



DEPARTMENT OF THE ARMY
 WALTER REED ARMY MEDICAL CENTER
 WASHINGTON, DC 20307-5001



MS16
 P-7

REPLY TO
 ATTENTION OF:

September 9, 1993

Health Physics Office

SUBJECT: Additional Information for Review of Renewal of U.S. Nuclear Regulatory Commission License No. 08-01738-02, mail control No. 117725

Nuclear Materials Safety Branch
 Division of Radiation Safety and Safeguards
 ATTENTION: Mr. Thomas K. Thompson
 U.S. Nuclear Regulatory Commission, Region I
 475 Allendale Road
 King of Prussia, Pennsylvania 19406-1415

Information in this record was deleted
 in accordance with the Freedom of Information
 Act, exemptions 2
 FOIA-2006-0225

Dear Mr. Thompson:

In response to your letter of August 11, 1993, pertaining to the renewal of License No. 08-0738-02, Control No. 117725, the following additional information is provided:

a. The Radiation Control Committee (RCC) follows the criteria set down in 10 CFR 33.15 for evaluating physicians and other individuals to use radioactive material for nonhuman uses. After evaluations have been completed using the aforementioned criteria and additional information, the RCC makes a final decision to approve or disapprove an individual as an authorized user.

b. Information Notice 90-09 has been carefully reviewed. It does not state that license renewals not having an Interim Waste Storage Plan will have a condition placed on it which will only allow storage of LLW for a rolling two year period. It does state however, that "not all licensees who will need to store LLW onsite will need amendments to their licenses to do so". Our existing license has no condition limiting storage of radioactive material or waste, except by total activity. We intend to maintain our total inventory, to include storage of waste, below existing limits. A rolling two year LLW storage condition will conflict with our NRC approval for decay in storage of materials with half-lives of up to 90 days. This requires us to hold some waste for a minimum of 2.5 years with no upper limit specified. Our waste is processed and stored in a decommissioned research reactor building which is solely occupied and secured by the Health Physics Office. The waste consist of dry, solid lab material, which is compacted into 55-gallon steel drums properly labeled and ready for disposal. It is stored under dry, temperature controlled conditions on four-level warehouse racks, and secured in a locked building surrounded by a locked perimeter fence. This facility has capacity to safely hold 500 drums.

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c. Our request for a case by case exemption from the requirements of 10 CFR 35 Subpart J is hereby withdrawn.

d. Radiation safety office audits of the performance of radioactive material authorizations are conducted semiannually. The elements of each audit include compliance with Army and hospital regulations, terms and conditions of the NRC license, proper posting of signs and labels, activity on hand, location, inventory records, logs, procedures, and required personnel actions.

e. All protocols for the use of unbound radioactive iodine involve less than 10 mCi per experiment; however, iodination procedures are required to be performed in a designated glove box which is inside a chemical fume hood. Exhaust is pulled through a charcoal filter and HEPA filter before venting to the outside. The hood exhaust air and room air are periodically monitored to ensure compliance with federal standards. All nonhuman use labs use less than 100 mCi at any one time. Nuclear Medicine is the only location where quantities greater than 100 mCi are handled. One compactor is used at the Health Physics waste processing facility to compact dry, solid LLW in 55-gallon drums. The facility is secured by the Health Physics Office and routinely surveyed for contamination. The compactor is exhausted through a HEPA particulate filter and charcoal cartridge air samples are used to monitor the exhaust air for volatile gases.

f. The model training program that was published in Appendix A to Regulatory Guide 10.8 Revision 2 will be established for all radiation workers. Records will be maintained to demonstrate compliance with applicable regulations.

g. Animal holding facilities are maintained in clean areas. Animals are taken from the holding facility to a restricted area by authorized users for the introduction of radioactive material. Animals are then sacrificed, placed in a marked freezer, and picked up by Health Physics Office for appropriate disposal. Protocols requiring the holding of animals containing radioactive material greater than exempt quantities will include provisions to ensure that the holding facility is secured from unauthorized access. Only authorized users will handle animals, animal wastes and carcasses. Cages will be cleaned and decontaminated by authorized users to ensure proper disposal of radioactive material and that they are free of radioactive contamination.

h. Trigger levels for removable contamination will be >50% and >100% of Reg Guide 8.23, Table 2 limits. Trigger levels for radiation levels will be 2 times background or 1 mR/hr for gamma and 2 mR/hr or 25% of 10 CFR 20.101(a) limits.

i. Our request for authorization to decay in storage I-125 LLW for 5 half-lives rather than 10 half-lives is hereby withdrawn.

j. Amendment No. 63, dated June 22, 1993, added the Gillette building to our license. See enclosure.

k. It has been noted that M.1 and M.2 of Reg Guide 10.8, Revision 2 are missing some required information.

l. Minimum requirements for surveys in non-medical use areas will be determined by types and quantity of material. For gamma and high energy beta emitting material the users will survey daily with G-M survey meters. Health Physics will survey weekly when ≥ 200 uCi is used at any one time and monthly when < 200 uCi is used. For soft beta emitting material the users will perform daily wipes at the end of each day of use when using > 100 uCi at any one time. Health Physics will survey weekly when ≥ 200 uCi is used at any one time and monthly when < 200 uCi is used.

I hope the above information adequately addresses your concerns pertaining to the renewal of our broad scope license. Please contact the undersigned at (301) 427-5161 if further information is required.

Enclosure
as



ARTHUR G. SAMILJAN
Lieutenant Colonel, U.S. Army
Chief, Health Physics Office

MATERIALS LICENSE

Amendment No. 63

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10 of the 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		In accordance with the letter dated March 26, 1993,	
1. Department of the Army Walter Reed Army Medical Center (WRAMC)		3. License number 08-01738-02 is amended in its entirety to read as follows:	
2. Washington, D.C. 20307-5001		4. Expiration date April 30, 1993 (Extended)	
		5. Docket or Reference No. 030-01317	
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 1-83	A. Any	A. 400 millicuries of each radionuclide with a possession limit of 400 curies	
B. Iodine 131	B. Any	B. 2 curies	
C. Xenon 133	C. Any	C. 2 curies	
D. Krypton 85	D. Any	D. 1 curie	
E. Gold 198	E. Any	E. 1 curie	
F. Phosphorus 32	F. Any	F. 2 curies	
G. Carbon 14	G. Any	G. 2 curies	
H. Iodine 125	H. Any	H. 1 curie	
I. Iridium 192	I. Any	I. 1 curie	
J. Chromium 51	J. Any	J. 750 millicuries	
K. Sulfur 35	K. Any	K. 1 curie	
L. Hydrogen 3	L. Any	L. 5 curies	
M. Molybdenum 99	M. Molybdenum 99/ Technetium 99m Generators	M. 23 curies	
N. Technetium 99m	N. Any	N. 23 curies	
O. Strontium 90	O. Sealed sources	O. []	
P. Cesium 137	P. Sealed sources	P. []	
Q. Gadolinium 153	Q. Sealed sources	Q. []	
R. Iodine 125	R. Sealed sources (Norland Inst. Co., Model 178A591A)	R. 400 millicuries	
S. Iodine 125	S. Sealed sources (3M Company seeds)	S. 500 millicuries	
T. Iodine 125	T. Sealed sources (AECL Models C235 or C324, or Amersham Corp. Model IMC.P2)	T. 4 sources, not to exceed 300 millicuries each	

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

08-01738-02

Docket or Reference number

030-01317

Amendment No. 63

(Items 6., 7. & 8. continued)

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess; any one time under the license
U. Cesium 137	U. Sealed sources	U. []
V. Cobalt 60	V. Sealed sources	V. []
W. Americium 241	W. Any	W. 100 microcuries
X. Americium 241	X. Sealed sources	X. []
Y. Nickel 63	Y. Sealed sources and foils	Y. 1 curie
Z. Iodine 129	Z. Sealed sources	Z. 1 curie
AA. Thorium	AA. Any	AA. 5 kilograms
BB. Uranium	BB. Any	BB. 50 kilograms
CC. Uranium depleted in Uranium 235	CC. Plated Metal	CC. 400 kilograms
DD. Americium 241	DD. Sealed sources	DD. []
EE. Cesium 137	EE. Sealed source	EE. []
FF. Cesium 137	FF. Sealed sources	FF. []

9. Authorized use

- A. through T. Medical research, diagnosis, and therapy; research and development as defined in 10 CFR 30.4.
- U. through Z. Research and development as defined in 10 CFR 30.4; teaching.
- AA. and BB. Teaching and laboratory research.
- CC. Shielding.
- DD. Standards and reference sources.
- EE. In an [] for calibration of instruments.
- FF. Instrument calibration.

CONDITIONS

10. Location of use: Walter Reed Army Medical Center, Washington, D. C.; WRAMC Forest Glen Section and Annex, Silver Spring, Maryland; Walter Reed Army Institute of Research Animal Holding Facility, Fort Meade, Maryland; U.S. Army Medical Laboratory, WRAMC Department of Pathology, Fort Meade, Maryland; and U.S. Army Institute of Dental Research Facility, Fort Meade, Maryland; Rickman Building, 13 Taft Court, Rockville, Maryland; Key West Research Center, 9620 Medical Center Drive, Rockville, Maryland; and Gillette Building, 270 Research Center, 1413 Research Boulevard, Rockville, Maryland.
11. Radiation Safety Officer: LTC Arthur G. Samiljan.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

08-01738-02

Docket or Reference number

030-01317

Amendment No. 63

(Continued)

CONDITIONS

12. A. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee, Col. Joan T. Zajtchuk, Chairman.
- B. The use of licensed material in or on humans shall be by a physician as defined in Section 35.2 of 10 CFR Part 35.
- C. Physicians designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR Part 35, Subpart J.
13. Experimental animals administered licensed materials or their products shall not be used for human consumption.
14. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
15. 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 foil temperatures from exceeding that specified by the manufacturer.
16. Notwithstanding the requirements of 10 CFR 35.49 (a) and (b), the licensee may use for medical use any byproduct material or reagent kit for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND).
17. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
18. If only a single radionuclide specified in NUREG 0767, is possessed, the possession limit is the quantity specified in Schedule of Limiting Possession Limits, NUREG-0767. If two or more radionuclides are possessed, the possession limit for each is determined as follows: the sum of the quotients of the quantities possessed divided by the quantities of those radionuclides specified in the Schedule of Limiting Possession Limits, NUREG-0767 shall not exceed unity.
19. 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. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

08-01738-02

Docket or Reference number

030-01317

Amendment No. 63

continued)

CONDITIONS

- B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

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 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 July 18, 1979
- B. Letter dated January 13, 1984
- C. Letter dated May 8, 1987
- D. Letter dated March 16, 1988
- E. Letter dated March 28, 1988
- F. Application dated August 5, 1988
- G. Letter dated September 23, 1988
- H. Letter dated July 28, 1989
- I. Letter dated September 12, 1989
- J. Letter dated January 19, 1990
- K. Letter dated July 16, 1990
- L. Letter dated March 15, 1991
- M. Letter dated July 11, 1991
- N. Letter dated April 8, 1992
- O. Letter dated August 4, 1992
- P. Letter dated November 24, 1992
- Q. Letter dated March 26, 1993

For the U.S. Nuclear Regulatory Commission

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JUN 22 1993

By

David A. Moore

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406