

MATERIALS LICENSE

Amendment No. 78

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.

301299

Licensee	In accordance with letter dated May 7, 1996
1. University of Michigan Occupational Safety & Environmental Health	3. License Number 21-00215-04 is amended in its entirety to read as follows:
2. Radiation Safety Service 1239 Kipke Drive Ann Arbor, MI 48109-1010	4. Expiration Date September 30, 2000
	5. Docket or Reference No. 030-01988

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. 60 Curies
B. Polonium-210	B. Any	B. 1 millicurie
C. Americium-241	C. Any	C. 2 millicuries
D. Californium-252	D. Any	D. 6 millicuries
E. Any byproduct material with atomic numbers 3 through 83, inclusive; except byproduct material with atomic number 53.	E. Any	E. 15 Curies each isotope with atomic numbers 3 through 83; except as listed below. Total possession limit not to exceed 200 Curies.

Any isotope with
Atomic Number 53 10 curies total

F. Hydrogen-3	F. Plated Sources	F. 200 Curies
G. Nickel-63	G. Plated Sources	G. 10 Curies
H. Polonium-210	H. Plated Sources	H. 100 millicuries
I. Americium-241	I. Plated Sources	I. 100 millicuries

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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 |
|---|--|--|
| J. Californium-252 | J. Plated Sources | J. 6 millicuries |
| K. Cesium-137 | K. Sealed Sources | K. 1.85 Curies |
| L. Curium-244 | L. Sealed Sources | L. 0.001 Curie |
| M. Cobalt-60 | M. Sealed Sources | M. 100 Curies |
| N. Polonium-210 | N. Sealed Sources | N. 10 Curies |
| O. Americium-241 | O. Sealed Sources | O. 1 Curie |
| P. Californium-252 | P. Sealed Sources | P. 10 millicuries |
| 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 | S. 100 Curies |
| T. Antimony-124 | T. Antimony-Beryllium Photo- neutron, Activation Source | T. 30 Curies |
| U. Lanthium-140 | U. Lanthium-Beryllium Photo- neutron, Activation Source | U. 50 Curies |
| V. Gallium-72 | V. Gallium-Deuterium Photo- neutron, Activation Source | V. 30 Curies |
| W. Uranium (Depleted in Uranium-235) | W. Nickel-clad metal | W. 100 pounds |

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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 |
| X. Iodine-131 | X. Iodo-methyl-norcholesterol (NP-59) | X. 500 millicuries |
| Y. Iodine-131 | Y. Meta-iodo-benzylguanidine | Y. 2 curies |
| 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 |
| 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-RAMCO-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 |
| JJ. Any byproduct material identified in 10 CFR 35.200 | JJ. Any radiopharmaceutical identified in 10 CFR 35.200 | JJ. 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 |
| 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 |
| OO. Any byproduct material with atomic number 1 through 83, inclusive | OO. Solid and/or liquid waste | OO. See Subitem 9.00 below |
| PP. Curium-244 | PP. Plated source | PP. 2.0 millicuries |

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; survey instrument and dosimeter calibration, and leak testing as a service to customers.
- 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.
- 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.

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- 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 in vitro 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 35.100.
- 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.
- OO. Possession incident to interim storage of waste in accordance with statements, representations and procedures contained in letter dated June 8, 1994.
- PP. To be used for instrument testing, standardization, and calibration.

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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; UM Botanical Gardens, Ann Arbor, Michigan; Biological Station at Pellston, Michigan; Research Vessel "Laurention" to be operated on Great Lakes and other waterways; portable gas chromatograph units which contain license 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, James E. Carey, M.S.
- 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. Licensed material for survey instrument calibration, dosimeter calibration, and leak testing services shall be used by Joseph Miklos, Patricia Brazil, or Timothy Almburg.
- D. 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.

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- (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 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, 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.
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. 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.

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23. 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; and

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), November 6, 1992, March 2, 1993, August 2, 1993, September 2, 1993, February 19, 1993 (excluding Attachment 3.0, Item 2.0) October 20, 1993, and June 8, 1994, April 4, 1995 (excluding attachments 2.0 - Quality Management Program and 3.0 - Respiratory Protection Program), July 28, 1995 (excluding Attachment 2.0, Proposed Disposal Procedure), and May 7, 1996 (excluding Item 2.0).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

October 7, 1996

By

Patricia J. Pedone
Nuclear Materials Licensing Branch, Region III

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(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

PROGRAM CODE: 02110
STATUS CODE: 2
FEE CATEGORY: 3B 7B EX 2B 3E 3P
EXP. DATE: 20000930
FEE COMMENTS: 170.11(A)(4)
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MICHIGAN, UNIVERSITY OF
RECEIVED DATE: 960509
DOCKET NO: 3001988
CONTROL NO.: 301299
LICENSE NO.: 21-00215-04
ACTION TYPE: AMENDMENT

RL

2. FEE ATTACHED
AMOUNT: 560
CHECK NO.: 994740

3. COMMENTS

SIGNED
DATE

S. Hersey
5-15-96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED / /)

1. FEE CATEGORY AND AMOUNT: *3B 7B EX 2B 3E 3P*

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ☒
RENEWAL ☐
LICENSE ☐

3. OTHER

SIGNED
DATE

SC
5/16/96

Log	<i>May 9 11</i>
Remitter	
Check No.	<i>994740</i>
Amount	<i>560</i>
Fee Category	<i>3B 7B EX 3P 3E 3P</i>
Type of Fee	<i>AmD</i>
Date Check Rec'd	<i>5-15-96</i>
Date Completed	<i>5-16-96</i>
By	<i>SC</i>

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OSEH
Occupational Safety &
Environmental Health

University of Michigan
Occupational Safety & Environmental Health
Campus Safety Services Building
1239 Kipke Drive, Ann Arbor, MI 48109-1010
Phone: 313 747-1143 • Fax: 313 763-1185

Henry D. Baier, Director

May 7, 1996

Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: **Amendments to Byproduct Material License [21-00215-04]**

Licensing Personnel:

The University of Michigan (U-M) is requesting four amendments to the U-M Byproduct Material License [21-00215-04]. The amendments are detailed below and in the attachments to this correspondence. Please find enclosed a \$560 check from the U-M to cover the amendment fee in accordance with 10 CFR 170.31 (Schedule of Material License Fees / June 1995).

1.0 Curium-244 Plated Source (2.0 millicuries)

Authorization is requested to add 2.0 millicuries of curium-244 in the form of plated sources. The sources will be used for laboratory experiments involving alpha spectroscopy and may be used for calibrating and testing radiation detectors, instrumentation, and measuring devices.

2.0 Removal, Replacement, Relocation, Storage, and Disposal of Byproduct Material Contained in Measuring, Gauging, or Controlling Devices in Accordance with 10 CFR 31.5.

Authorization is requested to allow U-M Radiation Safety Service (RSS) / Occupational Safety & Environmental Health (OSEH) radiological safety personnel to remove, replace, relocate, store, and dispose of sealed and plated byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

Removal, replacement, relocation, storage, and/or disposal of such byproduct material may be performed by U-M RSS / OSEH personnel (or contractors) under the direction of a RSS health physicist or Radiation Safety Officer (RSO) in accordance with guidance provided by the source / device vendor, or may be performed by the source / device vendor.

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REGION III

301299

May 7, 1996

The byproduct material will be controlled and secured by RSS / OSEH personnel during removal, replacement, relocation, storage, and/or disposal to prevent unauthorized or inadvertent use.

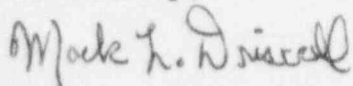
Maintenance or repair of devices containing byproduct material in accordance with 10 CFR 31.5 will be performed by a vendor or contractor licensed to perform such work by the Nuclear Regulatory Commission or an Agreement Statement.

3.0 New Radiation Policy Committee Member (Management Representative)

Associate Vice President of Business Operations William B. Krumm has retired from the U-M. The acting or interim Associated Vice President of Business Operations and management representative on the U-M Radiation Policy Committee (RPC) will be Paul A. Spradlin. Paul Spradlin has previously served as the Director of the U-M Plant Extension. The NRC will be informed upon selection of the permanent Associate Vice President of Business Operations.

Thank you for your time, effort, and consideration with this amendment request. Please do not hesitate to contact me at Radiation Safety Service [(313) 764-4420] should you have any questions, comments, or concerns regarding this amendment.

Sincerely,



Mark L. Driscoll
Director / Radiation Safety Officer
Radiation Safety Service

enclosures

MLD/mld
NRC0196

cc: Henry D. Baier, Director, Occupational Safety & Environmental Health
James E. Carey, Chair, Radiation Policy Committee

OCT 28 1996

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

Dear Mr. Driscoll:

Enclosed is Amendment No. 78 to your NRC Material License No. 21-00215-04 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.

Please note that 10 CFR Part 30, Section 30.36 was amended (Federal Register Notice dated January 16, 1996, copy enclosed) to include provisions for a one-time, five year license renewal extension for licensees that satisfied specific criteria. Your institution satisfied the criteria and Item 4 (Expiration Date) of your license has been amended to include the five year extension.

We have not authorized you to perform service operations on devices you possess as described in Item 2.0 of your May 7, 1996 letter. In order to authorize your request to perform removal, replacement, relocation, storage, and disposal of byproduct material contained in generally licensed devices pursuant to 10 CFR Part 31, Section 31.5, it will be necessary for you to provide the following information:

1. Be advised that your request to perform certain services on "generally licensed devices" is not authorized under Part 31 and consequently, your possession of these "generally licensed" devices will need to be specifically authorized on your license. Please specify the isotopes, form, activity per source/device, and total activity that you wish to possess for these devices so that we can amend Items 6., 7., 8., and 9. of your license accordingly.

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2. Please specify the minimum training and experience requirements for the individuals that will be performing the services outlined in your May 7, 1996 letter. At a minimum, these individuals should have satisfactorily completed the manufacturer's training course on the installation and servicing of the devices or document that they have received equivalent training to perform servicing operations on the devices. Also confirm that you will maintain records of the training/qualifications of the individuals authorized to service the devices;
3. You must provide each individual, who will perform service operations on the devices, with operating and emergency procedures and a copy of the current service and operation manual(s) specific to each device. You also need to ensure that service personnel receive updated manuals. Submit a copy of your operating procedures and include the following items:
 - a. Step-by-step procedures for performing the requested services;
 - b. Surveys to be performed (around the housing) to ensure the device is in the safe, store, or off position, and during other specific maintenance, cleaning, or servicing operations when sources may not be shielded by the device. Include distances and points around gauges where radiation exposures will be measured, maximum levels, and the records that will be maintained of the results. Sketches may be helpful;
 - c. Procedures describing when the device can be safely used and checked for proper operation upon completion of the service;
 - d. Procedures for final survey of the device during modes of operation, following source installation, maintenance, cleaning, and leak testing;
 - e. Records maintained for each in-house service (including a radiation profile) to indicate that radiation levels have not changed or increased as a result of the service performed.
4. Confirm that the service operations you will perform will not include any service on the sealed sources or any operation that could compromise the integrity of the source.

M. Driscoll

-3-

Information submitted in response to this letter should be referenced as additional information to **previous Control Number 01299**. If you have any questions, please contact me at (630) 829-9868.

Sincerely,

Original Signed By
Patricia J. Pelke
Nuclear Materials Licensing Branch

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

Enclosure: As stated

DOCUMENT NAME: M:\03001988.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

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NAME	PJPELKE:jaw								
DATE	9/2/96								

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