



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 12, 2007

Docket No. 03008856
Control No. 140157

License No. 47-15279-01

William E. Wallace, Jr., Ph.D.
Chairman, Radiation Safety Committee
Department of Health and Human Services
U. S. Public Health Service
Center for Disease Control & Prevention
National Institute of Occupational Health & Safety
1095 Willowdale Road
Morgantown, WV 26505-2888

**SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, LICENSE
AMENDMENT, CONTROL NO. 140157**

Dear Dr. Wallace:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Your application should have been signed by a management representative rather than radiation safety officer. A letter signed by a management representative indicates that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.

As part of this amendment, several revisions of your license were made in accordance with current NRC practices. License Condition No. 8.I. was revised to limit the total amount of nickel-63 sources you may possess. License Condition No. 12 was replaced with the standard license condition format. The former License Condition No. 21 was removed because License Conditions 6, 7, and 8. A through I limits the radionuclides and total amounts possessed.

In accordance with 10 CFR 30.35, the materials authorized on your license require financial assurance in the amount of \$225,000. We currently have a licensing action open regarding your financial assurance, and we will be following up on financial assurance issues in a separate letter.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

W. Wallace
Department of Health and Human Services

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Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material**; then **Toolkit Index Page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 32

cc:
Stephanie D. Kraynak, M.S., Radiation Safety Officer

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SUNSI Review Complete: EUlrich

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|--------|---------------|---------------------------------------|---------|--------------------------|---------|--------------------------|--|--|
| OFFICE | DNMS/RI | <input checked="" type="checkbox"/> N | DNMS/RI | <input type="checkbox"/> | DNMS/RI | <input type="checkbox"/> | | |
| NAME | EUlrich //BU/ | | | | | | | |
| DATE | 3/12/07 | | | | | | | |

OFFICIAL RECORD COPY

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.

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|---|---|
| Licensee | In accordance with the letter dated February 23, 2007, |
| 1. U.S. Department of Health and Human Services U.S. Public Health Service Centers for Disease Control & Prevention National Institute of Occupational Health & Safety | 3. License No. 47-15279-01 |
| 2. 1095 Willowdale Road Morgantown, West Virginia 26505-2888 | 4. Expiration Date: August 31, 2014 |
| | 5. Docket No. 030-08856 |

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| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| A. Hydrogen 3 | A. Any | A. 350 millicuries |
| B. Carbon 14 | B. Any | B. 50 millicuries |
| C. Phosphorus 32 | C. Any | C. 200 millicuries |
| D. Phosphorus 33 | D. Any | D. 50 millicuries |
| E. Sulfur 35 | E. Any | E. 75 millicuries |
| F. Chlorine 36 | F. Any | F. 2 millicuries |
| G. Chromium 51 | G. Any | G. 30 millicuries |
| H. Iodine 125 | H. Any | H. 100 millicuries |
| I. Nickel 63 | I. Foil and/or plated source in a detector cell registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation | I. 15 millicuries per source and 150 millicuries total |
| 9. Authorized use: | | |
| A. through H. Research and development as defined in 10 CFR 30.4; animal studies. | | |
| I. Sample analysis in compatible gas chromatography devices that have been registered either with the U. S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State | | |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License No.
47-15279-01Docket No.
030-08856Amendment No.
32**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at the Appalachia Laboratory for Occupational Safety and Health, 1095 Willowdale Road, Morgantown, West Virginia.
11. The Radiation Safety Officer (RSO) for this license is Stephanie D. Kraynak
12. Licensed material shall be used by, or under the supervision of, Leon F. Butterworth, B.S., Vincent Castranova, Ph.D., Jeffrey S. Fedan, Ph.D., H. Fred Frascch, Ph.D., Jason E. Ham, Ph.D. (Ni-63 only), Michael J. Keane, M.S.E., Michael I. Luster, Ph.D., Qiang Ma, M.D., Ph.D., Robert R. Mercer, Ph.D., Diane B. Miller, Ph.D., Eisuke P. Murono, Ph.D., James P. O'Callaghan, Ph.D., Dale W. Porter, Ph.D., K. Murali K. Rao, M.S., Steven H. Reynolds, Ph.D., Petia Simeonova, M.D., Ph.D., James S. Spahr, M.P.H., Val Vallyathan, Ph.D., and William E. Wallace, Jr., Ph.D.,
13. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
15. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.
16.
 - 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. 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.
 - C. 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.
 - D. 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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- E. The leak test shall be capable of detecting the presence of 0.005 microcuries (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcuries 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.
- F. 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.
- G. Records of leak test results shall be kept in units of microcuries and shall be maintained for five years.
17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
18. 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 five 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.
19. 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 U. S. Nuclear Regulatory Commission or an Agreement State to perform such services.
20. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it:
- A. 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
 - B. 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
 - C. Maintains the records of the disposal of licensed materials for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each container, and the name of the individual who performs 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."

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SUPPLEMENTARY SHEET**

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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 February 18, 2004 [ML040510100]
- B. Letter dated February 23, 2007 [ML070650614]



For the U. S. Nuclear Regulatory Commission

Date March 12, 2007

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