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REGION 1

Food and Drug Administration
Rockville MD 20857

2006 DEC 29 AM 9:30

NMSB2

December 28, 2006

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

Subject: ^{AMENDMENT} ~~Renewal~~ of License 19-07538-01

07004544

Dear Sir or Madam:

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

Sincerely Yours,

Petro Shandruk, RSO
Chief, Radiation Programs Branch
DMQRP, OCER (HFZ-240)
Center for Devices and
Radiological Health

Enc: License amendment
(2 copies)

cc: Lillian J. Gill
Senior Associate Director, CDRH

139912

NMCG/RGN MATERIALS-002

NRC FORM 313
(10-2005)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2008

Estimated burden per response to comply with this mandatory collection request: 4.4 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 F53), 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.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER 19-07538-01
- C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

12720 Twinbrook Parkway, Bldgs. 1 & 2, Rockville, MD 20857
10903 New Hampshire Ave., Silver Spring, MD

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

PETRO SHANDRUK

TELEPHONE NUMBER

(240) 276-3285

RECEIVED REGION I
2006 DEC 29 AM 9:30

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

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Petro Shandruk, Radiation Safety Officer, CDRH

SIGNATURE

Petro Shandruk

DATE

12/23/06

FOR NRC USE ONLY

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

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

REQUEST FOR AMENMENT OF LICENSE 19-07538-01

ADDITION OF: -PRINCIPAL USERS
-A RADIOACTIVE MATERIAL

This request employs the number format used on the NRC MATERIALS LICENSE, Form 374. The additions will be preceded in the request by the italicized word *Add*. 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., 7., 8., 9, 11. A., 11. B.1, 2

CONDITIONS

6. *Add* Carbon 14,
7. *Add* any chemical and/or physical form of Carbon 14
8. *Add* 100 millicuries as the maximum amount of possession at any one time
9. *Add* Carbon 14 under category: "Research and development as defined in 10 CFR 30.4"

11. A. Licensed material in item 6.A. through 6.E. shall be used by, or under the supervision of, Peter Goering. *Add* Abiy Desta, Michael O'Hara and Thomas Umbreit.
11. B. Licensed material in items 6.E. through 6.G. shall be used by, or under the supervision of Peter Goering. *Add* Mary D. Walker. *Delete* Frank Cerra.

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: 240-276-3285
FAX: 240-276-3282
Email: petro.shandruk@fda.hhs.gov

Abiy B. Desta

Education

Catholic University of America, Washington D.C. 1991 - 1993

The Colorado College, Colorado Springs, CO. 1984 - 1988

Professional Experience

March '01-Present,

Biologist

Radiation Biology Branch, Division of Biology

Office of Science and Technology

Center for Devices and Radiological Health

U.S. Food and Drug Administration (HFZ-120)

August '00-March '01

Biochemist

SFA Advanced Technology Division (On-site contractor for the Radiation Biology Branch, Office of Science and Technology CDRH/FDA).

Supervisor: Debbie Wilson, 301-350-5153

8315 Largo Drive West Suite 200 Largo, MD 20774

April '95- August '00

Biochemist

Mentor Technologies Inc. (On-site contractor for the Radiation Biology Branch, Office of Science and Technology CDRH/FDA).

Supervisor: Dr. Yong M. Cho

7404 Executive Place, Suite 100

Lanham, MD 20706

June '89- April '95

Senior Laboratory Technician

Department of Biology

The Catholic University of America

Washington D.C. 20064.

Radiation Training

1989 Radiation Safety Course offered by the Baltimore-Washington Chapter of the Health Physics Society

1992 -1995 Annual training by the radiation safety officer at Catholic university of America

1995 – 2000 Annual training by radiation safety office, Center for Devices and Radiological Health, US-FDA

Radio isotope experience

1989 – 1995 C¹⁴ & P³² Catholic University of America

1995 – 2000 C¹⁴ Radiation Biology Branch (CDRH/FDA)

Dr. Thomas H. Umbreit

Education

University of Wisconsin-Madison, Madison, 1973 – 1977, Wisconsin, PhD. Microbiology
University of Delaware, Newark, Delaware, 1969 – 1973, M.S. Biological Sciences
Duke Univ., Durham, NC, 1965 – 1969, A.B. Zoology

Professional Experience

Toxicologist, 1994 – Present: Center for Devices and Radiological (CDRH)/FDA, Rockville, MD
Toxicologist, 1990 – 1994: Agency for Toxic Substances and Disease Registry (ATSDR), Atlanta, GA
Research Associate and Assistant Prof: 1983-1990. Robert Wood Johnson Medical School, Dept
Environmental and Community Medicine.
Post Doc: 1980-1983: Joint Graduate Program in Toxicology, Rutgers Univ. / Rutgers Medical School
Visiting Assistant Professor, 1980. Dept Biology, Bowling Green State Univ., Ohio.
Research Associate, 1980. Dept Biology, Univ. New Mexico
Post Doc: 1977-1979. Waksman Institute of Microbiology, Rutgers Univ., Rutgers, NJ

Radiation Training

Mid 1980s 3 day course in use and laboratory safety of radionuclides, Rutgers University
2006 Radiation Safety Refresher Training at CDRH by Clym Environmental Services

Radio isotope experience

1981 – 1990 C-14 labeled estrogens
1994 H-3

Dr. Michael D. O'Hara

Education

Wayne State University, 1985, Ph.D. Biological Sciences
SUNY Buffalo, 1978, M. Sc., Natural Sciences
D'Youville College, Buffalo, NY, 1977, BS Biology

Professional Experience

1996 - Present Staff Fellow, CDRH/FDA

1984 – 1996: Radioisotope researcher and primary Cs-137 investigator at Thomas Jefferson University, Philadelphia, PA

Radiation Training

2006 *CDRH by Clym Environmental Services*
Radiation Safety Refresher Training

1984 – 1996 *Thomas Jefferson University, Philadelphia, PA*
Radiation Physics, Safety and Treatment Planning
Radiation Biology for Residents
Radiation Safety

1980 – 1984 *Henry Ford Hospital*
Radiation Physics and Treatment Planning
Radiation Oncology Treatment Planning
Radiation Biology
Radiation Safety

1978 – 1979 *Roswell Park Memorial Institute*
Radiobiology of the cell cycle
Cancer Radiobiology
Radiation Biology Seminar
Radiation Oncology Seminar
Radiation Safety

1970 – 1980 *SUNY @ Buffalo reactor*
Radiation Physics and Laboratory
Introduction to Radiation Biology and Radiation Chemistry

Radio isotope experience

1984 – 1996 C-14, H-3, P-32, S-35, Cs-137 used at:
Henry Ford Hospital & Thomas Jefferson University

Mary D. Walker

Education

Georgetown University, Washington, DC, 1995, M.S. Radiological Science
University of Maryland School of Medicine, 1981, B.S. Radiological Science

Professional Experience

1992 – Present
Physical Scientist, CDRH/FDA

1989 – 1992
Physical Scientist, NIST, Gaithersburg, MD

1984 – 1989
Physicist, Institute for Radiological Imaging Sciences, Germantown, MD

1983 – 1984
X-ray Technologist, Washington Radiology Associates, Washington, DC

1981 – 1983
X-ray Technologist, George Washington University Hospital, Washington, DC

Radiation Training

CDRH in house radiation safety training; dealing with X-rays and sealed sources

NIST in house radiation safety training; dealing with X-rays, sealed sources (Co-60 and Cs-137)

Sealed source radio isotope experience

1989 – Present Am-241, Co-60 and Cs-137 at NIST and CDRH

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MATERIALS LICENSE

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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. Department of Health & 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 23, 2005,</p> <p>3. License number 19-07538-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date June 30, 2015</p> <hr/> <p>5. Docket No. 03004544 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3</p> <p>B. Phosphorus 32</p> <p>C. Sulfur 35</p> <p>D. Iodine 125</p> <p>E. Any byproduct material with atomic numbers 3 through 83</p> <p>F. Plutonium 239</p> <p>G. Americium 241</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Sealed Sources</p> <p>F. Plated Sources</p> <p>G. 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. 300 millicuries</p> <p>D. 1 millicurie</p> <p>E. 1 millicurie per source and 5 millicuries total</p> <p>F. 4 microcuries</p> <p>G. 14 millicuries per source and 28 millicuries total</p>
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9. Authorized use:

A. through D. Research and development as defined in 10 CFR 30.4.

E. through G. Calibration, standardizing and testing of the licensee's instruments.

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**MATERIALS LICENSE
 SUPPLEMENTARY SHEET**

Duplicate

License Number

19-07538-01

Docket or Reference Number

030-04544

Amendment No. 35

10. Licensed material may be used at the licensee's facilities located at 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.D. shall be used by, or under the supervision of Peter Goering.
- B. Licensed material in items 6.E. through 6.G. 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.
- 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.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

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License Number

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030-04544

Amendment No. 35

- 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.
- 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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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

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License Number

19-07538-01

Docket or Reference Number

030-04544

Amendment No. 35

20. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level 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."
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.
- Application dated January 27, 1998
 - Letter dated April 2, 1998
 - Letter dated January 6, 2000 (ML003678663)
 - Letter dated April 16, 2003 (ML031260073)
 - Letter dated August 5, 2004 (ML042190374)
 - Letter dated January 25, 2005 (ML050380492)

For the U.S. Nuclear Regulatory Commission

*Original signed by Elizabeth Ullrich*Date December 23, 2005

By

Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

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

12/28/2006, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 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** 139912.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.