



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

APR 26 2004

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Paul Ward, M.S., J.D.
Analytical Bio-Chemistry Laboratories, Inc.
7200 E. ABC Lane
Columbia, MO 65202

Dear Mr. Ward:

Enclosed is Amendment No. 26 amending your NRC Material License No. 24-13365-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Kevin G. Null
Materials Licensing Branch

License No. 24-13365-01
Docket No. 030-05154

Enclosure: Amendment No. 25

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 2
FOIA- 2005-0293

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MATERIALS LICENSE

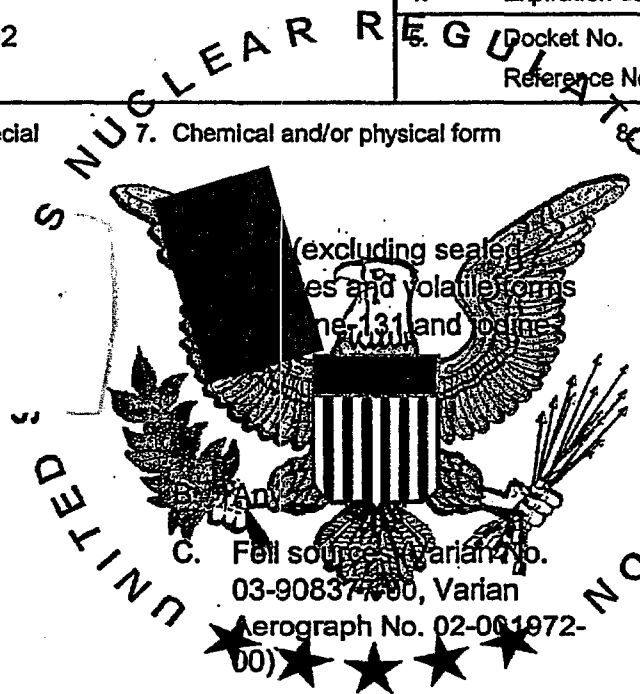
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, 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.

PC 03211

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| <p>Licensee</p> <p>1. Analytical Bio-Chemistry Laboratories, Inc.</p> <p>2. 7200 E. ABC Lane Columbia, MO 65202</p> | <p>In accordance with letter dated February 6, 2004,</p> <p>3. License number 24-13365-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date March 31, 2007</p> <p>5. Pocket No. 030-05154 Reference No.</p> |
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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. <i>[Handwritten]</i></p> <p>B. Carbon-14</p> <p>C. Nickel-63</p> <p>D. Nickel-63</p> <p>E. Carbon-14</p> <p>F. Cesium-137</p> <p>G. Hydrogen-3</p> <p>H. Europium-154 Cesium-137</p> <p>J. Barium-133</p> | <p>7. Chemical and/or physical form</p> <p>(excluding sealed sources and volatile forms of ¹³¹I and ¹³³Xe)</p> <p>B. AD</p> <p>C. Foil source (Varian No. 03-908374-00, Varian Aerograph No. 02-001972-00)</p> <p>D. Foil Sources (Hewlett-Packard Model No. 19235)</p> <p>E. Solid and/or liquid waste</p> <p>F. Sealed sources (registered pursuant to Section 32.210 of 10 CFR part 32 or an Agreement State)</p> <p>G. Any</p> <p>H. Liquid or solid</p> <p>I. Liquid or solid</p> <p>J. Liquid or solid</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. Not to exceed <i>[Handwritten]</i> per total nuclide and, except as listed below:</p> <p>phosphorus-33 10 curies</p> <p>Sulfur-35 10 curies</p> <p>B. 20 curies</p> <p>C. No single foil to exceed 8 millicuries</p> <p>D. No single foil to exceed 15 millicuries</p> <p>E. See Item 9.E. below</p> <p>F. No single source to exceed 30 microcuries</p> <p>G. 1.0 curie</p> <p>H. 2 microcuries</p> <p>I. 300 microcuries</p> <p>J. 750 microcuries</p> |
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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

K. Manganese-54

K. Any

K. 200 millicuries

L. Lutetium-177

L. Any

L. 500 millicuries

M. Technetium-99

M. Any

M. 30 millicuries

N. [

N. Any

O. 30 curies

O. Technetium-99m

O. Any

O. 1 microcurie

P. Cobalt-60

P. Any

Q. 1 microcurie

Q. Gadolinium-153

Q. Any

R. 60 microcuries

R. Terbium-160

R. Any

S. 5 microcuries

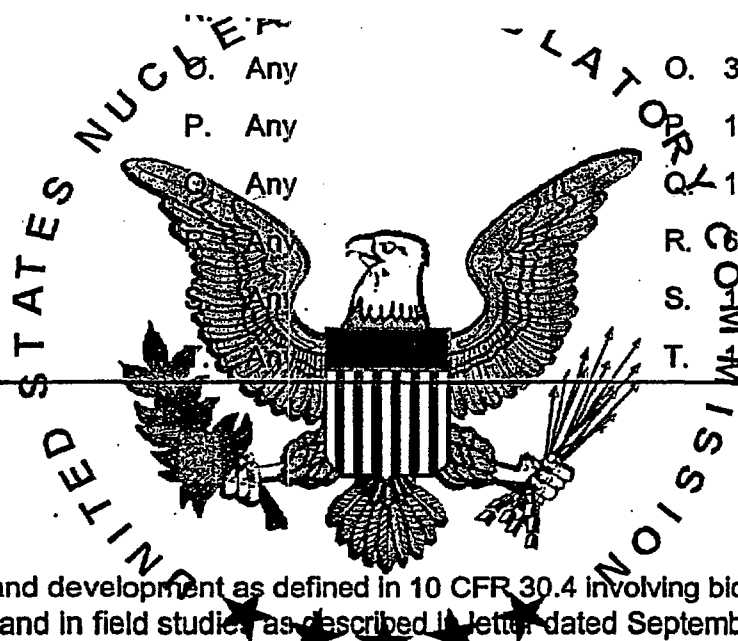
S. Thulium-170

S. Any

T. 150 microcuries

T. Holmium-166m

T. Any



9. Authorized Use:

A. and B.

- (1) Research and development as defined in 10 CFR 30.4 involving bio-tracer studies in animals and plants and in field studies as described in letter dated September 9, 1996.
- (2) For possession, use, and processing incident to manufacture of radiochemicals.
- (3) For storage prior to distribution of manufactured radiochemicals.
- (4) For packaging and distribution of manufactured radiochemicals to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement State.
- (5) For ¹²⁵Iodine, the licensee shall not obtain material in volatile form until the fume hood(s) have been tested to assure compliance with the release concentrations listed in 10 CFR Part 20, Appendix B, Table 2.

Handwritten notes:
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- C. and D. For use in gas chromatographs for sample analysis and for cleaning.
- E. Possession incident to interim storage of waste in accordance with statements, representations and procedures contained in letter dated September 9, 1996.
- F. To be used as calibration sources.
- G. Research and development as defined in 10 CFR 30.4 involving bio-tracer studies in animals and plants and in field studies as described in letter dated September 9, 1996.
- H. through J. For instrument calibration.
- K., L., and M. Research and development as defined in 10 CFR 30.4, possession, use and processing incident to manufacture of radiochemicals; storage prior to distribution of manufactured radiochemicals; and packaging and distribution of manufactured radiochemicals to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement State.
- N. and O. Research and development as defined in 10 CFR 30.4.
- P. through T. Research and development as defined in 10 CFR 30.4 including studies in animals described in letter dated April 15, 2003.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Columbia, Missouri. EX2
11. **A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Kevin Roberson, Chairperson.**
- B. The Radiation Safety Officer for the activities authorized by this license is Paul Ward, M.S., J.D.**
12. This license does not authorize commercial distribution of licensed material to medical use licensees pursuant to 10 CFR 32.72, to persons generally licensed pursuant to 10 CFR Part 31 or equivalent regulations of any Agreement State or to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.20 inclusive, or equivalent regulations of any Agreement State.
13. The licensee shall not use licensed material in or on human beings.

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14. The licensee shall provide the following information to customers licensed by the NRC or an Agreement State for human use:
- products manufactured by ABC Labs, Inc. are required to be prepared by a radiopharmacist licensed by the NRC or Agreement State prior to human use; or
 - prepared by a physician who is an authorized user and who meets the requirements specified in 10 CFR 35.920, or equivalent Agreement State regulation; or
 - prepared by an individual under the supervision of either as specified in 10 CFR 35.25 or an equivalent Agreement State regulation.
15. The licensee shall notify, in writing, the NRC within 3 years of issuance of Amendment No. 17, the status of activities authorized by this license as it pertains to broad scope activities and to the manufacture and distribution of radiochemical products. If said activities have not been initiated within the 3 year period, the licensee shall provide a basis for continuance of such authorizations. The report shall be filed with the U.S. Nuclear Regulatory Commission, Region III, ATTN: Branch Chief, Materials licensing Branch, 801 Warrenville Road, Lisle, Illinois 60532.
16. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
17. Except as otherwise specified in this license, the licensee shall have available and follow the instructions contained in the manufacturer's instruction manual for chromatography devices.
18. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.
19. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

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D. Sealed sources need not be leak tested if:

- (i) they contain only hydrogen-3; or
- (ii) they contain only a radioactive gas; or
- (iii) the half-life of the isotope is 30 days or less; or
- (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
- (v) they are not designed to emit alpha particles, 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

- 20. In accordance with 10 CFR 20.2002, the licensee may dispose of hydrogen-3 and carbon-14 by the land application method described in the letter dated September 9, 1996, in such a manner that limits waste water entering the lagoon to concentrations not exceeding those specified in 10 CFR 20.2003.
- 21. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 22. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

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23. The licensee 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. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
- B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter 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 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.

24. 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 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. Letters dated September 9, 1996 (with enclosures), February 28, 1997 (with attachments), August 5, 1998, September 30, 1998, (items 1 through 4 only), October 7 1998, (excluding all reference to distribution of synthesized products), October 9, 1998, January 13, 1999, October 22, 1999 (excluding reference to medical distribution), January 18, 2000, March 30, 2000, April 6, 2001, January 31, 2003, April 15, 2003; August 26, 2003 (excluding reference to the Chair of the Radiation Safety Committee); and
- B. Fax transmittals dated October 21, 1998 and April 14, 2003.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date APR 26 2004

By Kevin G. Null
Kevin G. Null
Materials Licensing Branch
Region III