

November 30, 2006

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

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MS-16

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REGION 1
2006 DEC -4 PM 1:04

Dear Mr. Lawyer,

Re: License # 29-28330-01

03030943

In reference to our application to amend 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 NRC Form 313A of his training and experience including his training at a radiopharmacy laboratory on molybdenum-99m breakthrough test, preparation of radiopharmaceutical cold kit, dispensing of a radiopharmaceutical dose, packaging & monitoring of a simulated incoming & outgoing radioactive package and segregation of radioactive waste.

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

Encl.

139668
NMSS/RGN MATERIALS-C02

A Division of Cardiology Associates

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

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;">DR. LOUIS D. FUSILLI</div>			
2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed <div style="text-align: center;">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	100	March 26, 2006
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
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	John Capitanelli, M.D.	Mallinckrodt, Inc. Pine Brook, NJ #24-04206-14MD	6/26/06
- Observed the following items during the radiopharmacy visit: molybdenum-99m breakthrough test, preparation of radiopharmaceutical cold kit, dispensing of a radiopharmaceutical dose, packaging & monitoring of a simulated incoming & outgoing radioactive package, segregation of radioactive waste			

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	John Capitanelli, M.D.	North Jersey Nuclear Diagnostic Center # 29-28330-01	700 hrs
Tl-201					

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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

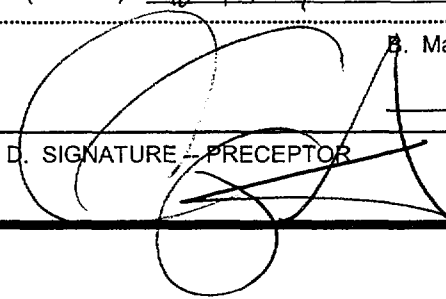
☐ YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics
N/A

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

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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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>John Capitanelli, M.D.</u>	B. Supervisor is: <input checked="" type="checkbox"/> Authorized User <input checked="" type="checkbox"/> Radiation Safety Officer <input type="checkbox"/> Authorized Medical Physicist <input type="checkbox"/> Authorized Nuclear Pharmacist
C. Supervisor meets requirements of Part 35, Section(s) <u>190, 290, 990</u> for medical uses in Part 35, Section(s) <u>100, 200, 500</u>	
D. Address	E. Materials License Number <u>29-28330-1</u>
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. <input type="checkbox"/> has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) _____, as documented in section(s) <u>6A & 6B</u> 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 checked="" 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 checked="" type="checkbox"/> N/A	
11d. <input type="checkbox"/> I am an Authorized Nuclear Pharmacist; or <input type="checkbox"/> I am a Radiation Safety Officer; or <input checked="" type="checkbox"/> I meet the requirements of <u>190, 290, 990</u> section(s) of 10 CFR Part 35 or equivalent Agreement State requirements to be a preceptor <input checked="" type="checkbox"/> AU or <input type="checkbox"/> AMP for the following byproduct material uses (or units): <u>100, 200, 500</u>	
A. Address <u>999 McBride Ave</u> <u>West Paterson, NJ 07424</u>	B. Materials License Number <u># 29-28330-01</u>
C. NAME OF PRECEPTOR (print clearly) <u>JOHN CAPITANELLI, M.D.</u>	D. SIGNATURE -- PRECEPTOR 
E. DATE <u>11/30/2006</u>	