

MATERIALS LICENSE

Amendment No. 69

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.

OFFICIAL RECORD COPY

<p>Licensee</p> <p>1. Department of the Army Walter Reed Army Medical Center (WRAMC)</p> <p>2. Washington, D.C. 20307-5001</p>	<p>In accordance with the letter dated December 6, 1996,</p> <p>3. License Number 08-01738-02 is amended in its entirety to read as follows:</p> <p>4. Expiration Date June 30, 2004</p> <p>5. Docket or Reference No. 030-01317</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. Any byproduct material with atomic numbers 1-83	A. Any	A. 400 millicuries of each radionuclide with a total possession limit of 26 curies
B. Iodine 131	B. Any	B. 2 curies
C. Xenon 133	C. Any	C. 2 curies
D. Krypton 85	D. Any	D. 1 curie
E. Phosphorus 32	E. Any	E. 2 curies
F. Carbon 14	F. Any	F. 2 curies
G. Iodine 125	G. Any	G. 1 curie
H. Iridium 192	H. Any	H. 1 curie
I. Chromium 51	I. Any	I. 750 millicuries
J. Sulfur 35	J. Any	J. 1 curie
K. Hydrogen 3	K. Any	K. 5 curies
L. Molybdenum 99	L. Molybdenum 99/ Technetium 99m Generators	L. 23 curies
M. Technetium 99m	M. Any	M. 23 curies
N. Strontium 90	N. Sealed sources	N. 1 curie
O. Cesium 137	O. Sealed sources	O. 1 curie
P. Gadolinium 153	P. Sealed sources	P. 1 curie
Q. Iodine 125	Q. Sealed sources (3M Company seeds)	Q. 1 curie
R. Iodine 125	R. Sealed sources (Norland Inst. Co., Model 178A591A or AECL Models C235 or C324, or Amersham Corp. Model IMC.P2)	R. 4 sources, not to exceed 300 millicuries each

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 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 |
| S. Cesium 137   | S. Sealed sources                | S. [ ]   |
| T. Cobalt 60  | T. Sealed sources                | T. [ ]   |
| U. Americium 241                                      | U. Any                           | U. 100 microcuries   |
| V. Americium 241                                      | V. Sealed sources                | V. [ ]   |
| W. Nickel 63  | W. Sealed sources and foils      | W. 1 curie   |
| X. Iodine 129   | X. Sealed sources                | X. 1 curie   |
| Y. Thorium  | Y. Any                           | Y. 5 kilograms   |
| Z. Uranium  | Z. Any                           | Z. 50 kilograms  |
| AA. Cesium 137  | AA. Sealed sources               | AA. [ ]  |
| BB. Americium 241                                     | BB. Sealed sources               | BB. [ ]  |
| CC. Cesium 137  | CC. Sealed source                | CC. [ ]  |
| DD. Paladium 103                                      | DD. Sealed sources               | DD. 3 curies   |
| EE. Uranium depleted in Uranium 235                   | EE. Plated Metal                 | EE. 400 Kilograms  |

9. Authorized use

- A. through DD. Medical diagnosis, therapy and research in humans in accordance with any applicable Food and Drug Administration (FDA) requirements. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instruction.
- EE. Shielding in linear accelerators.

CONDITIONS

- 10. Location of use: Walter Reed Army Medical Center, Washington, D. C.; WRAMC Forest Glen Section and Annex, Silver Spring, Maryland; Walter Reed Army Institute of Research Animal Holding Facility, Fort Meade, Maryland; U.S. Army Medical Laboratory, WRAMC Department of Pathology, Fort Meade, Maryland; and U.S. Army Institute of Dental Research Facility, Fort Meade, Maryland; Rickman Building, 13 Taft Court, Rockville, Maryland and Gillette Building, 270 Research Center, 1413 Research Boulevard, Rockville, Maryland.
- 11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Colonel John R. Pierce, Chairperson.
- B. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

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- C. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J and shall be designated in writing by the licensee's Radiation Safety Committee.
- D. The Radiation Safety Officer for this license is Colonel William B. Johnson.
- 12. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location 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.
- 13. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 35.100, 35.200, 35.300, 35.400 and 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 U.S. Food and Drug Administration (FDA) and other Federal and State requirements.
- 14. 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 temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.  
B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
- 15. The licensee shall conduct a physical inventory every three months to account for all sealed sources and devices containing licensed material received and possessed pursuant to 10 CFR 35.59, 35.400 and 35.500 and every six months for all other sealed sources and devices.
- 16. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.  
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 three months.  
C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.  
D. 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.

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- E. Sealed sources and detector cells 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 transfer 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.
- F. The 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 and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
18. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days and Sulfur 35, Cobalt 58, Iridium 192, Scandium 46, for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
  - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument 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.

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C. A record of each such 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.

19. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
20. The licensee shall possess and use byproduct material for human research 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, and 35.300.
21. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
22. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
23. Radioactive waste generated shall be stored in accordance with the statements, representations, and procedures included with the waste storage plan described in the licensee's letter/application dated September 9, 1993 and October 29, 1993.
24. Notwithstanding the requirements of 10 CFR 35.315(a)(7), the licensee may control contamination in rooms used to house radiopharmaceutical therapy patients in accordance with the commitments and procedures contained in the letters dated April 8, 1992 and November 24, 1992.

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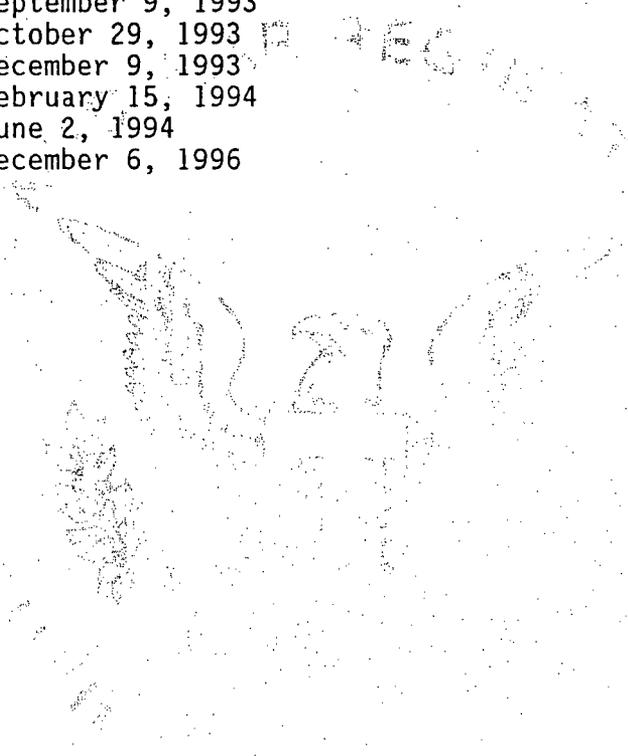
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25. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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 January 21, 1993
- B. Letter dated September 9, 1993
- C. Letter dated October 29, 1993
- D. Letter dated December 9, 1993
- E. Letter dated February 15, 1994
- F. Letter dated June 2, 1994
- G. Letter dated December 6, 1996



MAR 26 1997

Date \_\_\_\_\_

For the U.S. Nuclear Regulatory Commission

**ORIGINAL SIGNED BY:**  
**TARA L. WEIDNER**

By \_\_\_\_\_

Nuclear Materials Safety Branch  
Region I  
King of Prussia, Pennsylvania 19406