

MATERIALS LICENSE

Amendment No. 68

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

Licensee		In accordance with the letter dated August 2, 1996,	
1. VA Connecticut Health Care System- West Haven Campus		3. License Number 06-00092-05 is amended in its entirety to read as follows:	
2. 950 Campbell Avenue West Haven, Connecticut 06516		4. Expiration Date August 31, 2004	
		5. Docket or Reference No. 030-01237/030-01283	
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 between 3 and 83 and half-life less than or equal to 120 days	A. Any	A. Not to exceed 300 millicuries per radionuclide and 5 curies total	
B. Any byproduct material with Atomic Numbers between 3 and 83	B. Sealed sources	B. Not to exceed 300 millicuries per source and 5 curies total	
C. Hydrogen 3	C. Any	C. 500 millicuries	
D. Carbon 14	D. Any	D. 300 millicuries	
E. Calcium 45	E. Any	E. 100 millicuries	
F. Technetium 99m	F. Any	F. 4 curies	
G. Cesium 137	G. Sealed source (J. L. Shepherd calibrator Model 28-5 containing sealed source Model 6810)	G. 100 millicuries per source and 200 millicuries total	
H. Gadolinium 153	H. Sealed sources	H. 2 curies per source and 4 curies total	
9. Authorized use			
A. through H. 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 and calibration of instruments.			

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 950 Campbell Avenue, West Haven, Connecticut and the Newington Campus, 555 Willard Avenue, Newington, Connecticut.
11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Holley M. Dey, M.D., Chairperson.

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- 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.
- 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 Terry Yoshizumi, Ph.D.
12. 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.
13. 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.
14. 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.
15. 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.
- 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

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- (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.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
17. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days 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.
 - 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.

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18. 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 letters dated September 13, 1992 and November 29, 1994.
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. 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 February 14, 1991
- B. Letter dated November 12, 1993
- C. Letter dated May 19, 1994
- D. Letter dated May 6, 1996

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Thomas K. Thompson

Date

SEP 24 1996

By

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

SEP 24 1996

Vincent Ng
Director
VA Connecticut Healthcare System
Department of Veterans Affairs Medical Center
950 Campbell Avenue
West Haven, CT 06516

Dear Mr. Ng:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:

Thomas K. Thompson
Division of Nuclear Materials Safety

License No. 06-00092-05
Docket No. 030-01237
Control No. 123567

Enclosure:
Amendment No. 68

cc: Francis K. Herbig
Health Physics Programs (115HP)
Department of Veterans Affairs
915 North Grand Blvd.
St. Louis, MO 63106

DOCUMENT NAME: R:\WPS\MLTR\L0600092.05

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	Beardsley		Thompson				
DATE	08/20/96		08/4/96		08/ /96		08/ /96

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DEPARTMENT OF VETERANS AFFAIRS

Medical Center
950 Campbell Avenue
West Haven CT 06516

030-01237

AUG 02 1996

In Reply Refer To:

U.S. Nuclear Regulatory Commission
Region I
Nuclear Materials Safety Branch
and Safeguards
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: Possession Limit Increase Requested on Tc-99m

License No. 06-00092-05, VA Connecticut Healthcare System, West Haven Campus

Dear Sir:

This is an amendment application for the possession limit increase at the VA Connecticut Healthcare System, West Haven Campus (License No. 06-0092-05). The amendment application pertains to the increase of the possession limit of technetium-99m from 2 curies to 4 curies.

Background and Justifications:

1. Biomedical Research Laboratory

We are anticipating a R&D project involving technetium-99m up to 0.5 curies at the beginning of the experiment. Related to this project, we also anticipate the possession of a technetium generator in the research laboratory. Under these circumstances, there is a need to modify the current possession limit of 2 curies at any one time.

2. Clinical Nuclear Medicine Laboratory

We use a unit dosage which is supplied by a local company; therefore, we believe that the total possession of technetium-99m at any one time would be somewhere between 2 curies and 4 curies.

In summary, we specifically request that the possession limit of technetium-99m be increased from 2 curies to 4 curies at any one time.

If you have any questions, please call Dr. Terry Yoshizumi, Radiation Safety Officer at (203) 932-5711 X3604.

Sincerely,

Vincent Ng

Vincent Ng
Director, VA Connecticut Healthcare System

FOR AND IN THE
ABSENCE OF

123567

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ML 10

AUG 13 1996



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
St Louis MO 63125

August 8, 1996

In Reply Refer To:

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

SUBJECT: NRC License No. 06-0092-05

The enclosed correspondence from the West Haven, Connecticut VA Medical Center has been received and is forwarded to your office for processing. If there are questions, please contact the facility.

Please provide a copy of any correspondence relative to licensing actions for this Medical Center to:

Department of Veterans Affairs
Health Physics Programs (115HP)
915 North Grand Blvd.
St. Louis, MO 63106

Sincerely,

Cindy Bukowsky

for

Francis K. Herbig
Health Physics Programs

AUG 13 1996

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
: PROGRAM CODE: 02110
: STATUS CODE: 0
: FEE CATEGORY: EX 78
: EXP. DATE: 20040831
: FEE COMMENTS: V
: DECOM FIN ASSUR REQD: Y
: ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: V. A., DEPARTMENT OF
RECEIVED DATE: 960816
DOCKET NO: 3001237
CONTROL NO.: 123567
LICENSE NO.: 06-00092-05
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: -----
CHECK NO.: -----

3. COMMENTS

SIGNED Rachel Sitron
DATE 8/16/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /__/))

1. FEE CATEGORY AND AMOUNT: -----

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT -----
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED -----
DATE -----