



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

May 17, 2007

Docket No. 03033297  
Control No. 140454

License No. 37-30075-01

Robert Luthmann, Ph.D.  
Radiation Safety Officer  
Capital Area R.T. Associates  
Oakwood Center Radiation Oncology  
880 Century Drive  
Mechanicsburg, PA 17055

SUBJECT: CAPITAL AREA R.T. ASSOCIATES, LICENSE AMENDMENT, CONTROL NO.  
140454

Dear Dr. Luthmann:

This refers to your license amendment request. Enclosed with this letter is the amended license reducing the possession limits for your high dose-rate remote afterloader. In addition, pursuant to discussions with Varian Medical Systems and our Sealed Source and Device Registry office, we understand that Varian currently supplies the sources for your device that are constructed equivalent to those previously supplied for use in your device. The license has been updated to reflect this change.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

R. Luthmann  
Capital Area R.T. Associates

2

Thank you for your cooperation.

Sincerely,

***Original signed by Penny Lanzisera***

Penny Lanzisera  
Senior Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety

Enclosure:  
Amendment No. 12

---

**Official Use Only - Security-Related Information**

R. Luthmann  
Capital Area R.T. Associates

3

DOCUMENT NAME: C:\FileNet\ML071380342.wpd

**SUNSI Review Complete: PLanzisera**

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/end. "E" = Copy w/ attach/end. "N" = No copy.

OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI			
NAME	PLanzisera /PAN/						
DATE	5/17/07						

OFFICIAL RECORD COPY

[REDACTED]

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<b>Licensee</b>		<b>In accordance with the letter dated</b> <b>April 24, 2007,</b>	
1. Capital Area R. T. Associates Oakwood Center Radiation Oncology		3. License number 37-30075-01 is amended in its entirety to read as follows:	
2. 880 Century Drive Mechanicsburg, Pennsylvania 17055		4. Expiration date April 30, 2015	
		5. Docket No. 030-33297 Reference No.	
6. Byproduct, source, and/or special nuclear material.	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	
A. (b)(7)(F)	A. (b)(7)(F)	A. (b)(7)(F)	
B. (b)(7)(F)	B. (b)(7)(F)	B. (b)(7)(F)	
9. Authorized use:			
A. One source for medical use permitted by 10 CFR 35.600, (b)(7)(F)			
(b)(7)(F)			
(b)(7)(F) One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.			
B. Shielding in a remote afterloader unit.			

**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at 880 Century Drive, Mechanicsburg, Pennsylvania.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

**37-30075-01**

Docket or Reference Number

**030-33297**

Amendment No. 12

11. The Radiation Safety Officer for this license is Robert W. Luthmann, Ph.D.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14:
- B. The following individuals are authorized users for medical use as indicated:
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|-------------------------|-------------------------|
| Stephen J. Milito, M.D. | (b)(7)(E)               |
- C. The following individuals are authorized medical physicists as indicated:
- | <u>Authorized Medical Physicists</u> | <u>Material and Use</u> |
|--------------------------------------|-------------------------|
| Donald E. Velkley, Ph.D.             | (b)(7)(E)               |
| Robert W. Luthmann, Ph.D.            |                         |
13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

**37-30075-01**

Docket or Reference Number

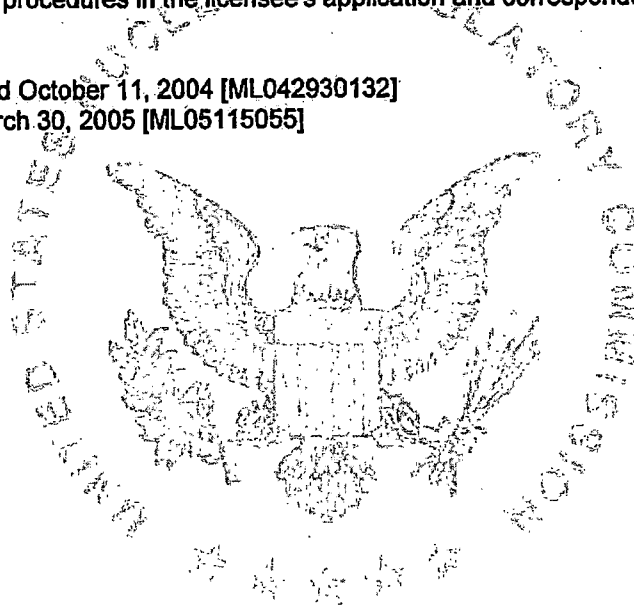
**030-33297**

Amendment No. 12

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated October 11, 2004 [ML042930132]

B. Letter dated March 30, 2005 [ML05115055]



For the U.S. Nuclear Regulatory Commission

Date May 17, 2007

By

***Original signed by Penny Lanzisera***

Penny Lanzisera

Medical Branch

Division of Nuclear Materials Safety

Region I

King of Prussia, Pennsylvania 19406

April 24, 2007

HMS61

United States Nuclear Regulatory Commission  
Region 1  
Division of Nuclear Materials Safety  
475 Allendale Road  
King of Prussia, Pennsylvania 19406-1415

To Whom It May Concern:

03033297

This letter is a request for an amendment for License No. 37-30075-01.  
Capital Area R.T. Associates requests that the maximum amount for  
possession of th (b)(7)(F)  
(b)(7)(F)

If you have any questions please feel free to contact me at 717-691-3235.

Sincerely,



Robert W. Luthmann, Ph.D.  
Radiation Safety Officer

RECEIVED  
REGION 1  
2007 APR 26 AM 10:51

140454

NMSS/RGN1 MATERIALS-002

This is to acknowledge the receipt of your letter/application dated

4/24/2007 and to inform you that the initial processing which includes an administrative review has been performed.

☒ Adm. 37-30075-01  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 140454.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.



# OAKWOOD CENTER

Radiation Oncology

Stephen J. Milito, M.D., Medical Director  
Robert W. Luthmann, Ph.D., Physicist  
Linnie P. Cough, Administrative Director

December 6, 2005

Director  
Office of Nuclear Material Safety and Safeguards  
Attn: Ernesto Quinones,  
USNRC, MS T8F3  
United States Nuclear Regulatory Agency  
Washington, D.C.  
20555-0001

Dear Mr. Quinones,

I am writing in regards to the NRC Order EA-05-090, ISSUANCE OF ORDER FOR INCREASED CONTROLS FOR CERTAIN RADIOACTIVE MATERIALS LICENSEES. We are licensed with the NRC as:

License No. 37-30075-01  
Docket No. 030-33297  
Capital Area R.T. Associates  
880 Century Drive  
Mechanicsburg, PA 17050

Compliance for our facility, Oak Wood Center Radiation Oncology, is unnecessary. (b) (7)

(b)(7)(F)

(b)(7)(F)

have any questions, please feel free to contact me at 717-691-3235.

If you

Sincerely,



Robert W. Luthmann, Ph.D.

Physicist

Oak Wood Center Radiation Oncology  
880 Century Drive  
Mechanicsburg, PA 17050

[www.oakwoodradonc.com](http://www.oakwoodradonc.com)

880 Century Drive, Mechanicsburg, PA 17055 • 717/691-3235 • Fax: 717/691-3243  
A PinnacleHealth and Holy Spirit Health Systems Service



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

December 6, 2005

Docket No. 03033297  
Control No. 137821

License No. 37-30075-01

Stephen J. Milito, M.D.  
Medical Director  
Capital Area R.T. Associates  
Oakwood Center Radiation Oncology  
880 Century Drive  
Mechanicsburg, PA 17055

SUBJECT: CAPITAL AREA R.T. ASSOCIATES, LICENSE AMENDMENT, CONTROL NO.  
137821

Dear Dr. Milito:

This refers to your license amendment request. Enclosed with this letter is the amended license naming Dr. Luthmann the Radiation Safety Officer.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material**; then **toolkit index page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

*Original signed by Penny Lanzisera*

Penny Lanzisera  
Senior Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety

Enclosure:  
Amendment No. 11

S. Milito  
Capital Area R.T. Associates

2

cc:  
Robert W. Luthmann, Ph.D., Radiation Safety Officer

S. Milito  
Capital Area R.T. Associates

3

DOCUMENT NAME: G:\Docs\Mailed\Lic Cvr Letter\37-30075-01.137821.12122005.wpd

**SISP Review Complete: PLanzisera**

After declaring this document "An Official Agency Record" it is [REDACTED]

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/enc "E" = Copy w/ attach/enc "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI			
NAME	PLanzisera/PL						
DATE	12/6/2005						

OFFICIAL RECORD COPY

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated October 6, 2005,
1. Capital Area R. T. Associates Oakwood Center Radiation Oncology	3. License number 37-30075-01 is amended in its entirety to read as follows:
2. 880 Century Drive Mechanicsburg, Pennsylvania 17055	4. Expiration date April 30, 2015
	5. Docket No. 030-33297 Reference No.

6. Byproduct, source, and/or special  
nuclear material

A. (b)(7)(F)

B. (b)(7)(F)

## 7. Chemical and/or physical form

A. (b)(7)(F)

B. (b)(7)(F)

8. Maximum amount that licensee may  
possess at any one time under this  
license

A. (b)(7)(F)

B. (b)(7)(F)

## 9. Authorized use:

- A. One source for medical use permitted by 10 CFR 35.600 (b)(7)(F)
- (b)(7)(F) One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
- B. Shielding in a remote afterloader unit.

**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at 880 Century Drive, Mechanicsburg, Pennsylvania.
11. The Radiation Safety Officer for this license is Robert W. Luthmann, Ph.D.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
**37-30075-01**Docket or Reference Number  
**030-33297**

Amendment No. 11

**12. Licensed material is only authorized for use by, or under the supervision of:**

- A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

Authorized UsersMaterial and Use

Stephen J. Milito, M.D.

(b)(7)(F)

- C. The following individuals are authorized medical physicists as indicated:

Authorized Medical PhysicistsMaterial and Use

Donald E. Velkey, Ph.D.

(b)(7)(F)

Robert W. Luthmann, Ph.D.

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

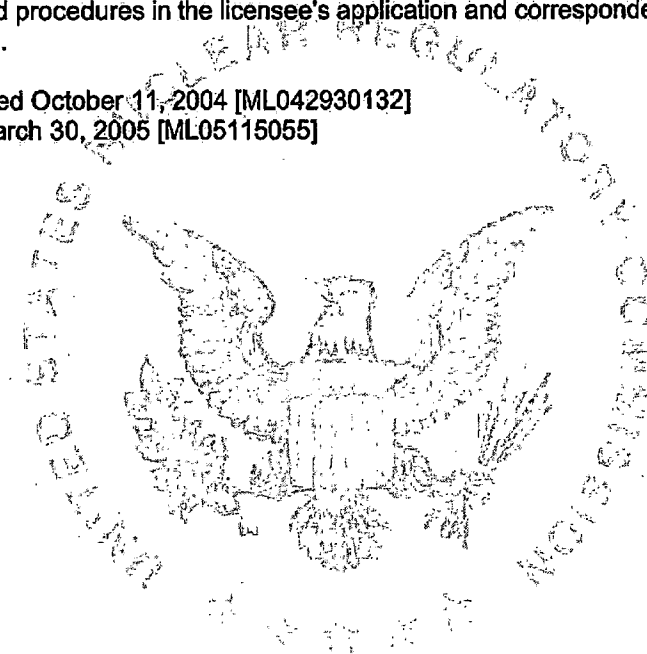
**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
**37-30075-01**Docket or Reference Number  
**030-33297**

Amendment No. 11

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated October 11, 2004 [ML042930132]

B. Letter dated March 30, 2005 [ML05115055]



For the U.S. Nuclear Regulatory Commission

Date December 6, 2005

By

***Original signed by Penny Lanzisera***

Penny Lanzisera  
Medical Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 5, 2005

Docket No. 03033297  
Control No. 137441

License No. 37-30075-01

Steven J. Milito, M.D.  
Medical Director  
Capital Area R.T. Associates  
Oakwood Center Radiation Oncology  
880 Century Drive  
Mechanicsburg, PA 17055

SUBJECT: CAPITAL AREA R.T. ASSOCIATES, LICENSE AMENDMENT, CONTROL NO.  
137441

Dear Dr. Milito:

This refers to your license amendment request dated August 2, 2005. Enclosed with this letter is the amended license adding Robert W. Luthmann, Ph.D. as Authorized Medical Physicist. As requested by Linnie Cough of your staff in a telephone conversation on August 5, 2005, David J. Salinger, M.D. and Robert J. Baker, Ph.D. have been removed from your license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22©(14).

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material**; then **toolkit Index page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

*Original signed by Sandra Gabriel*

Sandra Gabriel  
Senior Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety

Enclosure: Amendment No. 10



S. Milito  
Capital Area R.T. Associates

2



DOCUMENT NAME: E:\Filenet\ML052230132.wpd

**SISP Review Complete: (Reviewer's Initials) slg2**

After declaring this document "An Official Agency" [redacted]

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input type="checkbox"/> N	DNMS/RI	<input type="checkbox"/> DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>
NAME	SGabriel/SLG					
DATE	8/5/05					

OFFICIAL RECORD COPY

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated August 2, 2005,
1. Capital Area R. T. Associates Oakwood Center Radiation Oncology	3. License number 37-30075-01 is amended in its entirety to read as follows:
2. 880 Century Drive Mechanicsburg, Pennsylvania 17055	4. Expiration date April 30, 2015
	5. Docket No. 030-33297 Reference No.

6. Byproduct, source, and/or special  
nuclear materialA. (b)(7)(F)  
B. (b)(7)(F)  

7. Chemical and/or physical form

A. (b)(7)(F)  
B. (b)(7)(F)  
8. Maximum amount that licensee may  
possess at any one time under this  
licenseA. (b)(7)(F)  
B. (b)(7)(F)  

9. Authorized use:

- A. One source for medical use permitted by 10 CFR 35.600 (b)(7)(F)  
(b)(7)(F) (b)(7)(F)  
(b)(7)(F). One source in its shipping container as necessary for replacement of the source in the  
remote afterloader unit.
- B. Shielding in a remote afterloader unit.

**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at 880 Century Drive,  
Mechanicsburg, Pennsylvania.
11. The Radiation Safety Officer for this license is Stephen J. Milito, M.D.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
**37-30075-01**Docket or Reference Number  
**030-33297**

Amendment No. 10

12. Licensed material is only authorized for use by, or under the supervision of:

- A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

Authorized UsersMaterial and Use

Stephen J. Milito, M.D.

(b)(7)(F)

- C. The following individuals are authorized medical physicists as indicated:

Authorized Medical PhysicistsMaterial and Use

David E. Cunningham, Ph.D.

(b)(7)(F)

Donald E. Velkley, Ph.D.

Robert W. Luthmann, Ph.D.

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
**37-30075-01**Docket or Reference Number  
**030-33297**

Amendment No. 10

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated October 11, 2004 [ML042930132]  
B. Letter dated March 30, 2005 [ML05115055]

For the U.S. Nuclear Regulatory Commission

Date August 5, 2005

By

*Original signed by Sandra Gabriel*

.....  
Sandra Gabriel  
Medical Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

July 14, 2005

Docket No. 03033297  
Control No. 137172

License No. 37-30075-01

Stephen J. Milito, M.D.  
Medical Director  
Capital Area R.T. Associates  
Oakwood Center Radiation Oncology  
880 Century Drive  
Mechanicsburg, PA 17055

SUBJECT: CAPITAL AREA R.T. ASSOCIATES, CORRECTED COPY OF LICENSE,  
CONTROL NO. 137172

Dear Dr. Milito:

Enclosed is the Corrected Copy of Amendment No. 9 for License No. 37-30075-01. As discussed with Linnie Cough of your staff on July 13, 2005, NRC administrative review identified minor typographical errors in Condition Nos. 3 and 12C of your license. These conditions have been updated to correct the errors.

We apologize for any inconvenience these errors may have caused.

Sincerely,

*Original signed by Pamela J. Henderson*

Pamela J. Henderson, Chief  
Medical Branch  
Division of Nuclear Materials Safety

Enclosure:  
Corrected Copy of Amendment No. 9

S. Milito  
Capital Area R.T. Associates

2

[REDACTED]  
DOCUMENT NAME: E:\Filenet\ML051990499.wpd

**SISP Review Complete: (PJH)**

After declaring this document "An Official Agency Record" it [REDACTED]

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/enc. "E" = Copy w/ attach/enc. "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI		
NAME	SGabriel/SLG		PHenderson/PJH				
DATE	7/14/05		7/14/05				

OFFICIAL RECORD COPY



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
**37-30075-01**Docket or Reference Number  
**030-33297**

Amendment No. 9

**CORRECTED COPY****12. Licensed material is only authorized for use by, or under the supervision of:**

- A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

Authorized UsersMaterial and Use

David J. Salinger, M.D.

(b)(7)(F)

Stephen J. Milito, M.D.

- C. The following individuals are authorized medical physicists as indicated:

Authorized Medical PhysicistsMaterial and Use

David E. Cunningham, Ph.D.

(b)(7)(F)

Donald E. Velkley, Ph.D.

Robert J. Baker, Ph.D.

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET****CORRECTED COPY**License Number  
**37-30075-01**Docket or Reference Number  
**030-33297**

Amendment No. 9

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated October 11, 2004 [ML042930132]  
B. Letter dated March 30, 2005 [ML05115055]

For the U.S. Nuclear Regulatory Commission

Date July 14, 2005

By

*Original signed by Sandra Gabriel*

Sandra Gabriel  
Medical Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

July 12, 2005

Docket No. 03033297  
Control No. 137172

License No. 37-30075-01

Stephen J. Millito, M.D.  
Medical Director  
Capital Area R.T. Associates  
Oakwood Center Radiation Oncology  
880 Century Drive  
Mechanicsburg, PA 17055

SUBJECT: CAPITAL AREA R.T. ASSOCIATES, LICENSE AMENDMENT, CONTROL NO.  
137172

Dear Dr. Millito:

This refers to your license amendment request. Enclosed with this letter is the amended license adding Robert J. Baker, Ph.D. as Authorized Medical Physicist for your high dose rate remote afterloader unit. As discussed with Linnie Cough of your staff on July 11, 2005, Dr. Baker will receive device-specific training from Varian before participating in any clinical treatments.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22©(14).

Current NRC regulations and guidance are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/who-we-are/governing-laws.html> or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

*Original signed by Sandra Gabriel*

Sandra Gabriel  
Senior Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety

S. Millito  
Capital Area R.T. Associates

2

Enclosure:  
Amendment No. 9

S. Milito  
Capital Area R.T. Associates

3

DOCUMENT NAME: E:\Filenet\ML051930284.wpd

SISP Review Complete: (SLG2)

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/enc. "E" = Copy w/ attach/enc. "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI		
NAME	SGabriel /SLG2/						
DATE	7/12/05						

OFFICIAL RECORD COPY

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Capital Area R. T. Associates Oakwood Center Radiation Oncology</p> <p>2. 880 Century Drive Mechanicsburg, Pennsylvania 17055</p>	<p>In application with the letter dated June 3, 2005,</p> <p>3. License number 37-30075-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date April 30, 2015</p> <p>5. Docket No. 030-33297 Reference No.</p>
---	---

6. Byproduct, source, and/or special nuclear material

A. (b)(7)(F)

B. (b)(7)(F)

7. Chemical and/or physical form

A. (b)(7)(F)

B. (b)(7)(F)

8. Maximum amount that licensee may possess at any one time under this license

A. (b)(7)(F)

B. (b)(7)(F)

9. Authorized use:

- A. One source for medical use permitted by 10 CFR 35.600. (b)(7)(F)  
(b)(7)(F) (b)(7)(F)  
(b)(7)(F) One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
- B. Shielding in a remote afterloader unit.

**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at 880 Century Drive, Mechanicsburg, Pennsylvania.
11. The Radiation Safety Officer for this license is Stephen J. Milito, M.D.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
37-30075-01Docket or Reference Number  
030-33297

Amendment No. 9

## 12. Licensed material is only authorized for use by, or under the supervision of:

- A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

Authorized Users

David J. Salinger, M.D.

Stephen J. Milito, M.D.

Material and Use

(b)(7)(F)

- C. The following individuals are authorized medical physicists as indicated:

Authorized Medical Physicists

David E. Cunningham, Ph.D.

Donald E. Velkley, Ph.D.

Robert J. Baker, Ph.D.

Material and Use

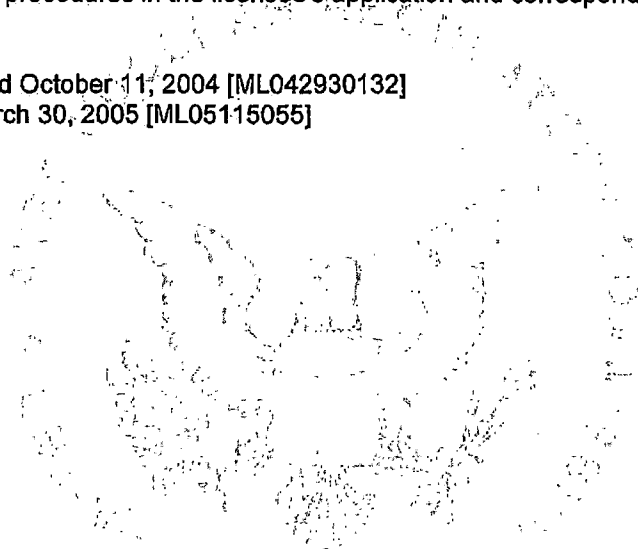
(b)(7)(F)

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
**37-30075-01**Docket or Reference Number  
**030-33297**Amendment No. **9**

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated October 11, 2004 [ML042930132]  
B. Letter dated March 30, 2005 [ML05115055]



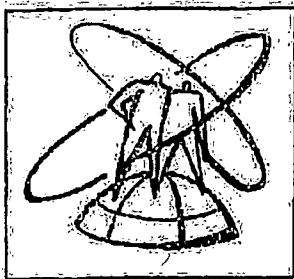
For the U.S. Nuclear Regulatory Commission

Date July 12, 2005

By

*Original signed by Sandra Gabriel*

Sandra Gabriel  
Medical Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

**OAKWOOD CENTER**

Radiation Oncology

880 Century Drive  
Mechanicsburg, PA 17055  
Phone: 1-717-691-3235  
Fax: 1-717-691-3243

WEBSITE: [www.oakwoodradonc.com](http://www.oakwoodradonc.com)E-mail: [smilito@oakwoodradonc.com](mailto:smilito@oakwoodradonc.com)[cough@oakwoodradonc.com](mailto:cough@oakwoodradonc.com)[dcunningham@oakwoodradonc.com](mailto:dcunningham@oakwoodradonc.com)**Stephen J. Milito, M.D., Medical Director**

Linnie P. Cough, Administrative Director

Jean M. Werner, Front Office Manager

David E. Cunningham, Ph.D. Director of Physics

**FAX**

M116

K-8.

37-30075-01

03033297

To: Sandy Galbreath From: Linnie Cough  
Fax: 110-337-5269 Date: 7/11/05  
Phone: \_\_\_\_\_ Page: \_\_\_\_\_  
Re: \_\_\_\_\_ CC: \_\_\_\_\_

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

•Comments:

Mail Control # 137172137172**NMSS/RGNI MATERIALS-002**

[REDACTED]



27/08/2005 08:19 661-259-1231  
State of California Health and Human Services Agency

SANTA CLARITA

PAGE 02

Department of Health Services

Page 1 of 5 pages

## RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee: Western Tumor Medical Group, Inc.	2. License Number: 2356-19	Amendment Number: 49
2. Address: 5522 Sepulveda Boulevard Van Nuys, CA 91411	4. Expiration date: May 22, 2011	(3)
Attention: Robert J. Baker, Ph.D. Radiation Safety Officer	5. Inspection agency: Los Angeles County Department of Health Services	

License Number 2356-19 is hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A. Group 6 as specified in Item 9.	A.	A.
1. (b)(7)(F)	1. (b)(7)(F)	1. (b)(7)(F)
2. (b)(7)(F)	2. (b)(7)(F)	2. (b)(7)(F)
3. (b)(7)(F)	3. (b)(7)(F)	3. (b)(7)(F)
B. Group 9 as specified in Item 9.	B.	B.
1. (b)(7)(F)	1. (b)(7)(F)	1. (b)(7)(F)
2. (b)(7)(F)	2. (b)(7)(F)	2. (b)(7)(F)

07/08/2005 08:19 551-259-1031

SANTA CLARITA

PAGE 03

State of California Health and Human Services Agency

Department of Health Services

Page 2 of 5 pages

## RADIOACTIVE MATERIAL LICENSE

License Number: 2356-19

Amendment Number: 49

9. Authorized Use

- A. Group 6 Brachytherapy and Ophthalmic treatments utilizing sealed or solid sources manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Title 10, Code of Federal Regulations, Part 32.74, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent state regulations (except for sources manufactured prior to August 16, 1974).

1. Applicator
2. To be used in a Nucletron Model MicroSelectron-HDR Classic Afterloader for brachytherapy treatments (10 Ci maximum source installed in device).
3. To be used in a Nucletron Corporation Model 105.999 HDR Afterloader for brachytherapy treatments (12 Ci maximum source installed in device).

- B. Group 9 1. Marker and calibration sources.

2. Storage only.

LICENSE CONDITIONS

10. Radioactive material shall be used only at the following locations:

(a) 5522 Sepulveda Boulevard, Van Nuys, CA.

(b)(7)(F)

(b) 23023 Sherman Way, West Hills, CA.

(b)(7)(F)

(c) 25751 McBean Parkway, Valencia, CA.

(b)(7)(F)

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.

12. (a) The individuals named below are authorized the specific uses of radioactive material described in Items 6, 7, 8, and 9 of this license as follows:

- |                                 |                |
|---------------------------------|----------------|
| (1) Bernard S. Lewinsky, M.D.   | Groups 6 and 9 |
| (2) Robert Paul Zimmerman, M.D. | Groups 6 and 9 |
| (3) William J. Robertello, M.D. | Groups 6 and 9 |
| (4) Gary A. Hafer, M.D.         | Groups 6 and 9 |

- (b) Radioactive material may be used by the following individuals for physical measurements only:

- (1) David R. Metcalf, Ph.D.
- (2) Randy Kaplan-James, M.S., DABR
- (3) Robert J. Baker, Ph.D.

07/08/2005 08:19 551-255-1031

SANTA CLARITA

PAGE 84

State of California Health and Human Services Agency

Department of Health Services

Page 3 of 5 pages

**RADIOACTIVE MATERIAL LICENSE**License Number: 2356-19Amendment Number: 49

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- (a) The letters, both with attachments, dated October 12, 1998, and October 13, 1998; as supplemented by the letter dated October 22, 1998, all signed by David R. Metcalf, Ph.D., Radiation Safety Officer, regarding the addition of a HDR for physical measurements only.
  - (b) The letter dated November 17, 1998, signed by David R. Metcalf, Ph.D., Radiation Safety Officer, regarding a correction for the use location of the HDR Afterloader.
  - (c) The letter, with attachment, dated January 10, 1999, signed by David R. Metcalf, Ph.D., regarding the shielding verification measurements for the HDR treatment room.
  - (d) The letters, both with attachments, dated March 27, 2000, and June 6, 2000, both signed by Randy Kaplan-James, MS, DABR, Medical Physicist, and David R. Metcalf, Ph.D., DABR, Radiation Safety Officer, regarding the addition of an HDR for physical measurements only.
  - (e) The letter, with attachments, dated October 30, 2000, both signed by Randy Kaplan-James, M.S., DABR, Medical Physicist, and David R. Metcalf, Ph.D., DABR, Radiation Safety Officer, regarding the performance of physical measurements for an HDR Afterloader.
  - (f) The license renewal application, with attachments, dated April 20, 1998, signed by David R. Metcalf, Ph.D., Radiation Safety Officer, and Bernard Lewinsky, M.D., President, Chief Executive Officer, and the letters, both with attachments, dated October 8, 2001, and October 31, 2001, both signed by David R. Metcalf, Ph.D., Radiation Safety Officer.
  - (g) The letter, with attachment, dated November 13, 2003, regarding the duties, responsibilities and authority of the Radiation Safety Officer, signed by Bernard Lewinski, President and Robert J. Baker, Ph.D.
14. (a) The Radiation Safety Officer in this program shall be Robert J. Baker, Ph.D.
- (b) The Custodian of sealed sources shall be David R. Metcalf, Ph.D.
- (c) The Alternate Radiation Safety Officer in this program shall be Randy Kaplan-James, Ph.D., DABR.
15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Title 17, California Code of Regulations, Section 30275 (c).
16. In lieu of the leak test intervals required by California Code of Regulations, Title 17, Section 30275 (c), sealed sources can be tested for leakage and/or contamination at longer intervals when they are specified in a certificate of registration issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. When a longer interval stipulated in a certificate of registration is used, the certificate must be maintained on file and available for inspection for as long as the associated leak test records are retained.
17. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Health Services:
- (a) The Radiation Safety Officer
  - (b) Qualified individuals designated in writing by the Radiation Safety Officer

07/08/2005 00:15 661-259-1831

SANTA CLARITA

PAGE 05

State of California-Health and Human Services Agency

Department of Health Services

Page 4 of 5 pages

**RADIOACTIVE MATERIAL LICENSE**License Number: 2356-19Amendment Number: 49

18. The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection.
19. Treatment and management of patients undergoing brachytherapy shall be in accordance with the guidance from any of the following:
  - (a) Chapter 5, "Safety Precautions in Clinical Application", National Council on Radiation Protection and Measurements (NCRP) Report No. 40, "Protection Against Radiation From Brachytherapy Sources" (NCRP Publications, P.O. Box 30175, Washington, D.C. 20014).
  - (b) Appendix N in the "Guide for the Preparation of Applications for Medical Programs", State of California, Department of Health Services, Radiological Health Branch.
  - (c) Documented rationale or patient-specific calculations demonstrating that members of the general public will be limited to 500 mrem total effective dose equivalent from patients who have been released
20. Remote afterloading device facilities shall be so constructed as to permit continuous observation of patients from outside the treatment room(s).
21. Written emergency instructions shall be posted conspicuously at the remote afterloading device control(s). Instructions shall include directions for manually turning off the remote afterloading device(s), removing the patient, securing the room(s) against unauthorized entry, and notifying the responsible authorized user or the Radiation Safety Officer.
22. Electrical interlock(s) on entrance door(s) to the remote afterloading device room(s) shall be tested for proper operation at least once every month or prior to use (if used less frequently). Records of test results shall be maintained available for inspection.
23. If there is a reason to suspect that the source position indicator or entrance door(s) interlock(s) is/are not functioning properly, use of the remote afterloading device(s) shall be discontinued until the condition has been corrected. A record of any such malfunction shall be made and maintained available for inspection.
24. Special Requirements for Remote Afterloading Device Spot Checks and Calibration:
  - (a) At intervals not to exceed daily or prior to use (if used less frequently), the following tests shall be performed:
    - (1) Source position indicator(s).
    - (2) Source positioning reproducibility, to within  $\pm 1$  mm.
    - (3) Inspection of guide tubes for kinks and other imperfections.
  - (b) Timing device accuracy shall be performed at intervals not to exceed monthly or prior to each use (if used less frequently).
  - (c) Source travel time error shall be performed at each source loading.
  - (d) At each source loading and then at intervals not to exceed three months, one month for Ir-192, or prior to use (if used less frequently), the licensee shall determine the dose accuracy to within  $\pm 5$  percent.
25. Remote afterloading devices authorized by this license shall not be operated unless the licensee has in his possession detailed written instructions specific for the make and model of the remote afterloading device.

07/08/2005 08:19 661-259-1231

SANTA CLARITA

PAGE 05

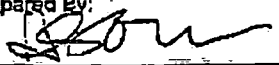


State of California-Health and Human Services Agency

Department of Health Services

Page 5 of 5 pages

**RADIOACTIVE MATERIAL LICENSE**License Number: **2356-19**Amendment Number: **42**

26. Each remote afterloading device shall be inspected and serviced in accordance with the manufacturer's recommendations.
27. For remote afterloading devices, specifically authorized personnel shall:
- (a) Install, relocate, maintain and repair devices containing radioactive material.
  - (b) Leak test, replace and dispose of sealed sources containing radioactive material used in devices.
28. Subsequent to each source loading, radiation surveys shall be performed prior to human use as follows:
- (a) A radiation survey shall be made of the unit source housing, with the source(s) in the shielded position. The maximum radiation levels at 20 centimeters from the surface of the source housing shall not exceed 3 milliroentgens per hour.
  - (b) Records of survey results shall be maintained for inspection.
29. Immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of each survey shall be maintained.
30. Treatment time calculations and data entry for remote afterloaders shall be individually verified by the responsible authorized user physician immediately prior to treatment.
31. At least 30 days prior to vacating any address of use listed in Condition 10 of this license, the licensee shall provide written notification thereof to the Department of Health Services, in accordance with Title 17, California Code of Regulations, Section 30256.
32. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 5522 Sepulveda Boulevard, Van Nuys, CA.

Prepared By: 	Reviewed By: 	Issued For the Department of Health Services By: 
Printed Name: Heidi S. O'Connell	Printed Name: Marcia Yao Smith	Printed Name: Gonzalo L. Perez
Date: March 22, 2004		Radiologic Health Branch MS 7610, P.O. Box 597414 Sacramento, CA 95899-7414



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 6, 2005

Docket No. 03033297  
Control No. 135812

License No. 37-30075-01

Stephen J. Millito, M.D.  
Medical Director & RSO  
Capital Area R.T. Associates  
Oakwood Center Radiation Oncology  
880 Century Drive  
Mechanicsburg, PA 17055

SUBJECT: CAPITAL AREA R.T. ASSOCIATES, ISSUANCE OF LICENSE RENEWAL,  
CONTROL NO. 135812

Dear Dr. Millito:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. Please note that your license was written in a format compatible with the revised 10 CFR Part 35, dated April 24, 2002. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. Please note that the last condition on your license indicates that "This license condition applies only to those procedures that are required to be submitted in accordance with the regulations." Therefore, any procedures submitted that were not required by regulation to be submitted, e.g., full calibration procedures, will not be considered a part of your license and were not reviewed during the licensing process. These procedures will be reviewed during inspections, as necessary.

Please note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify the NRC in writing when:
  - a) an authorized user, authorized medical physicist or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;

- b) the mailing address changes;
  - c) the name on the license changes; or
  - d) permitting an individual to function as a temporary Radiation Safety Officer in accordance with 10 CFR 35.24(c).
3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license
- a) when you decide to terminate all activities involving materials authorized under the license; or
  - b) if you decide not to acquire or possess and use authorized material.
4. Request and obtain a license Amendment before you:
- a) permanently change Radiation Safety Officers;
  - b) receive byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or
  - c) add or change the areas of use, except as allowed by 10 CFR 35.13(e) and with the appropriate notification described in 10 CFR 35.14(b)(4);
  - d) change the name or ownership of your organization;
  - e) change the address(es) of use identified on the license;
  - f) receive, prepare, or use byproduct material for a type of use that is not authorized on the license;
  - g) permit anyone to work as an authorized user or authorized medical physicist, except as allowed by 10 CFR 35.13(b) and with the appropriate notification described in 10 CFR 35.14(a); or
  - h) revise procedures required by 10 CFR 35.610, 35.642, 35.643, or 35.645, as applicable, where such revision reduces radiation safety.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

S. Milito  
Capital Area R.T. Associates

3

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in NUREG 1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

*An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).*

Current NRC regulations and guidance are available at the NRC Web sites listed below or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

***Original signed by Pamela J. Henderson***

Pamela J. Henderson, Chief  
Medical Branch  
Division of Nuclear Materials Safety

Enclosure:  
Amendment No. 8

NRC Web site addresses  
NRC regulations

<http://www.nrc.gov/reading-rm/doc-collections/cfr/>

Licensing guidance

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>

General Policy and Procedure for NRC Enforcement Actions

<http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf>

206 of the Energy Reorganization Act of 1974

<http://www.nrc.gov/who-we-are/governing-laws.html>



S. Milito  
Capital Area R.T. Associates

4

DOCUMENT NAME: G:\Docs\Mailed\Lic Cvr Letter\37-30075-01.135812.04072005.wpd

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/end "E" = Copy w/ attach/end "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	WLee/WJL1		PHenderson/PJH1					
DATE	4/6/2005		4/6/2005					

OFFICIAL RECORD COPY

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Capital Area R. T. Associates Oakwood Center Radiation Oncology</p> <p>2. 880 Century Drive Mechanicsburg, Pennsylvania 17055</p>	<p>In application with the application dated October 11, 2004,</p> <p>3. License number 37-30075-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date April 30, 2015</p> <p>5. Docket No. 030-33297 Reference No.</p>
---	--

<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. (b)(7)(F)</p> <p>B. (b)(7)(F)</p>	<p>7. Chemical and/or physical form</p> <p>A. (b)(7)(F)</p> <p>B. (b)(7)(F)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. (b)(7)(F)</p> <p>B. (b)(7)(F)</p>
--	---	---

9. Authorized use:

A. One source for medical use permitted by 10 CFR 35.600 (b)(7)(F)

(b)(7)(F) (b)(7)(F)

(b)(7)(F) One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

B. Shielding in a remote afterloader unit.

**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at 880 Century Drive, Mechanicsburg, Pennsylvania.
11. The Radiation Safety Officer for this license is Stephen J. Milito, M.D.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
**37-30075-01**Docket or Reference Number  
**030-33297**

Amendment No. 8

12. Licensed material is only authorized for use by, or under the supervision of:

- A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

Authorized UsersMaterial and Use

David J. Salinger, M.D.

(b)(7)(F)

Stephen J. Millito, M.D.

- C. The following individuals are authorized medical physicists as indicated:

Authorized Medical PhysicistsMaterial and Use

David E. Cunningham, Ph.D.

(b)(7)(F)

Donald E. Velkley, Ph.D.

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
**37-30075-01**Docket or Reference Number  
**030-33297**

Amendment No. 8

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated October 11, 2004 [ML042930132]  
B. Letter dated March 30, 2005



For the U.S. Nuclear Regulatory Commission

Date April 6, 2005

By

***Original signed by Pamela J. Henderson***

Pamela J. Henderson, Chief  
Medical Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

MS-16

RECEIVED  
REGION 1

**RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION  
LICENSE RENEWAL APPLICATION**

05 APR -4 A8:41

TO: Willie J. Lee, Health Physicist  
U.S. Nuclear Regulatory Commission  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406  
(610) 337-5090

J-2

RE: License Number 37-30075-01  
Docket Number 03033297

DATE: March 30, 2005

Capitol Area Radiation Therapy (CART) Associates response to the NRC letter of inquiries dated March 22, 2005

**Question 1.**

*"Your renewal application (Item 5.1-Source Description) requests authorization for several different sealed sources, including those manufactured by RTS Technology, Byk Mallinckrodt, CIS-US, Inc., and MDS Nordion. Please note that the Sealed Source and Device Registry currently approves the following sealed sources for your GammaMed HDR unit:*

a) (b)(7)(F)

b) (b)(7)(F)

*Only these sources will be listed on your NRC license. In addition, Item 9.A (Authorized Use) will be changed to (b)(7)(F) (distributed as (b)(7)(F))*

**CART Associates response:** CART Associates requests a renewal for the following sources:

a) (b)(7)(F)

b) (b)(7)(F)

**Question 2.**

(b)(7)(F)

135812  
NMSS/RGNI MATERIALS-002

(b)(7)(F)

**Question 3.**

***"Your renewal application (Item 9.2.1-Independent Monitor) describes the treatment room area radiation monitor and backup battery supply. Confirm that this monitor and backup battery supply will be provided in each of the two treatment vaults. Confirm that HDR remote afterloader use will be suspended if the area monitor fails."***

**CART Associates response:** CART Associates confirms that both treatment rooms have the following area radiation monitor with battery backup supply;  
**Nuclear Associates Primalert 10**

**CART Associates confirms that HDR afterloader use will be suspended if the area monitor fails.**

**Question 4.**

***Your renewal application (Item 9.1.6-Visual and Audio Patient Surveillance) describes the patient viewing and communication systems and the backup closed circuit television (CCTV) monitor. Confirm that primary and backup CCTV's are provided for both treatment rooms. Also describe the backup systems or procedures to be used in case of failure of the two-way audio communication system.***

**CART Associates response:** CART Associates confirms that the primary and backup patient viewing systems (CCTV) are provided for both treatment rooms. CART Associates confirms that in the event of failure of the two-way audio communication system the treatment shall not be initiated and an on-going treatment shall be terminated until the primary system is corrected or the backup system is installed. CART Associates confirms that it will purchase and maintain on site a backup audio system to be used in the event of failure of the primary system in either treatment room.

**Question 5.**

***"Please confirm that the locks, warning signs, and warning lights described in Items 9.1.3, 9.1.7, and 9.1.8 of your renewal application apply to both treatment rooms."***

**CART Associates response:** CART Associates confirms that the locks, warning signs, and warning lights described in Items 9.1.3, 9.1.7, and 9.1.8 of your renewal application apply to both treatment rooms.

**Question 6.**

***Please provide additional information about the interlocks described in Item 9.1.5 of your application. Confirm that these interlock systems (1) are provided for both treatment rooms, (2)***

cause the source to retract if the room door is opened, and (3) prevent initiation of the treatment cycle if the door is not closed.

**CART Associates response:** CART Associates confirms that the door interlock systems are completely independent and are provided for both rooms. Both door interlock systems cause the source to retract if the door is opened. Both door interlock systems prevent initiation of the treatment cycle if the door is not closed.

**Question 7.**

*Your renewal application (Item 10.8-Daily Quality Assurance and Addendum K) describes checks to be performed each day of patient treatment. Please update these procedures to comply with all of the requirements of 10 CFR 35.643, including verification of proper operation of (1) source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility; (2) emergency response equipment; (3) clock (date and time) in the HDR unit's computer; and (4) decayed source activity in the unit's computer. Describe your method for checking proper operation of the area radiation monitor. Describe your method for checking timer accuracy and range of acceptable results.*

**CART Associates response:** CART Associates updated the HDR treatment procedures to include proper operation of (1) source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility; (2) emergency response equipment; (3) clock (date and time) in the HDR unit's computer, and (4) decayed source activity in the console computer. Documentation for the completion of the procedures is included on the Patient Treatment Quality Assurance form. This form is appended to this response.

The following method is used for checking proper operation of the area radiation monitor. Nuclear Associates PrimaAlert 10.

- a.) Disconnect the detector from the primary power source.
- b.) Place a 10 microCurie Cesium 137 source on the face of the unit.  
Proper operation is indicated by a flashing red light.

The following method is used for checking proper operation of the console timer. The treatment delivery unit is connected to an optical source viewing system and positioned in a manner to permit visualization with a remote CCTV (see attached photographs). The delivery console unit is programmed to position the source at an appropriate dwell position for a preset time. The observer initiates a digital timer when the source reaches the dwell position and terminates the timer when the source leaves the position. The digital measuring device has an accuracy of .01 sec. However the technique accuracy is limited by the response time of the observer, which is known to be less than 0.5 seconds.

The technique is used for a minimum of two times on every treatment day. The times are selected to be less than and greater than the actual clinical treatment time. The accuracy of this technique of timer accuracy determination is less than 0.5 seconds. The measurement for a setting of 100 seconds must be between 99.5 and 100.5 seconds.

**Question 8.**

*Confirm that you will post at the HDR unit console the emergency procedures submitted as Item 10.13 of your renewal application. Please update these procedures to add the following: (1) include conditions for performing a patient survey; (2) describe wording on the sign used to prohibit admittance by unauthorized personnel, such as "No Entry"; (3) include the names and telephone numbers of the authorized users, authorized medical physicists, and RSO to be contacted if the unit or console operates abnormally; (4) address maintenance and calibration prior to resuming HDR use.*

CART Associates confirms that they will post at the treatment console the emergency procedures attached to this response. These procedures have been updated to include the following: (1) conditions for performing a patient survey; (2) prohibition of admittance by unauthorized personnel; (3) names and telephone numbers of the authorized users, authorized medical physicists, and RSO to be contacted if the unit or console operates abnormally; (4) maintenance and calibration requirements prior to resumption of HDR operation. A copy of the revised Emergency Procedures is attached.

**Question 9.**

*Please confirm that you reserve the right to upgrade your survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.*

CART Associates reserves the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

**Question 10.**

*Please confirm that you will provide dosimetry that meets the requirements listed under ACriteria@ in NUREG 1556, Vol. 9 A Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licenses,@ dated October 2002.*

CART Associates confirms that we will provide dosimetry that meets the requirements listed under ACriteria@ in NUREG 1556, Vol. 9 A Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licenses,@ dated October 2002.

**Question 11.**

*Please confirm that you have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501.*

CART Associated confirms that we have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501.

**Question 12.**

*Please confirm that you have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20.*



CART Associates confirms that we have developed and will maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20.

A handwritten signature in black ink, appearing to read "Stephen J. Milto", is written over the printed name and address.

Stephen J. Milto, M.D.  
Capitol Area R. T. Associates  
Oakwood Center Radiation Oncology  
880 Century Drive  
Mechanicsburg, PA 17055

# **OAKWOOD CENTER RADIATION ONCOLOGY**

## **HDR EMERGENCY INTERVENTION PROCEDURES**

### **GammaMed 12i AFTERLOADER**

Hierarchy of Interrupt Actions in case Emergency Retract is necessary. Each step assumes the failure of the previous step(s).

1. Press the Interrupt Button on the Console Unit.
2. Press the Emergency Button on the Console Unit.
3. Open the Treatment Room Door to allow Console Unit to Indicate "Door Open."
4. Enter the Treatment Room with survey meter and press Emergency Button on HDR Unit. Only the authorized emergency trained personnel listed below may enter the room.
5. Turn the Emergency Hand Crank in the direction of the arrow.
6. If radiation survey shows source is still in patient remove the applicator from the patient and insert the applicator containing the stuck or broken source into the Emergency Container. DO NOT cut the cable or guide tube, or disconnect guide tube from applicator or HDR unit.
7. Remove patient from treatment and re-survey patient. Seal Treatment Room door with radioactivity warning label and a sign stating the following: "DANGER ADMITTANCE PROHIBITED." Notify the RSO, Physician and VARIAN MEDCAL SYSTEMS.
8. Subsequent to corrective measures or repairs, do not initiate treatments until the licensed medical radiation physicist has completed an evaluation and calibration of the treatment unit and the RSO has approved the unit for use.

**VARIAN EMERGENCY TELEPHONE: 1.800.864.1672**

**Authorized User: Stephen J. Milito, M.D.**

(W) 717.691.3235 (H) (b)(6) (Cellular) (b)(6)

**Radiation Safety Officer: Stephen J. Milito, M.D.**

(W) 717.691.3235 (H) (b)(6) (Cellular) (b)(6)

**Radiation Physicist: David E. Cunningham, Ph.D.**

(W) 717.691.3235 (H) (b)(6) (Cellular) (b)(6)

**Radiation Physicist: Donald E. Velkley, Ph.D.**

(W) 717.691.3235 (H) (b)(6) (Cellular) (b)(6)

**PERSONAL INFORMATION WAS REMOVED  
BY NRC. NO COPY OF THIS INFORMATION  
WAS RETAINED BY THE NRC.**

## HDR PHYSICS CONSULT

Patient: \_\_\_\_\_ ID No.: \_\_\_\_\_

Unit: \_\_\_\_\_ Serial No.: \_\_\_\_\_

Source: \_\_\_\_\_ Model No.: \_\_\_\_\_ Serial No.: \_\_\_\_\_

Survey meter: \_\_\_\_\_ Serial No.: \_\_\_\_\_ Cali. Date: \_\_\_\_\_

The following checks must be performed each day the unit is used for patient treatment.

1. Source position accuracy: \_\_\_\_\_ Criterion \_\_\_\_\_ mm

Channel	1	2	3	4	5
Deviation (mm)					

	Satisfactory	Unsatisfactory
1. Door Interlock:	<input type="checkbox"/>	<input type="checkbox"/>
2. Catheter Disconnect Interlock:	<input type="checkbox"/>	<input type="checkbox"/>
3. Source Exposure Indicator Lights-Console	<input type="checkbox"/>	<input type="checkbox"/>
4. Source Exposure Indicator Lights-HDR Unit	<input type="checkbox"/>	<input type="checkbox"/>
5. Source Exposure Indicator Lights-Facility	<input type="checkbox"/>	<input type="checkbox"/>
6. Source Retraction:	<input type="checkbox"/>	<input type="checkbox"/>
7. Audio and Visual Equipment:	<input type="checkbox"/>	<input type="checkbox"/>
8. Radiation Wall Monitor (with check source):	<input type="checkbox"/>	<input type="checkbox"/>
9. Timer Accuracy:	<input type="checkbox"/>	<input type="checkbox"/>
10. Radiation survey meter operation:	<input type="checkbox"/>	<input type="checkbox"/>
11. Emergency Response Equipment:	<input type="checkbox"/>	<input type="checkbox"/>
12. Console Computer Date and Time:	<input type="checkbox"/>	<input type="checkbox"/>
13. Radiation survey meter operation:	<input type="checkbox"/>	<input type="checkbox"/>
14. Meter Reading of patients Tx. Area	<input type="checkbox"/>	<input type="checkbox"/>
Before treatment:	_____	_____
After treatment:	_____	_____

### DOSIMETRY:

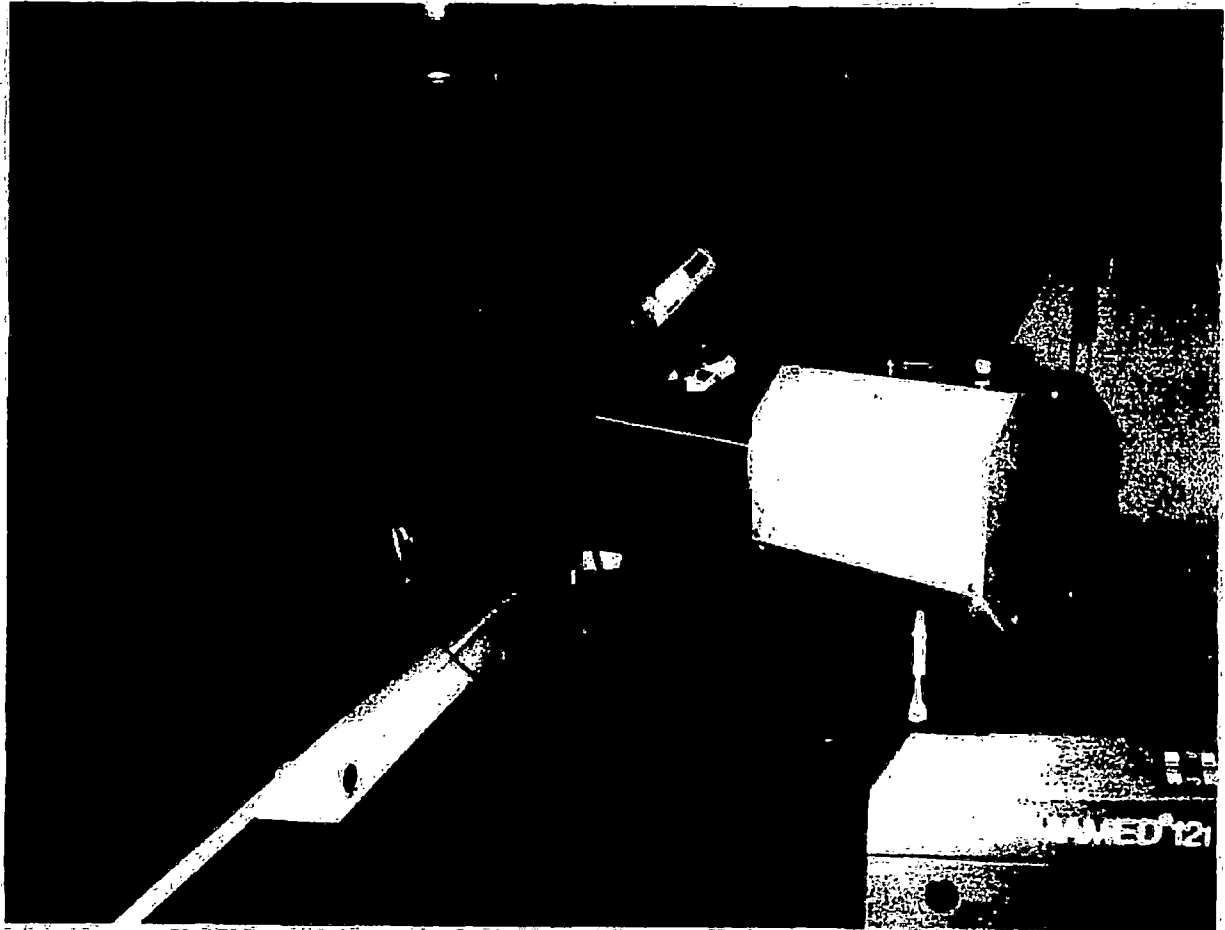
Source installed on: \_\_\_\_\_ Activity  $A^0$  = \_\_\_\_\_ Ci

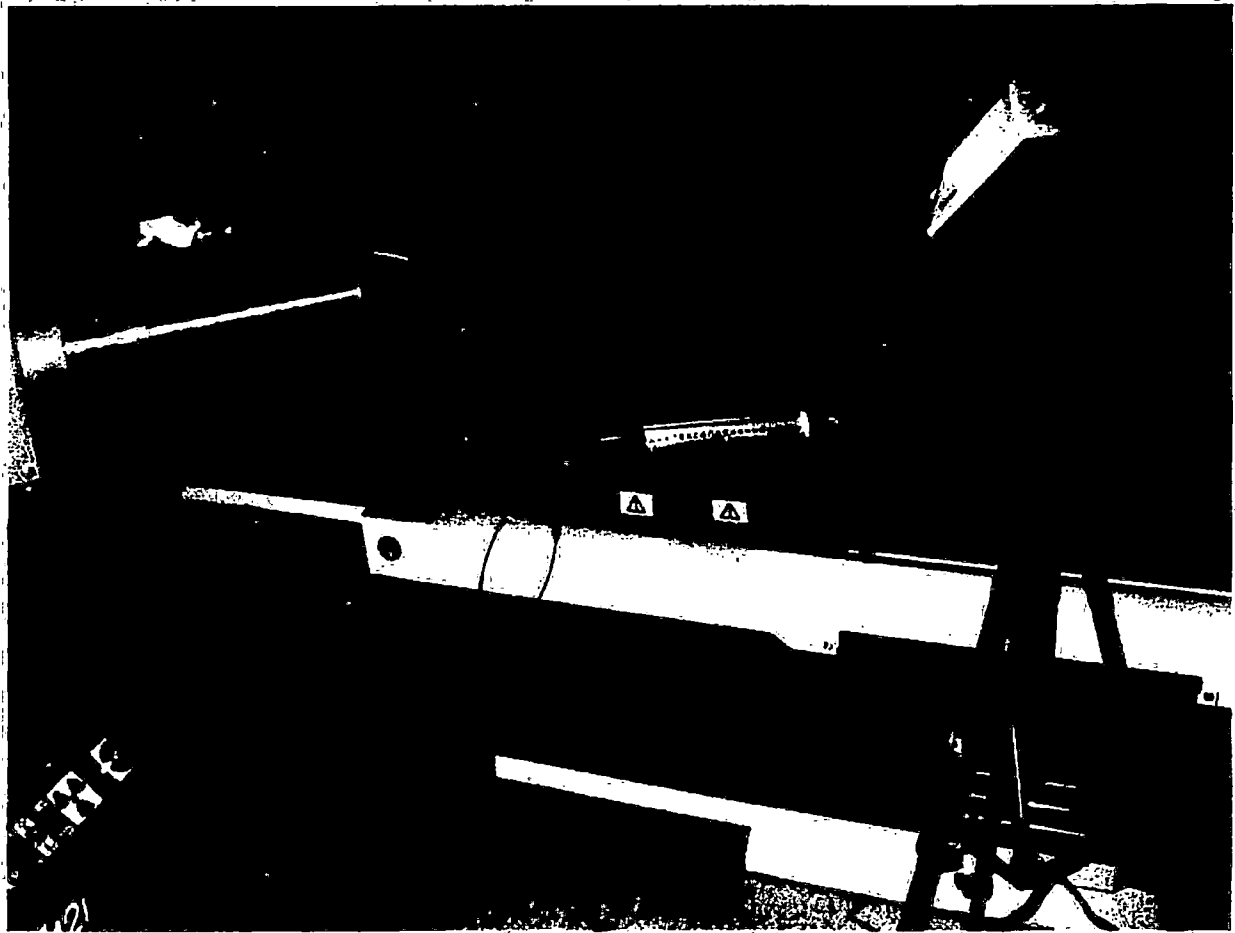
Calibration date: \_\_\_\_\_ Measured Activity: \_\_\_\_\_ Ci

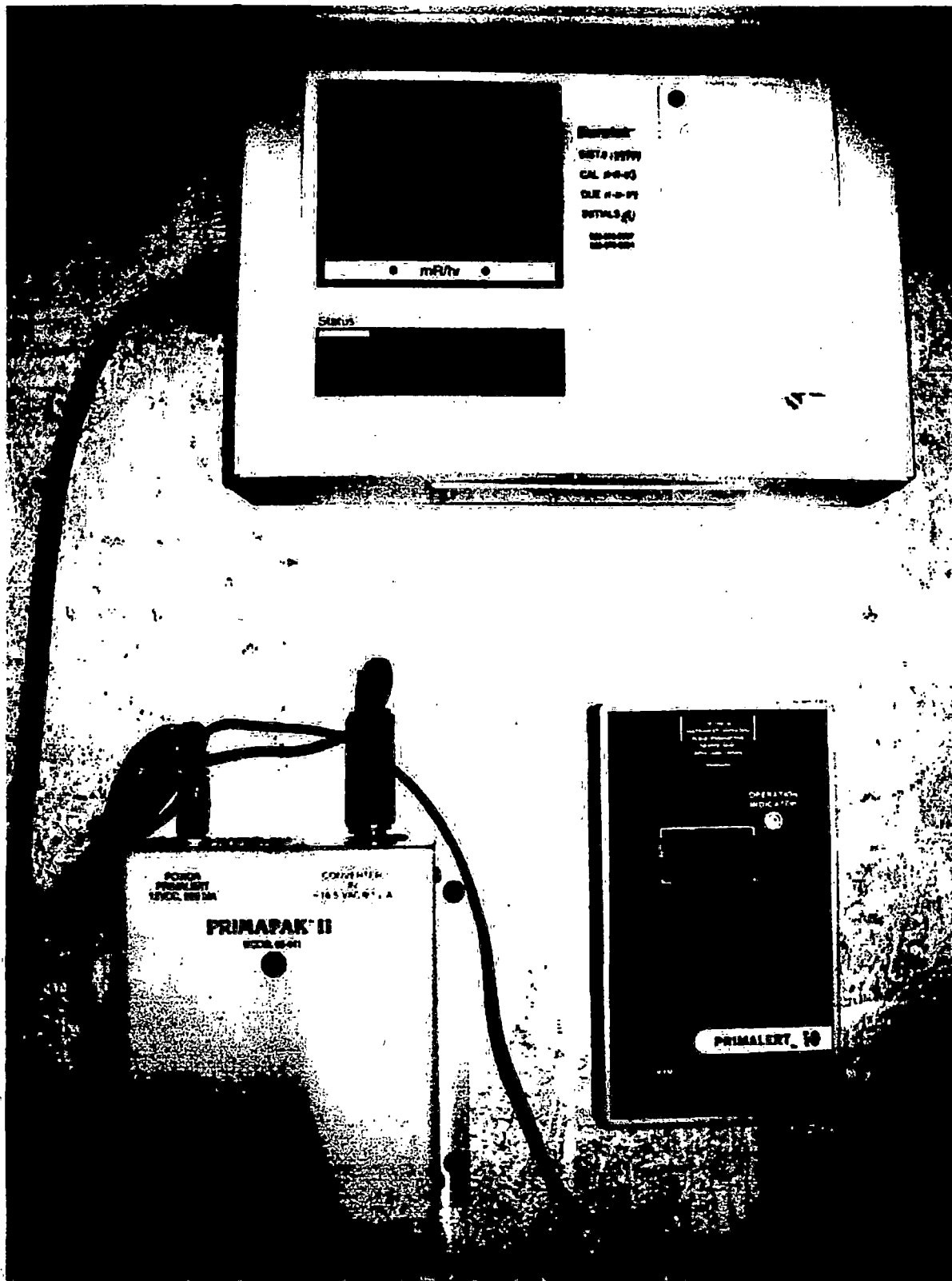
Decayed Activity on Treatment Date: \_\_\_\_\_

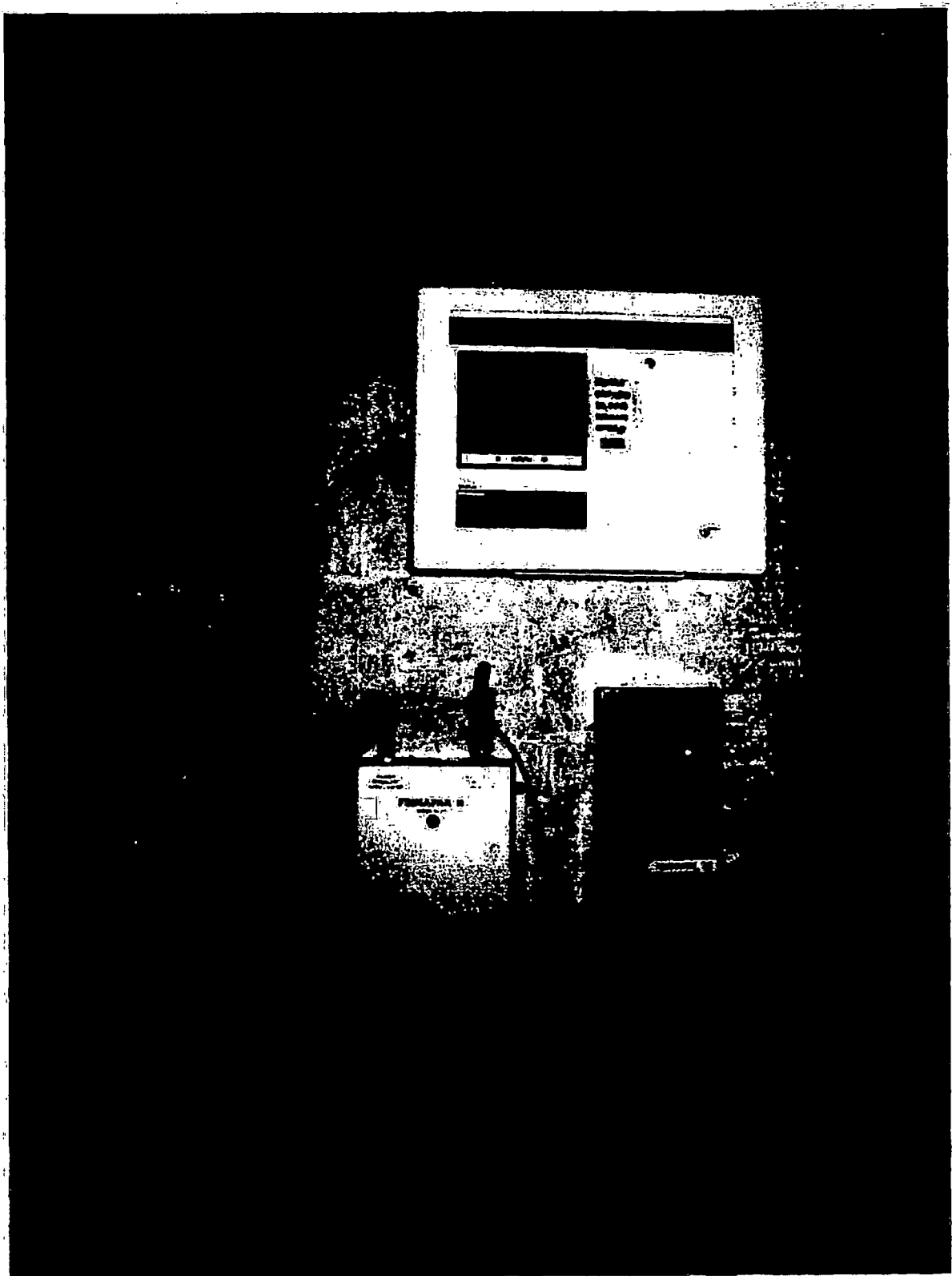
Calculated Decay Factor: \_\_\_\_\_ HDR Console Decay Factor: \_\_\_\_\_

Physicist: \_\_\_\_\_ Date: \_\_\_\_\_









**REQUEST FOR ADDITIONAL INFORMATION  
LICENSE RENEWAL APPLICATION**

TO: Stephen J. Millito, M.D.  
Capitol Area R. T. Associates  
Oakwood Center Radiation Oncology  
880 Century Drive  
Mechanicsburg, PA 17055

RE: License Number 37-30075-01  
Docket Number 03033297  
Mail Control Number 135812

DATE: March 22, 2005

Please respond to the following items:

1. Your renewal application (Item 5.1-Source Description) requests authorization for several different sealed sources, including those manufactured by RTS Technology, Byk Mallinckrodt, CIS-US, Inc., and MDS Nordion. Please note that the Sealed Source and Device Registry currently approves the following sealed sources for your GammaMed HDR unit:

a) (b)(7)(F)

b) (b)(7)(F)

Only these sources will be listed on your NRC license. In addition, Item 9.A (Authorized Use) will be changed to (b)(7)(F) distributed as (b)(7)(F)

2. (b)(7)(F)

3. Your renewal application (Item 9.2.1-Independent Monitor) describes the treatment room area radiation monitor and backup battery supply. Confirm that this monitor and backup battery supply will be provided in each of the two treatment vaults. Confirm that HDR remote afterloader use will be suspended if the area monitor fails.



4. Your renewal application (Item 9.1.6-Visual and Audio Patient Surveillance) describes the patient viewing and communication systems and the backup closed circuit television (CCTV) monitor. Confirm that primary and backup CCTV's are provided for both treatment rooms. Also describe the backup systems or procedures to be used in case of failure of the two-way audio communication system.
5. Please confirm that the locks, warning signs, and warning lights described in Items 9.1.3, 9.1.7, and 9.1.8 of your renewal application apply to both treatment rooms.
6. Please provide additional information about the interlocks described in Item 9.1.5 of your application. Confirm that these interlock systems (1) are provided for both treatment rooms, (2) cause the source to retract if the room door is opened, and (3) prevent initiation of the treatment cycle if the door is not closed.
7. Your renewal application (Item 10.8-Daily Quality Assurance and Addendum K) describes checks to be performed each day of patient treatment. Please update these procedures to comply with all of the requirements of 10 CFR 35.643, including verification of proper operation of (1) source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility; (2) emergency response equipment; (3) clock (date and time) in the HDR unit's computer; and (4) decayed source activity in the unit's computer. Describe your method for checking proper operation of the area radiation monitor. Describe your method for checking timer accuracy and range of acceptable results.
8. Confirm that you will post at the HDR unit console the emergency procedures submitted as Item 10.13 of your renewal application. Please update these procedures to add the following: (1) include conditions for performing a patient survey; (2) describe wording on the sign used to prohibit admittance by unauthorized personnel, such as "No Entry"; (3) include the names and telephone numbers of the authorized users, authorized medical physicists, and RSO to be contacted if the unit or console operates abnormally; (4) address maintenance and calibration prior to resuming HDR use.
9. Please confirm that you reserve the right to upgrade your survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.
10. Please confirm that you will provide dosimetry that meets the requirements listed under "Criteria" in NUREG 1556, Vol. 9 "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licenses," dated October 2002.
11. Please confirm that you have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501.
12. Please confirm that you have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20.

*Please note that procedures submitted for ALARA Program, HDR Source Exchange Quality Assurance, Source Inventory, Quality Management of Brachytherapy Procedures, and Source Calibration were not required for license renewal and were not reviewed. These items will be addressed during the next inspection, as required.*

Willie J. Lee, Health Physicist  
U.S. Nuclear Regulatory Commission  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406  
(610) 337-5090

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  
Capital Area R. T. Associates  
Oakwood Center Radiation Oncology  
880 Century Dr. Mechanicsburg, PA 17055

2. NRC/REGIONAL OFFICE:  
U.S. Nuclear Regulatory Commission  
Region I, 475 Allendale Road  
King of Prussia, Pennsylvania 19406-1415

**REPORT**

3. DOCKET NUMBER(S)  
03033297

4. LICENSEE NUMBER(S)  
37-30075-01

5. DATE(S) OF INSPECTION  
3/10/2005

**LICENSEE:**

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

\_\_\_\_\_ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

- ☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

**Licensee's Statement of Corrective Actions for Item 4, above.**

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Penny Lanzisera	/RA/	3/10/2005

Docket File Information

**SAFETY INSPECTION REPORT  
AND COMPLIANCE INSPECTION**

1. LICENSEE  <b>Capital Area R.T. Associates Mechanicsburg, PA 17055</b>	2. NRC/REGIONAL OFFICE  <b>U.S. Nuclear Regulatory Commission Region I, 475 Allendale Road King of Prussia, Pennsylvania 19406-1415</b>
REPORT NOS      2005-001	

3. DOCKET NUMBER(S) 03033297	4. LICENSE NUMBER(S) 37-30075-01	5. DATE(S) OF INSPECTION 3-10-05
6. INSPECTION PROCEDURES USED 87132	7. INSPECTION FOCUS AREAS 02.01-02.08	8. INSPECTOR Lanzisera/Xu

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S) 2230	2. PRIORITY 2	3. LICENSEE CONTACT 37-30075-01	4. TELEPHONE NUMBER 717-691-3235
----------------------------	------------------	------------------------------------	-------------------------------------

☒ Main Office Inspection      Next Inspection Date: 3/07

☐ Field Office \_\_\_\_\_

☐ Temporary Job Site \_\_\_\_\_

**PROGRAM SCOPE**

This was a routine, unannounced inspection of the licensee. This is a freestanding clinic performing cancer treatments using a high dose-rate remote afterloader. The licensee treats approximately 25 patients per year for breast and gynecological cancers. For treatments using the mammosite device, the licensee uses ultrasound prior to each fractionated treatment to verify proper inflation of the balloon. Two authorized medical physicists and one authorized user are primarily involved in the treatments. The source is replaced approximately every four months, with the most recent source received January 2005. Dose rates around the new area of use were measured, and no concerns were noted. In addition, the inspectors verified that treatments were conducted with sources of less than 10 curies of activity.

The subjects in TI 2800-032 were reviewed during the inspection, and no concerns were identified.

U.S. NUCLEAR REGULATORY COMMISSION		Conversation Date: 06/27/05	
TELEPHONE CONVERSATION RECORD		Time: 3:30 p.m.	
Mail Control No.: 137172	License No.: 37-30075-01	Docket No.: 03033297	
Licensee/Applicant Participant(s): Linnie Cough, Administrator Robert J. Baker, Ph.D., Physicist	Organization: Capital Area R.T. Associates	Telephone No.: 717-691-3235	
Person(s) Calling: SGabriel, RI			
Subject: Amendment request			
<p>Summary:</p> <p>NRC received the fax of the front page of a California radioactive materials license listing Dr. Baker as RSO and listing HDR as an authorized use. This license does not, however, show Dr. Baker as AMP for HDR. I asked Dr. Baker to provide either a copy of a license listing him as AMP for HDR within the past 7 years or a statement signed by another authorized individual, documenting Dr. Baker's recent HDR experience.</p> <p>Dr. Baker's first day of work is today. I asked Linnie whether any patients are scheduled for HDR treatments and how urgent the need is to add Dr. Baker to the license. She said she does not anticipate any HDR treatments until August.</p>			
Action Required/Taken: Await response from licensee			
Prepared By: SGabriel		Date: 7/1/05	

Initial	Announced	<input checked="" type="checkbox"/> Unannounced	<input checked="" type="checkbox"/> Routine	Special
---------	-----------	---	---	---------

**NRC FORM 591M PART 3**  
(10-2003) 10 CFR 2.201

**U.S. NUCLEAR REGULATORY COMMISSION**

*Docket File Information*  
**SAFETY INSPECTION REPORT  
AND COMPLIANCE INSPECTION**

<b>1. LICENSEE</b> <b>Capital Area R. T. Associates</b> <b>880 Century Drive</b> <b>Mechanicsburg, PA</b>	<b>2. NRC/REGIONAL OFFICE</b> <b>U.S. Nuclear Regulatory Commission</b> <b>Region I, 475 Allendale Road</b> <b>King of Prussia, Pennsylvania 19406-1415</b>
--	--

**REPORT NOS**      2007-001

<b>3. DOCKET NUMBER(S)</b> 03033297	<b>4. LICENSE NUMBER(S)</b> 37-30075-01	<b>5. DATE(S) OF INSPECTION</b> March 21, 2007
<b>6. INSPECTION PROCEDURES USED</b> 87132	<b>7. INSPECTION FOCUS AREAS</b> All	<b>8. INSPECTOR</b> R. McKinley

**SUPPLEMENTAL INSPECTION INFORMATION**

<b>1. PROGRAM CODE(S)</b> 2230	<b>2. PRIORITY</b> 2	<b>3. LICENSEE CONTACT</b> Stephen Milito, M.D.	<b>4. TELEPHONE NUMBER</b> (717)691-3235
-----------------------------------	-------------------------	--	---

☒ Main Office Inspection  
☐ Field Office  
☐ Temporary Job Site

Next Inspection Date: March 2009

**PROGRAM SCOPE**

The licensee is a free-standing cancer clinic. They treat about 28 patients per year, almost all of which are mammosites. There is 1 authorized user and 2 medical physicists. One of the latter is the RSO. There is also a therapist involved in treatments. The HDR is a (b)(7)(F) as specified on the license. All QA has been performed as required.

NRC FORM 591M PART 3 (Rev. by RI 07/06)

C:\FileNet\ML070950167.wpd

SUNSI Review Completed By: /RA/

☒ Non-Public   
 ☒ Non-Sensitive