



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
HEADQUARTERS, USA MEDICAL DEPARTMENT ACTIVITY
126 MISSOURI AVENUE
FORT LEONARD WOOD, MISSOURI 65473-8952

March 26, 2010

Health Physics Service

U.S. Nuclear Regulatory Commission, Region III
Nuclear Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Sir or Madam:

Request that NRC License 24-15095-01 be amended with the following changes: Add Dr. Mustafa Ali-Khan as an Authorized User under 10 CFR 35.400, enclosed is his preceptor attestation. This was approved by the facility's Radiation Control Committee.

Point of contact for this action is Captain Shannon J. Malloy, Radiation Safety Officer, commercial phone (573) 329-1907.

Sincerely,

A handwritten signature in black ink, appearing to read "Roman Bilynsky", is written over a light blue horizontal line.

Roman O. Bilynsky, MD
Colonel, U.S. Army
Deputy Commander for Clinical Services
Chairman, Radiation Control Committee

Enclosure

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**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

Mustafa Ali-Khan, MD

State or Territory Where Licensed

Missouri

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)

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	National Naval Medical Center 8901 Wisconsin Avenue Bethesda, Maryland 20889-5600	25	02/23/2009 - 03/06/2009
Radiation protection	National Naval Medical Center 8901 Wisconsin Avenue Bethesda, Maryland 20889-5600	15	02/23/2009 - 03/06/2009
Mathematics pertaining to the use and measurement of radioactivity	National Naval Medical Center 8901 Wisconsin Avenue Bethesda, Maryland 20889-5600	10	02/23/2009 - 03/06/2009
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>	National Naval Medical Center 8901 Wisconsin Avenue Bethesda, Maryland 20889-5600	8	02/23/2009 - 03/06/2009
Radiation biology	National Naval Medical Center 8901 Wisconsin Avenue Bethesda, Maryland 20889-5600	22	02/23/2009 - 03/06/2009
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 700 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	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009

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	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009
Administering dosages of radioactive drugs to patients or human research subjects	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009
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	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009

Supervising Individual: **Sidney R. Hinds II, MD**
License/Permit Number listing supervising individual as an authorized user: **License #08-01738-02**

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.

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 Mustafa Ali-Khan, MD 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 Mustafa Ali-Khan, MD 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 Sidney R. Hinds II, MD	Signature 	Telephone Number (202) 782-0169	Date 06/30/2009
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License/Permit Number/Facility Name
License #08-01738-02 / Walter Reed Army Medical Center

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.300)
[10 CFR 35.390, 35.392, 35.394, and 35.396]

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

Name of Proposed Authorized User

State or Territory Where Licensed

Mustafa Ali-Khan, MD

Missouri

Requested Authorization(s) (check all that apply):

35.300 Use of unsealed byproduct material for which a written directive is required

OR

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

35.300 Parenteral administration of any other radionuclide for which a written directive is required

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 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 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.
- c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.
- d. Skip to and complete Part II Preceptor Attestation.

2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements (check all that apply):

35.390 35.392 35.394 35.490 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training 35.390 35.392 35.394 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	National Naval Medical Center 8901 Wisconsin Avenue Bethesda, Maryland 20899-5600	18	02/23/2009 - 03/06/2009
Radiation protection	National Naval Medical Center 8901 Wisconsin Avenue	21	02/23/2009 - 03/06/2009
Mathematics pertaining to the use and measurement of radioactivity	National Naval Medical Center 8901 Wisconsin Avenue Bethesda, Maryland 20889-5600	6	02/23/2009 - 03/06/2009
Chemistry of byproduct material for medical use	National Naval Medical Center 8901 Wisconsin Avenue Bethesda, Maryland 20899-5600	15	02/23/2009 - 03/06/2009
Radiation biology	National Naval Medical Center 8901 Wisconsin Avenue	20	02/23/2009 - 03/06/2009
Total Hours of Training:		80	

b. Supervised Work Experience 35.390 35.392 35.394 35.396

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

Supervised Work Experience		Total Hours of Experience: 700	
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	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009
Calculating, measuring, and safely preparing patient or human research subject dosages	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2004 - 06/30/2009

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience (continued)

Supervising Individual: **Sidney R. Hinds II, MD**
License/Permit Number listing supervising individual as an authorized user: **License #08-01738-02**

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:

- 35.390 With experience administering dosages of:
- 35.392 Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- 35.394 Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- 35.396 Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience

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

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	7	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	07/01/2004 - 06/30/2009
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	3	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	07/01/2004 - 06/30/2009
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required	0	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	07/01/2004 - 06/30/2009
Parenteral administration of any other radionuclide for which a written directive is required	0	Walter Reed Army Medical Center Nuclear Medicine / Nuclear Pharmacy License #08-01738-02	07/01/2004 - 06/30/2009
(List radionuclides)			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Sidney R. Hinds II, MD	License #08-01738-02

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:

- 35.390 With experience administering dosages of:
- 35.392 Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- 35.394 Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- 35.396 Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

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 35.390:

Board Certification

I attest that _____ has satisfactorily completed the training and experience requirements in 35.390(a)(1).
Name of Proposed Authorized User

OR

Training and Experience

I attest that Mustafa Ali-Khan, MD has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).
Name of Proposed Authorized User

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that Mustafa Ali-Khan, MD has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that Mustafa Ali-Khan, MD has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

I attest that Mustafa Ali-Khan, MD has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Third Section

I attest that Mustafa Ali-Khan, MD has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

- Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

- Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.390 35.392 35.394 35.396

I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor Sidney R. Hinds II, MD	Signature 	Telephone Number (202) 782-0169	Date 06/30/2009
License/Permit Number/Facility Name License #08-01738-02 / Walter Reed Army Medical Center			

Commander
USA MEDDAC ATTN: MCXP PMD RP
126 Missouri Ave (Box 1232)
Fort Leonard Wood MO 65473-8952



U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIAL LICENSING BRANCH
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