

CORRECTED COPY

MATERIALS LICENSE

Amendment No. 26

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, 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 letter dated March 5, 1986	
1. Veterans Administration Medical Center		3. License number 06-11222-01 is amended in its entirety to read as follows:	
2. 555 Willard Avenue Newington, Connecticut 06111		4. Expiration date November 30, 1990	
		5. Docket or Reference No. 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 listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. As necessary for uses authorized in Subitem 9.A.	
B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 2 curies of each byproduct material authorized in Subitem 6.B.	
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C.	
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D.	
E. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	E. Prepackaged kits	E. 5 millicuries of each byproduct material authorized in Subitem 6.E.	
F. Xenon 133	F. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed In- vestigational Exemption for a New Drug" (IND) that has been accepted by FDA	F. 500 millicuries	

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

CORRECTED COPY

License number

06-11222-01

Docket or Reference number

030-01283

Amendment No. 26

(6., 7., and 8. continued)

6. Byproduct, source, and/or
special nuclear material7. Chemical and/or physical
form8. Maximum amount that
licensee may possess
at any one time
under this license

G. Americium 241

G. Sealed Source (Amersham
Model No. AMC.24)

G. 14 millicuries

H. Any byproduct
material with
Atomic Nos. 3
through 83, inclusive;

H. Any

H. 25 millicuries of
each byproduct
material with Atomic
Nos. 3 through 83,
inclusive; Total 1
curie

I. Carbon 14

I. Any

I. 500 millicuries

J. Chlorine 36

J. Any

J. 50 millicuries

K. Chromium 51

K. Any

K. 100 millicuries

L. Hydrogen 3

L. Any

L. 500 millicuries

M. Indium 114m

M. Any

M. 40 millicuries

N. Iodine 125

N. Any

N. 200 millicuries

O. Iodine 131

O. Any

O. 200 millicuries

P. Krypton 79

P. Any

P. 200 millicuries

Q. Krypton 83m

Q. Any

Q. 200 millicuries

R. Sodium 24

R. Any

R. 50 millicuries

S. Xenon 133

S. Any

S. 100 millicuries

T. Mercury 197

T. Any

T. 50 millicuries

U. Mercury 203

U. Any

U. 50 millicuries

V. Bromine 82

V. Any

V. 50 millicuries

9. Authorized use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, Title 10, Code of Federal Regulations.

B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

E. In vitro studies.

F. Blood flow and pulmonary function studies.

G. For use in Searle Analytic Model SS-10244 Anatomical Marker.

H. through V. Medical diagnosis and therapy; Research and development as defined in 10 CFR 30.4(q) including research with humans as approved by a Radioactive Drug Research Committee registered with the F.D.A., Animal studies.

CONDITIONS

10. Licensed material shall be used only at V.A. Medical Center, 555 Willard Avenue, Newington, Connecticut.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

CORRECTED COPY

License number
06-11222-01

Docket or Reference number
030-01283

Amendment No. 26

(continued)

CONDITIONS

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radioisotope Committee, Mohamed A. Antar, M.D., Ph.D., Chairman.
- B. The use of licensed material in or on humans shall be by a physician as defined in Section 35.3(b) of 10 CFR Part 35.
- C. Physicians designated to use licensed material in or on humans shall meet the training criteria established in Appendix A of Regulatory Guide 10.8 (Revision 1), dated October 1980, and as revised December 2, 1985 (47 FR 54376).
- D. The Radiation Protection Officer for the activities authorized by this license is Albert U. Buatti, M.S..
12. 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.
 - 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.
13. Patients containing Iodine-131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of Gold 198) shall remain hospitalized until the residual activity is 30 millicuries or less.
14. A(1) Any sealed source specified in Item 7.G or possessed pursuant to Items 7.H through 7.V shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.
- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
- B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 06-11222-01

Docket or Reference number
030-01283

Amendment No. 26

CORRECTED COPY

(14 continued)

CONDITIONS

- C. 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, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, 631 Park Avenue, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- D. 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.
15. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".
16. Licensed material in items 6.A. through 6.D. shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.
17. Experimental animals administered licensed materials or their products shall not be used for human consumption.
18. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
19. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

CORRECTED COPY

License number

06-11222-01

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Amendment No. 26

(Continued)

CONDITIONS

20. 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 February 29, 1984
- B. Letter dated November 5, 1984
- C. Letter dated April 22, 1986

For the U.S. Nuclear Regulatory Commission

Original Signed By:

John D. Kinneman

By

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

Date

24 FEB 1988