



# RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

FOIA - 93-16

RESPONSE TYPE

☒ FINAL☐ PARTIAL

DATE

FEB 1 - 1993

DOCKET NUMBER (if applicable)

REQUESTER

KENNETH COBLE

## PART I. AGENCY RECORDS RELEASED OR NOT LOCATED (See checked boxes)

<input type="checkbox"/>	No agency records subject to the request have been located.
<input type="checkbox"/>	No additional agency records subject to the request have been located.
<input type="checkbox"/>	Requested records are available through another public distribution program. See Comments section.
<input type="checkbox"/>	Agency records subject to the request that are identified in Appendix(es) _____ are already available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC.
<input type="checkbox"/>	Agency records subject to the request that are identified in Appendix(es) _____ are being made available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC, in a folder under this FOIA number.
<input type="checkbox"/>	The nonproprietary version of the proposal(s) that you agreed to accept in a telephone conversation with a member of my staff is now being made available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC, in a folder under this FOIA number.
<input type="checkbox"/>	Agency records subject to the request that are identified in Appendix(es) _____ may be inspected and copied at the NRC Local Public Document Room identified in the Comments section.
<input type="checkbox"/>	Enclosed is information on how you may obtain access to and the charges for copying records located at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC.
<input checked="" type="checkbox"/>	Agency records subject to the request are enclosed. *
<input type="checkbox"/>	Records subject to the request have been referred to another Federal agency(ies) for review and direct response to you.
<input checked="" type="checkbox"/>	Fees * *
<input type="checkbox"/>	You will be billed by the NRC for fees totaling \$ _____.
<input type="checkbox"/>	You will receive a refund from the NRC in the amount of \$ _____.
<input type="checkbox"/>	In view of NRC's response to this request, no further action is being taken on appeal letter dated _____, No. _____.

## PART II. A - INFORMATION WITHHELD FROM PUBLIC DISCLOSURE

Certain information in the requested records is being withheld from public disclosure pursuant to the exemptions described in and for the reasons stated in Part II, B, C, and D. Any released portions of the documents for which only part of the record is being withheld are being made available for public inspection and copying in the NRC Public Document Room, 2120 L Street, N.W., Washington, DC in a folder under this FOIA number.

## COMMENTS

\*The record is identified on the enclosed Appendix A.

\*\*The search time required to process your request did not exceed two free hours and reproduction did not exceed 100 free pages. Consequently, you will not be billed by the NRC for processing.

9303180293 930201

PDR FOIA

COBLE93-16

PDR

SIGNATURE, DIRECTOR, DIVISION OF FREEDOM OF INFORMATION AND PUBLICATIONS SERVICES

To be released entirely

	<u>Date</u>	<u>Description</u>
1.	01/06/93	Materials License No. 21-00215-04, Amendment No. 70 (9 pages)

CORRECTED COPY

## MATERIALS LICENSE

Amendment No. 70

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.

Licensee

1. University of Michigan

2. Radiation Safety Service  
1101 North University Bldg.  
Ann Arbor, MI 48109In accordance with letter dated  
July 16, 19923. License number 21-00215-04 is amended in  
its entirety to read as follows:

4. Expiration date September 30, 1995

5. Docket or  
Reference No. 030-019886. Byproduct, source, and/or  
special nuclear material7. Chemical and/or physical  
form8. 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

E. Any byproduct  
material with atomic  
numbers 3 through  
83, inclusive

F. Hydrogen-3

G. Nickel-63

H. Polonium-210

I. Americium-241

J. Californium-252

K. Cesium-137

L. Curium-244

M. Cobalt-60

N. Polonium-210

O. Americium-241

P. Californium-252

A. Any

B. Any

C. Any

D. Any

E. Any

F. Plated Sources

G. Plated Sources

H. Plated Sources

I. Plated Sources

J. Plated Sources

K. Sealed Sources

L. Sealed Sources

M. Sealed Sources

N. Sealed Sources

O. Sealed Sources

P. Sealed Sources

A. 60 Curies

B. 1 millicurie

C. 2 millicuries

D. 6 millicuries

E. 15 Curies each  
isotope with a  
total possession  
limit of 200  
Curies

F. 200 Curies

G. 10 Curies

H. 100 millicuries

I. 100 millicuries

J. 6 millicuries

K. 1.85 Curies

L. 0.001 Curie

M. 100 Curies

N. 10 Curies

O. 1 Curie

P. 10 millicuries

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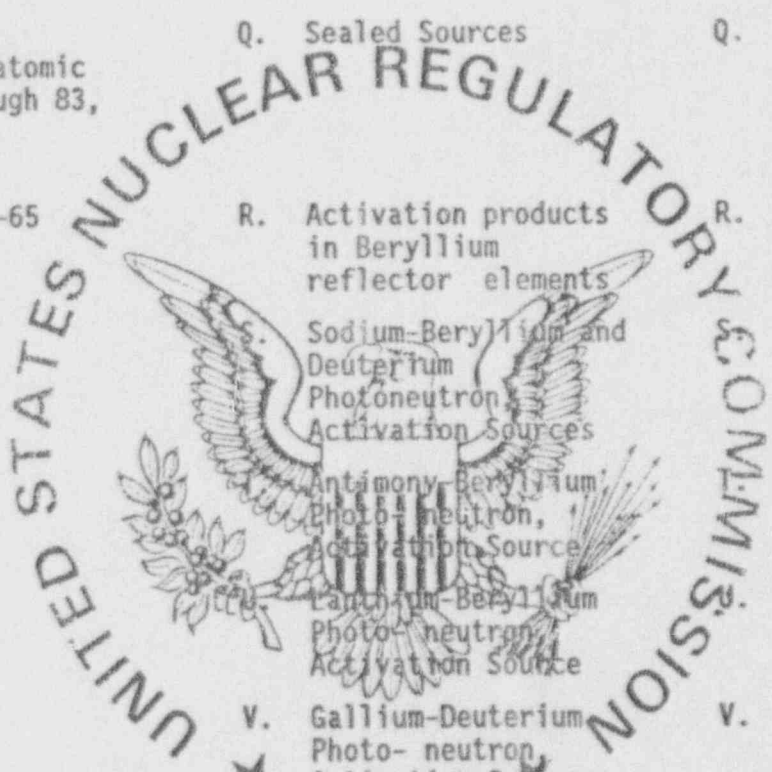
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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
Q. Any byproduct material with atomic numbers 1 through 83, inclusive	Q. Sealed Sources	Q. 30 Curies for each isotope with a total possession limit of 300 Curies
R. Cobalt-60/Zinc-65	R. Activation products in Beryllium reflector elements	R. 80 Curies of each nuclide
S. Sodium-24	S. Sodium-Beryllium and Deuterium Photoneutron Activation Sources	100 Curies
T. Antimony-124	T. Antimony-Beryllium Photoneutron Activation Source	30 Curies
U. Lanthium-140	U. Lanthium-Beryllium Photoneutron Activation Source	50 Curies
V. Gallium-72	V. Gallium-Deuterium Photo-neutron Activation Source	30 Curies
W. Uranium (Depleted in Uranium-235)	W. Nickel-clad metal	W. 100 pounds
X. Iodine-131	X. Iodo-methyl-norcholesterol (NP-59)	X. 500 millicuries
Y. Iodine-131	Y. Meta-iodo-benzylguanidine	Y. 2 curies



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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

Z. Iodine-125

Z. Meta-iodo-  
benzylguanidine

Z. 2 curies

AA. Americium-241

AA. Sealed Sources

AA. 20 Curies

BB. Californium-252

BB. Sealed Sources

BB. 0.85 milligram

Z. Iodine-125

Z. Meta-iodo-  
benzylguanidine

Z. 2 curies

CC. Californium-252

CC. Sealed Source

CC. 3.41 milligrams

DD. Cesium-137

DD. Sealed source (J.L.  
Shepherd Model 6810)

DD. 800 Curies

EE. Cesium-137

EE. Sealed Sources  
(ORNL RAN-50 or  
AECL ISO-1000)

EE. 2880 Curies

FF. Cesium-137

FF. Sealed source (J.L.  
Shepherd Model 6810)

FF. One source not to  
exceed 115 curies

GG. Iodine-125

GG. Any

GG. 500 millicuries

HH. Cesium-137

HH. Sealed sources (3M  
Model Nos. 6B6H or  
6H6E)

HH. No single source  
to exceed 44  
millicuries 480  
millicuries total

II. Any byproduct  
material identified  
in 10 CFR 35.100

II. Any  
radiopharmaceutical  
identified in 10 CFR  
35.100

II. 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

JJ. Any byproduct material identified in 10 CFR 35.200

JJ. Any radiopharmaceutical identified in 10 CFR 35.200

JJ. As needed

KK. Any byproduct material identified in 10 CFR 35.300

KK. Any radiopharmaceutical identified in 10 CFR 35.300

KK. As needed

LL. Any byproduct material identified in 10 CFR 35.400

LL. Any brachytherapy source identified in 10 CFR 35.400

LL. As needed

MM. Any byproduct material identified in 10 CFR 35.500

MM. Sealed sources identified in 10 CFR 35.500

MM. As needed

NN. Cesium-137

NN. Sealed sources (AECL Model C-161)

NN. 4200 curies

9. Authorized Use:

A. through J., M. through Q., S. through V. and AA. - To be used for Medical Research and research and development as defined in Section 30.4 of 10 CFR Part 30, including animal studies.

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

L. For use as calibration sources.

R. To be used for storage only.

W. To be used as shielding and for instrument calibration.

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9. (Continued)

- X., Y., and Z. For distribution as iodo-methyl-morcholesterol (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.
- BB. and CC. To be used for research and development as defined in Section 30.4 10 CFR Part 30.
- DD. To be used in J. L. Shepherd Mark I Model 25 irradiator for irradiation of biological specimens.
- EE. To be used in an AECL Gammacell 1000 irradiator for irradiation of blood and blood components.
- FF. To be used in a J.L. Shepherd Model 81-12 irradiator for radiation dosimetry studies, instrument calibrations, and quality and proficiency testing (excluding the irradiation of explosives and flammable materials).
- GG. To be used for manufacturing on vial and in vivo test kits in accordance with procedures described in letters dated April 6, 1988 and July 17, 1989.
- HH. To be used in a custom irradiation configuration as described in letter dated February 28, 1990 in accordance with the procedures contained in letter dated February 28, 1990 and transmittal dated March 14, 1990.
- II. Medical use described in 10 CFR 35.200.
- JJ. Medical use described in 10 CFR 35.200.
- KK. Medical use described in 10 CFR 35.300.
- LL. Medical use described in 10 CFR 35.400.
- MM. 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.
- NN. To be used in an AECL Model Gammacell 40 self-contained irradiator for irradiation of biological materials.

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CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at the University of Michigan, Ann Arbor, Michigan; Dearborn, Michigan; Flint, Michigan; Willow Run Facilities, Belleville, Michigan; Bioquant, Inc., 1919 Green Road, Ann Arbor, Michigan; UM Botanical Gardens, Ann Arbor, Michigan; Biological Station at Pellston, Michigan; Research Vessel "Laurention" to be operated on Great Lakes and other waterways.
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, James E. Carey, M.D.
- B. Licensed material for human use shall be used by or under the supervision of individuals designated by the licensee's Subcommittee on the Human Uses of Radioisotopes, Brahm Shapiro, M.D., Chairman. 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.
- C. The Radiation Protection Officer for the activities authorized by this license is Mark L. Driscoll.
12. 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.

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12. (Continued)

- 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 semipermanently 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, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch, describing the equipment involved, the test results, and the corrective action taken.
13. Sealed sources containing licensed material shall not be opened.
14. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
15. Detector cells containing licensed material shall not be opened or the sources removed from the detector cell by the licensee.

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16. 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.
17. 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.
18. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
19. Experimental animals administered licensed materials or their products shall not be used for human consumption.
20. The licensee shall maintain records of information important to safe and effective decommissioning at The University of Michigan, Ann Arbor, Michigan per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.
21. Pursuant to Sections 20.106(b) and 20.302 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. Ash residues may be disposed of as ordinary waste provided appropriate surveys are made to determine that concentrations of licensed material appearing in the ash residues cannot be distinguished from background.
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 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 May 24, 1988

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22. (Continued)

- B. Letters dated April 6, 1988, July 17, 1989, March 14, 1990, June 11, 1990, June 15, 1990, August 1, 1990, May 17, 1991, July 16, 1992 (excluding items 2.0 and 4.0) and November 6, 1992.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

1/6/93

By

K. G. N. III  
Materials Licensing Section, Region III

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