



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

107

JUL 31 2003

Mack Richard, M.S., CHP
Radiation Safety Officer
Indiana University Medical Center
Clinical Building 159
541 Clinical Drive
Indianapolis, IN 46202-5111

Dear Mr. Richard:

Enclosed is Amendment No. 77 to your NRC Material License No. 13-02752-03 in accordance with your request. Please note that the changes made to your license are printed in bold font. This amendment authorizes the [redacted] on an "as needed" basis and we have amended Subitems 7.N. and 9.N. to include the most recent revisions for the source models and device model currently registered for the Nucletron MicroSelectron HDR Classic. Note that we have authorized your possession (in Subitem 7.N.) to include all of the sources currently approved for use in this device. *exp 2*

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify me at the U.S. Nuclear Regulatory Commission, Region III office (630) 829-9868 so that I can provide appropriate corrections and answers.

Sincerely,

Patricia J. Pelke
Health Physicist
Materials Licensing Branch

License No. 13-02752-03
Docket No. 030-01609

Enclosure: Amendment No. 77

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 2
FOIA- 2005-0793

H/12

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.

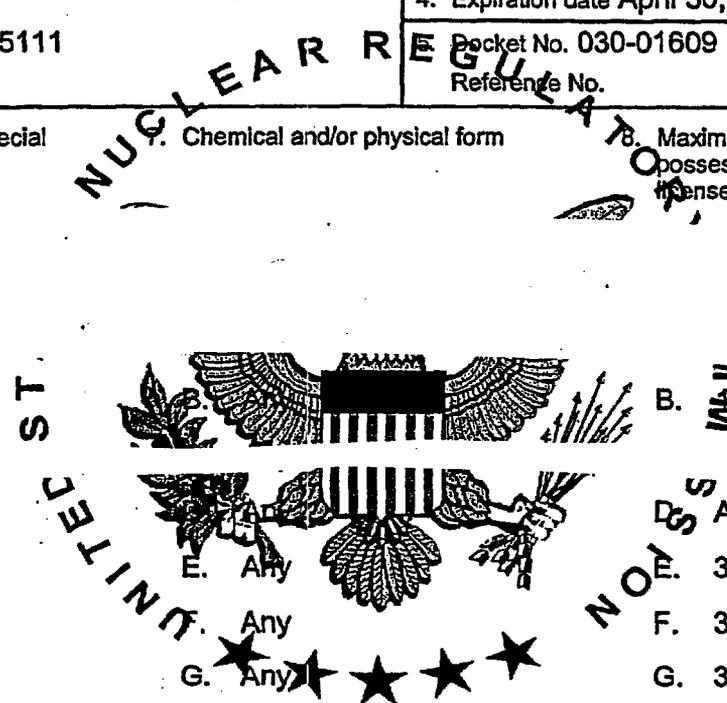
<p>Licensee</p> <p>1. IUPUI/Indiana University Medical Center Radiation Safety Office</p> <p>2. 541 Clinical Drive Indianapolis, IN 46202-5111</p>	<p>In accordance with letter dated May 20, 2003,</p> <p>3. License number 13-02752-03 is amended in its entirety to read as follows:</p> <p>4. Expiration date April 30, 2013</p> <p>Pocket No. 030-01609 Reference No.</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

A.		
B. Hydrogen-3	B. [redacted]	B. 1/2 curies
C.		EX2
D. Technetium-99m	D. Any	D. As Needed
E. Iodine-125	E. Any	E. 3.5 curies
F. Iodine-131	F. Any	F. 3.5 curies
G. Sulfur-35	G. Any	G. 3 curies
H. Phosphorus-32	H. Any	H. 3 curies
I. Phosphorus-33	I. Any	I. 3 curies
J. Americium-241	J. Any	J. 50 millicuries
K. L.		EX



MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number 13-02752-03

Docket or Reference Number 030-01609

Amendment No. 77

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

M

N

O. Americium-241

P. Cesium-137 as permitted by 10 CFR 35.600

Q

R. Uranium (depleted in Uranium-235)

S

STATE



R. Cadmium Plate Metal

O. 1000 millicuries

P. 48 sources not to exceed 20 millicuries per source

R. 34 kilograms

Et2

EX2

Et2

9. Authorized Use:

A. through I. and S. For medical diagnosis, therapy, and research in humans. Research and development as defined in Section 30.4 of 10 CFR Part 30 (including animal studies).

J. For research and development as defined in Section 30.4 of 10 CFR Part 30.

K. Medical therapy and research in humans and animals studies, and research and development as defined in Section 30.4 of 10 CFR Part 30. Also, for calibration of the licensee's survey instruments.

L. To be used in a [] for irradiation of medical specimens and research materials, excluding explosive and/or flammable materials.

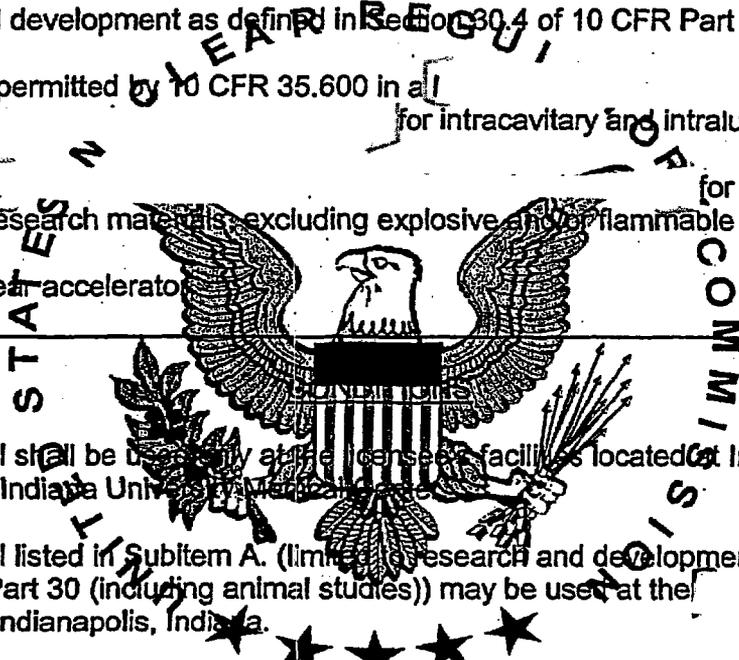
MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number 13-02752-03

Docket or Reference Number 030-01609

Amendment No. 77

- M. To be used in a [] for irradiation of medical specimens and research materials, excluding explosive and/or flammable materials.
- N. One source for medical use permitted by 10 CFR 35.600 to be used in [] at the time of installation. The device may also be used for conducting animal studies, dosimetry studies and in-vitro studies with cells. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.
- O. For research and development as defined in Section 30.4 of 10 CFR Part 30
- P. For medical use permitted by 10 CFR 35.600 in a [] for intracavitary and intraluminal treatment of cancer.
- Q. To be used in a [] for irradiation of medical specimens and research materials, excluding explosive and/or flammable materials.
- R. Shielding in a linear accelerator



- 10. A. Licensed material shall be used only at the licensee's facilities located at Indiana University/IUPUI/Indiana University Medical Center.
- B. Licensed material listed in Subitem A. (limited to research and development as defined in Section 30.4 of 10 CFR Part 30 (including animal studies)) may be used at the [] Indianapolis, Indiana.
- 11. The Radiation Safety Officer for this license is Mack L. Richard, M.S.
- 12. A. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.
- B. Individuals designated to work as authorized users, authorized nuclear pharmacists, or authorized medical physicists, as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee, Mervin C. Yoder, Jr., M.D., Chairman. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.
- C. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Mervin C. Yoder, Jr., M.D., Chairman.
- 13. 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

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-02752-03

Docket or Reference Number
030-01609

Amendment No. 77

for an emergency plan for responding to a release of licensed material.

14. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 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.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- 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.
- E. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material; or not more than 10 microcuries of alpha-emitting material.
- 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. 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: Director, Division of Nuclear Materials Safety, 801 Warrenville Road, Lisle, IL 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.
- 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-02752-03

Docket or Reference Number
030-01609

Amendment No. 77

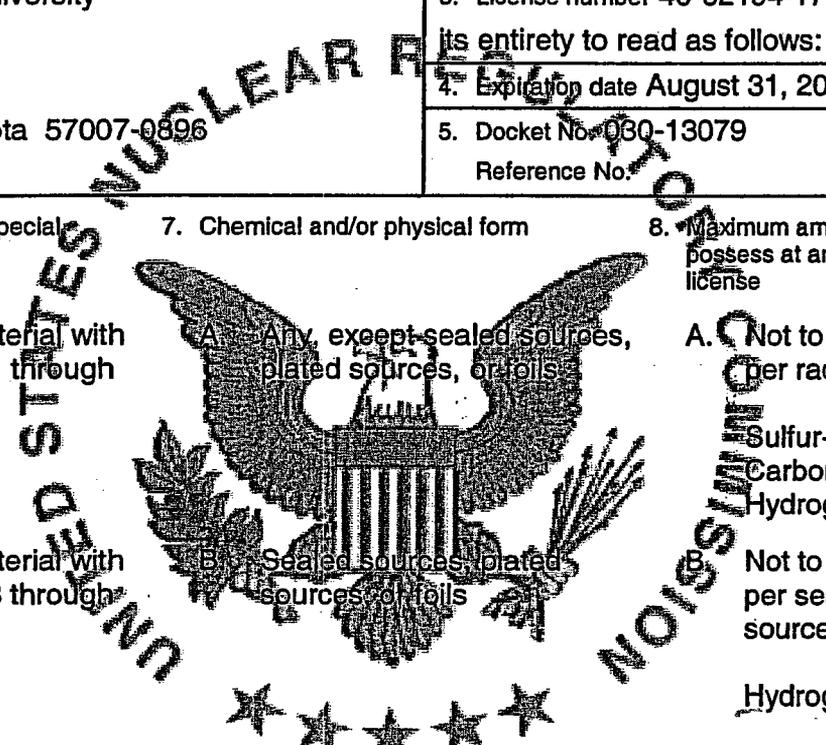
15. Pursuant to 10 CFR Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.
16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.
17. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by NRC. *4/11/77*
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside. *4/11/77*
18. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.
19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
20. The licensee is authorized to hold byproduct 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.
21. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
22. 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."

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.

Licensee	In accordance with letter dated August 14, 2003
1. South Dakota State University	3. License number 40-02194-17 is amended in its entirety to read as follows:
2. P.O. Box 2202 Brookings, South Dakota 57007-0896	4. Expiration date August 31, 2011
	5. Docket No. 080-13079 Reference No.

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. Any byproduct material with Atomic Numbers 1 through 83, inclusive	A. Any, except sealed sources, plated sources, or foils	A. Not to exceed 50 millicuries per radionuclide except: Sulfur-35 100 millicuries Carbon-14 500 millicuries Hydrogen-3 100 millicuries
B. Any byproduct material with Atomic Numbers 3 through 83, inclusive	B. Sealed sources, plated sources, or foils	B. Not to exceed 20 millicuries per sealed sources, plated sources, or foils, except: Hydrogen-3: 1 curie
C. Americium-241	C. Sealed sources registered either with NRC under 10 CFR 32.210 or with an Agreement State and incorporated in a compatible gauging device	C. Not to exceed 110 millicuries per source
D. Curium-244	D. Sealed sources registered either with NRC under 10 CFR 32.210 or with an Agreement State and incorporated in a compatible device	D. Not to exceed 30 millicuries per source



Handwritten signatures and initials:
 E.P. 6/2
 [Signature]

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
40-02194-17

Docket or Reference Number
030-13079

Amendment No. 18

9. Authorized use:

- A. through D. Research and development as defined in 10 CFR 30.4, including small animal research, academic instruction, and calibration of licensee's instruments.

CONDITIONS

10. A. Licensed material specified in Items 7.A. and 7.B. shall be used only at South Dakota State University, Brookings, South Dakota, and at locations identified in application dated February 21, 2001.
- B. Licensed material specified in Items 7.C. and 7.D. may be 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 shall only be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Gary L. Yarrow, Ph.D., Chairperson.
- B. The Radiation Safety Officer for this license is Gary L. Yarrow, Ph.D.
12. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
13. This license does not authorize commercial distribution of licensed material.
14. 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.
- 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

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
40-02194-17

Docket or Reference Number
030-13079

Amendment No. 18

- (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(c)(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 IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. 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.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
17. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by U.S. Nuclear Regulatory Commission. *ERL*
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside. *ERL*
18. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
19. Licensed material shall not be used in or on human beings.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
40-02194-17Docket or Reference Number
030-13079

Amendment No. 18

20. Pursuant to 10 CFR 20.1302(c) and 10 CFR 20.2002, the licensee is authorized to dispose of licensed 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.
21. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash provided:
- Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate 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.
 - A record of each disposal permitted under this License Condition shall be retained for 3 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.
22. 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."
23. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.
24. Notwithstanding the requirements of License Condition 25, the licensee is authorized to make program changes and changes to procedures specifically identified in the application dated February 21, 2001, and facsimile received September 19, 2001, which were previously approved by the Commission and incorporated into the license without prior Commission approval as long as:
- the proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation;
 - the revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program;
 - the licensee's staff is trained in the revised procedures prior to implementation; and
 - the licensee's audit program evaluates the effectiveness of the change and its implementation.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
40-02194-17Docket or Reference Number
030-13079

Amendment No. 18

25. 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 February 21, 2001
- B. Facsimile received September 19, 2001



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

*/RA/*Date: November 3, 2003

By:

Jacqueline D. Cook, Senior Health Physicist
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011