



In alliance with
The University of Vermont

June 7, 2012

K-8

Nuclear Materials Safety Section
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard
King of Prussia, PA 19406

RE: Fletcher Allen Health Care
License # 44-10187-03 030-03289

Please amend our radioactive materials license to add Matthew Deeley, M.S. as an Authorized Medical Physicist. Enclosed are a copy of his letter from the ABR, preceptor statement signed by me, an AMP on our license, and documentation of training on the High Dose Rate brachytherapy system.

Also, please amend our license to remove Dr. Edward Nicholas as an Authorized User effective June 30, 2012. Dr. Nicholas has taken a position at another institution.

Thank you for your attention to this. If you have questions please contact Marleen M. Moore, M.S., Radiation Safety Officer, at (802) 847-3506. All correspondence should be copied to Marleen Moore, M.S., Garden Pavilion, ACC 2, Fletcher Allen Health Care.

Sincerely,

John Brumsted, M.D.
President and Chief Executive Officer
Fletcher Allen Health Care

Marleen M. Moore, M.S.
Radiation Safety Officer and Authorized Medical Physicist
Fletcher Allen Health Care

Attachments

REC'D IN LAB 06/21/2012

577757
NMSS/RGNI MATERIALS-002

**AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION
[10 CFR 35.51]**

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized Medical Physicist

Matthew A Deeley

- Requested Authorization(s) (check all that apply)
- 35.400 Ophthalmic use of strontium-90
 - 35.600 Teletherapy unit(s)
 - 35.600 Remote afterloader unit(s)
 - 35.600 Gamma stereotactic radiosurgery unit(s)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

- a. Provide a copy of the board certification.
- b. Go to the table in 3.c. and describe training provider and dates of training for each type of use for which authorization is sought.
- c. Skip to and complete Part II Preceptor Attestation.

2. Current Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above

- a. Go to the table in section 3.c. to document training for new device.
- b. Skip to and complete Part II Preceptor Attestation

3. Education, Training, and Experience for Proposed Authorized Medical Physicist

- a. Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

Degree	Major Field
College or University	

- b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.

AND

Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics			
Performing sealed source leak tests and inventories			
Performing decay corrections			
Performing full calibration and periodic spot checks of external beam treatment unit(s)			
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)			
Performing full calibration and periodic spot checks of remote afterloading unit(s)			
Conducting radiation surveys around external beam treatment unit(s), stereotactic radiosurgery unit(s), remote after loading unit(s)			

Supervising Individual** : License/Permit Number listing supervising individual as an authorized Medical Physicist

for the following types of use:

- Remote afterloader unit(s)
 Teletherapy unit(s)
 Gamma stereotactic radiosurgery unit(s)

+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

** If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Hands-on device operation	Marleen Moore January, 2011 - June, 2012 documentation attached		
Safety procedures for the device use	Doug Boyles, Varian service 10/3/2011 documentation attached		
Clinical use of the device	Marleen Moore, Y Cathy Cai January, 2011- June, 2012 documentation attached		
Treatment planning system operation	Marleen Moore, Y Cathy Cai January, 2011 - June, 2012 documentation attached		

Supervising Individual: License/Permit Number listing supervising individual as an authorized Medical Physicist
If training is provided by Supervising Medical Physicist, (if more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)
Marleen Moore, M.S. AMP : **44-10187-03**

for the following types of use:

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

If Applicable:

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following:

1. Board Certification

I attest that Matthew A Deeley has satisfactorily completed the requirements in
Name of Proposed Authorized Medical Physicist
10 CFR 35.51(a)(1) and (a)(2).

OR

2. Education, Training, and Experience

I attest that _____ has satisfactorily completed the 1-year of full-time
Name of Proposed Authorized Medical Physicist
training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

AND

Second Section

Complete the following:

I attest that Matthew A Deeley has training for the types of use for which authorization
Name of Proposed Authorized Medical Physicist
is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

AND

Third Section

Complete the following:

I attest that Matthew A Deeley has achieved a level of competency sufficient to
Name of Proposed Authorized Medical Physicist
function independently as an Authorized Medical Physicist for the following:

- 35.400 Ophthalmic use of strontium-90 35.600 Teletherapy unit(s)
- 35.600 Remote afterloader unit(s) 35.600 Gamma stereotactic radiosurgery unit(s)

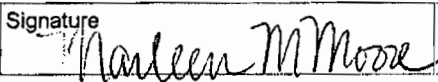
AND

Fourth Section

Complete the following for preceptor attestation and signature:

I meet the requirements in 10 CFR 35.51, or equivalent Agreement State requirements for Authorized Medical Physicist for the following:

- 35.400 Ophthalmic use of strontium-90 35.600 Teletherapy unit(s)
- 35.600 Remote afterloader unit(s) 35.600 Gamma stereotactic radiosurgery unit(s)

Name of Preceptor	Signature	Telephone Number	Date
Marleen M Moore		(802) 847-3506	06/16/2012
License/Permit Number/Facility Name			
Fletcher Allen Health Care License # 44-10187-03			



June 14, 2012

Matthew Aaron Deeley, MS
Medical Physics
Fletcher Allen Health Care
111 Colchester Ave.
Burlington, VT 05401

Therapeutic Medical Physics
ABR ID: P4899

Dear Mr. Deeley,

I am pleased to inform you that you passed the oral examination held from May 20 - 23, 2012 in Louisville, Kentucky. The American Board of Radiology hereby grants you a Certificate in Therapeutic Medical Physics.

In addition, you have satisfied the NRC training requirements enabling you to be recognized as an ABR Diplomate in Therapeutic Medical Physics who is eligible to become an Authorized Medical Physicist (AMP) via the certification pathway in 10 CFR 35.51(a). Thus, you will receive the "AMP-Eligible" designation on your certificate. Please be aware that, although not noted explicitly on the certificate, by virtue of being AMP eligible, you have also satisfied the certification portion of the regulatory requirements in 10 CFR 35.50(c)(1) for Radiation Safety Officer (RSO) authorization.

Beginning this year, all new diplomates will be enrolled in "continuous certification," a process that links the ongoing validity of certificates to meeting the requirements of Maintenance of Certification (MOC). Certificates will no longer have "valid-through" dates but instead will have the date of initial certification accompanied by the statement that "ongoing certification is contingent upon meeting the requirements of Maintenance of Certification." Further information regarding the MOC process will be provided to you in a separate letter.

Our printer will send your certificate to the above address in approximately four months. If you have an address change, you must update your address in your ABR personal database (PDB) by July 14, 2012. Your name will appear on the certificate as it is shown above. If you wish to have your name displayed differently on your certificate, please e-mail Sherri Tradup at stradup@theabr.org with your requested change by July 14, 2012. Please be sure to title the e-mail "Certificate Name Change." Legal name changes cannot be made on the PDB, as they require supporting documentation, which can be emailed to info@theabr.org. Your name and demographic information also will be included in a directory published by the American Board of Medical Specialties. It is your responsibility to notify other local, state, or national organizations of your certification.

Personally, and on behalf of the Board of Trustees of the American Board of Radiology, I wish to congratulate you for this distinguished achievement.

Sincerely,

Gary J. Becker, MD
Executive Director

Fletcher Allen Health Care
Gammamed Training Record
Matthew Deeley, M.S.

<u>Topic</u>	<u>Documented date</u>	<u>Presenter/Oversight</u>
New source testing	1/3/2012	M Moore
Day of use testing	as attached (20)	M Moore/Y Cai
Abacus Planning	as attached (8)	M Moore/Y Cai
Brachyvision Planning	as attached (8)	M Moore/Y Cai
Patient treatment	as attached (>20)	M Moore/Y Cai
Emergency procedures including source retraction	1/4/2011	Doug Boyles

All plans and patient treatment documentation has been reviewed by Marleen Moore,

Matthew Deeley has completed in excess of the 8 hours of "hands on " training. He is very able to function independently as an Authorized Medical Physicist for remote afterloader (HDR) applications.

  _____

Marleen M Moore, M.S.
Authorized Medical Physicist

20 day of use testing

Must follow source

Day of use QA - HDR unit

Date	2/7/11	2/8/11	2/9/11	2/14/11	2/15/11	2/16/11	2/23/11	2/24/11	3/3/11	3/4/11	3/9/11	3/10/11	3/11/11	3/23/11	4/6/11
Emergency source container and tool kit	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Video system operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Survey meter operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Date, time verification	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓*	✓
Decay correction factor verification	31/139	41/141	42/142	49/149	50/150	52/152	64/162	73/173	75/175	76/176	85/185	87/187	88/188	103/103	110/110
Guide tube and applicator condition and length	✓x3	✓x3	✓	✓x3	✓	✓x3	✓	✓x3	✓x1	✓x1	✓x1	✓	✓x1	✓x4	✓x3
Missing guide tube test	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Door interlock operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Console indicator light operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Independent radiation monitor operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Internal radiation monitor operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
console "interrupt" operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Elapsed time measurement	3.72	4.06	4.21	4.94	4.81	5.28	6.34	7.12	7.53	7.65	8.50	8.75	8.78		10.88
Source positioning accuracy	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
console "emergency off" operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Intercom operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
printer operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Initials	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm

* Did to daylight saving

Day of use QA - HDR unit

Date	4/10/11	4/11/11	4/12/11	4/18/11	4/19/11	4/20/11	7/31/11	4/27	4/28	5/5	5/12/11	5/18/11	5/25/11	5/26/11	6/1/11
Emergency source container and tool kit	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Video system operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Survey meter operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Date, time verification	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Decay correction factor verification	110/110	116/116	117	125/125	125/125	126/126	131/131	134/134	136/136	145/145	155/155	164/164	175/175	176/176	181/181
Guide tube and applicator condition and length	x2 ✓	x3 ✓	x3 ✓	x3 ✓	✓	x3 ✓	x3 ✓	x3 ✓	x3 ✓	x1 ✓	x1 ✓	x1 ✓	x1 ✓	x1 ✓	✓
Missing guide tube test	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Door interlock operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Console indicator light operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Independent radiation monitor operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Internal radiation monitor operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
console "interrupt" operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Elapsed time measurement	11.13	11.53	11.72	12.3	12.50	12.50	12.72	13.44	13.63	14.59	15.38	16.40	17.56	17.47	18.60
Source positioning accuracy	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm
console "emergency off" operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Intercom operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
printer operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Initials	Mr	Mr	Mr	Mr	Mr	Mr	Mr	Mr	Mr	Mr	Mr	Mr	Mr	Mr	Mr

Set 10 sec stop watch

Day of use QA - HDR unit

Date	6/1/11	6/8/11	6/9/11	6/15/11	6/16/11	6/23/11	6/30/11	7/7/11	7/11/11	7/28/11	8/3/11	8/15/11	8/17/11	8/19/11	8/24/11
Emergency source container and tool kit	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Video system operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	tripod ✓
Survey meter operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Date, time verification	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Decay correction factor verification	188/188	199/199	201/201	213/213	215/215	229/229	245/245	262/262	112/112	131/131	140/140	155/155	158/158	161/161	169/169
Guide tube and applicator condition and length	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Missing guide tube test	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Door interlock operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Console indicator light operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Independent radiation monitor operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Internal radiation monitor operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
console "interrupt" operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Elapsed time measurement	18.91	19.94	20.03	21.31	21.53	22.97	23.97	26.3	11.10	12.94	14.10	15.38	15.85	16.16	16.90
Source positioning accuracy	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm	<1mm
console "emergency off" operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Intercom operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
printer operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Initials	ju	ju	ma	ju	ma	ma	ma	ma	ma	ma	ma	ma	ma	ma	ju

SOURCE
CAMERA

* ceiling camera not functioning / tripod camera OK - page 8/24

Unit moved to new location
and new source
Day of use QA - HDR unit

No patient
for source
change

Date	9/22/10	10/1/10	10/14/10	10/24/10	11/10/10	11/19/10	11/24/10	12/1/10	12/8/10	1/14/11	1/26/11	2/7/11	2/23/11	3/4/11	
Emergency source container and tool kit	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Video system operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Survey meter operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Date, time verification	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Decay correction factor verification	228/128	✓	17/17	125/125	151/151	161/161	172/172	184/184	196/196	101/101	125/125	126/126	127/127	134/134	136/136
Guide tube and applicator condition and length	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Shield in place?	✓	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Missing guide tube test	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Exposure reading (mR/h) at unlead door	6.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	N/A	N/A	
Wooden door interlock operation	✓	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	N/A	N/A	
Shielded door interlock operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Console indicator light operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Independent radiation monitor operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Internal radiation monitor operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
console "interrupt" operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Elapsed time measurement	22.91	11.1	11.10	12.34	14.85	15.94	17.35	17.90	19.75	19.87	12.46	12.75	38.22	13.59	13.75
Source positioning accuracy	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
console "emergency off" operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Intercom operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
printer operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Initials	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm	

* one 320mm guide tube
remains from service
** set time to EST

Emergency operated properly
but system locked after
unable to reset
and operate
properly

8 Brachy plans
8 Abacus

First	Dates of implants	Na	Type	Prescribed dose	MD	Planner	
01/26/2011	1/26/2011, 1/27/2011, 2/3/2011, 2/4/2011	Ty	cylinder boost	3 Gy x 4 to surface	HG	MAD/YCC	Brachy
02/07/2011	2/7/11, 2/8/11, 2/15/11, 2/16/11	Ja	T&O	7 Gy Pt A x 4	HG	MAD/MMM	Brachyvis
02/09/2011	2/9/11, 2/16/11, 2/23/11	Kc	cylinder boost	6.5 Gy at 0.5 cm x 3	DZR	YCC	
03/04/2011	3/4/11, 3/11/11	Re	cylinder boost	6 Gy x 2 at surface	HG	MAD/MMM	Abacus
04/06/2011	4/6/11, 4/7/11, 4/8/11	He	split tandem	7 Gy/fx at 65% cov x 3 + exte	HG	MAD/MMM	Brachyvis
04/11/2011	4/11/11, 4/12/11, 4/18/11, 4/19/11	Ha	T&O	7 Gy to >70% PTV	HG	MAD/MMM	Brachyvis
04/20/2011	4/20/11, 4/21/11, 4/27/11, 4/28/11	M	T&O	7 Gy Pt A x 4	HG	MAD/MMM	Brachyvis
04/28/2011	4/28/11, 5/5/11, 5/12/11	Is	cylinder prim.	7Gy at .5cm x 3	HG	YCC	Abacus
05/18/2011	5/18/11, 5/25/11, 6/1/11	Le	cylinder prim.	7Gy at .5cm x 3	HG	MAD/YCC	Abacus
05/26/2011	5/26/11, 6/2/11, 6/9/11	M	cylinder prim.	7Gy at .5cm x 3	HG	MAD/MMM	Abacus
06/08/2011	6/8/11, 6/15/11	Du	cylinder boost	5 Gy at 0.5 cm x 2	HG	MAD/YCC	Abacus
06/16/2011	6/16/11, 6/23/11, 6/30/11, 7/7/11	Br	cylinder boost	7 Gy surf x 4	HG	MAD/YCC	Brachyvis
07/28/2011	7/28/11, 8/4/11, 8/15/11	Ca	cylinder prim.	7Gy at .5cm x 3	HG	MAD/YCC	Brachyvis
08/09/2011	8/19/11, 8/26/11, 8/31/11	Bu	cylinder prim.	7 Gy at 0.5cm x 3	HG	MAD/YCC	Abacus
08/17/2011	8/17/11, 8/25/11, 8/31/11	Ha	cylinder prim.	7Gy at .5cm x 3	HG	YCC	Abacus
08/24/2011	8/24/11, 8/31/11	Sn	cylinder boost	5 Gy surf x 2	HG	MAD/YCC	Abacus
09/12/2011	9/12/11, 9/21/11, 9/26/11	Sa	cylinder prim.	7Gy at .5cm x 3	HG	MAD/MMM	Abacus
10/12/2011	10/12/11, 10/14/11	M	cylinder boost	5 Gy surf x 2	HG	MMM	Abacus
11/14/2011	11/14/11, 11/21/11, 11/28/11	M	cylinder prim.	10 Gy at surf x 3	HG	MMM	Abacus
12/05/2011	12/5, 12/6, 12/12, 12/13	M	split tandem	5.2 Gy x 4 to > 90% of PTV	HG	MAD/MMM	Brachy
02/09/2012	2/9/2012, 2/16, 2/21	Pu	cylinder prim.	10 Gy at surf x 3	HG	MMM	Abacus
03/28/2012	3/28/12, 4/4/12, 4/11/12	W	cylinder prim.	10 Gy at surf x 3	HG	YCC	Abacus
04/04/2012	4/4/12, 4/11/12, 4/18/12	Cr	cylinder prim.	10 Gy at surf x 3	HG	YCC	Abacus
04/09/2012	4/9/2012, 4/10/2012, 4/16/2012, 4/17/2012	Fo	split tandem	5.2 Gy x 4 to > 90% of PTV	HG	MAD/YCC	Brachyvis
04/18/2012	4/18/12, 5/4/12	Ch	cylinder boost	6 Gy x 2 at surface	HG	YCC	Abacus
05/16/2012	5/16, 5/22, 5/30	Ch	cylinder prim.	10 Gy at surf x 3	HG	YCC	Abacus
05/30/2012	5/30, 6/6	M	cylinder boost	6 Gy x 2 at 0.5 cm	HG	MAD/MMM	Abacus

Matthew Deeley participated in the patient treatments performed on the following dates. This is documented by his initials, countersigned by one of the AMP's, given on the patient treatment summary sheet or post procedure survey record. For all treatments, one of the AMP's was in attendance throughout the procedure.

2011: 2/4, 2/16, 3/2, 3/3, 3/9, 3/10, 3/11, 4/6, 4/7, 4/8, 4/19, 4/20, 4/21, 4/27, 6/8, 6/30, 8/17, 8/24, 8/30, 9/12, 9/21, 9/26, 11/14

2012: 4/9, 4/10, 4/11, 4/16, 4/18, 5/30

M Moore

At Source change 10/3/2011

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Varian Brachytherapy

GammaMed Customer Emergency Training Course

1. Introduction

The following information is to be presented to the site Radiation Safety Officer (RSO), authorized user and the medical physicist and provides an overview of the *GammaMed* safety features and emergency responses. This training does not represent clinical or applications training.

US ONLY:

During all patient treatments, the authorized user and either a medical physicist or the site Radiation Safety Officer must be physically present (see U.S. NRC Bulletin 93-01, April 20, 1993).

The site Radiation Safety Officer shall be responsible for the formal radiation safety training as required by site policy and local regulatory requirements. For the *GammaMed* transportable models, this course shall be conducted with relevant personnel at all operational sites.

2. Regulatory Compliance / Site Specific Issues

It is the responsibility of the site to ensure regulatory compliance through the provision of maintenance and adequate testing of safety equipment and facilities.

Feature	Available
Independent Treatment Room Radiation Monitor	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Slave Radiation Monitor in Console Area	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Beam on lamps	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Calibrated Survey Meter	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Patient Video Monitoring	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Patient Audio Monitoring	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Emergency Lighting in Treatment Room	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Emergency Lighting in Console Area	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
GAMMAMED Emergency Procedures on Display	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
VARIAN 24hr. Emergency Dispatch or Regional Office phone number displayed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

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3. GammaMed Safety Features

Confirm that the location of the following features and the correct operation where required.

System Passwords	Confirmed <input checked="" type="checkbox"/>
Power Key Switch on Console (On/Off)	Confirmed <input checked="" type="checkbox"/>
Mode Key Switch on Console	Confirmed <input checked="" type="checkbox"/>
Mains & Battery Indicator on Console	Confirmed <input checked="" type="checkbox"/>
Normal & Special Mode Indicators on Console	Confirmed <input checked="" type="checkbox"/>
Safe Indicator on Console	Confirmed <input checked="" type="checkbox"/>
Locked Indicator on Console	Confirmed <input type="checkbox"/> N/A
Start and Interrupt Switches on Console	Confirmed <input checked="" type="checkbox"/>
Emergency Return Switches	Confirmed <input checked="" type="checkbox"/>
(Console area and treatment room)	Confirmed <input checked="" type="checkbox"/>
Treatment Room Door Interlock Switch	Confirmed <input checked="" type="checkbox"/>
Last Man Out Switch / optional	Confirmed <input type="checkbox"/> N/A
UPS for Console	Confirmed <input checked="" type="checkbox"/>
Afterloader self-contained Emergency Retract Batteries	Confirmed <input checked="" type="checkbox"/>
Afterloader Emergency Return Button	Confirmed <input checked="" type="checkbox"/>
Key on Afterloader Released/Locked	Confirmed <input checked="" type="checkbox"/>
Afterloader Radiation Detector	Confirmed <input checked="" type="checkbox"/>
Afterloader Wire Lock (transportable units only)	Confirmed <input type="checkbox"/> N/A
Closed-end catheters and applicators	Confirmed <input checked="" type="checkbox"/>
Importance of containment issues discussed	Confirmed <input checked="" type="checkbox"/>

4. Retract Operations / Conditions

There are five separate levels of Active Wire retract condition on the GammaMed Afterloader.

4.1 Normal Retract

A normal motor retract occurs due to treatment completion or treatment interruption.

Confirmed

4.2 Emergency Retract by Error Conditions

Automatic Emergency Return is initiated (e.g. Failure of Data Connection). The motor retracts until source is in shielded position and Safe Indicator is lit.

Confirmed

4.3 Emergency Retract by Pressing Emergency Return Switch

Automatic Emergency Return is initiated. The motor retracts until source is in shielded position and Safe Indicator is lit.

Confirmed

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4.4 Emergency Retract by Pressing Emergency Button Trolley

Automatic Emergency Return is initiated. The motor retracts until source is in shielded position and Safe Indicator is lit.

Confirmed

4.5 Active Source Wire Manual Retract Hand Wheel

The manually operated Active Source Wire Emergency Retract hand wheel is provided in the event that the Afterloader fails to retract the active wire to its park position:

Active Source Wire only (Not for Dummy Wire Manual Retract) Confirmed

5. Emergency Procedures

It is essential that the user familiarize themselves with and regularly rehearse the procedures outlined below.

Refer to the GammaMed User Manual and relevant User Manual Amendment sheets for relevant Emergency Procedures.

Confirmed

With an **Inactive** wire installed, discuss failure mode scenarios and simulate activating Emergency Return Switches and using Manual Retract hand wheel to return source to a Safe Position.

Confirmed

6. Emergency Procedures

Varian Brachytherapy must be immediately notified by phone and provide a written account of the occurrence as soon as possible when any activity related emergency is encountered during the use GammaMed equipment.

U.S. Contact:

24 Hours GammaMed Dispatch (800) 864-1672
 VBT North America Customer Support Manager
 Charlottesville, VA
 Ph: 434-977-8495, Extension 239
 VBT Radiation Safety Officer
 Varian Brachytherapy
 Charlottesville, VA
 Ph: 434-977-8495, Extension 275

Confirmed

International Sites Contact:

The Regional Service Office as applicable.

Confirmed

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7. Acknowledgment of course demonstration

To be copied to each member of site personnel attending training course.

Institution Name:	<i>Fletcher Allen Health Ctr</i>
Address:	<i>111 Colchester Ave Burlington, VT 05401</i>
GammaMed Afterloader Serial Number:	<i>630896</i>
Date on which training completed:	<i>10/3/11</i>
GammaMed Representative: (Print name)	<i>Douglas Boyles</i>
Signature:	<i>[Signature]</i>
Customer Representative(s): (list names)	<i>[Signature] James Goodwin</i>
	<i>[Signature] Matthew A. Deeley</i>
	<i>Marleen Moore Marleen M Moore</i>

This is to acknowledge the receipt of your letter application dated

06/07/2012, and to inform you that the initial processing which includes an administrative review has been performed.

44-10187-03
 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 577757.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.