



# Health

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December 13, 2005

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RECEIVED

License Assistance Team  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission  
475 Allendale Road  
King of Prussia, PA 19406-1415

**Re: Materials License # 29-01663-01  
Docket # 030-02439**

Dear Sir/Madam:

We request you to amend our license, incorporating the following changes:

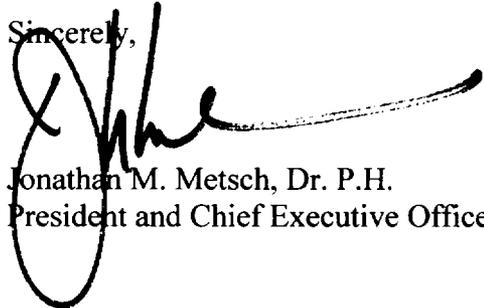
- Kindly add the following person as a second Radiation Safety Officer, Melchor D. Romero, M.D.
- Dr. Romero is an authorized user and is listed in our license.

Kindly note that we are requesting this change as an addition and not as a substitute for John V. Cholankeril, M.D., who still remains as our primary Radiation Safety Officer.

A copy of our license is enclosed.

Thank you for your attention to this matter.

Sincerely,

  
Jonathan M. Metsch, Dr. P.H.  
President and Chief Executive Officer

138112  
NMSS/RGNI MATERIALS-002

## Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

### Model RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license (see Figure 8.7). Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24. Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SDR Certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to NRC, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;

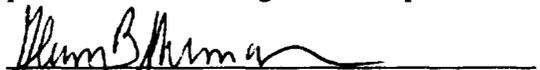
APPENDIX F

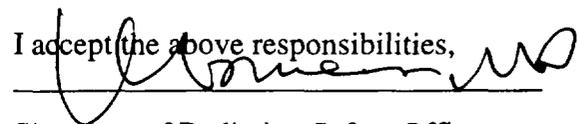
- Audits of the radiation protection program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

**Model Delegation of Authority**

Memo To: Radiation Safety Officer  
From: Chief Executive Officer  
Subject: Delegation of Authority

You, MELCTOR ROMERO, MD, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at anytime. It is estimated that you will spend 3 hours per week conducting radiation protection activities.

  
\_\_\_\_\_  
Signature of Management Representative

I accept the above responsibilities,  
  
\_\_\_\_\_  
Signature of Radiation Safety Officer

cc: Affected department heads

**MATERIALS LICENSE**

Duplicate

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Jersey City Medical Center Campus</p> <p>Radiology Department/Nuclear Medicine Division</p> <p>2. 355 Grand Street</p> <p>Jersey City, New Jersey 07302</p>	<p>In accordance with the letter dated July 29, 2005,</p> <p>3. License number 29-01663-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date September 30, 2013</p> <hr/> <p>5. Docket No. 030-02439</p> <p>Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material permitted by 10 CFR 31.11</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Prepackaged Kits</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 500 millicuries</p> <p>D. 2 millicuries</p>
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9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.

B. Any imaging and localization study permitted by 10 CFR 35.200.

C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.

D. In vitro studies.

**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at 50 Baldwin Avenue, Jersey City, New Jersey and 355 Grand Street, Jersey City, New Jersey.

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number	29-01663-01
Docket or Reference Number	030-02439
Amendment No.	53

11. The Radiation Safety Officer for this license is John V. Cholankeril, M.D.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
  - B. The following individuals are authorized users for medical use as indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
John V. Cholankeril, M.D.	35.100; 35.200; 35.300; <u>In vitro</u> studies
Anthony F. Tramontana, M.D.	35.100; 35.200; 35.300; <u>In vitro</u> studies
Manuel C. Aragoes, M.D.	35.300
[ Melchor Romero, M.D.	35.100; 35.200 ]
Mamatha R. Gowda, M.D.	35.100; 35.200
Feng Tao, M.D.	35.100; 35.200

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

Duplicate

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
29-01663-01

Duplicate

Docket or Reference Number  
030-02439

Amendment No. 53

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated July 17, 2003
- B. Letter dated September 8, 2003
- C. Letter dated January 19, 2004
- D. Letter dated March 15, 2004

For the U.S. Nuclear Regulatory Commission

Date August 18, 2005

By

*Original signed by Richard McKinley*

Richard McKinley  
Medical Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

Duplicate

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

12/13/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 29-01663-01  
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

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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** 139112.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.