

21st Century Oncology  
Radiation Therapy Services, Inc.

July 15<sup>th</sup>, 2008

Br. 1

Licensing Assistance Team  
Division of Nuclear Material Safety  
U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

2008 JUL 21 PM 12:44

RECEIVED  
REGION I

RE: Radioactive Material License # 09-31141-01

03037177

To Whom It May Concern:

We would like to request an amendment to the referenced Radioactive Materials License to include Alexis Harvey, M.D., as an Authorized User. Find enclosed copy of Dr. Harvey's ABR Certificate, Nucletron Training Certificate, and Preceptor Attestation Form.

Should you have any question regarding this application, feel free to call me at 239-768-7377.

Sincerely,

Daniel H. Galmarini, DABR  
Director of Physics,

142636  
NMSS/RGNI MATERIALS-002

**AUTHORIZED USER TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.400 and 35.600)  
[10 CFR 35.490, 35.491, and 35.690]

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: 10/31/2008

Name of Proposed Authorized User

State or Territory Where Licensed

Alexis Harvey, M.D.

Requested

35.400 Manual brachytherapy sources

35.600 Teletherapy unit(s)

Authorization(s)

35.400 Ophthalmic use of strontium-90

35.600 Gamma stereotactic radiosurgery unit(s)

(check all that apply)

35.600 Remote afterloader 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. For 35.600, go to the table in 3.e. 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 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**

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

**3. Training and Experience for Proposed Authorized User**

- a. Classroom and Laboratory Training  35.490  35.491  35.690

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

**Total Hours of Training:**

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**3. Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking survey meters for proper operation		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
<b>Approved by:</b> <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**3. Training and Experience for Proposed Authorized User (continued)**

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User	

d. Supervised Work and Clinical Experience for 10 CFR 35.690

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

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**3. Training and Experience for Proposed Authorized User (continued)**

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
<p><b>Approved by:</b></p> <p><input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME</p> <p><input type="checkbox"/> Royal College of Physicians and Surgeons of Canada</p> <p><input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association</p>		
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User

e. For 35.600, 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
Device operation	<b>Nucletron March 9, 2007</b>		
Safety procedures for the device use	<b>Nucletron March 9, 2007</b>		
Clinical use of the device	<b>Nucletron March 9, 2007</b>		
Supervising Individual. <i>If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)</i>		License/Permit Number listing supervising individual as an Authorized User	

Authorized for the following types of use:

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

f. Provide completed Part II Preceptor Attestation.

**AUTHORIZED USER 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.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

**First Section**

Check one of the following for each requested authorization:

**For 35.490:**

**Board Certification**

I attest that \_\_\_\_\_ has satisfactorily completed the requirements in  
Name of Proposed Authorized User

35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

**OR**

**Training and Experience**

I attest that \_\_\_\_\_ has satisfactorily completed the 200 hours of  
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

**For 35.491:**

I attest that \_\_\_\_\_ has satisfactorily completed the 24 hours of  
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

**Second Section**

**For 35.690:**

**Board Certification**

I attest that **Alexis Harvey, M.D.** has satisfactorily completed the requirements in  
Name of Proposed Authorized User

35.690(a)(1).

**OR**

**Training and Experience**

I attest that \_\_\_\_\_ has satisfactorily completed 200 hours of classroom  
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

**AND**

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**Preceptor Attestation (continued)**

**Third Section**

**For 35.690: (continued)**

I attest that Alexis Harvey, M.D. has received training required in 35.690(c) for device  
Name of Proposed Authorized User

operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

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

**AND**

**Fourth Section**

I attest that Alexis Harvey, M.D. has achieved a level of competency sufficient to  
Name of Proposed Authorized User

achieve a level of competency sufficient to function independently as an authorized user for:

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

**Fifth Section**

**Complete the following for preceptor attestation and signature:**

I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

35.400 Manual brachytherapy sources     35.600 Teletherapy unit(s)

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

35.600 Remote afterloader unit(s)

Name of Preceptor  
**Ashraf Youssef, M.D.**

Signature 

Telephone Number    Date  
856-848-7374    6/18/08

License/Permit Number/Facility Name  
**NRC Lic. # 09-31141-01 / 21st Century Oncology, Inc.**



# CERTIFICATE OF TRAINING

awarded to

**Alexis Harvey**

for completing the following course:

**Physician Training - Overview for HDR Brachytherapy**


***At 21st Century Oncology, FT. Myers, FL***

Date

**March 9, 2007**

Presented by:

**Nucletron Corporation, 8671 Robert Fulton Drive, Columbia, Maryland**

  
**Joe Iannitto**  
Instructor



# The American Board of Radiology

*Organized through the cooperation of the  
American College of Radiology, the American Roentgen Ray Society,  
the American Radium Society, the Radiological Society of North America,  
the Section on Radiology of the American Medical Association,  
the American Society for Therapeutic Radiology and Oncology,  
and the Association of University Radiologists*  
Hereby certifies that

**Alexis Harvey, M.F.**

*Has pursued an accepted course of graduate study  
and clinical work, has met certain standards and qualifications and  
has passed the examinations conducted under the authority of  
The American Board of Radiology*

On this sixth day of June, 1991

*Thereby demonstrating to the satisfaction of the Board  
that she is qualified to practice the specialty of*

**Radiation Oncology**



*Thomas J. Dunphy, M.D.*  
President

*Douglas Hayward, M.D.*  
Secretary-Treasurer

*Francis P. Fielding, M.D.*  
Executive Director



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

7/15/09, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (09-31141-01) 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

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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** 142636.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)  
(6-96)

Sincerely,  
Licensing Assistance Team Leader