NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 46

MATERIALS LICENSE

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. Yale-New Haven Hospital	In accordance with the letter dated July 8, 1996,
2. 20 York Street New Haven, Connecticut 06504	3. License Number 06-00819-03 is amended in its entirety to read as follows:
	4. Expiration Date June 30, 2005
	5. Docket or Reference No. 030-01244/06-17434-01

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 between 3 and 83	A. Sealed sources	A. Not to exceed 500 millicuries per radionuclide and 25 curies total
B. Any byproduct material with Atomic Numbers between 3 and 83 and half-life less than or equal to 120 days	B. Any, other than sealed sources	B. Not to exceed 1 curie per radionuclide and 50 curies total
C. Any byproduct material with Atomic Numbers between 3 and 83 and half-life greater than 120 days	C. Any, other than sealed sources	C. See Condition 12
D. Molybdenum 99	D. Any	D. 20 curies
E. Technetium 99m	E. Any	E. 20 curies
F. Iodine 125	F. Sealed sources included in 10 CFR 35.400	F. 5 curies
G. Cesium 137	G. Sealed sources included in 10 CFR 35.400	G. 3 curies
H. Iridium 192	H. Sealed sources (Byk-Mallinckrodt Model CIL BV, RTS Model 722, or RTS Model 723)	H. 2 sources not to exceed 15 curies each
I. Iridium 192	I. Sealed sources (RTS Model 721, or RTS Model 724)	I. 2 sources not to exceed 12 curies each
J. Americium 241	J. Any sealed source	J. 10 curies per source and 90 curies total
K. Americium 241	K. Sealed source (Amersham Model AMC.24)	K. 50 millicuries per source and 250 millicuries total
L. Depleted Uranium	L. Metal	L. 314 kilograms

A. through G. 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; instrument calibration; student instruction; and in-vitro studies.

H. One source to be used in a Isotopen Technik Dr. Sauerwein GmbH Model GammaMed IIi high dose rate remote afterloading brachytherapy device for interstitial, intercavitary or bronchial therapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

I. One source to be used in a Isotopen Technik Dr. Sauerwein GmbH Model GammaMed 12i high dose rate remote afterloading brachytherapy device for interstitial, intercavitary or bronchial therapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

J. 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.

K. Medical diagnosis and research. Research and development as defined in 10 CFR 30.4, including animal studies and student instruction.

L. For use as shielding in linear accelerators, a Isotopen Technik Dr. Sauerwein GmbH Model GammaMed IIi high dose rate remote afterloading brachytherapy device, and a Isotopen Technik Dr. Sauerwein GmbH Model GammaMed 12i high dose rate remote afterloading brachytherapy device.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 20 York Street and 60 Temple Street, New Haven, Connecticut.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Robert Lange, Ph.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. 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.

E. The Radiation Safety Officer for this license is Michael J. Bohan.

F. Medical Physicists shall meet the training criteria established in 10 CFR 35.961 and shall be designated in writing by the licensee's Radiation Safety Committee. For purposes of satisfying the requirements of 10 CFR 35.961(b) for the medical physicist for the high dose rate remote afterloading brachytherapy unit, the licensee may accept experience in the tasks listed in the source calibration and

the safety checks required by this license for the high dose rate remote afterloading brachytherapy unit in lieu of the tasks listed in 10 CFR 35.632, 35.634, and 35.641.

12. A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. 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 the applicable quantity specified in 10 CFR 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. Notwithstanding Paragraph A of this Condition and 10 CFR 33.100, Schedule A, Column II, the applicable quantities for the following radionuclides are reduced to:

Carbon 14	100 millicuries
Krypton 85	100 millicuries
Iodine 129	100 microcuries
Any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33.100, Schedule A	100 microcuries

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 35.75, the licensee may release from confinement patients being treated with temporary ocular brachytherapy plaques in accordance with the letters dated July 2, 1993, May 24, 1994, and April 7, 1995.

15. Notwithstanding the requirements of 10 CFR 35.49(a), the licensee may use for any medical use any byproduct material as a sealed source. 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.

16. 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.

17. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
06-00819-03

Docket or Reference Number
030-01244

Amendment No. 46

18. 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.

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

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

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. 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.

22. 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.

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

24. 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.

25. 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.

26. A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.

B. Each entrance to the treatment room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation

position until the entrance door is closed and the source "on-off" control is reset at the control panel.

C. Electrical interlocks on each entrance door to the treatment room shall be tested for proper operation at least once each day of use.

D. In the event of malfunction of the door interlock, the unit shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

27. Prior to initiation of a treatment program, and subsequent to each source exchange for each high dose rate remote afterloading brachytherapy unit, a radiation survey shall be made of:

A. The source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 millirem per hour.

B. All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:

(1) That radiation doses to occupationally exposed individuals do not exceed the limits specified in 10 CFR 20.1201(a), 20.1207 and 20.1208.

(2) That radiation doses to individual members of the public do not exceed the limits specified in 10 CFR 20.1301(a).

28. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such service:

A. Installation, and replacement of the sealed sources contained in the GammaMed 12i high dose rate remote afterloading brachytherapy unit.

B. Maintenance or repair operations on any high dose rate remote afterloading brachytherapy unit and associated equipment involving work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

29. Installation and replacement of the sealed sources contained in the GammaMed IIi high dose rate remote afterloading brachytherapy unit may be replaced in accordance with the letter dated November 2, 1988, as amended by the letter dated April 7, 1995. Individuals performing source installations and replacements shall have been by the unit's manufacturer in the procedure used.

30. In lieu of the source inventory described in 10 CFR 35.406, the licensee shall:

A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each high dose remote brachytherapy procedure.

B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

C. Make a record of the survey including survey instrument used, dose rate, time, date and name of the individual making the survey.

D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

31. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

32. At the beginning of each day of use, the licensee shall perform the following checks of the equipment and facilities associated with the high dose rate remote afterloading brachytherapy unit in accordance with the manufacturer's instructions:

A. The permanent radiation monitor will be checked with a dedicated check source for proper operation;

B. Source status indicators integral to the high dose rate remote afterloading brachytherapy unit, as well as the fixed radiation detection device located in the treatment room doorway will be checked using a dedicated check source;

C. Electrical interlocks installed at the entrance to the dedicated treatment room will be tested for proper operation;

D. The treatment console will be checked for proper operation, and all indicator lamps, other status and operational displays, and the printer for the device will be checked for proper operation;

E. The intercom and closed-circuit video systems will be checked to verify proper operation; and

F. The integrity of the source guide tubes will be checked.

A record of each of these checks will be maintained for a period of three years and will include the date of the check, the results of the check, and the initials of the individual who performed the check.

33. The high dose rate remote afterloading unit shall not be used unless the following checks have been performed in accordance with the manufacturer's instructions within the preceding thirty (30) days:

A. A check of the accuracy of source positioning to ±1 millimeter;

B. A check of the timer accuracy and linearity;

C. Measurement of source guide tubes to confirm the length to an accuracy of ±1 millimeter; and

D. A check, with the AC power disconnected, of the backup battery which verifies emergency source retraction capability upon power failure.

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SUPPLEMENTARY SHEET

License Number: 06-00819-03

Docket or Reference Number: 030-01244

Amendment No. 46

A record of each of these checks will be maintained for a period of three years and will include the date of the check, the results of the check, and the initials of the individual who performed the check.

34. The high dose rate remote afterloading brachytherapy device training program, outlined in the letters dated May 24, 1994 and April 7, 1995, shall be performed by, or under the supervision and in the physical presence of, the manufacturer's representative.

35. During all patient treatments, both the authorized user or a physician under the supervision of the authorized user, and either the medical physicist or the Radiation Safety Officer must be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech.

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

37. 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. Letter dated June 17, 1991
B. Letter dated July 2, 1993
C. Letter dated May 24, 1994
D. Letter dated April 7, 1995
E. Letter dated July 8, 1996

For the U.S. Nuclear Regulatory Commission

Date NOV 15 1996

By ORIGINAL SIGNED BY:
THOMAS K. THOMPSON

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

NOV 15 1996

Norman G. Roth, VP
Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

Dear Mr. Roth:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:
THOMAS K. THOMPSON

Thomas K. Thompson, Sr. Health Physicist
Division of Nuclear Materials Safety

License No. 06-00819-03
Docket No. 030-01244
Control No. 123464

Enclosure:
Amendment No. 46

DOCUMENT NAME: R:\WPS\MLTR\L0600819.03
To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RI									
NAME	thompson TKT									
DATE	11/15/96	11/ /96		11/ /96		11/ /96		11/ /96		

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TEMPLE NUCLEAR MEDICINE, P.C.
Gerald S. Freedman, M.D. - Medical Director
60 Temple Street
Suite 2D
New Haven, CT 06510
Tel (203) 789-2299 Fax (203) 789-2231

October 21, 1996
Tom Thompson
U.S. Nuclear Regulatory Commission, Region I
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Termination of Freedman and Associates NRC license No: 06-17434-01
Docket No.: 030-12747 / Control No.: 123465

Dear Mr. Thompson:

In reference to your letter dated October 10, 1996, Freedman and Associates, Nuclear Medicine, P.C., 60 Temple Street, New Haven, CT 06510 requests termination of its' existing license and transfer of all allowed activities under the license to Yale-New Haven Hospital's broad scope License No.: 06-00819-03. All existing licensed radioactive materials will be transferred to YNHH's license immediately upon the successful termination of this license and amendment of YNHH's license. A closeout survey and inventory transfer will be conducted on or about October 21, 1996. A copy of the survey will be sent to the NRC as part of this licensing action.

Please disregard my earlier requests, in two letters dated July 17, 1996 and September 9, 1996, to transfer my existing license to the Stafford Professional Building, 8 E. Main Street, Clinton, CT. Any plans to initiate licensed activities at this site will be done under a separate license application.

If you have any further questions concerning the termination and transfer of all activities currently under this license please contact Dr. Gerald Freedman at (203) 789-2299.

Sincerely,

Gerald S. Freedman, M.D., R.S.O.
Freedman & Associates, Nuclear Medicine, P.C.

cc: Michael J. Bohan, YNHH Radiation Safety Officer
Robert C. Lange, Ph.D., Chairman, YNHH Radiation Safety Committee
Ravinder Nath, Ph.D., Chief, YNHH Radiological Physics
Norman G. Roth, V.P., YNHH Administration
Bruce McClennan, M.D., Chairman, Dept. of Diagnostic Radiology
John P. Seibyl, M.D., Chairman, YNHH Nuclear Medicine
State of Connecticut, Dept. of Environmental Protection, Radiation Control Unit

ML 10

123465/123464

OCT 31 1996

FAX REC'D

Michael A. Varela
Assistant RSO
Yale-New Haven Hospital
Radiation Safety Office
Room WW-204
20 York Street
New Haven, CT 06510-3220

DATE: 23 October 1996

SITE: Freedman and Associates
Temple Medical Center
Nuclear Medicine Facility
60 Temple Street
Suite 2D
New Haven, CT 06510

SUBJECT: Close-out survey for NRC's termination of *Freedman and Associates* NRC-licensed activities (License #06-17434-01), and subsequent amendment to *Yale-New Haven Hospital's* NRC limited medical broad scope byproduct material License #06-00819-03.

Instrumentation & Wipe Samples Counting Parameters

- Ludlum Model 3 G-M survey meter with pancake probe, Ludlum Model 44-9, with analog dial set on the 0.1X scale.
- Picker Model Spectroscaler 4, with an MeV range setting of 0.2, and an LL: = 400 and UL = 625 (counting 122 - 137 KeV photopeaks; simulated Tc-99m setting).
- *Isotope Products Laboratories* ^{57}Co standard of 0.864 µCi on 01 April 1995.

CLOSE-OUT SURVEY RESULTS:
(All data keyed to the enclosed topographical sketch of facility; specifically, the areas of preparation and injection are the only areas that were wiped, besides being surveyed with the G-M pancake probe in search for hot spots to wipe. All data taken and analyzed as of the date shown above.)

^{57}Co std: $A_{(10/23/95)}$ = 410,011 dpm ..... Std. Count = 330,109 cpm

Freedman and Associates' Close-Out Survey Report/Y-NHH/2

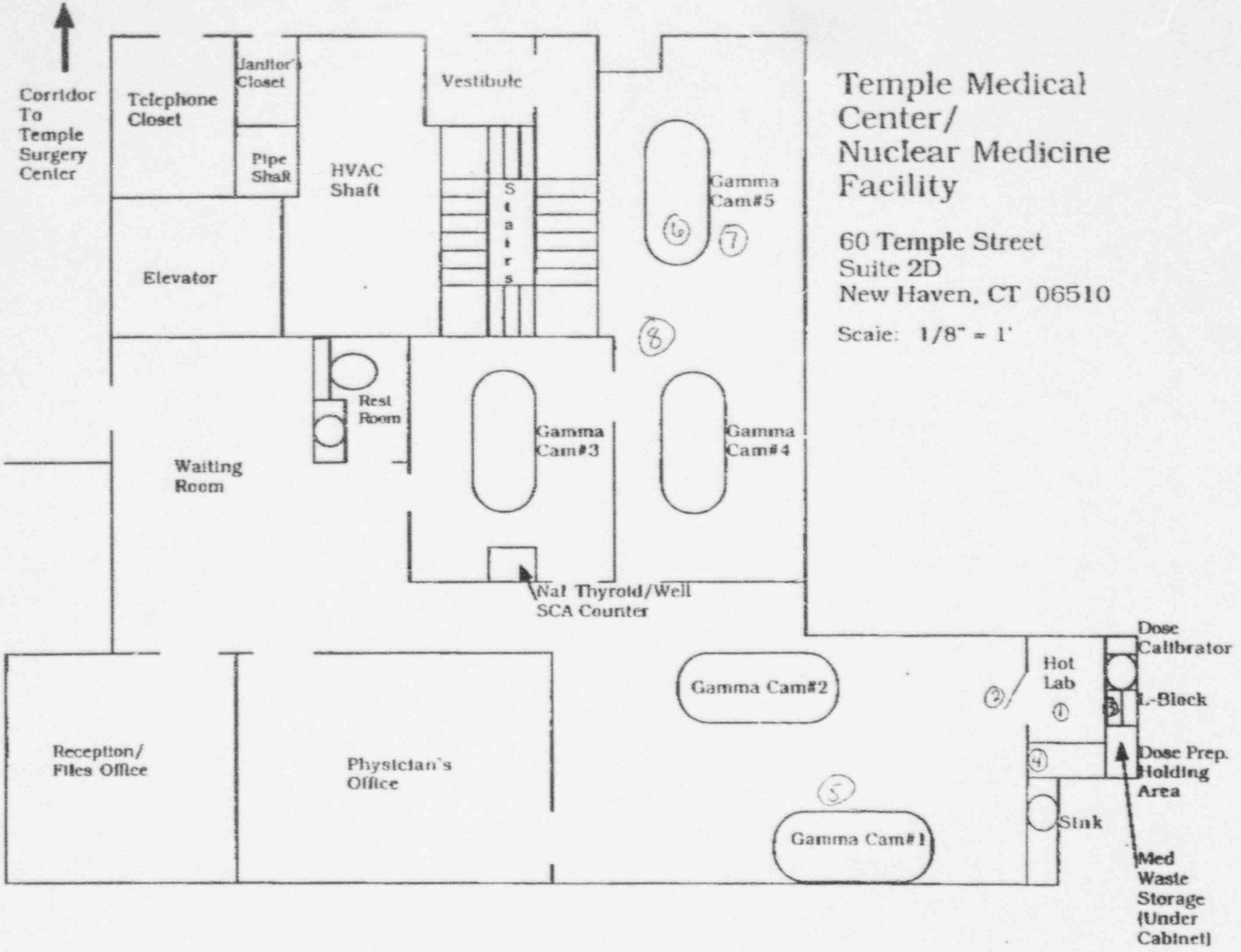
Hot Spots: All areas of Temple's hot lab and injection and storage areas were surveyed with the Ludlum G-M meter -- especially areas where spills might have landed (floor) and where contaminated hands and sleeves might have rubbed any contamination (doorknobs L-Block edges, Table edges, and instrument controls). After removal of normal Tc-99m waste, all surveys with the pancake probe revealed 0.01 mR/hr levels, which are equal to the normal background levels in that area of Temple. Conclusion: No hot spots were found.

Wipe Data

Area Surveyed	Contamination Level (dpm/100 cm^2)
1. Hot Lab Floor	3
2. Hot Lab Doorknobs	4
3. L-Block (Inside and Outside)	4
4. Formica Countertop & Edges	5
5. Camera #1 Gurney (Pt. Injection Table)	< LLD
6. Camera #5 Gurney (Pt. Injection Table)	7
7. Injection Arms (Removable Plastic Inserts)	10
8. Computer, Fax & Instrumentation Surfaces	7

Surveyor: Michael A. Varela

Michael A. Varela, Asst. RSO, Y-NHH



TELEPHONE CONVERSATON RECORD	**Date:** September 5, 1996	**Time:**
Mail Control No.: 123465,123464	**License No.:** 06-17434-01/06-00819-03	**Docket No.:**
Person Called: Michelle Rispoli,Chief Tech.	**Organization:** Freedman and Assoc./Yale-New Haven Hosp.	**Telephone Number:**
Person Calling: Thomas K. Thompson		
Subject: Amend. request clarification.		
Summary: Asked Michelle if she would explain their request. Do they want to maintain a stg. only license or terminate upon xfer to Yale- New Haven?		
Action Required/Taken:		
Signature: Thomas K. Thompson	**Date:** 9/5/96	

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Yale-New Haven Hospital
20 York Street, New Haven, CT 06504

Radiation Safety Office
WW-204

July 8, 1996

License No.: 06-00819-03
Docket No.: 030-01244
Control No.: 113173

U.S. Nuclear Regulatory Commission
Region I
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License Amendment Application for Second Area of Use

Gentlemen:

Yale-New Haven Hospital (YNHH) has recently acquired administrative control of Temple Medical Center, 40-60 Temple Street, 2nd Floor, New Haven, CT 06510. The hospital requests this site be added through amendment as another area of use on YNHH's broad scope License No. 06-00819-03. The hospital wants to complete this licensing action as soon as possible; therefore, we request this action be considered under an expedited review process.

Licensed use at this site, by YNHH, will be the provision of prostate implants and standard nuclear medicine services. The existing NRC specific nuclear medicine License No.: 06-17434-01, Freedman and Associates, Nuclear Medicine, P.C., 60 Temple Street, Suite 2D, New Haven, CT 06510, will be terminated. Dr. Freedman's letter requesting termination of his license is enclosed with this letter to ensure these actions are considered in tandem.

As shown by the attached map of New Haven, Temple Medical Center is located approximately 1/4 mile from Yale-New Haven Hospital. All transfers of radioactive materials between the two sites will be done with all applicable DOT and NRC transportation requirements. Additionally, maps of the Temple Medical Center's physical facilities involved are attached.

The sealed sources used in the brachytherapy program will routinely be received, inspected and stored in Temple's nuclear medicine hot lab. When needed, they will be transferred across the Temple building's corridor to the surgical facility for the prostate implant. Since both areas are located on the second floor of the facility, routine movement of materials within the Temple Medical Center will be confined to the second floor area.

The existing equipment in Dr. Freedman's program, including gamma cameras, a dose calibrator, a NaI(Tl) based thyroid and well counter, and any survey equipment will be included with and supplemented by YNHH's equipment. As always, NRC required calibrations, surveys and quality assurance activities will be incorporated into and supervised by the YNHH Radiation Safety Office under the conditions of the hospital's license.

Attached to this letter, you will find a check in the amount of $560.00 to cover the amendment fees. If there are any further questions concerning this amendment application, please contact the Radiation Safety Office at (203) 785-2950.

Sincerely,

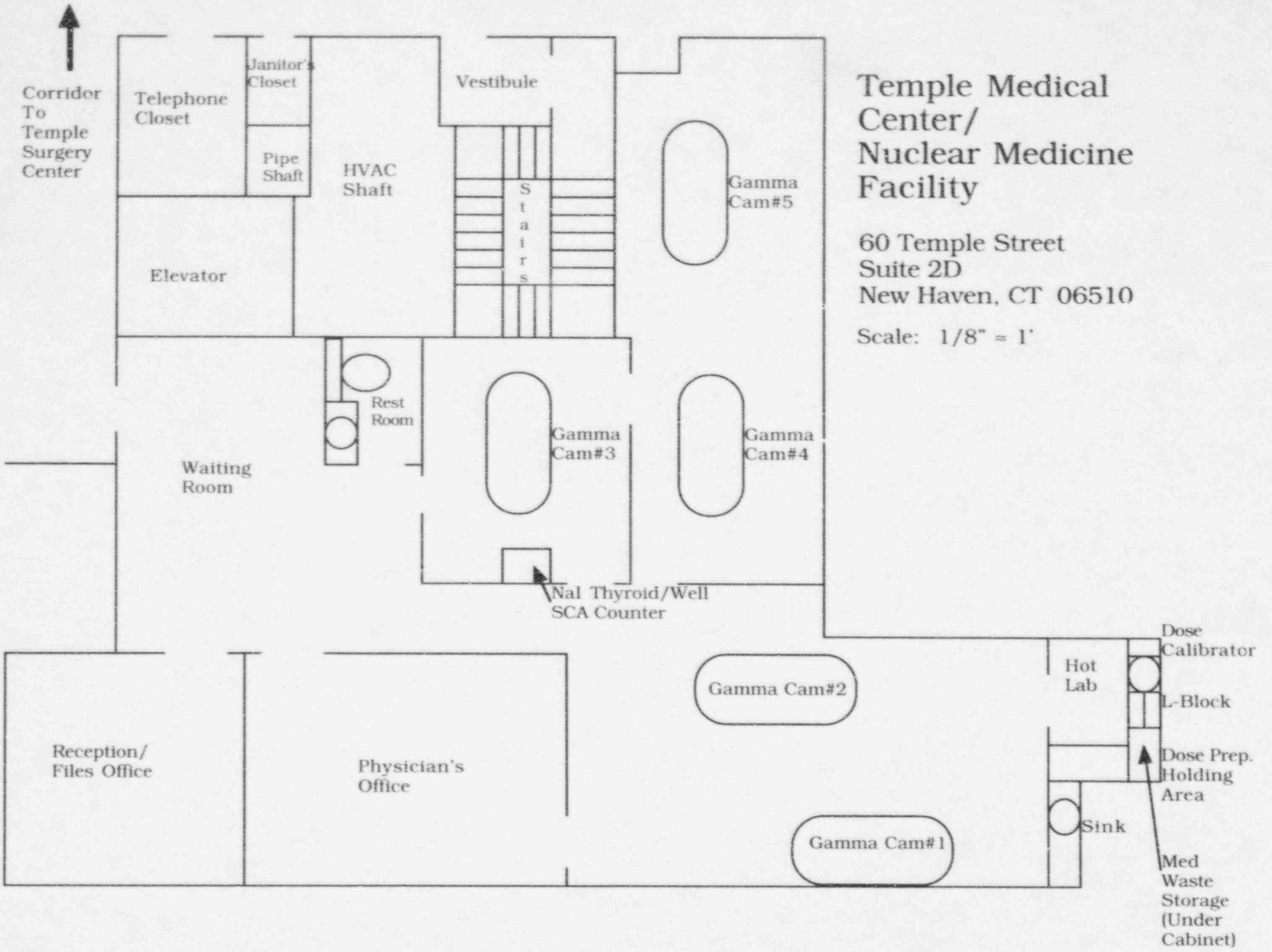
Michael J. Bohan, RSO
Medical Health Physicist

Norman G. Roth
V.P. Administration

cc: Gerald S. Freedman, M.D., Freedman and Associates, Nuclear Medicine. P.C.
Robert C. Lange. Ph.D., Chairman, YNHH Radiation Safety Committee
Ravinder Nath, Ph.D., Chief, Radiological Physics
John P. Seibyl, M.D., Acting Chairman, Nuclear Medicine
State of Connecticut, Dept. of Environmental Protection, Radiation Control Unit

Attachments: YNHH Check No.: 395539, $560.00
Map of New Haven
Room Diagram - Temple Nuclear Medicine
Room Diagram - Temple Surgical Center
Termination Letter - NRC License No.: 06-17434-01


MAP 6
NEW HAVEN AREA STREETS
MAP 6
A
B
C
D
E
F
G
1
2
3
4
5
6
7
8
EAST ROCK PARK
BEAVER HILLS PARK
PARK
NEW HAVEN
Temple Medical Center
Yale-New Haven Hospital
YALE UNIVERSITY
WOOSTER SQUARE PARK
POST OFFICE
NEW HAVEN R.R. STATION
SOUTH CENTRAL COMMUNITY COLLEGE
NORTH
New Haven Harbor
Quinnipiac R.
EAST SHORE PARK
0
1/4
1/2
MILE

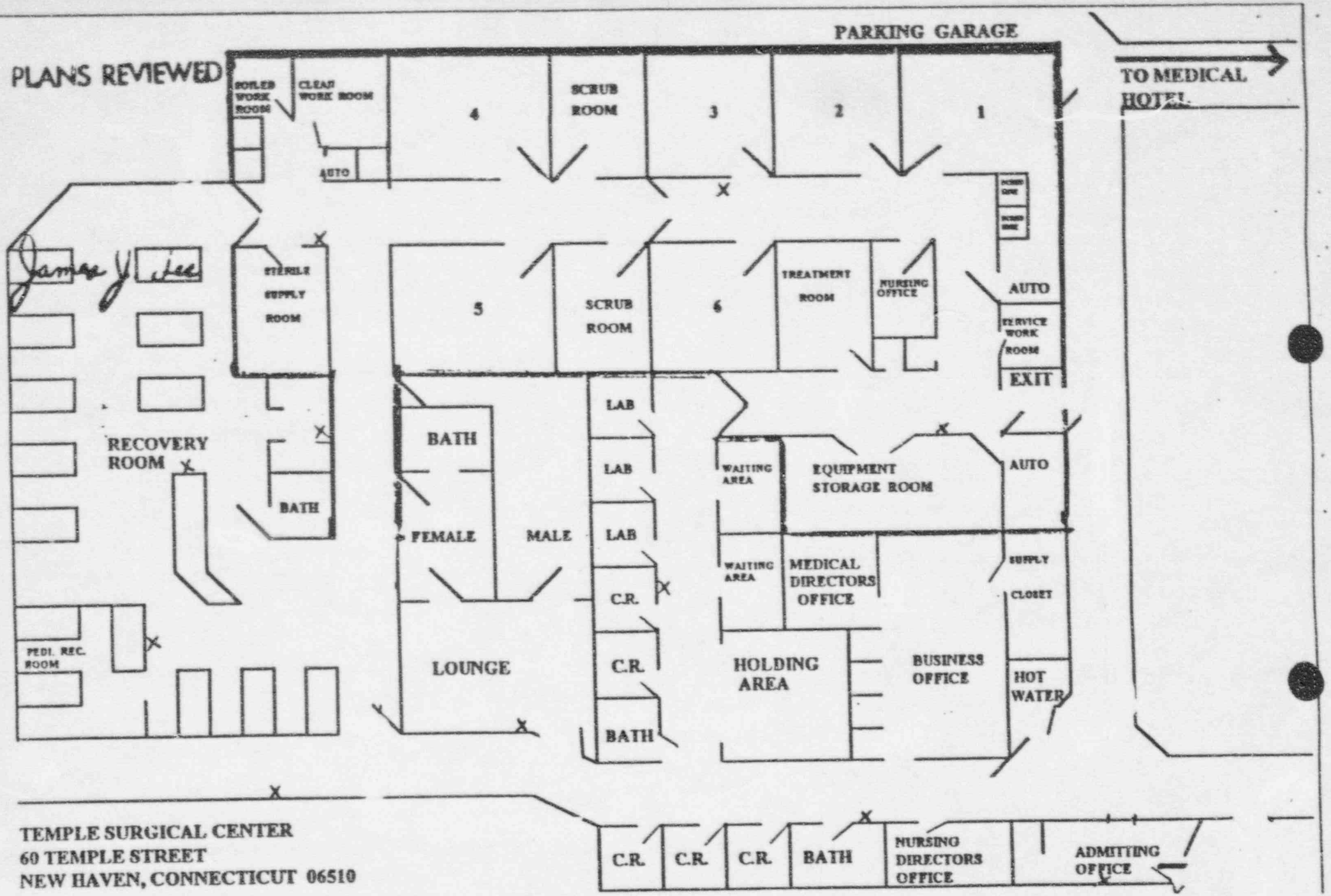


Temple Medical Center/ Nuclear Medicine Facility

60 Temple Street
Suite 2D
New Haven, CT 06510

Scale: 1/8" = 1'

PLANS REVIEWED



TEMPLE SURGICAL CENTER
60 TEMPLE STREET
NEW HAVEN, CONNECTICUT 06510

TEMPLE NUCLEAR MEDICINE, P.C.

Gerald S. Freedman, M.D. - Medical Director
60 Temple Street
Suite 2D
New Haven, CT 06510
Tel (203) 789-2299 Fax (203) 789-2231

July 17, 1996

License No.: 06-17434-01
Docket No.: 030-12747

U.S. Nuclear Regulatory Commission
Region I
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Transfer of Freedman and Associates NRC license No.: 06-17434-01

Gentlemen:

Freedman and Associates, Nuclear Medicine, P.C., 60 Temple St.-2D, New Haven, CT 06510, requests transfer of all allowed activities under the license at this location to Yale-New Haven Hospital's broad scope License No. 06-00819-03. All equipment and existing licensed radioactive materials will be transferred to YNHH's license immediately upon the successful acceptance of the YNNH's license amendment.

The existing license is to be terminated at this location and I request it be assigned to the Stafford Professional Building, Radiology Suite, 8 E.Main St., Clinton, CT 06413 as a "storage only" classification at this time. Enclosed is a $300.00 fee as advised by Brenda Brown of the NRC.

If you have any further questions concerning the termination and transfer of all activities currently under this license please contact Dr. Gerald Freedman at (203) 789-2299.

Sincerely,

Gerald S. Freedman, M.D., R.S.O.
Freedman & Associates - Nuclear Medicine, P.C.

cc: Michael J. Bohan, YNHH Radiation Safety Officer
Robert C. Lange, Ph.D., Chairman, YNHH Radiation Safety Committee
Ravinder Nath, Ph.D., Chief, YNHH Radiological Physics
Norman G. Roth, V.P., YNHH Administration
John P. Seibyl, M.D., Acting Chairman, YNHH Nuclear Medicine
State of Connecticut, Dept. of Environmental Protection, Radiation Control Unit

JUL 22 1996

NRC FORM 577
(1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

YALE-NEW HAVEN HOSPITAL
ATTN: MICHAEL J. BOHAN, RSO
MEDICAL HEALTH PHYSICIST
20 YORK STREET
NEW HAVEN, CT 06504

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE: 7-8-96

LICENSE NUMBER: 06-00819-03

CONTROL NUMBER: 123464

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7B	$	$	$ 580.00
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 580.00
PAYMENT RECEIVED	$ 560.00
AMOUNT DUE	$ 20.00

☒ Your request was received without the prescribed application fee.

☒ We received your Check No. 5539 in the amount of $ 560.00. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your apolication for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

☐ We received your Check No. _____ in payment of the fee.

☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.

☐ Your request was combined, prior to review, with your request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE – LICENSE FEE ANALYST	LFDCB	LFDCB
BRENDA BROWN	BB	
	8/6/96	

Distribution: PENDING FILE
MAF Correspondence FY
LFDCB Chief
LFDCB Analyst UC/DAF/SF(LT-3 2-7)
Invoice File w/encl
LFDCB R/F
DAF R/F
DATE 8-6-96

NRC FORM 577 (1-95)

This form was electronically produced by Elite Federal Forms, Inc.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02110
STATUS CODE: 0
FEE CATEGORY: 7B 2B
EXP. DATE: 20050531
FEE COMMENTS: 3E DEL PER 8/12/93 RE
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: YALE-NEW HAVEN HOSPITAL
RECEIVED DATE: 960722
DOCKET NO: 3001244
CONTROL NO.: 123464
LICENSE NO.: 06-00819-03
ACTION TYPE: AMENDMENT

1996 JUL 25 AM 11:04

2. FEE ATTACHED
AMOUNT: $560.00
CHECK NO.: 00395539

3. COMMENTS

SIGNED M. A. Serbia
DATE 7/22/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /)

1. FEE CATEGORY AND AMOUNT: (7B 2B) $580

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT /
RENEWAL
LICENSE

3. OTHER

SIGNED AC
DATE 8/30/96

I (9a)
Log Aug 2
Remitter
Check No 39539 / 401035
$560.00 / #2A Also acc
(7B 2B 123465)
Amd
Date Check Rec'd 8/2/96
Date Completed 8/30/96
By AC