



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 25 2005

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

030-04544

05 JAN 26 PM 2:41

RECEIVED  
REGION 1

Subject: Renewal of License 19-07538-01

Dear Sir or Madam:

Enclosed are two copies of NRC Form 313 and attachments renewing license number 19-07538-1.

The license renewal is being submitted in an amendment format, as a result of a January 3, 2005 telephone conversation between Mr. Petro Shandruk, CDRH Radiation Safety Officer and Ms. Betsy Ullrich, Senior Health Physicist of NRC's Nuclear Materials Safety Branch 2. It was agreed that our current license contained a limited number of changes over its current span and that the minor changes in its renewal could permit the abbreviated format.

Sincerely Yours,

Lillian J. Gill  
Senior Associate Director  
Center for Devices and  
Radiological Health

Enc: License renewal  
(2 copies)

136339  
NMS/REGNI MATERIALS-032

NRC FORM 313  
(4-2004)  
10 CFR 30, 32, 33,  
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2005

Estimated burden per response to comply with this mandatory collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY  
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM  
DIVISION OF NUCLEAR MATERIALS SAFETY  
U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TX 76011-4005

03004544

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input checked="" type="checkbox"/> C. RENEWAL OF LICENSE NUMBER <u>19-07538-01</u></p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</p> <p>Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health 9200 Corporate Blvd. Rockville, MD 20850</p>
<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>12709 Twinbrook Parkway, Rockville, MD 20857 12720 Twinbrook Parkway, Bldgs, 1 &amp; 2, Rockville, MD 20857 10903 New Hampshire Ave., Silver Spring, MD</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>PETRO SHANDRUK</p> <p>TELEPHONE NUMBER</p> <p>(301) 827-1231</p>

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>				
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>				
<p>9. FACILITIES AND EQUIPMENT.</p>	<p>10. RADIATION SAFETY PROGRAM.</p>				
<p>11. WASTE MANAGEMENT.</p>	<p>12. LICENSE FEES (See 10 CFR 170 and Section 170.31)</p> <table border="1"> <tr> <td>FEE CATEGORY</td> <td>Exempt Federal</td> <td>AMOUNT ENCLOSED</td> <td>\$ 0.00</td> </tr> </table>	FEE CATEGORY	Exempt Federal	AMOUNT ENCLOSED	\$ 0.00
FEE CATEGORY	Exempt Federal	AMOUNT ENCLOSED	\$ 0.00		

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

<p>CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE</p> <p>Lillian J. Gill, Senior Associate Director, CDRH</p>	<p>SIGNATURE</p> 	<p>DATE</p> <p>1/25/05</p>
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FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$	DATE	136339
APPROVED BY				DATE	

U. S. FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

REQUEST FOR RENEWAL OF LICENSE 19-07538-01

DELETION OF: -PRINCIPAL USERS  
-A RADIOACTIVE MATERIAL

This request employs the number format used on the NRC MATERIALS LICENSE, Form 374. The deletions will be preceded in the request by the italicized word *Delete*.

Licensee:

1. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health
2. DMQRP/OCER (HFZ-240)  
1350 Piccard Drive  
Rockville, MD 20850-4307

Items to be amended in this renewal:

Pages

Conditions 6.B., 11. A. ....1, 2

CONDITIONS

6. B. *Delete* Carbon 14

11. A. Licensed material in item 6.A. through 6.E. shall be used by, or under the supervision of, Peter Goering. *Delete* Larry Bockstahler, Larry Cress, and Barbara Zmudska.

Dr. Cress is no longer employed at the Center. The remainder of his radioactive materials will be disposed of as radioactive waste.

Drs. Bockstahler and Zmudska have not used radioactive materials for several years and have no future plans to use such materials.

For additional information, please contact:

Petro Shandruk  
Radiation Safety Officer  
U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
HFZ-240  
1350 Piccard Drive  
Rockville, MD 20850

Telephone: 301-827-1231  
FAX: 301-594-4760  
Email: [pxs@cdrh.fda.gov](mailto:pxs@cdrh.fda.gov)

**MATERIALS LICENSE**

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 style="text-align: center;">Licensee</p> <p>1. Department of Health &amp; Human Services Food and Drug Administration Center for Devices and Radiological Health</p> <p>2. DMQRP/OHIP (HFZ-240) 1350 Piccard Drive Rockville, Maryland 20850-4307</p>	<p>In accordance with the letter dated August 5, 2004,</p> <p>3. License number 19-07538-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date February 28, 2005</p> <hr/> <p>5. Docket No. 030-04544 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3</p> <p>B. Carbon 14</p> <p>C. Phosphorus 32</p> <p>D. Sulfur 35</p> <p>E. Iodine 125</p> <p>F. Any byproduct material with atomic numbers 3 through 83</p> <p>G. Plutonium 239</p> <p>H. Americium 241</p>	<p>Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Sealed Sources</p> <p>G. Plated Sources</p> <p>H. Sealed Sources (Texas Nuclear Corporation, custom source)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 100 millicuries</p> <p>B. 100 millicuries</p> <p>C. 100 millicuries</p> <p>D. 300 millicuries</p> <p>E. 1 millicurie</p> <p>F. 1 millicurie per source and 5 millicuries total</p> <p>G. 4 microcuries</p> <p>H. 14 millicuries per source and 28 millicuries total</p>
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9. Authorized use:

- A. through E. Research and development as defined in 10 CFR 30.4.
- F. through H. Calibration, standardizing and testing of the licensee's instruments.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
19-07538-01

Docket or Reference Number  
030-04544

Amendment No. 33

**CONDITIONS**

10. Licensed material may be used at the licensee's facilities located at 12709 Twinbrook Parkway; and 12720 Twinbrook Parkway, Buildings 1 and 2; Rockville, Maryland; and 10903 New Hampshire Avenue, Silver Spring, Maryland.
11. A. Licensed material in items 6.A. through 6.E. shall be used by, or under the supervision of, Larry Bockstahler, Larry Cress, Peter Goering, or Barbara Zmudska.
- B. Licensed material in items 6.F. through 6.H. shall be used by, or under the supervision of, Frank Cerra or Peter Goering.
- C. The Radiation Safety Officer for this license is Petro Shandruk.
12. Licensed material shall not be used in or on human beings.
13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
14. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. Each sealed source fabricated by the licensee 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 that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. 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.
- 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.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
19-07538-01

Docket or Reference Number  
030-04544

Amendment No. 33

- 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 transferred 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 U.S. Nuclear Regulatory Commission 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 Commission regulations.
- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- I. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
18. 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 Commission or an Agreement State to perform such services.
19. 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 temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

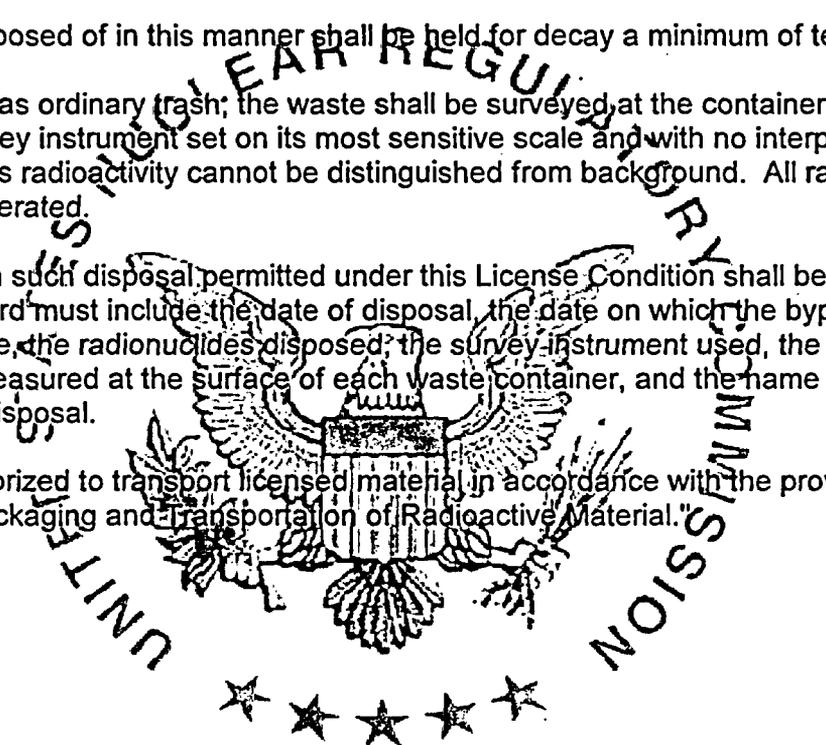
**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
19-07538-01

Docket or Reference Number  
030-04544

Amendment No. 33

- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
20. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
- B. 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 that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- C. A record of each such disposal permitted under this License 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.
21. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
19-07538-01

Docket or Reference Number  
030-04544

Amendment No. 33

22. 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. 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 January 27, 1998
- B. Letter dated April 2, 1998
- C. Letter dated January 6, 2000
- D. Letter dated April 16, 2003
- E. Letter dated August 5, 2004



For the U.S. Nuclear Regulatory Commission

Date August 11, 2004

By

*Original signed by Elizabeth Ullrich*

Elizabeth Ullrich  
Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

80341201

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

11/25/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Renew 19-07538-01  
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 136339.  
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 (R)  
(6-96)

Sincerely,  
Licensing Assistance Team Leader

BETWEEN: : (FOR LFMS USE)  
 : INFORMATION FROM LTS  
 : -----  
 :  
 License Fee Management Branch, ARM : Program Code: 03620  
 and : Status Code: 2  
 Regional Licensing Sections : Fee Category: EX 3M 1D  
 : Exp. Date: 20050228  
 : Fee Comments: 170.11(A) (5)  
 : Decom Fin Assur Req'd: Y  
 : ::

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED  
 Applicant/Licensee: HEALTH & HUMAN SERVICES, DEPT. OF  
 Received Date: 20050126  
 Docket No: 3004544  
 Control No.: 136339  
 License No.: 19-07538-01  
 Action Type: Renewal

2. FEE ATTACHED  
 Amount:             
 Check No.:           

3. COMMENTS

Signed Rebecca J. [Signature]  
 Date 11/21/2005

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /\_\_/)

- 1. Fee Category and Amount: \_\_\_\_\_
- 2. Correct Fee Paid. Application may be processed for:
  - Amendment \_\_\_\_\_
  - Renewal \_\_\_\_\_
  - License \_\_\_\_\_
- 3. OTHER \_\_\_\_\_

Signed \_\_\_\_\_  
 Date \_\_\_\_\_