



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

VIII

NOV 06 2002

Mark Driscoll
Radiation Safety Officer
The Regents of the University of Michigan
Radiation Safety Service
Occupational Safety & Environmental Health
University of Michigan
1239 Kipke Drive
Ann Arbor, MI 48109-1010

Dear Mr. Driscoll:

Enclosed is Amendment No. 87 to your NRC Material License No. 21-00215-04 in accordance with your request. Please note that the changes made to your license are printed in bold font. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please contact me at (630) 829-9868 so that I can provide appropriate corrections and answers.

Please be advised that we cannot release the Great Lakes research vessel "Laurentian" for unrestricted use (even by other members of your staff) and remove it from Condition 10. of your license until we have received and reviewed a copy of the results of the close-out survey that was performed. The survey should consist of exposure rate measurements to show that all sources of radioactive material have been removed and contamination checks of areas where radioactive materials were used or stored. Average radiation levels associated with surface contamination and removable contamination should not exceed those specified in the enclosed decontamination guide. Please submit the following information with your close-out survey:

- a. A diagram of your old facility with survey and wipe test results keyed to specific locations.
- b. The name of the person performing the survey.
- c. The date the survey was performed.
- d. The instrument(s) used for exposure rate measurements and for analysis of the wipes.
- e. Background readings.
- f. The date that the survey instrument was last calibrated.

In order to remove the materials listed in Subitems V.^f from your license, it will be necessary for you to provide documentation regarding the transfer and disposal of those

Ex 2

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

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specific materials. The information you provide should accurately identify the material that was transferred/disposed, the date of the transfer/disposal and include the name of the organization and license number (if applicable) of recipient. You should also include copies of the results of leak tests that were done on the sources prior to disposal/transfer.

Information submitted in response to this letter should be referenced as additional information to previous Control Number 310956.

Sincerely,



Patricia J. Pelke
Health Physicist
Materials Licensing Branch

License No. 21-00215-04
Docket No. 030-01988

Enclosure: Amendment No. 87

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, 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 02110

310956

Licensee

In accordance with letter dated August 6, 2002,

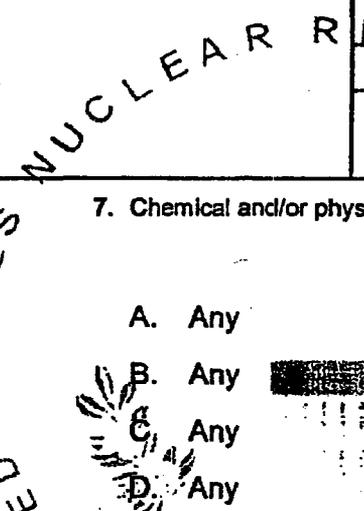
1. The Regents of the University of Michigan
Radiation Safety Service
Occupational Safety & Environmental Health
University of Michigan

3. License number 21-00215-04 is amended in its entirety to read as follows:

2. 1239 Kipke Drive
Ann Arbor, MI 48109-1010

4. Expiration date March 31, 2011

5. Docket No. 030-01988
Reference No. O A



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
- B. Polonium-210
- C. Americium-241
- D. Californium-252

- A. Any
- B. Any
- C. Any
- D. Any

- A. 50 Curies
- B. 1 millicurie
- C. 2 millicuries
- D. 6 millicuries

- F. Hydrogen-3
- G. Nickel-63
- H. Polonium-210
- I. Americium-241
- J. Californium-252
- K.
- L. Curium-244

- F. Plated Sources
- G. Plated Sources
- H. Plated Sources
- I. Plated Sources
- J. Plated Sources
- L. Sealed Sources

- F. 50 curies
- G. 5 curies
- H. 100 millicuries
- I. 100 millicuries
- J. 6 millicuries
- L. 3 millicuries

Ex 2

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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

- N. Polonium-210
- O. Americium-241
- P. Californium-252

- N. Sealed Sources
- O. Sealed Sources
- P. Sealed Sources

- N. 1 curies
- O. 1 curie
- P. 10 millicuries

R. Uranium (Natural or depleted in Uranium-235)

R. Metal, oxides

R. 100 pounds

S. Iodine-131

S. Iodo-methyl-norcholesterol (NP-59) or Meta-iodo-benzylguanidine (MIBG) or NaI

S. 2 curies

T. Iodine-125

T. Meta-iodo-benzylguanidine or NaI

T. 2 curies

U.

V.

W.

X.

Y.

Z.

AA. Cesium-137

AA. Sealed sources (3M Model Nos. Series 6510, 6570, 6550 (formerly 6B6G) or 6H6E)

AA. No single source to exceed 44 millicuries; 480 millicuries total

BB.

CC.

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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

GG . Any byproduct material with Atomic numbers 1 through 83; inclusive, or atomic numbers 92, 95, 96, or 98.

GG. Solid and/or liquid waste

GG. See Subitem 9.GG. below

HH. Curium-244

HH. Plated source

HH. 2.0 millicuries

II. Gadolinium-153

II. Sealed sources (which have been registered in accordance with Section 32.210 of 10 CFR Part 32 or equivalent Agreement State regulations)

II. No single source to exceed the maximum activity specified in the certificate of registration issued by the NRC or an Agreement State

JJ. Americium-241

JJ. Sealed sources (which have been registered in accordance with Section 32.210 of 10 CFR Part 32 or equivalent Agreement State regulations)

JJ. No single source to exceed the maximum activity specified in the certificate of registration issued by the NRC or an Agreement State

KK. Any byproduct material with Atomic Numbers 84 through 104

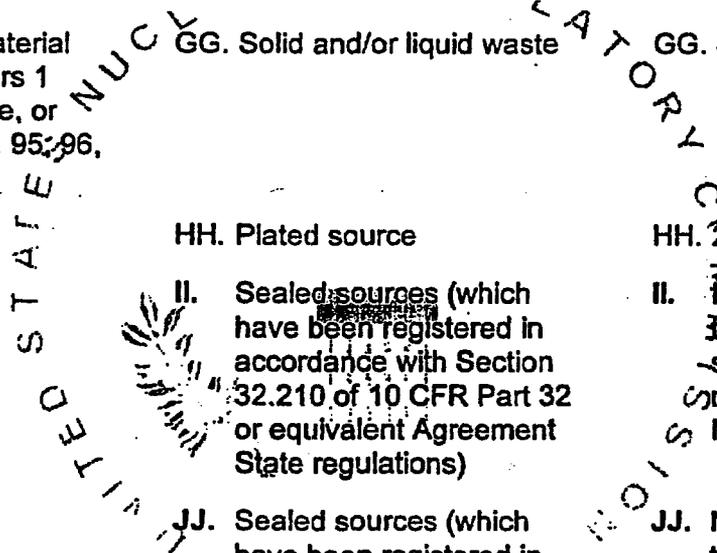
KK. Activation products

KK. Not to exceed 500 microcuries per radionuclide; total possession not to exceed 50 millicuries.

NN. Any byproduct material identified in 10 CFR 31.11

NN. Pre-packaged kits

NN. As needed



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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

OO. Any radionuclide with Atomic Numbers 3-104

OO. Activation products and/or contamination

OO. Not to exceed 500 microcuries per radionuclide; total possession not to exceed 50 millicuries.

9. Authorized Use:

A. through J., M. through Q., and U. Medical use as defined in Section 35.2 of 10 CFR Part 35 (which includes diagnosis, therapy, and research in humans) and research and development as defined in Section 30.4 of 10 CFR Part 30, including animal studies; survey instrument and dosimeter calibration, and leak testing as a service to customers.

K. Brachytherapy sources for topical, interstitial and intracavitary treatment of cancer in accordance with 10 CFR 35.400 and for source storage.

L. For use as calibration sources.

R. To be used for shielding, instrument testing, standardization, and calibration.

S. and T. For distribution as Iodo-methyl-norcholesterol (NP-59) or meta-iodo-benzylguanidine (MIBG), as specified in Item 7., to any person whose NRC or Agreement State License authorizes receipt of this product from the University of Michigan.

V. and W. To be used for research and development as defined in Section 30.4 10 CFR Part 30.

X. To be used in [] for irradiation of biological specimens. Ex 2

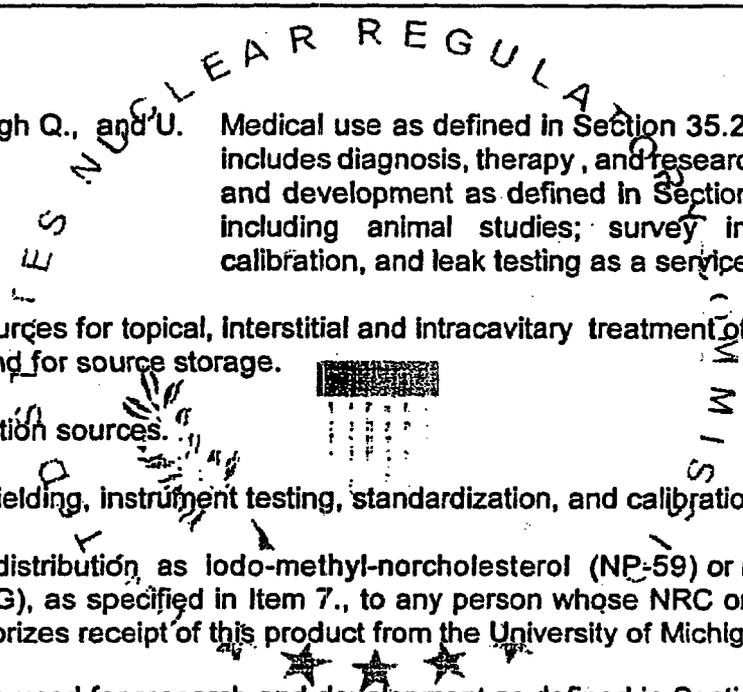
Y. To be used in an [] for irradiation of blood and blood components. Q 2

Z. To be used in a [] for radiation dosimetry studies, instrument calibrations, and quality and proficiency testing (excluding the irradiation of explosives and flammable materials). Q 2

AA. To be used in a custom irradiator (low dose rate device/LDRD) configuration described in Appendix G of application dated September 27, 2000.

BB. Medical use described in 10 CFR 35.100.

CC. Medical use described in 10 CFR 35.200.



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- DD. Medical use described in 10 CFR 35.300.
- EE. Medical use described in 10 CFR 35.400.
- FF. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.
- GG. Possession incident to interim storage of waste in accordance with statements, representations and procedures contained in application dated September 27, 2000.
- HH. To be used for instrument testing, standardization, and calibration.
- II. and JJ. To be used for medical radiography in humans in single photon emission computed tomography (SPECT) devices that have been registered in accordance with Section 32.210 of 10 CFR Part 32 or equivalent Agreement State regulations.
- KK. Possession incident to irradiation studies of geological samples.
- LL. To be used in an [redacted] for irradiation of biological materials (excluding explosive and flammable materials).
- MM. To be used in an [redacted] irradiation of biological materials (excluding explosive and flammable materials).
- NN. To be used for in-vitro studies.
- OO. Possession incident to equipment, tools and instruments used in specialized applications that contain activation products and/or residual contamination as described in letters dated August, 21, 2001 and October 19, 2001.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located on the campuses of the University of Michigan, Ann Arbor, Michigan; Dearborn, Michigan; Flint Michigan; [redacted] Belleville, Michigan; [redacted] Ann Arbor, Michigan; [redacted] at Pellston, Michigan; [redacted] to be operated on the Great Lakes and other waterways. Portable gas chromatography units which contain licensed materials listed in item 6.F. and 6.G. may be also used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.
- 11. A. Licensed material for non-human use shall be used by or under the supervision of individuals designated by the licensee's Radiation Policy Committee, Ruthann Nichols, Ph.D., Chairperson.
- B. The use of licensed material in or on humans shall be by a physician as defined in Section 35.2 of 10 CFR Part 35.

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C. Physician's designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR Part 35, Subpart J. and shall be designated by the licensee's Subcommittee on the Human Uses of Radioisotopes, Brahm Shapiro, M.D., Chairman.

12. The Radiation Protection Officer for the activities authorized by this license is Mark L. Driscoll.

13. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transfer or indicating that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.
- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.
- (3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.
- B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.
- C. Each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.
- D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semi-permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A 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, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch, describing the equipment involved, the test results, and the corrective action taken.

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14. Sealed sources containing licensed material shall not be opened.
15. The licensee shall conduct a physical inventory every 3 months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400 and 10 CFR 35.500 and every 6 months for all other sources and/or devices.
16. Detector cells containing licensed material shall not be opened or the sources removed from the detector cell by the licensee.
17. The licensee shall not perform repairs or alterations of the irradiators involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiators shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
18. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 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 normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
19. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
20. Experimental animals administered licensed materials or their products shall not be used for human consumption.
21. Notwithstanding the requirements of 10 CFR 35.415(a)(4), the licensee may use the alternative method for determining the dose rates in contiguous restricted and unrestricted areas described in Appendix C of application dated September 27, 2000.
22. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, and 10 CFR 35.500, the licensee may use for any medical use any byproduct material or reagent kit. The licensee shall possess and use byproduct material for medical use in accordance with the prescriptive and performance criteria in the other sections of 10 CFR 35. This does not relieve the licensee from complying with applicable United States Food and Drug Administration (FDA) and other Federal and State requirements.
23. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35 except Sections 35.49(a) and (b), 35.100, 35.200, 35.300, 35.400 and 35.500.

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24. A. Pursuant to Sections 20.1302 and 20.2001 of 10 CFR Part 20, the licensee is authorized to dispose of byproduct material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20.
- B. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Numbers 1-83, except for phosphorus-32, sulfur-35, technetium-99m, iron-59, calcium-45, and other isotopes as identified below, as ordinary waste in a landfill provided the concentration of the radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values in Table II, Column 2, 10 CFR Part 20, Appendix B. For hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver 108m, niobium-94, iodine 129, technetium-99, and thallium-204, the concentration can be no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B.
25. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.
26. 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. Application dated September 27, 2000 (with attachments); and
- B. Letters September 27, 2000, January 12, 2001, August 21, 200, October 19, 2001 and August 6, 2002 (except Items 2., 4. and 5.).



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

NOV 06 2002

Date _____

By _____

Patricia J. Pelke
Materials Licensing Branch
Region III