

Sang O. Lee, M.D.  
81 Northfield Avenue, Suite 102  
West Orange, NJ 07052

July 10, 2006

Mr. Steven Courtmanche  
Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
United States Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, Pennsylvania 19406-1415

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REGION I  
2006 AUG -2 AM 9:39

**Re: License Number: 29-30982-01**  
**Mail Control Number: 138901 - Additional Information**

Dear Mr. Courtmanche:

In reference to your letter dated June 13, 2006, I am providing the following information for your appropriate actions concerning the license number 29-30982-01, mail control number 138901:

Item 1 and 2:

A revised NRC Form 313 A is submitted documenting the changes in Items 5, 6a, and/or 6 b for 700 hours of training.

A separate attestation statement documenting concerning training for Tc-99m/Mo-99 generator by a nuclear pharmacy is attached.

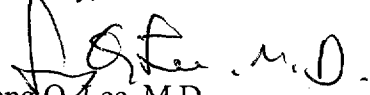
Item 3: The corporate name and address for the licensee is as follows:

Iftexhar Kadri, M.D., F.A.C.C.  
81 Northfield Ave, Suite 102  
West Orange, NJ 07052

Please call me at 973-736-2600, or Mr. Venkata Lanka, Consulting Physicist at 908-788-4931/973-972-5305, if any additional information is required.

Thank you for your assistance and cooperation in this regard.

Sincerely,

  
Sang O. Lee, M.D.

C: File

138901  
NRC/RGN MATERIALS-002

**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)

IFTEKHAR KADRI, M.D., F.A.C.C.

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

NEW JERSEY

**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	INSTITUTE FOR NUCLEAR MEDICINE EDUCATION	100	FEB 1 <sup>st</sup> 2006 COMPLETED
Radiation Protection	"		"
Mathematics Pertaining to the Use and Measurement of Radioactivity	"		"
Radiation Biology	"		"
Chemistry of Byproduct Material for Medical Use	"		"
OTHER			

## MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

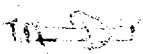

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
ALL ASPECTS OF TECHNICAL WORK IN NUCLEAR CARDIOLOGY INCLUDING: STRESS, ADMINISTRATION OF RADIO-PHARMACEUTICALS, GAMMA CAMERA IMAGING, CAMERA Q.C. HOT LAB ELUTION AND PREPARATION OF RADIO-PHARMACEUTICALS LAB	DR. SANG O. LEE, M.D.	81 NORTHFIELD AVE SUITE 102 WESTORANGE NJ 29-30982-01	FEB-2005 TO JUNE 2006 400 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
<sup>99m</sup> Tc	RESTING CARDIAC & STRESS IMAGING	220	SANG O. LEE, M.D.	81 NORTHFIELD AVE SUITE 102 WESTORANGE, NJ 29-30982-01	FEB-2005 TO JUNE 2006 300 HOURS

## 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
		
 CERTIFICATE ENCLOSED		

\* 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) \_\_\_\_\_

## 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

SANG O. LEE, 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)

for medical uses in Part 35, Section(s)

D. Address

81 NORTH FIELD AVE  
SUITE 102  
WEST ORANGE, NJ

E. Materials License Number

29-30982-01

## 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) 35.290  
as documented in section(s) 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 IMAGING & LOCALIZATION 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 35.390 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):

A. Address

SANG O. LEE, M.D.  
81 NORTH FIELD AVE; SUITE 102  
WEST ORANGE, NJ

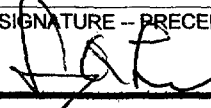
B. Materials License Number

29-30982-01

C. NAME OF PRECEPTOR (print clearly)

SANG O. LEE

D. SIGNATURE - PRECEPTOR



E. DATE

7/15/06

June 30, 2006

Iftekhhar Kadri, M.D.  
81 Northfield Ave, Suite 102  
West Orange, NJ 07052

Subject: Authorized User Training


To Whom It May Concern:

This letter is to inform the interest party of items observed at Mallinckrodt nuclear pharmacy in Pine Brook, NJ on 06/29/2006 by Iftekhhar Kadri, M.D. Iftekhhar Kadri, M.D. has observed elution of Ultra-TechneKow DTE generator manufactured by Mallinckrodt Inc. Iftekhhar Kadri, M.D. observed following items during the radio pharmacy visit at Mallinckrodt nuclear pharmacy in Pine Brook, NJ:

- Molybdenum-99m Breakthrough test / Alumina Breakthrough test
- Preparation of radiopharmaceutical cold kit
- Dispensing of a radiopharmaceutical dose
- Packaging and monitoring of a simulated incoming and outgoing radioactive package
- Segregation of radioactive waste

Please contact Yogesh Patel at (800) 261-0811 with any questions or concerns.

Sincerely,

  
Yogesh Patel, PharmD  
Pharmacy Manager – Pine Brook, NJ Facility  
Tyco Healthcare / Mallinckrodt Inc.