



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

December 20, 2004

Docket No. 03035646
Control No. 136090

License No. 29-30621-01

Santo Guillermain
RSO, Manager Environmental Health and Safety
Berlex Laboratories, Inc.
300 Fairfield Road
Wayne, NJ 07470

SUBJECT: BERLEX LABORATORIES, INC., ISSUANCE OF LICENSE AMENDMENT,
CONTROL NO. 136090

Dear Mr. Guillermain:

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

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).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

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

Enclosure:
Amendment No. 6

S. Guillermain
Berlex Laboratories, Inc.

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OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	JNicholson /JJN/		EUIrich /BU/					
DATE	12/20/2004		12/20/2004					

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.

<p style="text-align: center;">Licensee</p> <p>1. Berlex Laboratories, Inc.</p> <p>2. 300 Fairfield Road Wayne, New Jersey 07470</p>	<p>December 1, 2004,</p> <p>3. License number 29-30621-01</p> <hr/> <p>4. Expiration date March 31, 2011</p> <hr/> <p>5. Docket No. 030-35646 Reference No.</p>
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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Molybdenum 99</p> <p>B. Technetium 99m</p> <p>C. Barium 133</p> <p>D. Cesium 137</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Sealed Source (Isotope Product Laboratories Model RV-133)</p> <p>D. Sealed Source (Isotope Product Laboratories Model RV-137)</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 10 curies</p> <p>B. 10 curies</p> <p>C. 250 microcuries</p> <p>D. 250 microcuries</p> |
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9. Authorized use:

- A. and B. Research and development as defined in 10 CFR 30.4; quality control testing.
- C. and D. Calibration of the licensee's dose calibrator.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 300 Fairfield Road, Wayne, New Jersey.
11. A. Licensed material shall be used by, or under the supervision of, Nanci Bompey, Mark Stone, or Harish Champaneri.
- B. The Radiation Safety Officer for this license is Santo Guillermain.

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12. The licensee shall not use licensed material in or on human beings.
13. This license does not authorize distribution to persons licensed pursuant to 10 CFR 37.72 or 32.74; to persons exempt from licensing; or to general licensees.
14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
15. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at 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.
- 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.
- 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.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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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. The licensee is authorized to hold byproduct 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 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.
19. 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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20. 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 19, 2001 (ML010440437)
- B. Letter dated March 14, 2001 (ML010800048)
- C. Letter dated December 2, 2002 (ML023440351)



For the U.S. Nuclear Regulatory Commission

Date December 20, 2004

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