

INDIANA UNIVERSITY

March 23, 2011

IU 
MEDICAL
GROUP

U. S. Nuclear Regulatory Commission
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Sir or Madam:

Krannert Institute of Cardiology would like to amend its NRC Byproduct Materials License, Number 13-32435-01, to add Ronald Mastouri, M.D. as an Authorized User of materials licensed under 10 CFR 35.100 and 35.200. Enclosed is NRC Form 313A(AUD) documenting Dr. Mastouri's training and experience.

If there are any questions concerning this license amendment, please contact Patrick Byrne, DABR, CHP, DABSNM at 877-317-5811.

Sincerely,



Angela Rinehart
Service Line Administrator- Cardiology
Phone: 317-962-0575

DEPARTMENT OF MEDICINE

KRANNERT INSTITUTE
OF CARDIOLOGY

1801 North Senate Boulevard
M.P.C.II, Suite 4000
Indianapolis, Indiana 46202

317-962-0500
Fax: 317-962-0501

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NRC FORM 313A (AUD)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, and 35.590]APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User

Ronald A. Mastouri, M.D.

State or Territory Where Licensed

Indiana

Requested Authorization(s) (check all that apply)

☒ 35.100 Uptake, dilution, and excretion studies☒ 35.200 Imaging and localization studies☐ 35.500 Sealed sources for diagnosis (specify device _____)**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. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

☐ **2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

- a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
- b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the 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			

Total Hours of Experience:

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

☐ 35.290☐ 35.390 + generator experience in 32.290(c)(1)(ii)(G)

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U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☒ 3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Institute for Nuclear Medical Education Indianapolis, Indiana	40	March 4-7, 2010 May 13-16, 2010
Radiation protection	Institute for Nuclear Medical Education Indianapolis, Indiana	12	March 4-7, 2010 May 13-16, 2010
Mathematics pertaining to the use and measurement of radioactivity	Institute for Nuclear Medical Education Indianapolis, Indiana	8	March 4-7, 2010 May 13-16, 2010
Chemistry of byproduct material for medical use (not required for 35.590)	Institute for Nuclear Medical Education Indianapolis, Indiana	12	March 4-7, 2010 May 13-16, 2010
Radiation biology	Institute for Nuclear Medical Education Indianapolis, Indiana	8	March 4-7, 2010 May 13-16, 2010
Total Hours of Training: 80			

- b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience		Total Hours of Experience: 650	
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	Krannert Institute of Cardiology/13-32435-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/08 to 12/10
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Krannert Institute of Cardiology/13-32435-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/08 to 12/10

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages	Krannert Institute of Cardiology/13-32435-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/08 to 12/10
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Krannert Institute of Cardiology/13-32435-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/08 to 12/10
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Krannert Institute of Cardiology/13-32435-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/08 to 12/10
Administering dosages of radioactive drugs to patients or human research subjects	Krannert Institute of Cardiology/13-32435-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/08 to 12/10
Eluting generator systems appropriate for the 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	Cardinal Health/34-29200-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/25/11

Supervising Individual

Jothihran Mahenthiran, M.D.

License/Permit Number listing supervising individual as an
authorized user

13-32435-01

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).

☐ 35.190 ☒ 35.290 ☐ 35.390 ☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

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U.S. NUCLEAR REGULATORY COMMISSION

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. (Not required to meet training requirements in 35.590)

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 use requested:

For 35.190

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in

Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

☒ I attest that Ronald Mastouri has satisfactorily completed the 60 hours of training and

Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in

Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

☒ I attest that Ronald Mastouri has satisfactorily completed the 700 hours of training

Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

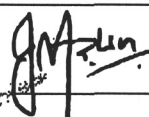
Complete the following for preceptor attestation and signature:

☒ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:☐ 35.190☒ 35.290☐ 35.390☐ 35.390 + generator experience

Name of Preceptor

Jothiharan Mahenthiran, M.D.

Signature



Telephone Number

317 621 8500

Date

3/15/2011

License/Permit Number/Facility Name

13-32435-01/Krannert Institute of Cardiology

Kramment Institute of Cardiology
1801 N Senate
MPC 2, Suite 4000
Indianapolis, IN 46202

Att: Sheri Stricker (Nuclear Dept)

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