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

MS16 K-4

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

## 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 29-30982-0, mail control number 138901:

Item1 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:

Iftekhar 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,  $\frac{1}{2}$   $\mathcal{M}_{\mathcal{M}}$ 

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NC FORM 313A 10-2005)	U.S. NUCLEAR REGULATOR		· · · · · · · · · · · · · · · · · · ·
MEDICAL USE TR	RAINING AND EXPERIENCE EPTOR ATTESTATION		APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008
Note: Descriptions of training and e criteria in the applicable regul	PART I TRAINING AND EXPER xperience must contain sufficient deta ation (10 CFR Part 35)		raining and experience
1. Name of Individual, Proposed Authoriz (e.g., 10 CFR 35.50)	ation (e.g., Radiation Safety Officer), and EKHAR KADRI, M		
2. For Physicians, Podiatrists, Dentists, P N	harmacists – State or Territory Where Lie EW JERSEY	zensed	
	3. CERTIFICATION	· · ·	
<ul> <li>Provide a copy of the board certific continue if applying under other su</li> </ul>	ibparts.)		-
<ol> <li>Provide documentation in appropri 35.51(c); 35.290(c)(1)(ii)(G) for AU 35.590(c); or 35.690(c).</li> </ol>	ate items 4 through 10 of training or o seeking 35.200 authorization; 35.39	clinical case wor 0(b)(1)(ii)(G); 35	k required by 35.50(e); .396(d)(1) and 35.396(d)(2);
c. Provide completed Part II Precepto	or Attestation, Items 11a through 11d.		
Stop here after completing items 3 experience requirements.	a, 3b, and 3c when using board certif	ication to meet	10 CFR Part 35 training and
A INDIVIDUALS IDENTIFIED	ON A LICENSE OR PERMIT AS RA	DIATION SAF	ETY OFFICERS (RSO),
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AUTHORIZED US AUTHORIZED NUCLEAI	oadscope permit listing the current au	thorization and	(b) or (c)
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6	b. SUPERVISED CLIN	NICAL CASE E	XPERIENCE (describe ex	perience elements in 6	a)
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RC FORM 313A MEDICAL USE	TRAINING AND EXPER	IENCE AND PRECEPTO	U.S. NUCLEAR REGULATORY COMMISSIO R ATTESTATION (continued)
		NS 35.50(e), 35.51(c), 35.	
Training Elemen	it Typ	e of Training *	Location and Dates
111-52			
	in the second se	4	
CERTIFICATI	E ENCLOSED		
Types of training may incluvendor training.	ide supervised (complete	item 10 for 35.50(e), 35.5	1(c), and 35.690(c)), didactic, or
7. FORMAL TRAINING	Physicians (for use	s under 35.400 and 35.60	00) and Medical Physicists
Degree, Area of Study or Residency Program	Name of Program a 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)
NIA			
8. RADIA	TION SAFETY OFFICE	R (RSO) ÖNE-YEAR FU	ILL-TIME EXPERIENCE
.*		,	identified in item 6a) under supervison.
N/A of		the RSO for License	• No
9. MEDICA	AL PHYSICIST ONE-Y	EAR FULL-TIME TRAINI	NG/WORK EXPERIENCE
	ear of full-time training (fo dical physics (35,51) und		a) in therapeutic radiological physics
	al physicist (35.961) or m	neets requirements for Aut	horized Medical Physicists (35.51);
		and	
	ear of full-time work evne		ng radiation therapy services described
	dentified in item 6a) for (s	specify use or device)	
	dentified in item 6a) for (s		a medical physicist (35.961) or meets

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NRC FORM 313A	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 B. Supervisor is:						
SANS OILEE, M.D. Authorized User	Authorized Medical Physicist					
X Radiation Safety Officer	Authorized Nuclear Pharmacist					
C. Supervisor meets requirements of Part 35, Section(s)						
for medical uses in Part 55, Section(s)	E Motoriolo Licence Mumber					
D. Address	E. Materials License Number					
SUITE 102						
WESTORANSE, NJ	29-30982-01					
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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).						
l attest the individual named in Item 1:						
has satisfactorily completed the requirements in Part 35, Section(s) a	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						
N/A types of use, as documented in section(s) of this						
 11c.						
has achieved a level of competency sufficient to independently operation	ate a nuclear pharmacy (for 35.980); <b>O</b>					
has achieved a level of competency sufficient to function independent	tly as an authorized					
USER for IMASING & LUC	uses (or units); OF					
has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety						
Officer for a medical use licensee ; <b>Of</b>						
11d.						
I am an Authorized Nuclear Pharmacist; <b>OF</b> I am a Radiation S	Safety Officer; <b>Or</b>					
I meet the requirements of <u>35.390</u> section(s	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 B	. Materials License Number					
SANS O'LEE, M.D.	. Materiais Liverise Muniber					
SANS O.LEE, M.D. 81 NORTHFIELDAVE; SUTTEN2						
WEST ORAWSE, NJ	29-30982-01					
C. NAME OF PRECEPTOR (print clearly) D. SIGNATURE PRECEPTOR	E. DATE					
SANS O.LEE FLAT	7/15/06					
	PAGE 4					

**tyco** Healthcare

Mallinckrodt

Mallinckrodt Inc. 26 Chapin Road, Unit 1110 P.O. Box 671 Pine Brook, NJ 07058

Tele: 973 227-0179 Fax: 973 227-0678 www.mallinckrodt.com

June 30, 2006

Iftekhar 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 Iftekhar Kadri, M.D. Iftekhar Kadri, M.D. has observed elution of Ultra-TechneKow DTE generator manufactured by Mallinckrodt Inc. Iftekhar 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

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- 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.