



One Nolte Drive • Kittanning, PA 16201

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*NMJB1*

Licensing Assistant Section  
Nuclear Materials Safety Branch  
U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

December 12, 2007

*03003023*

RE: Lic. No. 37-02569-01

Please add Dr. Frank Mino, M.D., to our license as an authorized user for uses authorized under 10 CFR 35.100, 35.200, 35.300, and 35.11.

He is currently authorized for this use under a license to the VA Pittsburgh Health Care System, Permit Number 37-01230-03.

Enclosed is documentation in support of this request.

Sincerely

John I. Lewis  
President / CEO

*141508*

NMSS/RGN1 MATERIALS-002

# Department of Veterans Affairs

Page 1 of 5 pages	<b>MATERIALS PERMIT</b>	Amendment No. 77
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In accordance with VHA Directive 1105.1 and reliance on statements made by the applicant, permission is hereby granted to receive, possess, transfer, and store radioactive materials listed below, and to use this material for the purpose and at the places listed below.

<p style="text-align: center;">Permittee</p> <p>1. VA Pittsburgh Health Care System</p> <p>2. University Drive Pittsburgh, Pennsylvania 15240</p>	<p>3. In accordance with <b>your request of October 15, 2007</b>, Permit Number 37-01230-03 is amended to read as follows:</p> <p>4. Expiration date: <b>September 30, 2014</b></p> <p>5. Docket or Reference Number: 030-02978</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. Gadolinium 153 permitted by 10 CFR 35.500</p> <p>E. Any byproduct material permitted by 10 CFR 31.11</p> <p>F. Any byproduct material with Atomic Numbers 1-83</p> <p>G. Hydrogen 3</p> <p>H. Carbon 14</p> <p>I. Sulfur 35</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed sources (Isotope Products Laboratories Model NES 8412; and NES 8426)</p> <p>E. Prepackaged kits</p> <p>F. Any</p> <p>G. Any</p> <p>H. Any</p> <p>I. Any</p> | <p>8. Maximum amount the permittee may possess at any one time under this permit</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. As needed</p> <p>D. 300 millicuries per source and 4 curies total</p> <p>E. As needed</p> <p>F. 200 millicuries of each byproduct material, 5 curies total</p> <p>G. 2 curies</p> <p>H. 500 millicuries</p> <p>I. 500 millicuries</p> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

9. Authorized Use:

- A. Any use permitted by 10 CFR 35.100.
- B. Any use permitted by 10 CFR 35.200.
- C. Any use permitted by 10 CFR 35.300.
- D. Medical use of sealed sources for diagnosis permitted by 10 CFR 35.500.
- E. *In vitro* studies permitted by 10 CFR 31.11.
- F. through I. Research and development as defined in 10 CFR 30.4, including animal studies, instrument calibration, student instruction, and *in vitro* studies.

**CONDITIONS**

10. Permitted material may be used at the permittee's facilities located at University Drive, Pittsburgh, Pennsylvania, and 7180 Highland Drive, Pittsburgh, Pennsylvania.
11. The Radiation Safety Officer for this permit is Chandrakant R. Patel, M.D.
12. Permitted material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user and/or authorized nuclear pharmacist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for the materials and uses indicated:
- | <u>Authorized User</u>      | <u>Material and Use</u>                       |
|-----------------------------|-----------------------------------------------|
| Herbert Klein, M.D., Ph.D.  | 35.100, 35.200, 35.300, 31.11, Gadolinium 153 |
| Andrew Scott La Pidos, M.D. | 35.100, 35.200, 35.300, 31.11, Gadolinium 153 |
| Frank A. Mino, M.D.         | 35.100, 35.200, 35.300, 31.11, Gadolinium 153 |
| Chandrakant R. Patel, M.D.  | 35.100, 35.200, 35.300, 31.11, Gadolinium 153 |
| Rupal Bandi, M.D.           | 35.100, 35.200, 31.11, Gadolinium 153         |
| Raymond Koku-Akwayena, M.D. | 35.100, 35.200, 31.11, Gadolinium 153         |
| Parvez Masood, MB, BS       | 35.100, 35.200, 31.11, Gadolinium 153         |
- C. **Permitted materials for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.**
13. Permitted material shall not be used in or on humans except as provided otherwise by specific condition of this permit.
14. Permitted material shall not be used in field applications where activity is released except as provided otherwise by specific condition of this permit.
15. Experimental animals, or the products from experimental animals, that have been administered permitted materials shall not be used for human consumption.
16. This permit does not authorize commercial distribution of permitted material.
17. For sealed sources not associated with 10 CFR 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified by the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. Notwithstanding Paragraph A of this permit condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. Each sealed source fabricated by the permittee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- D. In the absence of a certificate from a transferor indicating a leak test has been made within the intervals specified in the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

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- E. Sealed sources need not be tested if they contain only hydrogen 3, or they contain only a radioactive gas, or the half-life of the isotope is 30 days or less, or they contain not more than 100 microcuries of beta- and/or gamma-emitting material, or not more than 10 microcuries of alpha-emitting material.
- F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the National Health Physics Program in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Nuclear Regulatory Commission regulations.
- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the permittee or by other persons specifically licensed by the Nuclear Regulatory Commission or an Agreement State to perform such services.
18. Sealed sources containing permitted material shall not be opened or sources removed from source holders by the permittee.
19. A. The permittee shall conduct physical inventories to account for all sealed sources and/or devices received and possessed under this permit.
- (1) Quarterly, for sealed sources with either current activity greater than one millicurie or current activity greater than 1000 times the quantities in 10 CFR 20, Appendix C.
- (2) Semiannually, for all other sealed sources, except sources specifically exempted by 10 CFR 30.
- B. The permittee shall maintain records for five years from the date of each inventory and include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
- C. The permittee shall classify sealed sources, not in active use for their intended clinical or research purpose for a period of 24 months, as disused sources and evaluate the disused sources for disposal as expeditiously as possible.
- D. The permittee shall provide oversight for security of radioactive materials by:
- (1) Compliance with regulations per 10 CFR 20.1801 and 10 CFR 20.1802.
- (2) Prevention of adversary or unauthorized removal of, or access to, radioactive materials.
- (3) Use of two delay methods for sealed sources not in use.
- (4) Focus to security commensurate with possible risks of radioactive materials unauthorized use.
20. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by the Nuclear Regulatory Commission.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

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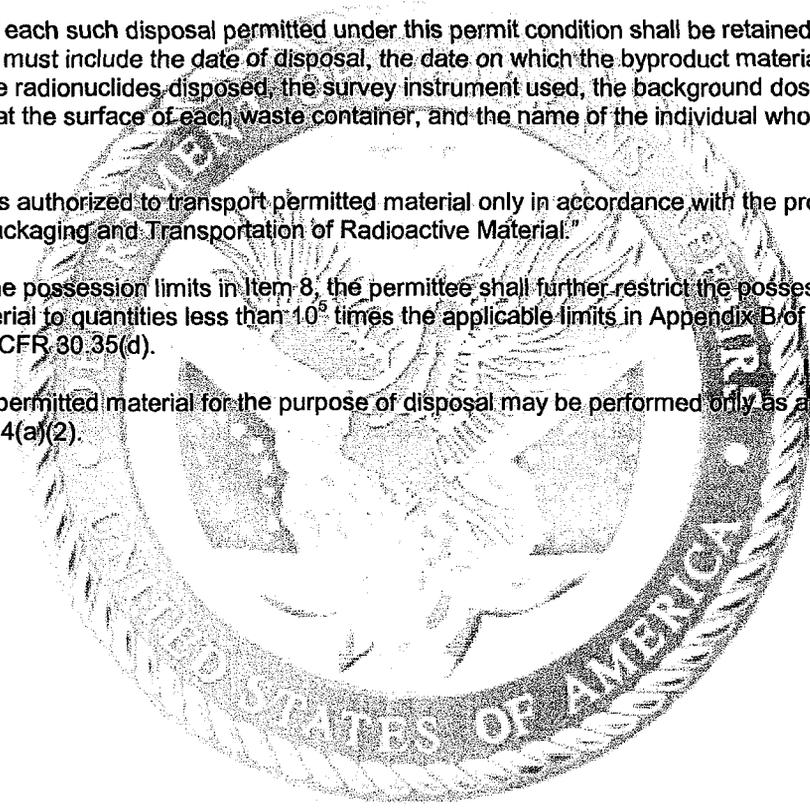
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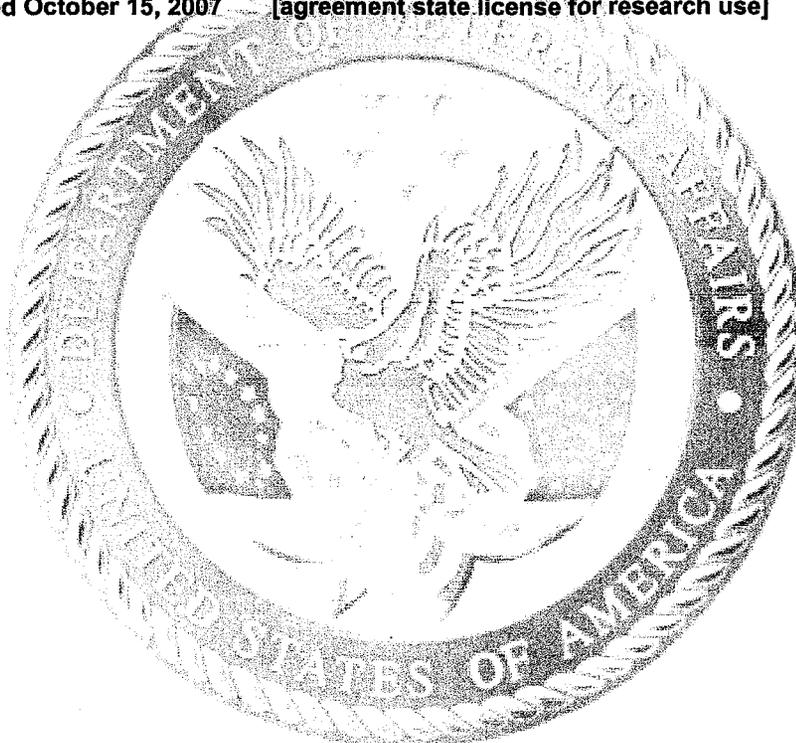
21. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Nuclear Regulatory Commission or an Agreement State to perform such services.
22. For radioactive material held for decay in storage other than that held in accordance with 10 CFR 35.92, the permittee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay in storage before disposal in ordinary trash, provided:
  - A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
  - B. A record of each such disposal permitted under this permit condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
23. The permittee is authorized to transport permitted material only in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
24. In addition to the possession limits in Item 8, the permittee shall further restrict the possession of unsealed byproduct material to quantities less than  $10^5$  times the applicable limits in Appendix B of 10 CFR 30, as specified in 10 CFR 30.35(d).
25. Incineration of permitted material for the purpose of disposal may be performed only as authorized by 10 CFR 20.2004(a)(2).



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

- A. Application dated August 30, 2004 [NHPP Form 313, with attachments]
- B. E-mail dated September 3, 2004 [additional information for renewal]
- C. Letter dated October 22, 2004 [add additional Gd-153 sources and increase maximum activity]
- D. Letter dated January 25, 2005 [add additional Gd-153 sources and medical authorized user]
- E. Facsimile dated July 31, 2007 [change RSO to Dr. Patel]
- F. E-mail dated October 15, 2007 [change in area of use and delete Cs-137 source]
- G. E-mail dated October 15, 2007 [agreement state license for research use]



**FOR THE DEPARTMENT OF VETERANS AFFAIRS**

Date OCT 29 2007

By *E. Lynn McGuire*  
E. Lynn McGuire  
Director, National Health Physics Program  
North Little Rock, Arkansas

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

12/12/2007, and to inform you that the initial processing which includes an administrative review has been performed.

Amend. 37-02569-01 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** 141508.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)  
(6-96)

Sincerely,  
Licensing Assistance Team Leader