



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 17, 2004

Docket No. 03001317  
Control No. 135458

License No. 08-01738-02

Colonel Thomas M. Fitzpatrick, M.C.  
Deputy Commander for Clinical Services  
Department of the Army  
Walter Reed Army Medical Center  
6900 Georgia Avenue, N.W.  
Washington, D.C. 20307-5001

SUBJECT: DEPARTMENT OF THE ARMY, ISSUANCE OF LICENSE AMENDMENT,  
CONTROL NO. 135458

Dear Colonel Fitzpatrick:

This refers to your letter received May 24, 2004, requesting renewal of License No. 08-01738-02 and consolidation of the authorizations contained on License No. 08-01738-03 into License No. 08-01738-02. As I discussed with your Radiation Safety Officer, LTC John Mercier, on August 10, 2004, in order to process your request for consolidation of the licenses in a timely manner, we elected to separate the request for consolidation from the request for renewal. Enclosed with this letter is the consolidated license. Under separate cover you will receive a copy of License No. 08-01738-03, which was terminated. Your license renewal has not yet been completed.

If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

*An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).*

In accordance with 10 CFR 2.390, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/reading-rm.html>.

Thank you for your cooperation.

Sincerely,

**Original signed by James P. Dwyer**

Information in this record was deleted  
in accordance with the Freedom of Information  
Act, exemptions 2  
FOIA- 2006-0238

James P. Dwyer  
Senior Health Physicist  
Nuclear Materials Safety Branch 1  
Division of Nuclear Materials Safety

*mm/21*  
~~ML 04 23 10 04~~

T. Fitzpatrick  
Department of the Army

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Enclosure:  
Amendment No. 77

cc:  
LTC John R. Mercier, Ph.D., Radiation Safety Officer

DOCUMENT NAME: G:\Docs\Current\Lic Cvr Letter\L08-01738-02.135458.wpd

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DATE	8/17/04								

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MATERIALS LICENSE

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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. 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 received May 24, 2004</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 (extended)</p> <p>5. Docket No. 030-01317 Reference No. 08-01738-03</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>(A) Any byproduct material with atomic numbers 1-83</p> <p>(B) Iodine 131</p> <p>(C) Xenon 133</p> <p>(D) Krypton 85</p> <p>(E) Phosphorus 32</p> <p>(F) Carbon 14</p> <p>(G) Iodine 125</p> <p>(H) Iridium 192</p> <p>(I) Chromium 51</p> <p>(J) Sulfur 35</p> <p>(K) Hydrogen 3</p> <p>(L) Molybdenum 99</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Any</p> <p>I. Any</p> <p>J. Any</p> <p>K. Any</p> <p>L. Molybdenum 99/ Technetium 99m Generators</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 400 millicuries of each radionuclide with a total possession limit of 26 curies</p> <p>B. 2 curies</p> <p>C. 2 curies</p> <p>D. 1 curie</p> <p>E. 2 curies</p> <p>F. 2 curies</p> <p>G. 1 curie</p> <p>H. [ ] Ex 2</p> <p>I. 750 millicuries</p> <p>J. 1 curie</p> <p>K. 5 curies</p> <p>L. 23 curies</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

M Technetium 99m

M. Any

M. 23 curies

N Strontium 90

N. Sealed sources

N.

O Cesium 137

O. Sealed sources

O.

P Gadolinium 153

P. Sealed sources

P.

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

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.

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7. Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

CC. Palladium 103

CC. Sealed sources

CC. 3 curies

DD. Iridium 192

DD. Sealed sources

DD. [ ]

EE. Uranium depleted in Uranium 235

EE. Plated Metal

EE. 400 Kilograms

FF. Cobalt 60

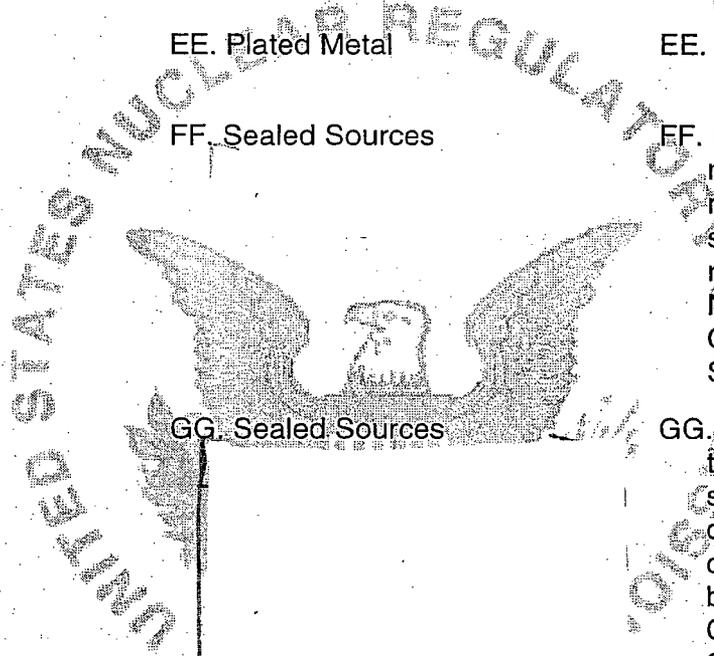
FF. Sealed Sources

FF. No single source to exceed the maximum activity per source or maximum activity per device specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State

GG. Cesium 137

GG. Sealed Sources

GG. No single source to exceed the maximum activity per source or maximum activity per device specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State



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.

FF. and GG.

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.

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**CONDITIONS**

10. A. Licensed material in Items 6.A through 6.EE may be used only at the licensee's facilities located at the Walter Reed Army Medical Center, Washington, D. C.; WRAMC Forest Glen Section and Annex, Silver Spring, Maryland; U.S. Army Medical Laboratory, WRAMC Department of Pathology, Fort Meade, Maryland; Rickman Building, 13 Taft Court, Rockville, Maryland and Gillette Building, 270 Research Center, 1413 Research Boulevard, Rockville, Maryland.
- B. Licensed material in Items 6.FF and 6.GG may be used or stored only at the licensee's facilities located at Walter Reed Army Medical Center, Washington, D.C. and Walter Reed Army Institute for Research, Forest Glen Annex, Silver Spring, Maryland.
11. A. Licensed material in Items 6.A through 6.EE shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Colonel Thomas M. Fitzpatrick, Chairperson.
- B. Licensed material in Items 6.FF and 6.GG shall be used by, or under the supervision of, individuals who have received the training described in the application dated October 15, 2001 and have been designated, in writing, by the Radiation Safety Officer.
- C. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.
- D. 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.
- E. Individuals designated to work as medical physicists for intravascular brachytherapy shall meet the training and experience criteria established in 10 CFR 35.961; or be named on a current U.S. Nuclear Regulatory Commission or Agreement State license, or a permit issued under a broad scope license as a medical physicist; and shall be designated, in writing, by the Radiation Safety Committee. In addition, the physicist must meet the recentness of training requirement in 10 CFR 35.972 and have recent, device-specific training and experience for each make and model of intravascular brachytherapy device used by the licensee.
- F. The Radiation Safety Officer for this license is Lieutenant Colonel John R. Mercier.
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.

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13. The licensee is exempted from decommissioning financial assurance requirements for possession of

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licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purposes of source changes only. This exemption is granted for no more than 30 days for any one source change.

- 14. 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.
- 15. 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.
- 16. 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.
- 17. 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.
18. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
19. The licensee shall not repair, remove, replace or alter any of the following: electrical and mechanical systems that control irradiator 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.

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20. For each  
the licensee shall:

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irradiator installed and used,

- 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
  - (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.

21. 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.
22. 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.
23. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
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. 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.
26. 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.
27. 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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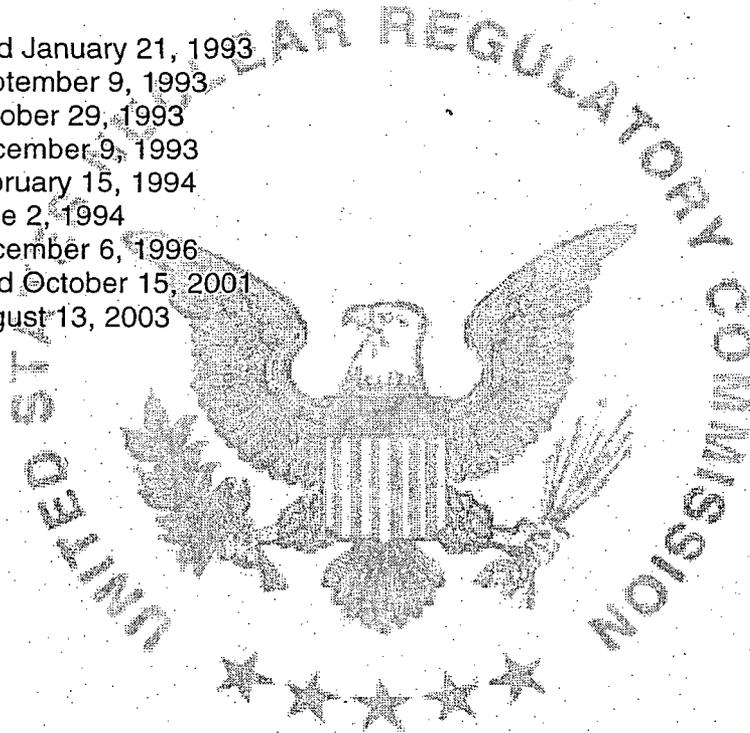
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28. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for 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
- H. Application dated October 15, 2001
- I. Letter dated August 13, 2003



For the U.S. Nuclear Regulatory Commission

*Original signed by James P. Dwyer*

Date August 17, 2004

By

James P. Dwyer  
 Nuclear Materials Safety Branch 1  
 Division of Nuclear Materials Safety  
 Region I  
 King of Prussia, Pennsylvania 19406

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