



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

April 24, 2005

Docket No. 03001317
Control Nos. 135047
136837

License No. 08-01738-02

Colonel Thomas M. Fitzpatrick, MC
Deputy Commander for Clinical Services
Department of the Army
Walter Reed Army Medical Center
6900 Georgia Avenue, NW
Washington, DC 20307-5001

SUBJECT: DEPARTMENT OF THE ARMY, WALTER REED ARMY MEDICAL CENTER,
ISSUANCE OF LICENSE RENEWAL, CONTROL NO. 135047

Dear Colonel Fitzpatrick:

This refers to your request for renewal of your NRC license and to your amendment request dated April 15, 2005. Enclosed with this letter is the renewed license. As requested in your renewal application, the decommissioned U.S. Army Medical Laboratory facility at Fort Meade, Maryland has been removed from your license and may be released for unrestricted use. In addition, LTC Mark Melanson, Ph.D. is now designated as Radiation Safety Officer for this license.

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 I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. Please note that the last condition on your license indicates that "This license condition applies only to those procedures that are required to be submitted in accordance with the regulations." Therefore, any procedures submitted that were not required by regulation to be submitted, e.g., calibration of dose calibrators, will not be considered a part of your license and were not reviewed during the licensing process. These procedures will be reviewed during inspections, as necessary.

Please note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

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2. Notify the NRC in writing when:
 - a) the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
 - b) the mailing address changes;
 - c) the name on the license changes; or
 - d) permitting an individual to function as a temporary Radiation Safety Officer in accordance with 10 CFR 35.24(c).
3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
4. Request and obtain a license Amendment before you:
 - a) permanently change Radiation Safety Officers;
 - b) receive byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c) change the name or ownership of your organization;
 - d) change the address(es) of use identified on the license;
 - e) receive, prepare, or use byproduct material for a type of use that is not authorized on the license; or
 - f) revise procedures required by 10 CFR 35.610, 35.642, 35.643, or 35.645, as applicable, where such revision reduces radiation safety.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order

T. Fitzpatrick
Department of the Army

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suspending, modifying or revoking your license as specified in NUREG 1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

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

Current NRC regulations and guidance are available at the NRC Web sites listed below or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Sandra Gabriel

Sandra Gabriel
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 79

NRC Web site addresses
NRC regulations

<http://www.nrc.gov/reading-rm/doc-collections/cfr/>

Licensing guidance

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>

General Policy and Procedure for NRC Enforcement Actions

<http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf>

206 of the Energy Reorganization Act of 1974

<http://www.nrc.gov/who-we-are/governing-laws.html>

cc:
LTC Mark Melanson, Ph.D., Radiation Safety Officer

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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</p> <p>2. 6900 Georgia Avenue, NW Washington, D.C. 20307-5001</p>	<p>In accordance with the application dated May 21, 2004 and the letter dated April 15, 2005,</p> <p>3. License number 08-01738-02 is amended in its entirety to read as follows:</p> <p>4. Expiration date April 30, 2015</p> <p>5. Docket No. 03001317 Reference No. 08-01738-03</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 through 83 | A. Any | A. 400 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 | D. [] |
| 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 | I. [] |

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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. Gadolinium 153

J. Sealed Sources

J.

K. Iridium 192

K. Any

K.

L. Cesium 137

L. Sealed Sources

L.

M. Americium 241

M. Sealed Source

M.

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

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

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

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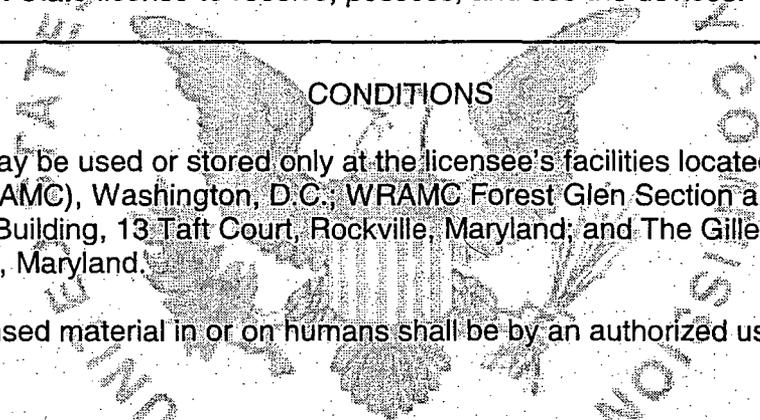
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9. Authorized use:

- 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.

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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:
- 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.
 - 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.
 - 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.
 - 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.
 - 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.
 - 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.

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- 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 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

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- (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:

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- 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

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