NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 7 PAGES
Amendment No. 79

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

1. Department of the Army
   Walter Reed Army Medical Center

2. 6900 Georgia Avenue, NW
   Washington, D.C. 20307-5001

In accordance with the application dated May 21, 2004 and the letter dated April 15, 2005,

3. License number 08-01738-02 is amended in its entirety to read as follows:

4. Expiration date April 30, 2015

5. Docket No. 03004317
   Reference No. 08-01738-03

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	A. Any	A. 100 millicuries per radionuclide and 26 curies total
B. Hydrogen 3	B. Any	B. 2 curies
C. Phosphorus 32	C. Any	C. 1 curie
D. Strontium 90	D. Sealed Sources (Isotope Products, Inc. Model BF 90TR Series [labeled as 67-850], Tracerlab Models RA-1A and RA-2A, Nuclear Enterprises Model 2503)	D. 500 millicuries
E. Molybdenum 99	E. Any	E. 23 curies
F. Technetium 99m	F. Any	F. 23 curies
G. Iodine 131	G. Any	G. 2 curies
H. Xenon 133	H. Any	H. 2 curies
I. Cesium 137	I. Sealed Sources (3M Health Physics Service Model Series 6500 [formerly 6D6C-CA])	I. 2 curies

License Number
08-01738-02
Docket or Reference Number
03001317
08-01738-03
Amendment No. 79

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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. Gadolinium 153	J. Sealed Sources (Isotope Products Laboratories Models NES.8424 and NEGL-0120, AEA Technology: Model GD.LIN2)	J. 6 curies
K. Iridium 192	K. Any	K. 2 curies
L. Cesium 137	L. Sealed Sources (3M Health Physics Service Model Series 6500 [formerly 6D6C-CA])	L. 50 millicuries
M. Americium 241	M. Sealed Source (Monsanto Agricultural Company Model 2704)	M. 1.4 curies
N. Plutonium 239	N. Any	N. 0.01 millicuries
O. Americium 241	O. Any	O. 0.01 millicuries
P. Depleted Uranium	P. Metal	P. 400 kilograms
Q. Cesium 137	Q. Sealed Sources (J.L. Shepherd & Associates Model 6810; ORNL Model A-0096; Amersham Corporation (Reviss Services Limited) Models CDC.PE1, CDC.PE2, CDC.PE3 (R6000), CDC.PE4 (R6010), CDC.PE5 (R6020), CDC.PE6 (R6030), CDC.PE7 (R6040), CDC.PE8 (R6050))	Q. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State
R. Cobalt 60	R. Sealed Sources (J. L. Shepherd & Associates Model 7810)	R. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State

UNITED STATES NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
08-01738-02
Docket or Reference Number
03001317
08-01738-03
Amendment No. 79

9. Authorized use:

A. through K. Medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instruction; and in-vitro studies.

L. through O. Calibration and checking of the licensee's instruments. Teaching and training of students.

P. Shielding in linear accelerators.

Q. and R. For irradiation of materials in self-shielded irradiator devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and which have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Walter Reed Army Medical Center (WRAMC), Washington, D.C.; WRAMC Forest Glen Section and Annex, Silver Spring, Maryland; Rickman Building, 13 Taft Court, Rockville, Maryland; and The Gillette Building, 1413 Research Boulevard, Rockville, Maryland.

11. A. The use of licensed material in or on humans shall be by an authorized user 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.

C. Licensed material in Items 6.A. through 6.P. for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

D. Licensed material in Items 6.Q. and 6.R. shall be used by, or under the supervision of, individuals who have received the training described in the revised application appended to the letter dated January 10, 2005, and have been designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.

E. The Radiation Safety Officer for this license is Lieutenant Colonel Mark Melanson, Ph.D.

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
08-01738-02
Docket or Reference Number
03001317
08-01738-03
Amendment No. 79

13. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.

14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

17. 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 six months or at 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
08-01738-02
Docket or Reference Number
03001317
08-01738-03
Amendment No. 79

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.

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.

I. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

18. 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 U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

19. 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.

20. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

21. For each J. L. Shepherd and Associates, Mark I or Model 81-22, cesium-137 irradiator installed and used, the licensee shall:

A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and

B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and

C. Have room monitors installed that will:

(i) Operate at all times when the irradiator is in use; and
(ii) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
08-01738-02
Docket or Reference Number
03001317
08-01738-03
Amendment No. 79

(iii) Detect any radiation leaking from the irradiator door; and
(iv) Be visible to the irradiator user when the user is next to the irradiator; or

D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:

(i) Determine the radiation level at the irradiator door when the door is closed; and
(ii) Check for any increase in radiation levels each time the irradiator door is opened.

E. If abnormal radiation levels or any malfunctions of the irradiator are detected at any time, the licensee shall cease using the irradiator, restrict access to the area housing the irradiator, immediately notify the Radiation Safety Officer, and submit all reports required under 10 CFR Parts 20, 21, or 30.

F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

22. The procedures contained in the manufacturer's instruction manual for the irradiator authorized by this license, shall be followed, and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

23. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

24. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

25. Notwithstanding the requirements of License Condition 26, the licensee is authorized to make program changes and changes to procedures specifically identified in the condition, which were previously approved by the U.S. Nuclear Regulatory Commission and incorporated into the license without prior Commission approval as long as:

License Number
08-01738-02

MATERIALS LICENSE
SUPPLEMENTARY SHEET

Docket or Reference Number
03001317
08-01738-03

Amendment No. 79

A. The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation.

B. 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.

C. The licensee's staff is trained in the revised procedures prior to implementation.

D. The licensee's audit program evaluates the effectiveness of the change and its implementation.

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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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. Letter dated January 10, 2005, enclosing revision of application dated May 21, 2004 [ML050650027]
B. Letter dated March 28, 2005 [ML050930009]

For the U.S. Nuclear Regulatory Commission

Date April 24, 2005

By ***Original signed by Sandra Gabriel***

Sandra Gabriel
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406