

October 23, 2006

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Dennis R. Lawyer
Health Physicist, Commercial and R&D Branch
Division of Nuclear Materials Safety, Region 1
Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Mr. Lawyer,

Re: License # 29-28330-01

03030943

We would like to apply for an amendment of our radioactive license # 29-28330-01 to include **Dr. Louis Fusilli** as one of our authorized users for 10 CFR 35.100 and 200 materials. We are enclosing the following documents to support this application:

1. Certificate of his didactic training from the Institute for Nuclear Medical Education
2. A preceptor attestation of his practical & clinical experience with radiation signed by myself as an authorized user
3. A preceptor attestation and a letter of his practical experience with radiation specific to eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, etc. signed by an authorized nuclear pharmacist.

If you have further question, please call our consulting physicist, Jessie Z. Trivino, M.S. at (201) 906-1803. Thank you very much for your immediate attention.

Sincerely,

John Capitanelli, M.D.
Medical Director and RSO

Encls.

139668
NMSS/RGN! MATERIALS-002

A Division of Cardiology Associates

999 McBride Avenue, West Paterson, New Jersey 07424 973-256-8106

FUNDAMENTALS
Radioisotope Handling
Attestation and Certification
Completion and Competency

This document is an affidavit that

Louis D. Fusilli, M.D.

*has successfully completed the prescribed didactic program of
education and has achieved the objectives of this program
as evidenced by written examination*




Certifying Official

This Program provides the following levels of documented accomplishment

- 100 Continuing Education Units (CEU)
- 100 Didactic Instructional Hours (DIH)
In compliance with 10CFR35/AEA 73-689
- 100 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, ABR, ABNM, CBNC

26 March 2006

Date Completed

203758

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the American Council on Education (ACE), recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

INME1132-Class I-Comp&Comp 1/00

NRC FORM 313A (04-2005)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005	
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) <div style="text-align: center; font-family: cursive;">DR. LOUIS D. FUSILLI</div>			
2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed <div style="text-align: center; font-family: cursive;">NEW JERSEY</div>			
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			
Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	INSTITUTE FOR NUCLEAR MEDICAL EDUCATION		DATE COMPLETED
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity		100	MAR. 26, 2006
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
OTHER			

APPENDIX B

NRC FORM 313A
(04-2005)

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 & UNPACKING RADIOACTIVE MATERIALS SAFELY & PERFORMING RELATED RADIATION SURVEYS	JOHN CAPITANELLI, M.D.	NORTH JERSEY NUCLEAR DIAGNOSTIC CENTER # 29-28330-01	750 HRS
- PERFORMING QC PROCEDURES ON DOSE CALIBRATOR & SURVEY METER	"	"	
- CALCULATING, MEASURING, & SAFELY PREPARING PATIENT DOSAGES	"	"	
- ADMINISTRATIVE CONTROLS TO PREVENT MEDICAL EVENTS	"	"	
- DECONTAMINATION OF RADIOACTIVE SPILLS	"	"	
- ADMINISTERING DOSAGES OF RADIOPHARMACEUTICALS TO PATIENTS	"	"	

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	CARDIAC STRESS TESTS	350	DR. JOHN CAPITANELLI	NORTH JERSEY NUCLEAR DIAGNOSTIC CENTER # 29-28330-01	700 HRS
Tl-201					

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NRC FORM 313A
(04-2005)

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 Numbers	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 N/A 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
- ☐ N/A (35.961) or medical physics (35.51) under the supervision of _____
- N/A and
- ☐ YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and
- ☐ N/A for topics identified in item 6a) for (specify use or device) _____ 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 313A
(04-2005)

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 35, provide the following information for each):

A. Name of Supervisor

B. Supervisor is:

JOHN CAPITANELLI, M.D.☒ Authorized User☐ Authorized Medical Physicist☒ Radiation Safety Officer☐ Authorized Nuclear PharmacistC. Supervisor meets requirements of Part 35, Section(s) 190, 290, 990for medical uses in Part 35, Section(s) 100, 200, 500

D. Address

E. Materials License Number

29-28330-1**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 the 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) _____,
as documented in section(s) 6A + 6B of this form.

11b. Select one

N/A

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 operate a nuclear pharmacy (for 35.980); **or**



has achieved a level of competency sufficient to function independently as an authorized
_____ for _____ 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 _____ 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 999 MCBRIDE AVE.
WEST PATERSON, NJ 07624

B. Materials License Number

29-28330-01

C. NAME OF PRECEPTOR (print clearly)

JOHN CAPITANELLI, M.D.

D. SIGNATURE -- PRECEPTOR

E. DATE

10/23/06

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APPENDIX B

<p>NRC FORM 315A (04-2003)</p>	<p>U.S. NUCLEAR REGULATORY COMMISSION</p>	<p>APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005</p>	
<p>MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION</p>			
<p>PART I - TRAINING AND EXPERIENCE</p>			
<p>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).</p>			
<p>1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)</p> <p style="margin-left: 40px;">DR. LOUIS FUSILLI, AUTHORIZED USER, 10 CFR 190, 10 CFR 290</p>			
<p>2. For Physicians, Podiatrists, Dentists, Pharmacists - State or Territory Where Licensed</p>			
<p>3. CERTIFICATION</p>			
<p>a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(e); continue if applying under other subparts.)</p>			
<p>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).</p>			
<p>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.</p>			
<p>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</p>			
<p>a. Provide a copy of the license or broadscope permit listing the current authorization and (b) or (c)</p>			
<p>b. Complete items 8c (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 AMP under 35.51(c).</p>			
<p>c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).</p>			
<p>5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical)</p>			
Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	N/A		
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
OTHER			

APPENDIX B

Dr. Louis Angeli

NRC FORM 313A (04-2005)		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		
General Education + Radiopharmaceutical Preparation	YOGESH PATEL	PINE BROOK, NJ 24-04206-14 MD	6/28/06		
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
N/A					

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APPENDIX B

NRC FORM 315A (04-2005)		U.S. NUCLEAR REGULATORY COMMISSION	
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)			
5c. 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 Numbers	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 N/A (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

☐ N/A (35.961) or medical physics (35.51) under the supervision of N/A and

☐ YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and

☐ N/A for topics identified in item 6a) for (specify use or device) _____ under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____.

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APPENDIX B

NRC FORM 313A (04-2003)		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 35, provide the following information for each):			
A. Name of Supervisor <u>YOGESH PATEL</u>	B. Supervisor is: <input type="checkbox"/> Authorized User <input type="checkbox"/> Authorized Medical Physicist <input type="checkbox"/> Radiation Safety Officer <input checked="" type="checkbox"/> Authorized Nuclear Pharmacist		
C. Supervisor meets requirements of Part 35, Section(s) _____ for medical uses in Part 35, Section(s) _____ <u>MALLINCKRODT, INC</u>			
D. Address <u>26 CHAPIN RD UNIT 1110</u> <u>PINE BROOK, NJ 07058</u>		E. Materials License Number <u>24-04206-14 MD</u>	
PART II - PRECEPTOR ATTESTATION <i>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 the training requirements in 35.690 or Part 35, Subpart J (except 35.980).</i>			
I attest the individual named in Item 1:			
11a. <input type="checkbox"/> has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) _____ as documented in section(s) _____ of this form.			
11b. Select one <input type="checkbox"/> meets the requirements in <input type="checkbox"/> 35.50(e), <input type="checkbox"/> 35.51(c), <input type="checkbox"/> 35.390(b)(1)(ii)(G), <input type="checkbox"/> 35.690(c) for _____ types of use, as documented in section(s) _____ of this form. <input type="checkbox"/> N/A			
11c. <input type="checkbox"/> has achieved a level of competency sufficient to operate a nuclear pharmacy (for 35.980); OR <input type="checkbox"/> has achieved a level of competency sufficient to function independently as an authorized _____ for _____ uses (or units); OR <input type="checkbox"/> has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; OR <input type="checkbox"/> N/A			
11d. <input checked="" type="checkbox"/> I am an Authorized Nuclear Pharmacist; OR <input type="checkbox"/> I am a Radiation Safety Officer; OR <input type="checkbox"/> I meet the requirements of _____ section(s) of 10 CFR Part 35 or equivalent Agreement State requirements to be a preceptor <input type="checkbox"/> AU or <input type="checkbox"/> AMP for the following byproduct material uses (or units): _____			
A. Address <u>26 CHAPIN RD UNIT 1110</u> <u>PINE BROOK, NJ 07058</u>		B. Materials License Number <u>24-04206-14 MD</u>	
C. NAME OF PRECEPTOR (print clearly) <u>YOGESH PATEL</u>	D. SIGNATURE - PRECEPTOR 		E. DATE <u>7/11/06</u>

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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 28, 2006

North Jersey Nuclear Diagnostic
999 McBride Ave
West Paterson, NJ 07424

Subject: Authorized User Training

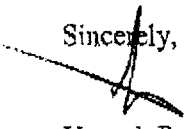
To Whom It May Concern:

This letter is to inform the interest party of items observed at Mallinckrodt nuclear pharmacy in Pine Brook, NJ on 06/28/2006 by Louis Fusilli, M.D. Louis Fusilli, M.D. has observed elution of Ultra-TechneKow DTE generator manufactured by Mallinckrodt Inc. Louis Fusilli, 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.

This is to acknowledge the receipt of your letter/application dated

10/23/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 29-28330-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 139668.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.