NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

CORRECTED COPY

MATERIALS LICENSE

Amendment No. 05

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. Dana-Farber Cancer Institute	In accordance with letter dated April 21, 1989, 3. License number 20-19761-02 is amended in its entirety to read as follows:
2. 44 Binney Street Boston, Massachusetts 02115	4. Expiration date January 31, 1997
	5. Docket or Reference No. 030-20020

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 Atomic Nos. 3 through 83, except as below	A. Any	A. 300 millicuries of each radionuclide; Not to exceed a total of 10 curies except as noted below:
B. Hydrogen 3	B. Any	B. 25 curies
C. Carbon 14	C. Any	C. 1 curie
D. Phosphorus 32	D. Any	D. 5 curies
E. Sulfur 35	E. Any	E. 5 curies
F. Iodine 131	F. Any	F. 2 curies
G. Iodine 125	G. Any	G. 5 curies
H. Gold 198	H. Any	H. 2 curies
I. Xenon 133	I. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	I. 5 curies
J. Osmium 191	J. Any	J. 5 curies
K. Iridium 191m	K. Any	K. 5 curies
L. Molybdenum 99	L. Any	L. 5 curies
M. Technetium 99m	M. Any	M. 5 curies
N. Iridium 192	N. Any	N. 2 curies

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 20-19761-02

Docket or Reference number: 030-20020

CORRECTED COPY

Amendment No. 05

9. Authorized use

A. through N. Medical diagnosis, therapy and research in humans. Research and development as defined in Section 30.4 of 10 CFR Part 30, including animal studies. Instrument calibration.

CONDITIONS

10. Licensed material shall be used only at 35 Binney Street, 44 Binney Street, 21-27 Burlington Avenue, and Michael A. Redstone Animal Facility, 462 Brookline Avenue, Boston, Massachusetts.

11. The Radiation Safety Officer for this license is Steven J. Alford, M.S.

A. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.2.

B. Physicians 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. The licensee shall maintain records of physicians designated as users.

C. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, S. Treves, M.D., Chairperson. The licensee shall maintain records of individuals designated as users.

12. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material 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.

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 are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 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 3 months.

C. In the absence of a certificate from a transferor indicating that a 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 20-19761-02

Docket or Reference number: 030-20020

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Amendment No. 05

(13. continued) CONDITIONS

E. Sealed sources and detector cells need not be leak tested if:

(i) they contain only hydrogen 3; or

(ii) they contain only a 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. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. 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 shall be removed 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 I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source 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.

14. Pursuant to 10 CFR 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of uranium contained as shielding material.

15. The licensee shall conduct a physical inventory every three 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 six months for all other sources and/or devices. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the information required in 10 CFR 35.59 (g).

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 20-19761-02

Docket or Reference number: 030-20020

CORRECTED COPY

Amendment No. 05

(Continued) CONDITIONS

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 foil temperatures from exceeding that specified by the manufacturer and approved by NRC.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

17. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(f)(1), 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.

18. The Licensee shall possess and use byproduct material for human research use 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.

19. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.100, 10 CFR 35.200 and 10 CFR 35.300, the licensee may use for 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. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.

21. 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.

D. A record of each 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.

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 20-19761-02
Docket or Reference number: 030-20020
Amendment No. 05

CORRECTED COPY

(Continued) CONDITIONS

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

23. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."

24. 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.

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 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 April 21, 1989
B. Letter dated December 3, 1991

Date FEB 05 1992

For the U.S. Nuclear Regulatory Commission

By Original Signed By: Thomas K. Thompson

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

FEB 0 5 1992

License No. 20-19761-02
Docket No. 030-20020
Control No. 110614

Dana-Farber Cancer Institute
ATTN: Steven J. Alford, M.S.
44 Binney Street
Boston, Massachusetts 02115

Dear Mr. Alford:

Enclosed is a Corrected Copy of Amendment No. 05 for License No. 20-19761-02.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

We have corrected Subitems 6.D. through 6.N. to indicate the quantities of byproduct materials requested in your Amendment No. 04 which was received after the original license renewal request.

We regret any inconvenience we may have caused and thank you for your phone call on January 21, 1992 alerting us to this error.

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Thomas K. Thompson

Thomas K. Thompson
Sr. Health Physicist
Medical Licensing Section
Division of Radiation Safety
and Safeguards

Enclosure: Corrected Copy of Amendment No. 05

"SECTION

1/24/92

Dana Farber Cancer 20-19761-02

Amend before Renewal
July → Nov Amend

up limits
5-35 & 5 Ci

P-32 & 5 Ci
I-125 & 5 Ci

RSO
Should be Steve Elford

New Bldg. name
44 21-27 Burlington Ave
should be

Send cc

MEMORANDUM OF CALL — Previous editions usable

TO: Tom Thompson

☐ YOU WERE CALLED BY- ☐ YOU WERE VISITED BY-
Steve Elford

OF (Organization)
Dana Farber Cancer

☐ PLEASE PHONE ▶ ☐ FTS ☐ AUTOVON
617-732-3005

☐ WILL CALL AGAIN ☐ IS WAITING TO SEE YOU
☐ RETURNED YOUR CALL ☐ WISHES AN APPOINTMENT

MESSAGE
Corrections needed on Renewal

RECEIVED BY: Ena Mack | DATE: 1/21/92 | TIME:

MEMORANDUM OF CALL — Previous editions usable

TO: Lou

☑ YOU WERE CALLED BY- ☐ YOU WERE VISITED BY-
M. Alford

OF (Organization)
Dana-Farber Cancer Inst.

☐ PLEASE PHONE ▶ ☐ FTS ☐ AUTOVON
617-732-3003

☐ WILL CALL AGAIN ☐ IS WAITING TO SEE YOU
☐ RETURNED YOUR CALL ☐ WISHES AN APPOINTMENT

MESSAGE
Called several times. Errors on his renewal

RECEIVED BY: CKG | DATE: 1/22 | TIME: 1[illegible]

63-110 NSN 7540-00-634-4018 STANDARD FORM 63 (Rev. Prescribed by GSA

CONVERSATION RECORD

TIME: 10:20 AM | DATE: 1/29/92

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☒ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Philip Cobb, RSO	New England Deaconess	(617) 732-8509

SUBJECT: Contaminated Package (20-00289-07)

ROUTING	
NAME/SYMBOL	INT

SUMMARY

Mr Cobb stated that the New Med Dept surgical package contains a Tc 99m/Mo 99 generator of less than 3 Curies and found 0.15 uCi of removable contamination on 1/24/92. The Grad RSO was told of this on Friday but didn't inform RSO until Monday. The package was received from Brigham's and Women who claims that New England Deaconess had contaminated it. The package is below Type A quantity for transport survey and thus Licensee doesn't require them to report contaminated packages to the NRC on writing. The incident will be documented on the RSO quarterly and any actions taken.

ACTION REQUIRED

Document

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Steven Courtemanche	Steven Courtemanche	1/30/92

ACTION TAKEN

SIGNATURE	TITLE	DATE
		2/199