

August 23, 2006

Mr. Tom Thompson
U.S. Nuclear Regulatory Commission
Region 1
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.

Enclosed:
Form 313
Updated Item 7
Updated NRC Form 313A

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

Sincerely,


Ishtiaq A. Malik, M.D.

P-7

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REGION 1



Krueger-Gilbert Health Physics, Inc.

3601 EAST JOPPA ROAD
BALTIMORE, MARYLAND 21234
(410) 665-KGHP (5447) FAX (410) 665-2074

August 23, 2006

Ishtiaq A. Malik, M.D.
Physician Office Building (POB) North Tower
Suite 3000
106 Irving Street NW
Washington, DC 20010

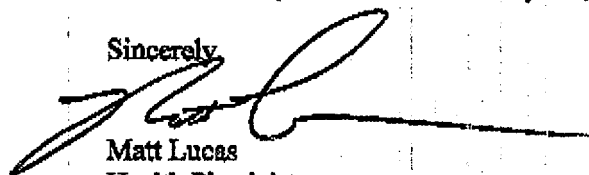
Dear Dr. Malik:

Enclosed please find additional information requested by the NRC for your radioactive materials license application. Prior to submitting this document to the NRC, review the information for completeness and accuracy and take the following action:

1. Have the enclosed draft letter typed on facility letterhead. You must also sign this letter.
2. Sign and date the application form.
3. Have Dr. Jain sign the enclosed Form 313A preceptor attestation form.
4. Retain one copy of the entire package in the facility's license file.
5. Forward the application and enclosures, in duplicate, to the Nuclear Regulatory Commission at the address indicated on the draft. An application fee of \$2,100 needs to be submitted as well.

If you have any questions or receive any correspondence from the NRC, do not hesitate to contact the office of Krueger-Gilbert Health Physics, Inc.

Sincerely,



Matt Lucas
Health Physicist

ITEM 7

7.1 Radiation Safety Officer

Frank DiGregorio

Documentation of training and experience for the above individual can be referenced under NRC license number 07-30790-01, Molecular Imaging Services, Inc.

7.2 Authorized Users

Ishtiaq A. Malik, M.D.

Documentation of training and experience for the above individual is enclosed on NRC Form 313A.

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
N/A		

* 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)
N/A			

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.
☒ N/A of _____ the RSO for License No. _____

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 _____
☒ N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);
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) _____
☒ N/A under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

NRC FORM 312A
(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 materials safely and performing related surveys	Diwakar Jain, M.D.	Drexel University College of Medicine	10/05 -02/06
Performing quality control procedures on dose calibrators and survey meters	"	"	" 10-6-05 10-7-05
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	"	" 10/13/05 10/20/05
Using procedures to safely contain spilled radioactive material and using proper decontamination procedures	"	"	" 10/27/05 10/31/05
Administering dosages of radioactive drugs to patients	"	"	" 11/3/05 11/10/05
Eluting generator systems for preparation of radioactive drugs, testing eluate for purity, and processing elute with reagent kits	"	"	" 11/17/05 11/24/05

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
Tc-99m	myocardial imaging	100	Diwakar Jain, M.D.	Drexel University	10/05 - 02/06
					12/1/06 12/8/06
					12/15/06 12/22/06
					12/29/06 1/5/06
					1/12/06 1/26/06
					2/2/06 2/16/06

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

Diwakar Jain, 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) 290

D. Address

245 N. 15th Street, Department of Cardiology
Drexel University College of Medicine
Philadelphia, PA 19102

E. Materials License Number

37-00485-01

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).

I attest the individual named in Item 1:

11a.



has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 290 (c)(1)(ii)
as documented in section(s) 6a & 6b 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

N/A

types of use, as documented in section(s) of this form.

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 myocardial 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 290 (c)(1)(ii) 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): myocardial perfusion

A. Address

245 N. 15th Street, Department of Cardiology
Drexel University College of Medicine
Philadelphia, PA 19102

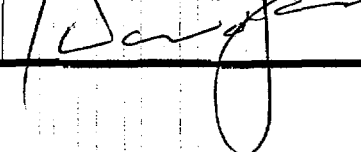
B. Materials License Number

37-00485-01

C. NAME OF PRECEPTOR (print clearly)

Diwakar Jain, M.D.


D. SIGNATURE -- PRECEPTOR



E. DATE

08/23/2006

NRC FORM 313A (10-2005)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008	
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION			
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) Ishtiaq A. Malek, 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 5c (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	March 7, 2004
Radiation Protection	Health & Radiological Seminars, Inc.	30	March 7, 2004
Mathematics Pertaining to the Use and Measurement of Radioactivity	Health & Radiological Seminars, Inc.	20	March 7, 2004
Radiation Biology	Health & Radiological Seminars, Inc.	20	March 7, 2004
Chemistry of Byproduct Material for Medical Use	Health & Radiological Seminars, Inc.	30	March 7, 2004
OTHER			

NRC FORM 313 (10-2005) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (7-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollections@nrc.gov , and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.			
APPLICATION FOR MATERIAL LICENSE					
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.					
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20355-0001		IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352			
ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19408-1415		ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-4005			
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.					
1. THIS IS AN APPLICATION FOR (Check appropriate item) <input checked="" type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____		2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) Ishtiaq A. Malik, M.D. Physician Office Building (POB), North Tower, Suite 3000 106 Irving Street, NW Washington DC 20010			
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED Physician Office Building (POB), North Tower, Suite 3000 106 Irving Street, NW Washington DC 20010		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Ishtiaq A. Malik, M.D. TELEPHONE NUMBER (703) 906-6160			
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.					
5. RADIOACTIVE MATERIAL a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.		6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.			
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.		8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.			
9. FACILITIES AND EQUIPMENT.		10. RADIATION SAFETY PROGRAM.			
11. WASTE MANAGEMENT.		12. LICENSE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7C AMOUNT ENCLOSED \$ 2,100.00			
13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 38, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 748 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.					
CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE Ishtiaq A. Malik, M.D. <i>PC</i> <i>President</i>		SIGNATURE  DATE <i>06/28/2008</i>			
FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

§ 35.50 Training for Radiation Safety Officer.

§ 35.50 Training for Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.290, 35.390, or, before October 24, 2005, §§ 35.920, or 35.930; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material involving the following--

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; or

(2) [Reserved]

(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as

Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and,

(d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) or (c)(2) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(e) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

§ 35.290 Training for imaging and localization studies.

§ 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under § 35.390 and meets the requirements in § 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16364, Mar. 30, 2005]



Health & Radiological Seminars, Inc.

Hereby certifies that

Ishtiq 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

Shannon R. Saville
Course Coordinator

March 7, 2004

David J. Goodenough

David J. Goodenough, Ph.D.
Scientific Advisor