivery technique that is an advancement over 3-Dimensional Conformal Radiation Therapy. IMRT uses thin beams of radiation aimed at the tumor from many angles reducing the damage to healthy tissue near the tumor. Our current linear accelerator delivers IMRT as does the new machine. In addition, the new machine will be able to treat with volumetric modulated arc therapy (VMAT). This is an IMRT treatment technique that improves the sparing of critical structures and healthy tissue—in *dramatically shorter treatment times*—without comprising target coverage and patient safety. Shorter treatment times will improve patient comfort and reduce the likelihood of patient movement after initial imaging and field adjustments are made.

Please have the appropriate individual attest to the following: *I state that the information contained in this material is complete, accurate and correct to the best of my knowledge and belief.*



4/17/2013

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Signed and dated by the President or Chief Executive Officer  
Nicklas Oldenburg, M.D.

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS  
D E P A R T M E N T O F H E A L T H

*Safe and Healthy Lives in Safe and Healthy Communities*

20 July 2007

Gabriela B. Masko, MD  
President  
Radiation Oncology Associates, Inc.  
825 North Main Street  
Providence, Rhode Island 02904

Dear Dr. Masko:

The Department has received your request dated 19 July 2007 (attached) requesting an exemption from certificate of need (CON) review for "one for one" replacement of a linear accelerator to provide external beam radiation therapy, pursuant to Section 3.18 of the CON Rules and Regulations (R23-15-CON). As stated, you are requesting an exemption to replace a Clinac 6-100 unit manufactured by Varian with a Clinac 600 CD unit manufactured by Varian. In your request, you state that the purpose, function and clinical applications of the proposed equipment are the same as for the current equipment.

The state agency takes notice that, in accordance with section 3.31 of the CON Rules and Regulations, tertiary or specialty care services are subject to CON review regardless of capital expense and that linear accelerators are included on the list of medical technology equipment.

Based on all of the facts and representations contained in your 19 July 2007 request, this Office finds that the proposed "one for one" equipment replacement shall be exempted from CON review. If any of the facts or circumstances, as considered herein, change then this exemption may become null and void.

If you have any questions please call me at 222-2788.

Sincerely,



Michael K. Dexter  
Chief  
Health Systems Development

Attachments