

Amendment No. 73

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, 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
Commander, Brooke Army Medical Center
ATTN: MCHE-DHR (Health Physics)
2. 2421 Dickman Road, Bldg. 1001
Ft. Sam Houston, Texas 78234-6390

In accordance with letter dated
November 25, 1996

3. License number 42-01368-01 is amended in its entirety to read as follows:

4. Expiration date April 30, 2001

5. Docket or Reference No 030-03258

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, except as specified below

B. Molybdenum-99

C. Technetium-99m

D. Iodine-131

E. Xenon-133

F. Gold-198

G. Any byproduct material with atomic numbers 1 through 84

H. Americium-241

I. Uranium (Depleted in Uranium-235)

A. Any, except sealed sources

B. Any, except sealed sources

C. Any, except sealed sources

D. Any, except sealed sources

E. Any, except sealed sources

F. Any, except sealed sources

G. Sealed sources or foils

H. Sealed sources

I. Cadmium plated metal

A. Not to exceed 100 millicuries per radionuclide (See Condition 18)

B. 15 curies

C. 15 curies

D. 1 curie

E. 3 curies

F. 700 millicuries

G. 10 curies (Not to exceed 3 curies per source or foil)

H. 50 millicuries

I. 273 kilograms

OFFICIAL RECORD COPY

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PDR ADDCK 03003258
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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. Uranium (Depleted in Uranium-235) | J. Metal | J. 150 kilograms |
| K. Cesium-137 | K. Sealed sources (ORIS/CBI Model CSL-15) | K. 11,200 curies [2 sets of sources (3 sources per set) not to exceed 5,610 curies per set] |

9. Authorized use:

- A. through H. Medical research, diagnosis, and therapy. In vitro studies. Studies in laboratory animals.
- I. Shielding in a linear accelerator.
- J. Shielding in technetium-99m/molybdenum-99 generators.
- K. To be used for the irradiation of biological materials in a Compagnie ORIS Industrie Model IBL-437C irradiator.

CONDITIONS

10. Licensed material shall be used only at the licensee's facility located at Brooke Army Medical Center, Ft. Sam Houston, Texas.
11. 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. 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 by the licensee's Radiation Safety Committee.
- C. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee.
12. The Radiation Safety Officer for this license is CPT Casmere H. Taylor.

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13. 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. 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.
- E. 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
 - (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.
- F. 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(b)(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.

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- G. 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.
14. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
 15. 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.
 16. 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.
B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
 17. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
 18. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of unsealed licensed material to quantities less than 10^5 times the applicable limits in Appendix B of 10 CFR Part 30, as specified in 10 CFR 30.35(d).
 19. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, and 10 CFR 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 United States Food and Drug Administration (FDA) and other Federal and State requirements.
 20. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 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.

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- B. 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.
- C. 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.
21. The licensee shall conduct a physical inventory every 3 months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400 and 10 CFR 35.500 and every 6 months for all other sources and/or devices.
22. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
23. The procedures contained in Compagnie ORIS Industrie instruction manual for the Model IBL-437C device 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.

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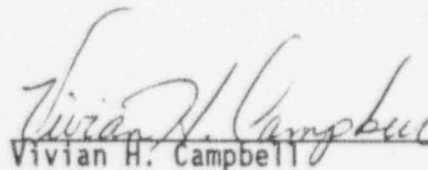
25. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Letter dated October 10, 1995
- B. Letter dated January 26, 1996
- C. Letter dated January 30, 1996
- D. Letter dated March 15, 1996
- E. Letter dated April 16, 1996
- F. Letter dated April 16, 1996 and received May 20, 1996
- G. Facsimile dated August 21, 1996
- H. Letter dated November 25, 1996

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date DEC 31 1996

By



Vivian H. Campbell
Senior Health Physicist
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

December 31, 1996

Department of the Army
ATTN: Casmere H. Taylor
MCHE-DHR(Health Physics)
Brooke Army Medical Center
2421 Dickman Rd., Bldg 1001
Ft. Sam Houston, TX 78234-6390

SUBJECT: LICENSE AMENDMENT

Please find enclosed License No. 42-01368-01. You should review this license carefully and be sure that you understand all conditions. If you have any questions, you may contact the reviewer who signed your license at 817-860-8143.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public which can result from failure to comply with NRC requirements, you must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Possess radioactive material only in the quantity and form indicated in your license.
3. Use radioactive material only for the purpose(s) indicated in your license.
4. Notify NRC in writing of any change in mailing address (no fee required if the location of radioactive material remains the same).
5. Request and obtain written NRC consent before transferring your license or any right thereunder, either voluntarily or involuntarily, directly or indirectly, through transfer of control of your license to any person or entity. A transfer of control of your license includes not only a total change of ownership, but also a change in the controlling interest in your company whether it is a corporation, partnership, or other entity. In addition, appropriate license amendments must be requested and obtained for any other planned changes in your facility or program that are contrary to your license or contrary to representations made in your license application, as well as supplemental correspondence thereto, which are incorporated into your license. A license fee may be charged for the amendments if you are not in a fee-exempt category.

6. Maintain in a single document decommissioning records that have been certified for completeness and accuracy listing all the following items applicable to the license:
 - Onsite areas designated or formerly designated as restricted areas as defined in 10 CFR 20.3(a)(14) or 20.1003.
 - Onsite areas, other than restricted areas, where radioactive materials in quantities greater than amounts listed in Appendix C to 10 CFR 20.1001-20.2401 have been used, possessed, or stored.
 - Onsite areas, other than restricted areas, where spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site have occurred that required reporting pursuant to 10 CFR 30.50(b)(1) or (b)(4), including areas where subsequent cleanup procedures have removed the contamination.
 - Specific locations and radionuclide contents of previous and current burial areas within the site, excluding radioactive material with half-lives of 10 days or less, depleted uranium used only for shielding or as penetrators in unused munitions, or sealed sources authorized for use at temporary job sites.
 - Location and description of all contaminated equipment involved in licensed operations that is to remain onsite after license termination.
7. Submit a complete renewal application with proper fee, or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.
8. Request termination of your license if you plan to permanently discontinue activities involving radioactive material.

You will be periodically inspected by 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; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 60 FR 34381, June 30, 1995.

Thank you for your cooperation.

Sincerely,

A handwritten signature in cursive script, reading "Vivian H. Campbell".

Vivian H. Campbell
Senior Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-03258
License: 42-01368-01
Control: 466263

Enclosures: As stated

DOCUMENT NAME: P:\Brooke.arm

To receive copy of document, indicate in box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

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VHCampbell	<i>NTD</i>						
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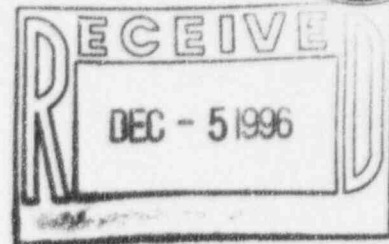


DEPARTMENT OF THE ARMY
BROOKE ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234-6200



REPLY TO
ATTENTION OF

November 25, 1996



Preventive Medicine

U.S. Nuclear regulatory Commission-Region IV
Material Radiation Protection Section
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Dear Sir or Madam:

Please find enclosed a request from Brooke Army Medical Center, Fort Sam Houston, TX, to amend Byproduct Material License No. 42-01368-01, Docket No. 030-03258

If you require additional information, I can be reached at extension (210)916-8338.

Sincerely,

Encl
as

Casmere H. Taylor
Captain, MS
Chief, Health Physics, BAMC

CF:
MCHO-CL-W, ATTN: COL Daxon (w/encl)
Commander, U.S. Army Center for Health Promotions and Preventive Medicine (Prov), ATTN: MCHB-MR-H, Aberdeen Proving Ground, MD 21010-5422 (w/encl)
MCHE-DH, ATTN: COL Gelnett
RCC

466263



DEPARTMENT OF THE ARMY

BROOKE ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234-6200



REPLY TO
ATTENTION OF

MCHE-DHR (385-11m)

25 November 1996

MEMORANDUM THRU Headquarters, U.S. Army Medical Command,
ATTN: MCHO-CL-W, 2050 Worth Road,
Fort Sam Houston, TX 78234-6000

FOR U.S. Nuclear Regulatory Commission-Region IV, Material
Radiation Protection Section, 611 Ryan
Plaza Drive Suite 1000, Arlington, Texas 76011

SUBJECT: Application for Amendment to U.S. Nuclear Regulatory
Commission (NRC) Byproduct Material License No. 42-01368-01,
Docket No. 030-03258

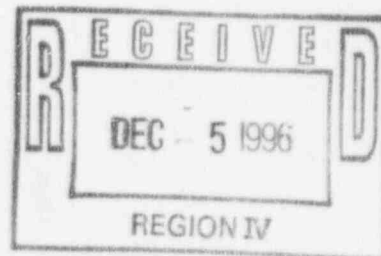
1. Request Brooke Army Medical Center (BAMC) NRC License No. 42-01368-01 be amended to authorize an increase of Iodine-131 (I-131), to a possession limit of 1 Curie (Ci). Our current I-131 possession limit as reflected in NRC Material License 42-01368-01, Amendment No. 66, subpart 6 (A) is 500 millicuries.
2. Currently, BAMC does not use I-131 for Monoclonal Antibody Studies.
3. Our point of contact is Captain Casmere H. Taylor, Radiation Protection Officer at (210)916-8338/8458 or FAX: (210)916-8434.

FOR THE COMMANDER:

Douglas E. Mills

DOUGLAS E. MILLS
Lieutenant Colonel, MS
Chief, Information Management
Division

CF:
MCHE-DR, ATTN: COL Shah
MCHE-DH, ATTN: Col Gelnett
MCHE-DHR
RCC



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