NRC FORM 374 (7-94)

U.S. NUCLEAR REGULATORY COMMISSION

SECOND CORRECTED COPY

MATERIALS LICENSE

Amendment No. 54

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.

Licensee	
1. Boston University Medical Center	In accordance with the letters dated June 14, 1996 and July 31, 1996, 3. License Number 20-02215-01 is amended in its entirety to read as follows:
2. 80 East Concord Street Boston, Massachusetts 02118	4. Expiration Date February 28, 2006
	5. Docket or Reference No. 030-01845/20-00275-08

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 number 3 through 83 with a half-life less than or equal to 120 days	A. Any	A. Not to exceed 1 curie per radionuclide and 10 curies total
B. Phosphorus 32	B. Any	B. 2 curies
C. Sulfur 35	C. Any	C. 3 curies
D. Iodine 125	D. Any	D. 2 curies
E. Iodine 131	E. Any	E. 2 curies
F. Nickel 63	F. Plated sources	F. Not to exceed 20 millicuries per source and 200 millicuries total
G. Strontium 90	G. Sealed sources (Nuclear Associates Model PTW-09)	G. 900 microcuries
H. Any byproduct material with Atomic Number 1 through 83 with a half-life greater than 120 days	H. Any	H. See Condition 12
I. Technetium 99m	I. Any	I. 5 curies
J. Molybdenum 99	J. Any	J. 5 curies
K. Palladium 103	K. Sealed sources	K. Not to exceed 100 millicuries per source and 4 curies total
L. Iodine 125	L. Sealed sources	L. Not to exceed 100 millicuries per source and 4 curies total
M. Iodine 131	M. Any	M. 2 curies
N. Cesium 137	N. Sealed sources	N. Not to exceed 100 millicuries per source and 4 curies total
O. Cesium 137	O. Sealed sources (Technical Operations Model 773)	O. 165 millicuries

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P. Iridium 192	P. Sealed sources	P. Not to exceed 100 millicuries per source and 4 curies total
Q. Strontium 90	Q. Sealed sources	Q. Not to exceed 100 millicuries per source and 4 curies total

9. Authorized use

A. through Q. 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 instrument calibration.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at the Boston University Medical Center, Boston, Massachusetts.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Richard Cohen, M.D., Chairperson.

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. Individuals designated in writing to work as authorized users or authorized nuclear pharmacists, as defined in 10 CFR 35.2, shall meet the training and experience criteria established in 10 CFR Part 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee.

D. The Radiation Safety Officer for this license is Victor N. Evdokimoff, M.S., CHP.

12. If only one radionuclide is possessed, the possession limit is the quantity less than or equal to 10,000 times the applicable quantity for that radionuclide in 10 CFR 30, Appendix B. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to 10,000 times the applicable quantity specified in 10 CFR 30, Appendix B, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

13. 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.

14. Notwithstanding the requirements of 10 CFR 35.49(a), 35.100, 35.200, 35.300, 35.400 and 35.500 the licensee may use for medical use any byproduct material. 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 Part 35. This does not relieve the licensee from complying with applicable U.S. Food and Drug Administration (FDA) and other Federal and State requirements.

15. Notwithstanding the requirements of 10 CFR 35.400(d) and (g), the licensee may use iridium-192 as seeds encased in nylon ribbon and palladium-103 as a sealed source in seeds for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions to the extent that the instructions are not applicable to the type of use proposed by the licensee.

16. 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

(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.

17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

18. 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.

19. 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.

20. 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.

21. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

22. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

23. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 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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24. Pursuant to 10 CFR 20.2002 and 20.2004(a)(3), the licensee is authorized to dispose of licensed material by incineration.

25. Notwithstanding the requirements of 10 CFR 35.315(a) (4), the licensee may use the alternate method for determining the dose rates in room 7W28 during the use of room 7W26 for radiopharmaceutical therapy for doses of 201 millicuries or less of iodine-131 as described in the applicaton dated May 30, 1995, page 61 and letter dated March 11, 1996.

26. Notwithstanding the requirements of 10 CFR 35.415(a) (4), the licensee may use the alternate method for determining the dose rates in contigous restricted and unrestricted areas described in the application dated May 30, 1995, page 58 and letters dated September 28, 1995, November 1, 1995, May 6, 1996 and June 11, 1996.

27. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

28. 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 May 30, 1995 except QM plan pages 19-26
B. Letter dated August 16, 1995
C. Letter dated September 28,1995 except Item 6
D. Letter dated November 1, 1995 except Item 3
E. Letter dated November 28, 1995
F. Letter dated December 21, 1995
G. Letter dated January 18, 1996
H. Letter dated March 11, 1996
I. Letter dated May 6, 1996
J. Letter dated June 11, 1996
K. Letter dated June 14, 1996
L. Letter dated July 31, 1996

For the U.S. Nuclear Regulatory Commission

Date OCT 25 1996

By ORIGINAL SIGNED BY:
THOMAS K. THOMPSON

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

OCT 25 1996

Aram Chobanian, M.D.
Medical Center Provost
Boston University Medical Center
80 East Concord Street
Boston, MA 02118

Dear Dr. Chobanian:

Enclosed is the Second Corrected Copy of Amendment No. 54 for License No. 20-02215-01. During an internal audit of your file, it was discovered that the expiration date on the license was in error. It has now been corrected to read "February 8, 2006".

We apologize for any inconvenience this error may have caused.

Sincerely,

ORIGINAL SIGNED BY:
THOMAS K. THOMPSON

for Mohamed Shanbaky, Ph.D., Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

License No. 20-02215-01
Docket No. 030-01845
Control No. 123343

Enclosure:
Second Corrected Copy of Amendment No. 54

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