NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 31

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. New England Deaconess Hospital Corporation 2. 185 Pilgrim Road Boston, Massachusetts 02215	In accordance with letter dated December 9, 1991, 3. License number 20-00289-07 is amended in its entirety to read as follows: 4. Expiration date February 29, 1992 5. Docket or Reference No 030-01808

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 Group VI of Schedule A, Section 35.100 of 10 CFR 35	A. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	A. 7 curies total for all sources authorized in Subitem 6.A.
B. Uranium (depleted in Uranium 235)	B. Cadmium plated metal	B. 310 kilograms
C. Any byproduct material with Atomic Nos. 3 through 83, inclusive	C. Any	C. 100 millicuries of each byproduct material with Atomic Nos. 3 through 83, inclusive
D. Hydrogen 3	D. Any	D. 1000 millicuries
E. Phosphorus 32	E. Any	E. 100 millicuries
F. Molybdenum 99	F. Any	F. 2.5 curies
G. Technetium 99m	G. Any	G. 2.5 curies
H. Iodine 131	H. Any	H. 500 millicuries
I. Iodine 125	I. Any	I. 200 millicuries
J. Dysprosium 165	J. Any	J. 300 millicuries
K. Xenon 133	K. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	K. 1 curie
L. Cesium 137	L. Sealed sources	L. 6.5 curies
M. Iridium 192	M. Seeds or wires	M. 3.5 curies
N. Gold 198	N. Seeds	N. 1 curie

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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
O. Yttrium 90	O. Microspheres	O. 1 curie
P. Americium 241	P. Sealed source for use in Renalyzer PRX90	P. 200 millicuries

9. Authorized use

A. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
B. For use as shielding in a linear accelerator.
C. through P. Medical research, diagnosis and therapy. Research and development as defined in Section 30.4, 10 CFR 30.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities, 185 Pilgrim Road, Deaconess, Farr, Baker, and Palmer Buildings; Cancer Research Institute, 195 Pilgrim Road; Meissner Building, 198 Pilgrim Road; Lowry Building, 110 Francis Street; rooms except as specified in letter dated December 8, 1986, located in the Shields Warren Radiation Laboratory, 50 Binney Street; 5th Floor of Building, 21-27 Burlington Avenue, Boston, Massachusetts; Medical and Technical Research Associates, Inc., 320 Washington Street, Boston, Massachusetts; the facilities at the Joslin Diabetes Center, One Joslin Place, Boston, Massachusetts as described in letter dated December 12, 1989; and Kennedy Hall Ambulatory Care Center, 1 Autumn Street, Boston, Massachusetts.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee.

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 Safety Officer for this license is Philip Cobb, M.P.H.

12. A(1) Each sealed source or detector cell acquired from another person and containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transferor indicating that a test has been made within 6 months before the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

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(12.A continued) CONDITIONS

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source or detector cell is exempt from such leak tests when the source or detector cell contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.

B. Each sealed source or detector cell fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source or detector cell. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source or detector cell until it has been repaired, decontaminated and retested.

C. Each sealed source containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months. The test may be conducted at 3 year intervals provided the sources have been authorized by the Commission (or an Agreement State) for a three year leak test interval.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or detector cell or from the surfaces of the device in which the sealed source or detector cell is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source or detector cell from use and shall cause it to be decontaminated and repaired or to be 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 Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406, describing the equipment involved, the test results, and the corrective action taken.

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(Continued) CONDITIONS

13. 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.

14. Experimental animals administered licensed materials or their products shall not be used for human consumption.

15. 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.

16. A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.

    B. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.

17. 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.

18. 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.

19. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices in Items 7.C. through 7.P. received and possessed under the license. Records of inventories shall be maintained for 3 years from the date of each inventory.

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

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(Continued) CONDITIONS

21. 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 January 3, 1979
B. Letter dated March 11, 1980
C. Letter dated November 6, 1980
D. Letter dated April 24, 1981
E. Letter dated June 30, 1981
F. Letter dated February 4, 1983
G. Letter dated April 29, 1984
H. Letter dated September 19, 1984
I. Letter dated July 11, 1985
J. Letter dated November 25, 1985, Items 2 through 11
K. Letter dated August 11, 1986
L. Letter dated September 4, 1986
M. Letter dated September 15, 1986
N. Two letters dated December 8, 1986
O. Letter dated August 31, 1988
P. Letter dated December 12,1989
Q. Letter dated May 8, 1990
R. Letter dated June 12, 1990
S. Letter dated May 7, 1990
T. Letter dated October 23, 1990
U. Letter dated December 11, 1990
V. Letter dated May 22, 1991
W. Letter dated December 9, 1991

For the U.S. Nuclear Regulatory Commission

Date JAN 30 1992

By Original Signed By:
Jenny Johansen

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

New England Deaconess Hospital

185 Pilgrim Road
Boston, Massachusetts 02215
(617) 732-9400

DEPARTMENT OF RADIOLOGY

Affiliated with Harvard Medical School

October 20, 1987

Robert D. Pence, Director
Division of Research
New England Deaconess Hospital
Boston, Massachusetts 02215

Dear Mr. Pence:

In response to your letter of October 15, 1987 regarding the incident of transferring Tc-99m Pertechnetate to Strichman Medical Equipment, Inc., as of January 1st, Strichman Medical Equipment, Inc. is the licensee of the patent of the Harvard multidetector scanning device which we have been involved with since 1977. We have an active collaborative arrangement with this company in the development of this system and have been supported by a grant through the Medical School for its continued development.

The transfer of the Tc-99m Pertechnetate for industrial purposes was thought to be in compliance with government regulations. Mark D. Doherty, the Product Manager at the company, has been my professional and personal acquaintance for over 10 years. He has been previously employed by both the Medical School and the Research Section in the Department of Radiology at Deaconess Hospital. He has familiarity and expertise in handling the radioactive isotopes and obtained a state permit naming him as the Radiation Safety Officer at the industrial site. It is my understanding that the state office of the Department of Labor and Industries said on two separate occasions that this registration of ionizing radiation sources was all that was needed for this industrial location to have on hand sealed and unsealed sources as listed. I apologize for my lack of understanding of the dual licensing of industrial locations by both the NRC and the state and have taken steps to correct this omission.

The company has moved to register the site with the NRC to have on hand industrial sources for floods, as listed on the state license. In addition, Mr. Cobb and myself have set forth to amend the license at the Deaconess Hospital to include this industrial site as a satellite as had been done on previous occasions with other areas where it was planned that research would be conducted.

(please see page two)

D/126

Robert D. Pence, Director
Division of Research
New England Deaconess Hospital

I hope this straightens out this unfortunate misunderstanding and we plan to have a more open dialogue with our radiation safety officer so that he may assist us in the proper transfer of these materials that are used in our collaborative research efforts.

Sincerely,

Thomas C. Hill, M.D.
Section Head, Nuclear Medicine
Department of Radiology

TCH:amr

cc: Dr. Chaffey
Dr. Clouse
Mr. Cobb ✓
Joyce Tower

The Commonwealth of Massachusetts

DEPARTMENT OF LABOR AND INDUSTRIES
DIVISION OF OCCUPATIONAL HYGIENE
1001 Watertown Street, West Newton 02165

REGISTRATION OF IONIZING RADIATION SOURCES

1. Employer Name STRICHMAN MEDICAL EQUIPMENT, INC.

Address 93 West Street Medfield, Mass. 02052

2. Confines of Installation (Building Number, Floor)

3. RADIATION PRODUCING EQUIPMENT (Use Additional Sheets if Necessary)

TYPE*	NUMBER		DESCRIPTION OF EQUIPMENT (Size, Rating, Mfr., General Location)	PURPOSE OR USE
	Fixed	Mobile		

*Specify X-ray machine, high voltage equipment, industrial x-ray, nuclear reactor, particle accelerator, static eliminator, etc.

4. RADIOACTIVE MATERIALS (Use Additional Sheets if Necessary)

TYPE*	NUMBER		DESCRIPTION OF MATERIAL*	QUANTITY USED		PURPOSE OR USE
	Fixed	Mobile		Annually	On Hand	
Tc99 unsealed			Tc99 unsealed to be dispensed into floods	520mc	20mc	Fill phantoms for test and calibration.
Co 57 sealed			Co 57 sealed sources to be used as calibration phantoms for brain imagers.	40mc	20mc	Used for calibration of equipment

COMMONWEALTH OF MASSACHUSETTS
No. 1287
SEP 9 1987
COMMISSIONER
DEPARTMENT OF LABOR AND INDUSTRIES

*Indicate if sealed or unsealed, source strength, location, etc.

5. RADIATION SAFETY OFFICER

Name and Address
Mark D. Doherty 55 Colonial Road

Qualifications

Date	(617) 359-5312 Business Telephone	Signature of Employer or Radiation Safety Officer

(SEE INSTRUCTIONS ON REVERSE SIDE)