

2007 APR -9 AM 10: 48



April 3, 2007

Ms. Michelle Beardsley, Senior Health Physicist  
U.S. Nuclear Regulatory Commission, Region 1  
Division of Nuclear Materials Safety  
475 Allendale Road  
King of Prussia, PA 19406-1415

MS16

J-1

03003303

**RE: Reply to Deficiency Letter**

**Application for amendment to NRC license number 45-01099-01, Control No: 140071**

Dear Ms. Beardsley:

This letter is in response to deficiency noted from the review of license amendment application dated 01/25/07 for Virginia Hospital Center, Arlington by the U.S. Nuclear Regulatory Commission, Region 1, Division of Nuclear Materials Safety. We have responded to the deficiency presented in the letter dated 03/09/07 regarding item 1 of your letter in the following manner.

As per your letter dated 03/09/07: "Regarding item No. 1 of your letter, please provide documentation confirming that the preceptor for Dr. Orange, Dr. George Sfakianakis, is an authorized user of Florida's equivalent materials to 35.100, 35.200 and 35.300."

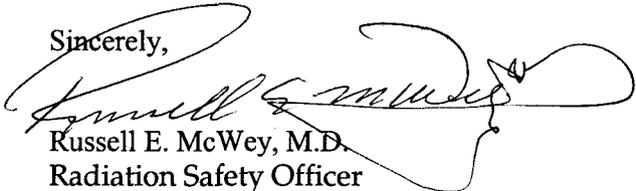
RESPONSE:

- (1) Dr. Sfakianakis is listed as an authorized user of Florida's equivalent materials to 35.100, 35.200 and 35.300 under Radioactive Materials license number 1319-1 issued by state of Florida Department of Health, Bureau of Radiation Control. A copy of this license is enclosed.

We are working on item No: 2 (a) and (b) for Dr. Sor's work experience specific to the use of I-131 and documentation of recent (within the past seven years) classroom/laboratory training applicable to medical use of sodium iodide I-131 for procedures requiring a written directive. At this point we want to pursue with the amendment request for adding Dr. Orange as an authorized user for 35.100, 35.200 and 35.300.

Please contact me should you have any additional questions concerning this matter and thank you for your attention.

Sincerely,

  
Russell E. McWey, M.D.  
Radiation Safety Officer

140071

NMSS/RGN1 MATERIALS-002

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL

**RADIOACTIVE MATERIALS LICENSE**

Pursuant to Chapter 404, Florida Statutes, and Chapter 64E-5, Florida Administrative Code (F.A.C.), and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to receive, acquire, possess and transfer the radioactive material(s) designated below and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the state of Florida, Department of Health now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Name: <b>UNIVERSITY OF MIAMI</b></p>	<p>3. License Number: <b>1319-1</b></p> <p>is hereby renewed in its entirety, with reference to application dated November 12, 2003 and correspondence dated April 8, June 2, October 27, 2004, January 27, August 19, December 20, December 21, 2005, and February 4, 2006.</p>
<p>2. Address: <b>Radiation Control Center (R-61) P. O. Box 016960 Miami, FL 33101</b></p>	<p>4. Expiration Date: <b>2/28/2011</b></p> <p>5. Category: <b>3M(2)</b></p>

6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
A. Any radioactive material described in section 64E-5.626, F.A.C.	A. Any radiopharmaceutical for diagnostic use involving measurements of uptake, dilution or excretion as described in section 64E-5.626, F.A.C.	A. As necessary
B. Any radioactive material described in section 64E-5.627, F.A.C.	B. Any radiopharmaceutical for diagnostic use involving imaging and localization as described in section 64E-5.627, F.A.C., except gases and aerosols	B. As necessary
C. Any radioactive material described in section 64E-5.630, F.A.C.	C. Any radiopharmaceutical for therapeutic use as described in section 64E-5.630, F.A.C.	C. As necessary

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6. Radioactive Material (Element And Mass Number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
D. Any radioactive material described in section 64E-5.632, F.A.C.	D. Any sealed source for brachytherapy as described in section 64E-5.632, F.A.C.	D. 2 curies
E. Technetium 99m	E. Aerosol	E. As necessary
F. Xenon 133	F. Gas	F. 600 millicuries
G. Gadolinium 153	G. Sealed source (E.I. DuPont Corp. Model NER-430 or NER-431, Gulf Nuclear Inc. Model GD-1, Amersham Corp. Model GDC-CY1, Lunar Corp. Model GD Series, or Biosources Ltd. Model OS-213A)	G. 1 source; not to exceed 1000 millicuries
H. Any radioisotope with atomic numbers between 1 and 83 inclusive	H. Any form	H. 100 millicuries total; no single isotope to exceed 25 millicuries
I. Gadolinium 153	I. Sealed sources (North American Scientific Model Number MED3601)	I. 4 sources, not to exceed 360 millicuries each
J. Cesium 137	J. Sealed sources (Isotope Products Laboratories, Model HEG-137)	J. 4 sources; not to exceed 30 millicuries each
K. Uranium 238	K. Depleted Metal	K. 120 pounds
L. Molybdenum 99/Technetium 99m	L. Solid and liquid (Molybdenum/Technetium 99m generators)	L. 7 curies

License Number: 1319-1  
Amendment No.: 42  
Control Number :20031015-1543

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9. Authorized Use:
- A. Any medical use described in section 64E-5.626, F.A.C.
  - B. Any medical use described in section 64E-5.627, F.A.C
  - C. Any medical use described in section 64E-5.630, F.A.C.
  - D. Any medical use described in section 64E-5.632, F.A.C.
  - E. To be used for pulmonary function studies as described in section 64E-5.627, F.A.C.
  - F. To be used for pulmonary function studies as described in section 64E-5.627, F.A.C.
  - G. One source for storage only.
  - H. To be used for human research in accordance with procedures submitted in application dated November 12, 2003 and correspondence dated December 20, 2005.
  - I. Two sources to be used in ADAC Scintillation Camera as a calibration and reference to perform transmission measurements to correct for nonuniform attenuation during patient studies as described in correspondence dated, February 4, 2006 and two sources for possession by the licensee for source exchanges.
  - J. To be used as a point source to in a ADAC Laboratories, Inc., gamma camera for attenuation purposes.
  - K. To be used as shielding in a ADAC gamma camera model MCD-AC as described in correspondence dated, February 4, 2006.
  - L. Production of technetium 99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals in accordance with section 64E-5.628, F.A.C., or calibration standards in accordance with sections 64E-5.617, F.A.C. This use does not include distribution.

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CONDITIONS

10. A. Licensed material may be used and stored at the following locations in Miami, Florida, owned by University of Miami:
- University of Miami / Sylvester Cancer Center, 1475 NW 12th Avenue, 33136
    - Nuclear Medicine – UMHC 1<sup>st</sup> Floor
    - PET/CT – Sylvester Clinic, Ground Floor
    - Radiation Oncology – Sylvester Clinic, Ground Floor
    - Patient's treatment rooms and other areas of temporary use approved by the RSO
  - University of Miami Bascom Palmer Eye Institute, 900 NW 17th Street, 33136
    - Patient's treatment rooms and other areas of temporary use approved by the RSO
  - University of Miami Rosenstiel Medical Science Building, 1600 NW 10th Ave., 33136
    - Storage of calibration and sealed source standards (Basement)
    - Storage of radioactive waste for decay (Basement Waste Room)
    - Human research in specific rooms approved by the RSO
- B. Licensed material may be used and stored at the following locations in Miami, Florida, not owned by University of Miami:
- Jackson Memorial Hospital (JMH), 1611 NW 12th Avenue, 33136
    - Nuclear Medicine – Central Building, 2<sup>nd</sup> Floor
    - Radiation Oncology – JMH Diagnostic Therapy Center, 1<sup>st</sup> Floor
    - Cath Labs #1 and #2 – Central Wing, 4<sup>th</sup> Floor
    - Patient's treatment rooms and other areas of temporary use approved by the RSO
  - Jackson South Community Hospital, 9333 SW 152<sup>nd</sup> Street, 33157
    - Nuclear Medicine – 1<sup>st</sup> Floor
    - Patient's treatment rooms and other areas of temporary use approved by the RSO
11. Failure to comply with the provisions of this license is a felony of the third degree pursuant to section 404.161, Florida Statutes. Also, violations may warrant an administrative fine of up to \$1,000.00 per violation per day, pursuant to section 404.162, Florida Statutes.

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12. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Human Use Radiation Safety Committee, George Sfakianakis, M.D., Chairperson. Records of such designation must be maintained for inspection by the Department of Health. Each physician approved by the Human Use Radiation Safety Committee shall meet all the requirements specified in Part VI, Subpart I, Chapter 64E-5, Florida Administrative Code (F.A.C.), for the uses approved, therein. Physicians participating in human research and are not qualified by the above must have procedures approved by the Human Use Radiation Safety Committee, Institutional Review Board and an active Food and Drug Administration Radioactive Drug Research Committee. Records of such approval must be maintained on file for inspection by the department.
- B. The following individuals or persons under their supervision are authorized for the materials and uses as indicated:

Authorized Material and Uses as Described in Items 6, 7, 8, and 9	Names
64E-5.626, 64E-5.627, 64E-5.630, 64E-5.631, and xenon 133	George Sfakianakis, M.D. Aldo N. Serafini, M.D. Shabbir H. Ezuddin, M.D. Marc P. Hickeson, M.D.
64E-5.626, 64E-5.627, 64E-5.630, and xenon 133	Mitchell Gregg, M.D. Daniel Seckinger, M.D.
64E-5.626, 64E-5.627, and xenon 133	Jeffrey Ross-Fidel, M.D. Sidney Hecht, M.D.
64E-5.632	Arnold Markoe, M.D. Aaron Wolfson, M.D. Christiane Takita, M.D. Alfred Brandon, M.D. David Huang, M.D. May Abdel-Wahab, M.D.

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12. C. The radiation safety officer is Jose M. Perez.
- D. Radiologic technologists who use and administer radioactive materials or perform brachytherapy or teletherapy procedures under the general supervision of an authorized user shall hold a valid certificate as required by Chapter 468, F.S.
- E. The authorized medical physicists for medical physicist support are individuals designated by the Human Use Radiation Safety Committee, George Sfakianakis, M.D., Chairperson. Records of such designation must be maintained for inspection by the Department of Health, Bureau of Radiation Control. Each physicist approved by the Radiation Safety Committee shall meet all the requirements specified in the Bureau of Radiation Control Information Notice 2005-01.
- F. The authorized medical physicists for medical physics support are:

Authorized Material and Uses as Described in Items 6, 7, 8, and 9	Names
64E-5.632	Elizabeth Landahl Bossart, Ph.D. Xiaodong Wu, Ph.D. Hua Shao, Ph.D. Alberto De La Zerda, Ph.D.

13. Radioactive material transported on public thoroughfares shall be packaged, prepared for shipment, and transported in accordance with Title 49, Code of Federal Regulations and Chapter 64E-5, F.A.C.
14. Sealed sources containing licensed material shall not be opened.
15. The licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:
- A. The dose rate is less than 5 millirem (50 microsieverts) per hour at a distance of 1 meter; or
- B. The amount of radioactive material in the patient is less than 30 millicuries.
- C. The patient is released under the terms of 64E-5.622(4), F.A.C. and Condition 25.
16. Licensed materials for certain in-vivo uses as described in 64E-5.206(7), F.A.C., may be used by any physician approved by the institution's radiation safety committee. A record of such approval shall be maintained for inspection by the department.

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