

P-7
MS-16

October 10, 2006

Mr. Tom Thompson
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19408

08-31176-01
03037314

RE: Mail control # 139163
Fax 610-337-5269
Radioactive Materials License Application
Ishtiaq A. Malik, M.D.

License Reviewers:


Enclosed please find additional information for the radioactive materials license application for Ishtiaq A. Malik, M.D. located in Washington, D.C. The requirement of 700 hours of training and experience is here enclosed; 200 class and laboratory hours at HRSI, 300 hours of training under Dr. Jain, and 400 hours under Dr. Robinson (TOTAL = 900 documented hours including work experience training in the specific subcategories outlined in 10 CFR 26.200 (b)(4) (i)).

Enclosed:

Updated NRC Form 313A, Dr. Jain attesting to 300 hours of training and experience
NRC Form 313A, Dr. Robinson attesting to an additional 400 hours of training and experience
Health and Radiological Seminars, Inc. certificate 200 hours of classroom & laboratory training
HRSI dates received confirmation email

If there are any questions or additional information is needed, please contact Mr. Matt Lucas, Health Physics Consultant, Krueger-Gilbert Health Physics, Inc. at (410) 665-5447 or the undersigned at (703) 906-6160.

Sincerely,


Ishtiaq A. Malik, M.D.

139163
NMSS/RGNI MATERIALS-002

DUPLICATE UNSIGNED

October 10, 2006

Mr. Tom Thompson
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19408

RE: Mail control # 139163
Fax 610-337-5269
Radioactive Materials License Application
Ishtiaq A. Malik, M.D.

License Reviewers:

Enclosed please find additional information for the radioactive materials license application for Ishtiaq A. Malik, M.D. located in Washington, D.C. The requirement of 700 hours of training and experience is here enclosed; 200 class and laboratory hours at HRSI, 300 hours of training under Dr. Jain, and 400 hours under Dr. Robinson (TOTAL = 900 documented hours including work experience training in the specific subcategories outlined in 10 CFR 35.290 (ii)(A-G)).

Enclosed:

Updated NRC Form 313A, Dr. Jain attesting to 300 hours of training and experience
NRC Form 313A, Dr. Robinson attesting to an additional 400 hours of training and experience
Health and Radiological Seminars, Inc. certificate 200 hours of classroom & laboratory training
HRSI dates received confirmation email

If there are any questions or additional information is needed, please contact Mr. Matt Lucas, Health Physics Consultant, Krueger-Gilbert Health Physics, Inc. at (410) 665-5447 or the undersigned at (703) 906-6160.

Sincerely,

Ishtiaq A. Malik, M.D.

Updated Form 313A signed by Dr. Diwakar Jain

NRC FORM 313A (10-2005)	U.S. NUCLEAR REGULATORY COMMISSION MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008
----------------------------	---	---

PART I -- TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Ishaiq A. Malik, M.D. Authorized User, 10 CFR 35.290

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed
 District of Columbia

3. CERTIFICATION

a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)

b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization, 35.390(b)(1)(ii)(G), 35.396(d)(1) and 35.396(d)(2); 35.590(c), or 35.690(c).

c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.

Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)

b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).

c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Health & Radiological Seminars, Inc.	100	December 2003 to March 2004
Radiation Protection	Health & Radiological Seminars, Inc.	30	December 2003 to March 2004
Mathematics Pertaining to the Use and Measurement of Radioactivity	Health & Radiological Seminars, Inc.	20	December 2003 to March 2004
Radiation Biology	Health & Radiological Seminars, Inc.	20	December 2003 to March 2004
Chemistry of Byproduct Material for Medical Use	Health & Radiological Seminars, Inc.	30	December 2003 to March 2004
OTHER			
		Total 200 hours	

NRC FORM 313A (10-2005) U.S. NUCLEAR REGULATORY COMMISSION
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Ordering, receiving, and unpacking radioactive material safely and performing the related radiation	Diwakar Jain, M.D.	see item 9	10/2005 to 11/2005 16 hours
Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters.	"	"	10/2005 to 11/2005 8 hours
Calculating, measuring, and safely preparing patient or human research subject dosages	"	"	10/2005 to 11/2005 12 hours
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	"	10/2005 to 11/2005 24 hours
Using procedures to safely contain spilled radioactive material and using proper decontamination procedures	"	"	10/2005 to 11/2005 12 hours
Administering dosages of radioactive drugs to patients or human research subjects	"	"	10/2005 to 11/2005 24 hours
Eluting generators, measuring and testing the eluate, and processing the eluate with reagent kits to prepare labeled radioactive drugs	"	"	10/2005 to 11/2005 24 hours
Reviewing case histories and interpreting scans	"	"	10/2005 to 11/2005 180 hours
		Total 300 hours	

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
NA					

NRC FORM 313A (10-2005) U.S. NUCLEAR REGULATORY COMMISSION
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates
NA		

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
NA			

8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision of _____ the RSO for License No. _____

N/A

9. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

N/A

and

YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____ under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

N/A

NRC FORM 313A (10-2003) U.S. NUCLEAR REGULATORY COMMISSION MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL - IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each):

A. Name of Supervisor: Divakar Jain, M.D. B. Supervisor is: [X] Authorized User [] Authorized Medical Physicist [] Radiation Safety Officer [] Authorized Nuclear Pharmacist C. Supervisor meets requirements of Part 35, Section(s) 290 for medical uses in Part 35, Section(s) 100 and 200 D. Address: 245 N. 15th Street, Department of Cardiology, Drexel University College of Medicine, Philadelphia, PA 19102 E. Materials License Number: 67-30484-81

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest (the individual named in Item 1):

11a. [X] has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 290 (c)(1)(i)(ii) as documented in section(s) 5, 6a of this form.

11b. Select one [] meets the requirements in [] 35.50(e) [] 35.51(c) [] 35.390(b)(1)(ii)(G) [] 35.690(c) for [] types of use, as documented in section(s) of this form. [X] N/A

11c. [] has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); OR [X] has achieved a level of competency sufficient to function independently as an authorized user for 10 CFR 35.100 and 200 uses (or units); OR [] has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; OR [] N/A

11d. [] I am an Authorized Nuclear Pharmacist; OR [] I am a Radiation Safety Officer; OR [X] I meet the requirements of 35.290 section(s) of 10 CFR Part 35 or equivalent Agreement State requirements to be a preceptor [X] AU or [] AMP for the following byproduct material uses (or units): 35.100 and 35.200

A. Address: 245 N. 15th Street, Department of Cardiology, Drexel University College of Medicine, Philadelphia, PA 19102 B. Materials License Number: 67-30484-81

C. NAME OF PRECEPTOR (print clearly): Divakar Jain, M.D.

D. SIGNATURE - PRECEPTOR

[Handwritten signature]

E. DATE: 0-8-06, 09/08/2006

NRC Form 313A signed by Dr. Joseph Robinson

NRC FORM 313A (10-2005)	U.S. NUCLEAR REGULATORY COMMISSION MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008
----------------------------	---	---

PART I -- TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Ishlaq A. Malik, M.D. Authorized User, 10 CFR 35.290

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

District of Columbia

3. CERTIFICATION

a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)

b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c)

c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.

Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)

b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).

c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Health & Radiological Seminars, Inc.	100	December 2003 to March 2004
Radiation Protection	Health & Radiological Seminars, Inc.	30	December 2003 to March 2004
Mathematics Pertaining to the Use and Measurement of Radioactivity	Health & Radiological Seminars, Inc.	20	December 2003 to March 2004
Radiation Biology	Health & Radiological Seminars, Inc.	20	December 2003 to March 2004
Chemistry of Byproduct Material for Medical Use	Health & Radiological Seminars, Inc.	30	December 2003 to March 2004
OTHER			
		Total 200 hours	

NRC FORM 313A (10-2008)		U.S. NUCLEAR REGULATORY COMMISSION			
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)					
8a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION					
Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience		
Reviewing case histories and interpreting scans	Joseph Robinson, M.D.	see item 9 :	2/2006 to 8/2008 250 hours		
Ordering, receiving, and unpacking radioactive material safely and performing the related radiation	"	"	2/2006 to 8/2006 25 hours		
Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters.	"	"	2/2006 to 8/2006 25 hours		
Calculating, measuring, and safely preparing patient or human research subject dosages	"	"	2/2006 to 8/2006 25 hours		
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	"	2/2006 to 8/2006 25 hours		
Using procedures to safely contain spilled radioactive material and using proper decontamination procedures	"	"	2/2006 to 8/2006 25 hours		
Administering dosages of radioactive drugs to patients or human research subjects	"	"	2/2006 to 8/2006 25 hours		
			Total 400 hours		
8b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)					
Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
NA					

NRC FORM 313A (10-2005) U.S. NUCLEAR REGULATORY COMMISSION
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates
NA		

* Types of training may include supervised (complete Item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
NA			

8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision of _____ the RSO for License No. _____

N/A

9. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

N/A

and

YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____ under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

N/A

NRC FORM 313A
(10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (If more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each):

A. Name of Supervisor

Joseph Robinson, M.D.

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 290

for medical uses in Part 35, Section(s) 100 and 200

D. Address

106 Irving Street, NW, Suite 3800
Washington DC, 20010

E. Materials License Number

19-31093-01

PART II -- PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

Attest the individual named in Item 1:

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 290 (c)(1)(i)(ii) as documented in section(s) 5, 6 of this form.

11b. Select one

meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for types of use, as documented in section(s) of this form.

N/A

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized user for 10 CFR 35.100 & 35.200 uses (or units); **OR**

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

I meet the requirements of 35.290 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor AU or AMP

for the following byproduct material uses (or units): 35.100 & 35.200

A. Address

106 Irving Street, NW, Suite 3800
Washington DC, 20010

B. Materials License Number

19-31093-01

C. NAME OF PRECEPTOR (print clearly)

Joseph Robinson, M.D.

D. SIGNATURE PRECEPTOR

E. DATE

Health and Radiological Health Seminars Inc., information



Health & Radiological Seminars, Inc.



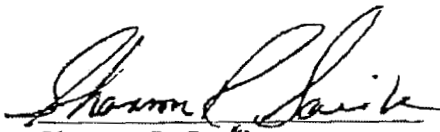
Hereby certifies that

Ishtiaq A. Malik, M.D.

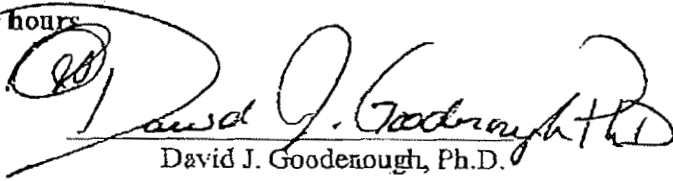
has successfully completed the 200 Hour Physician Training Program in Basic Radioisotope Handling conducted in accordance with the requirements of the U.S. Nuclear Regulatory Commission (10 CFR 35).

COURSE OUTLINE

- Radiation Physics and Instrumentation - 100 hours
- Mathematics pertaining to the use and measurement of radioactivity - 20 hours
- Radiopharmaceutical Chemistry - 30 hours
- Radiation Biology - 20 hours
- Radiation Protection - 30 hours


 Shannon R. Saville
 Course Coordinator

March 7, 2004


 David J. Goodenough, Ph.D.
 Scientific Advisor

MSN Hotmail -



mattlucas@msn.com

Printed: Tuesday, September 19, 2006 1:09 PM

From : Derek Noland <dereknoland_hrsl@yahoo.com>
Sent : Monday, September 11, 2006 10:40 AM
To : mattlucas@msn.com
Subject : Dr. Ishtlaq Malik & HRSI

Mr. Lucas,

Thank you for your call. I have checked our records, and Dr. Malik attended all four sessions of our course from December 2003 to March 2004, earning our certificate on March 7, 2004. Please let me know if you need more information.

Derek Noland, Program Director

Stay in the know. Pulse on the new Yahoo.com. Check It out.