NRC FORM 374
(7-94)

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, 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. St. Vincent's Medical Center	In accordance with the letter dated May 6, 1996,
2. 2800 Main Street Bridgeport, Connecticut 06606	3. License Number 06-00843-03 is amended in its entirety to read as follows:
	4. Expiration Date April 30, 2003
	5. Docket or Reference No. 030-01245

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 identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200 except generators	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. As needed
E. Uranium depleted in Uranium 235	E. Cadmium plated metal	E. 160 kilograms
F. Iridium 192	F. Sealed sources (BYK Mallinckrodt Model CI L BV)	F. 2 sources, 1 source not to exceed 12 curies and 1 source not to exceed 10 curies

9. Authorized use

A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.
B. Any imaging and localization procedure approved in 10 CFR 35.200.
C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.
D. Any brachytherapy procedure approved in 10 CFR 35.400.
E. Shielding in a linear accelerator.
F. One source to be used in a Nucletron Corporation MicroSelectron HDR remote afterloading brachytherapy device for interstitial, intraluminal and intracavitary radiotherapy in humans. The source activity may not exceed 10 curies at the time of installation. One source in its shipping container for source replacement.

ML 10

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number: 06-00843-03

Docket or Reference Number: 030-01245

Amendment No. 31

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 2800 Main Street, Bridgeport, Connecticut.

11. The Radiation Safety Officer for this license is Norman R. Vincent, M.D.

12. A. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
Norman R. Vincent, M.D.	35.100; 35.200; 35.300; 35.400; depleted uranium
Robert D. Russo, M.D.	35.100; 35.200; 35.300; 35.400; depleted uranium
John C. Olsavsky, M.D.	35.100; 35.200; 35.300; 35.400; depleted uranium
Henry J. Fox, M.D.	35.100; 35.200; 35.300; 35.400; depleted uranium
Robert D. Russo, Jr., M.D.	35.100; 35.200
Thomas D. Olsavsky, M.D.	35.100; 35.200; 35.300
Ralph W. Romano, M.D.	35.400; Strontium 89 and Phosphorus 32 for radiopharmaceutical procedures approved in 35.300; Iridium 192 in a high dose rate remote afterloading device for the treatment of humans
Bernard S. Jay, M.D.	35.100; 35.200; 35.300
Barbi L. Kaplan-Frenkel, D.O.	35.300; 35.400; Iridium 192 in a high dose rate remote afterloading device for the treatment of humans

B. The Medical Physicist for this license is Jerome A. Meli, Ph.D.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

14. 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.

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

16. 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.

17. 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).

18. 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 each 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.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 06-00843-03
Docket or Reference Number: 030-01245
Amendment No. 31

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).

20. 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).

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, 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 June 25, 1992
B. Letter dated March 2, 1993
C. Letter dated March 5, 1993
D. Letter dated May 6, 1996
E. Letter dated July 29, 1996
F. Letter received August 12, 1996

For the U.S. Nuclear Regulatory Commission

Date AUG 19 1996

By Original Signed By:
Michelle Beardsley

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

AUG 19 [redacted]

William J. Riordan
President/CEO
St. Vincent's Medical Center
2800 Main Street
Brideport, CT 06606

Dear Mr. Riordan:

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:
Michelle Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

License No. 06-00843-03
Docket No. 030-01245
Control No. 123213

Enclosure:
Amendment No. 31

DOCUMENT NAME: R:\WPS\MLTR\L0600843.03
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Beardsley MB							
DATE	08/07/96		08/ /96		08/ /96		08/ /96	

OFFICIAL RECORD COPY ML 10

MS 16
J-1

Ms. Michelle Beardsley
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

License No. 06-00843-03
Docket No. 030-01245
Control No. 123213

Dear Ms. Beardsley:

The following is the additional information you requested to ammend the above mentioned license.

1. Sources will be calibrated on installation, prior to clinical use, and monthly thereafter.

2. Source inventory will be done quarterly.

Sincerely yours,

Jerome A. Meli

Jerome A. Meli, Ph.D.

OFFICIAL RECORD COPY

ML 10

12343

FAX REC'D AUG 12 1996 P.01

NMSB TELEPHONE CONVERSATION RECORD

DATE OF CALL: 8-6-96

TIME OF CALL: 1130 am

PERSON CALLED: Jerome Mark Meli Ph.D. PHONE NO. 203-576-5086

(Outgoing Call)

PERSON CALLING: Michelle Beardsley

FACILITY NAME: St. Vincents Med. Ctr.

LICENSE NO.: 06-00843-03 DOCKET NO. 030-02745

SUBJECT:

License amendment

SUMMARY: Regarding their response letter dated 7-29-96, I questioned Dr. Meli as to their response to # 4. A. where they state that "Addendum to IV.A.2 should take @ 1 hr" -- I could not match this item to their original letter. He stated that this applied to "practice sessions" given to auth. users & device operators. I also requested a copy of his ABR certification in Therapeutic Radiology -- they had sent his ABR in Diagnostic Rad.

ACTION REQUIRED/TAKEN:

to send ABR certificate

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SIGNATURE: MB MAIL CONTROL NO. 123213

Follow-up call 8-7-96 1630 a.m. I explained that for the Nuclear Med HDR it was approved to take a 10 Ci source only. I also told Dr. Meli that regarding his response concerning source inventories - that he will need to perform & document this quarterly. In addition - please confirm that you will perform source calibration measurements (after installation) prior to pt. tx. & monthly

S:\PENDING\TELEREC.FRM - 10/14/93

MS 6
J-1

ST. VINCENT'S MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
2800 MAIN STREET
BRIDGEPORT, CT 06606

06-00343-03

TELEFAX

TO: MICHAEL BEARDSLEY

FROM: JEROME MELI

COMPANY: NRC

DATE: 8/6/96

CITY/STATE:

NO. OF PAGES: 2

FAX NO: 610-337-5393

FAX NO: 203-331-4530

SUBJECT: ABR CERTICIFICATE

CONTROL #123213

IF ANY PROBLEM DURING TRANSMISSION, PLEASE CALL (203) 576-5062.
This Facsimile contains PRIVILEGED AND CONFIDENTIAL INFORMATION intended only for the use of the addressee(s) named above. If you are not the intended recipient of this facsimile, or the employee or agent responsible for delivering it to the intended recipient, you are hereby notified that any dissemination or copying of this facsimile is strictly prohibited. If you have received this facsimile in error, please immediately notify us by telephone and return the original facsimile to us at the above address via the U.S. Postal Service. Thank you.

MEMO:

AS REQUESTED, FOLLOWING IS A COPY OF MY THERAPEUTIC RADIOLOGICAL PHYSICS CERTIFICATE.

123213

FAX RECD AUG - 6 1996

OFFICIAL RECORD COPY

ML 10

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology,
and the Association of University Radiologists

Hereby certifies that

Jerome A. Meli, Ph.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology

On this twenty-fifth day of November, 1991

Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Therapeutic Radiological Physics

BOARD OF
REGISTERED
IN THE
DISTRICT

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology,
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The American Board of Radiology

On this twenty-fifth day of November, 1991

Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Therapeutic Radiological Physics

MS16
J-1

St. Vincent's
Medical Center
2800 MAIN STREET, BRIDGEPORT, CONNECTICUT 06606-4292 • (203) 576-6000

July 29, 1996

Ms. Michelle R. Beardsley
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

LICENSE NO. 06-00843-03
DOCKET NO. 030-01245
CONTROL NO. 123213

Dear Ms. Beardsley:

The following is the additional information requested to ammend License No. 06-00843-03.

ITEM	RESPONSE
1.	We request that Dr. Romano be authorized for Sr-89 and P-32 only.
2.	Cammie Gee will be added to the license at a later date.
3.	The model is CI LBV.
4a.	The hands-on-training is specific to the HDR device proposed. The duration for each topic included in the training is specified in the original **Attachment 1** starting with section III. Addendum to IV.A.2: This will take about one hour.
4b.	Periodic retraining will be given at intervals not to exceed 12 months.
5.	The check source used to check the radiation monitor will be dedicated for this monitor.
6a.	Surveys in restricted areas will be done to ensure that exposures to personnel are in the spirit of ALARA and, when combined with other duties of the staff, do not exceed 5 rem per year.

123213

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AUG - 1 1996

Addendum to V.F (Survey Program). 2: With each source installation after the first, the exposure rate at B will be determined from an exposure measurement on the inside wall opposite B. This measurement will be adjusted for the wall attenuation.

6b. Area surveys will be conducted if the location of the HDR unit is changed from that originally described.

7. Addendum to Section VI: film badges will also be issued to

   a. Anyone whose duties might result in an annual dose in excess of 0.5 rem
   b. Minors and declared pregnant women whose duties might result in an annual dose in excess of 0.05 rem.

8. Amendment to 8. of **Attachment 8:** At the end of each treatment determine if the source is fully retracted by scanning with a survey meter. Scan the patient's body surface in the vicinity of the treatment site, scan the applicators, scan the length of the source guide tubes, and scan the safe of the HDR unit. Record the results of this survey on the log sheet along with the date, the patient's name, background exposure rate, the model and serial number of the HDR unit, the survey instrument used, and initials of the individual performing the surveys.

9a. All safety checks will be done according to the manufacturer's instructions where they exist.

9b. Amendment to VIII.B.1.c: Testing all control console functions including indicators which tell if the source is in or out of the safe, source stepping indicators, and door interlock indicators.

9c. Monthly checks of source positioning, timer accuracy, and linearity, and the backup battery will be done prior to use and within the preceding 30 days.

10a. Sources will be calibrated only on installation.

10b. If the measured source strength differs by more than +/-5% from that stated by the manufacturer, the physicist will review the entire calibration prior to putting the source into clinical use.

10c. As described in the original application, source strength will be determined with a calibrated well (re-entrant) chamber, for which, the effect of room scatter is generally negligible ("Evaluation of New Re-entrant Ionization Chambers for High Dose Rate Brachytherapy Calibrations", G. A. Ezzell, **Endocurie.Hypertherm. Oncol.9:**233-237.)

If the well chamber malfunctions, source strength will be determined from an in-air measurement as detailed in AAPM Report No. 41 **(Remote Afterloading Technology)**. In brief,

this method uses a calibrated thimble chamber (in our case, PTW Model 30-352, 0.6cc) placed at least 10 cm from the source which dwells at one position in a plastic or thin metal catheter. The chamber will have a side wall toward the source and its long axis perpendicular to that of the source. Contribution from room scatter will be accounted for by either of the two methods described in Report 41. These are (1) measuring the scatter directly by placing a shielding block (at least a tenth value layer) of small cross section (about 1 cm. diameter) between the source and chamber; (2) making exposure measurements at several distances from the source and determining room scatter as a linear regression deviation from the inverse square law. Contribution to the exposure measurement during source transit will be eliminated by either of the two methods described in Report 41. These are (1) using the programmable feature of the Keithely 617 electrometer. Charge integration is begun after the source reaches its calibration location and repetitive timed measurements are stored and displayed. These integrated charges do not contain contributions during source transit; (2) taking integrated exposure readings for two different control console times. Each reading contains the same contribution from source transit which is eliminated by simple subtraction of the integrated charges.

11. This is a single source device. In effect, an inventory is taken every time the source is used.

12. The survey meter will be at the control console for all treatments. A shielded container will be in the room for all treatments. A suture removal kit and sterile drapings will be in the room for all interstitial implants using flexible needles. Tools appropriate for loosening needles from templates used will be in the room for all such implants.

13. Our Quality Management Program will be reviewed to determine if any changes or modifications should be made which are specific to HDR.

Sincerely,

William J. Riordan
President/Chief Executive Officer
St. Vincent's Medical Center

WJR/nmf

JUL 12 1996

License No. 06-00843-03
Docket No. 030-01245
Control No. 123213

William J. Riordan
President/Chief Executive Officer
St. Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

Dear Mr. Riordan:

This is in reference to your letter dated May 6, 1996 to amend License No. 06-00843-03. In order to continue our review, we need the following additional information:

1. You request for Dr. Romano to be authorized for 35.300 materials, his recent experience appears to be with only Sr-89 and P-32; in order for him to be authorized for 35.300, in toto, he needs to have training/experience within the past 7 years with iodine-131 as required by 10 CFR 35.930 (b) (2). Please submit the required documentation, otherwise you may request for him to be authorized for Sr-89 and P-32 only.

2. Please submit documentation showing that Cammie Gee has the required training and experience as required by 10 CFR 35.961.

3. You state that the model number for the sealed source is "CI LBY", please clarify if this should be "CI LBV".

4. Regarding your Personnel Training program:

   a. Please indicate the duration of hands-on-training to be given and confirm that this will be specific to the device.

   b. Please confirm that periodic training will be given at intervals not to exceed 12 months (as opposed to annually).

5. Please confirm that the check source used to check the radiation monitor will be "dedicated" for this monitor.

6. Regarding your Survey program:

   a. Please confirm that surveys will be performed that will be sufficient to ensure that radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits in 10 CFR 20.1201.

b. Please confirm that surveys will be taken if and when the device location changes from previous conditions.

7. Regarding your Personnel Monitoring program, you state that others who enter the room will be badged only if it is "deemed necessary...". Please confirm that this will be according to the conditions specified in 10 CFR 20.1502.

8. Regarding your Operating Procedures, please confirm that the surveys taken of the patient will be over the body surface near the treatment site and that the device will include connectors and applicator apparatus, the full length of the catheter guide tube and the external surface of the device. In addition, please confirm that records of these surveys will be maintained for a period of 3 years which include the date of the survey, identification of the device (model and serial number), identification of the patient, identification of the instrument used to conduct the survey, a representative background dose rate, the survey results and the initials of the individual performing the surveys.

9. Regarding the Safety Checks performed on the device:

   a. Please confirm that they will be done according to the manufacturer's instructions.

   b. Please confirm that they will include checks of the source status indicators (safe or unsafe) including those which are integral to the afterloading device as well as any additional indicators installed at the treatment console or room entrance.

   c. Please confirm that the monthly checks of source position, timer accuracy/linearity and backup battery will be done prior to use and within the proceeding 30 days.

10. Regarding your procedure for Calibration Measurements:

   a. Please indicate the frequency of calibration measurements.

   b. Please confirm that if the results of these measurements are greater than +/- 5%, the results will be reviewed by the Radiation Safety Officer or Medical Physicist.

   c. Please describe the method used to determine the exposure rate under specific criteria (i.e., distances used for the measurement, whether the measurement is an "in-air" or done using a phantom, configuration of the chamber with respect to the source guide tube and device, scatter factors used to compute the exposure rate, etc.).

11. Please describe the method used for conducting quarterly inventories as required by 10 CFR 35.59.

12. Please confirm that all of the various pieces of equipment mentioned in your emergency procedures will be available and accessible during all treatments.

13. Please confirm that you will review your current Quality Management Program to determine whether any changes/modifications need to be made for High Dose Rate afterloading treatments. You may make changes to your program without prior NRC approval, however, these must be submitted to this Office within 30 days as required by 10 CFR 35.32 (e).

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 123213. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-6942.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

ORIGINAL SIGNED BY:

Michelle R. Beardsley
Division of Nuclear Materials Safety

License No. 06-00843-03
Docket No. 030-01245
Control No. 123213

Enclosures:
1. 10 CFR Parts 20 and 35

DOCUMENT NAME: R:\WPS\DLTR\L0600843.03
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Beardsley							
DATE	07/09/96		07/ /96		07/ /96		07/ /96	

OFFICIAL RECORD COPY

030-01245
06-00843-03

St. Vincent's
Medical Center
2800 MAIN STREET, BRIDGEPORT, CONNECTICUT 06606-4292 • (203) 576-6000

May 6, 1996

Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Sir:

1. Add Bernard S. Jay, M. D., as an authorized user under 10 CFR Parts 35. 00, 35.200 and 35.300. Dr. Jay completed his training in Radiology, and was certified by the American Board of Radiology (ABR) in 1979. A copy of his ABR certificate is enclosed. Dr. Jay was an Authorized User on the Byproduct Materials License of Freedman and Associates, Nuclear Medicine, 60 Temple Street, New Haven, CT 06510, US NRC Byproduct Materials License No. 06-17434-01, during the late 1980's. In addition, Dr. Jay has recently attended a Nuclear Medicine Update Course at Emory University School of Medicine. A copy of the Registration Certificate from that course is enclosed. Further, a copy of Form 313, showing recent participation in I-131 treatments for hyperthyroidism and thyroid carcinoma is enclosed. We believe that Dr. Jay meets all the requirements of Subpart J of 10 CFR Part 35 to be an Authorized User under 10 CFR Parts 35.100, 35.200 and 35.300.

2. Add Joseph A Gagliardi, M. D., as an authorized user under 10 CFR Parts 35.100, 35.200 and 35.300. Dr. Gagliardi completed his training in Radiology, and was certified by the American Board of Radiology (ABR) in 1991. A copy of his ABR certificate is enclosed. We believe that Dr. Gagliardi meets all the requirements of Subpart J of 10 CFR Part 35 to be an Authorized User under 10 CFR Parts 35.100, 35.200 and 35.300.

3. Add Robert D. Russo, M. D. as a Authorized User under 10 CFR Part 35.300. Dr. Russo completed his training in Radiology, and was certified by the American Board of Radiology (ABR) in 1979. A copy of his ABR certificate is enclosed. Dr. Russo is already an Authorized User on this license, under 10 CFR Parts 35.100 and 35.200. A copy of Form 313, attesting to Dr. Russo's recent participation in I-131 treatments for hyperthyroidism and thyroid carcinoma is enclosed. We believe that Dr. Russo meets all the requirements of Subpart J of 10 CFR Part 35 to be an authorized user under 10 CFR Part 35.300.

123213
MAY 13 1996

OFFICIAL RECORD COPY ML 10

4. Add Barbi L. Kaplan-Frenkel, D.O. as an Authorized User under 10 CFR Parts 35.300 and 35.400. Dr. Kaplan-Frenkel completed her training in Radiation Oncology, and was certified by the American Osteopathic Board of Radiology (AOBR) in 1994. A copy of her AOBR certificate is enclosed. We believe that Dr. Kaplan-Frenkel meets all the requirements of Subpart J of 10 CFR Part 35 to be an Authorized User under 10 CFR Parts 35.300 and 35.400.

5. Add Ralph W. Romano, M.D., as an Authorized User under 10 CFR Part 35.300. Dr. Romano completed his training in Radiology, and was certified by the American Board of Radiology (ABR) in 1974. A copy of his ABR certificate is enclosed. Dr. Romano is already an Authorized User on this license, under 10 CFR Part 35.400. A copy of Form 313, attesting to Dr. Romano's recent participation in Therapeutic use of Strontium-89 is enclosed. We believe that Dr. Romano meets all the requirements of Subpart J of 10 CFR Part 35 to be an authorized user under 10 CFR Part 35.300.

6. Add License Application for a High Dose Rate Remote Afterloader described in attached document.

A check for $470.00 is enclosed to cover the cost of these amendments.

We trust you will find the information provided complete. We are looking forward to the prompt renewal of our NRC License.

Sincerely,

William J. Riordan

William J. Riordan
President/Chief Executive Officer

WJR:mam

PARAGRAPH 1.

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
BERNARD S. JAY, M. D.	CT

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
DIAGNOSTIC RADIOLOGY INTERNAL MEDICINE INTERNAL MEDICINE (Recert.)		JUNE, 1979 JUNE, 1974 JUNE, 1986

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	YALE-NEW HAVEN HOSPITAL DIAGNOSTIC RADIOLOGY 1976-1979		
b. RADIATION PROTECTION	SAME AS ABOVE		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	SAME AS ABOVE		
d. RADIATION BIOLOGY	SAME AS ABOVE		
e. RADIOPHARMACEUTICAL CHEMISTRY	SAME AS ABOVE		

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE

SUPPLEMENT

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME

BERNARD S. JAY

STREET ADDRESS

27 ISLAND AVENUE

CITY	STATE	ZIP CODE
MADISON	CT	06443

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
	Thyroid scan		
	Thyroid uptake		
	Lung perfusion scan		
	Xenon ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Cryocystogram		
	Cardiac perfusion scan.		
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram		
	Gallium scan		

PROPOSED PHYSICIAN USER

BERNARD S. JAY, M. D.

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	3	
	TREATMENT OF HYPERTHYROIDISM	12	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other Sr-89		3	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR: Norman R. Vincent, M. D.

b. NAME OF INSTITUTION: St. Vincent's Medical Center

c. ADDRESS: 2800 Main Street

d. Bridgeport

e. MATERIALS LICENSE NUMBER(S): [illegible]

5. PRECEPTOR'S SIGNATURE: Norman R. Vincent MD FACR

7. PRECEPTOR'S NAME *(Please type or print)*: Norman R. VINCENT M.D

8. DATE: 4/11/96

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

APR 15 1991

License No. 06-20619-01
Docket No. 030-19990
Control No. 109651

Bernard S. Jay, M.D.
Meigswood 2B-C, Samson Rock Drive
Madison, Connecticut 06443

Gentlemen:

Please find enclosed Amendment No. 01 terminating License No. 06-20619-01 as requested by letter dated March 19, 1991.

Your cooperation with us is appreciated.

Sincerely,

Marlene J. Taylor

Marlene J. Taylor
Nuclear Materials Safety Section D
Division of Radiation Safety
and Safeguards

Enclosures:
Amendment No. 01

NRC Form 374A
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 1 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
06-20619-01

Docket or Reference number
030-19990

Amendment No. 01

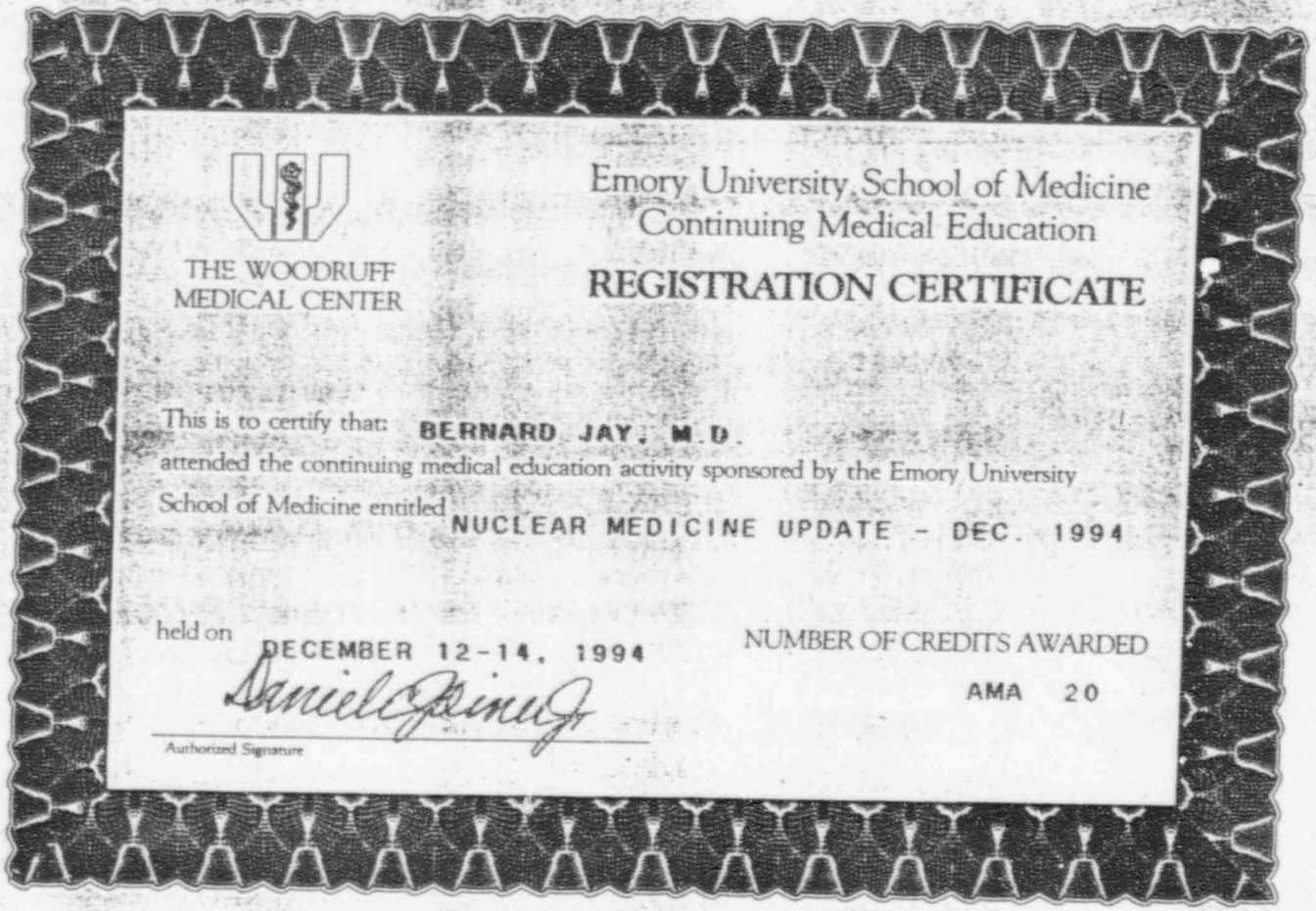
Bernard S. Jay, M.D.
Meigswood 2B-C, Samson Rock Drive
Madison, Connecticut 06443

In accordance with letter dated March 19, 1991, License Number 06-20619-01 is hereby terminated.

For the U.S. Nuclear Regulatory Commission

Date APR 15 1991

By Marlene J. Taylor
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406



THE WOODRUFF
MEDICAL CENTER

Emory University School of Medicine
Continuing Medical Education

REGISTRATION CERTIFICATE

This is to certify that: BERNARD JAY, M.D.
attended the continuing medical education activity sponsored by the Emory University School of Medicine entitled NUCLEAR MEDICINE UPDATE - DEC. 1994

held on DECEMBER 12-14, 1994

NUMBER OF CREDITS AWARDED
AMA 20

Daniel Spies Jr

Authorized Signature

NRC Form 374
(3-83)

U.S. NUCLEAR REGULATORY COMMISSION

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, 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. Bernard S. Jay, M.D.	3. License number 06-20619-01
2. Meigswood, 2 B-C Samson Rock Drive Madison, Connecticut 06443	4. Expiration date October 31, 1988
	5. Docket or Reference No. 030-19990

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.

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.

CONDITIONS

10. Licensed material shall be used only at Meigswood, 2 B-C, Samson Rock Drive, Madison, Conncecticut.

11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions, and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."

12. Licensed material shall be used by, Bernard S. Jay, M.D.

13. Licensed material shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.

14. 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:

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 06-20619-01

Docket or Reference number: 030-19990

(14. continued) CONDITIONS

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.

B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will 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.

15. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated July 9, 1983 and letter dated September 28, 1983; and Model ALARA Program contained in Appendix O of Regulatory Guide 10.8 (Rev. 1), "Guide for the Preparation of Applications for Medical Programs", October 1980. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

Date October 19, 1983

By _____

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

NRC FORM 313M (9-81) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved by OMB 3150-0041 Expires 9-30-83

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Bernard S. Jay, M.D.
Meigswood, 2 B-C
Samson Rock Drive
Madison, CT. 06443

TELEPHONE NO.: AREA CODE (203) 245 7352

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same as 1 a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Bernard S. Jay, M.D.

TELEPHONE NO.: AREA CODE (203) 245 7352

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO. _____
c. [ ] RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Bernard S. Jay, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Same as 4

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	x	
10 CFR 35.100, SCHEDULE A, GROUP I	x	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	xx	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	x	
10 CFR 35.100, SCHEDULE A, GROUP IV	n/a	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	n/a	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	n/a	

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	n/a	
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	n/a	
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	n/a	
GOLD-198 AS COLLOID FOR INTRA-CAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	n/a	
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	n/a	
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	n/a	

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Any Reagent Kit listed in Group III of Schedule A Section 35.100 of 10 CRF 35	Any form except generators listed in Group III A Section 35.100 of 10 CFR 35	as needed	Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Scheldule A Section 35.100 of 10 CFR 35

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1 NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2 STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
BERNARD S. JAY, M.D.	CONNECTICUT

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
DIAGNOSTIC RADIOLOGY		JUNE, 1979
INTERNAL MEDICINE		JUNE, 1974

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	YALE-NEW HAVEN HOSPITAL NUCLEAR MEDICINE DIVISION NEW HAVEN, CT. 1976-1979	100	250 (OJT)
b. RADIATION PROTECTION	SAME 1976-79	50	50 (OJT)
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	SAME 1976-79	15	20 (OJT)
d. RADIATION BIOLOGY	SAME 1976-79	15	15 (OJT)
e. RADIOPHARMACEUTICAL CHEMISTRY	SAME 1976-79	30	30 (OJT)

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
	ALL ISOTOPES USED IN diagnostic Nuclear MEDICINE during RESIDENCY at YALE-New HAVEN HOSPITAL	YALE-NEW HAVEN HOSP. NEW HAVEN, CT. DEPT. OF RADIOLOGY & NUCLEAR MEDICINE	1976-1979 RESIDENCY IN DIAGNOSTIC RADIOLOGY 3 MONTH NUCLEAR MEDICINE EXPOSURE during RESIDENCY	DIAGNOSTIC & THERAPEUTIC NUCLEAR MEDICINE

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

3 mos. Equivalent training in clinical nuclear medicine as part of Yale's Diagnostic Radiology Residency

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR: Alexander Gottschalk

b. NAME OF INSTITUTION: Yale School of Medicine

c. MAILING ADDRESS: 333 Cedar St.

d. CITY: New Haven, CT, 06510

5. MATERIALS LICENSE NUMBER(S): 06-00819-03

6. PRECEPTOR'S SIGNATURE: Alexander Gottschalk GOTTSCHALK

7. PRECEPTOR'S NAME *(Please type or print)*: Alexander Gottschalk

8. DATE: 12/2/87

NRC FORM 313M SUPPLEMENT B
(9-81)

RECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

3 months equivalent training in clinical nuclear medicine as part of Yale's Diagnostic Radiology Residency

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Vicente Caride, M.D.

b. NAME OF INSTITUTION
Yale University School of Medicine

c. MAILING ADDRESS
333 Cedar Street

d. CITY
New Haven, CT 06511

5. MATERIALS LICENSE NUMBER(S)
06-00819-03

6. PRECEPTOR'S SIGNATURE
V Caride

7. PRECEPTOR'S NAME *(Please type or print)*
Vicente Caride, M.D.

8. DATE
12/81

NRC FORM 313M SUPPLEMENT B
(9-81)

RECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

3 months equivalent training in clinical nuclear medicine as part of Yale's Diagnostic Radiology Residency

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Paul B. Hoffer, M.D.

b. NAME OF INSTITUTION
Yale University School of Medicine

c. MAILING ADDRESS
333 Cedar Street

d. CITY
New Haven, CT 06510

5. MATERIALS LICENSE NUMBER(S)
06-00819-03

6. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME *(Please type or print)*
Paul B. Hoffer, M.D.

8. DATE
12/22/81

NRC FORM 313M SUPPLEMENT B
(9-81)

NRC Form 374A (8-82) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 06-17434-01

Docket or Reference number: 030-12747

Amendment No. 04

Freedman & Associates
Nuclear Medicine
60 Temple Street
New Haven, Connecticut 06510

In accordance with letter dated November 4, 1983, License Number 06-17434-01 is amended as follows:

Conditions 12. and 15. are amended to read:

12. Licensed material listed in Item 6 above is authorized for use by the following individual(s) for the materials and uses indicated:

Gerald S. Freeman, M.D.	ALL
Gerald Berg, M.D.	Groups I, II, and III Xenon 133 Iodone 131 for treatment of hyperthyroidism and cardiac dysfunction
Bernard S. Jay, M.D.	Groups I, II, and III Xenon 133

15. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated April 22, 1982; letters dated July 20, 1982, and November 4, 1983; and the ALARA program contained in application dated April 22, 1982. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

Date JAN 05 1984

By Phillip C. Gramm
Nuclear Materials and Safeguards Branch
Region I
King of Prussia, Pennsylvania 19406

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

FEB 22 1990

Docket No. 030-19990 License No. 06-20619-01

Bernard S. Jay, M.D.
Meigswood 2B-C
Samson Rock Drive
Madison Connecticut 06443

Dear Dr. Jay:

Subject: INQUIRY NO. 90-001

This letter refers to a telephone inquiry by Mr. Steven R. Courtemanche of this office with you on February 1, 1990. This inquiry concerned activities authorized by the above listed NRC license.

From this discussion, we understand that you have never possessed material authorized by this license and do not plan to acquire such material in the near future. We further understand that you will notify this office by telephone or in writing prior to acquiring licensed material. If our understandings are incorrect, please inform us in writing.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter will be placed in the Public Document Room. No reply to this letter is required; however, we will be pleased to discuss any questions with you.

Your cooperation with us is appreciated.

Sincerely,

M. Shanbaky

Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center
State of Connecticut

FREEDMAN & ASSOCIATES-NUCLEAR MEDICINE

60 Temple Street
New Haven, Connecticut 06510
203-789-2299

Gerald S. Freedman, M.D.
William E. Allen III, M.D.

November 4, 1983

United States Nuclear
Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406

Gentlemen:

Effectively immediately, please add Dr. Bernard Jay to our nuclear medicine advisory board. He is licensed to practice nuclear medicine (NRC license #0620501901) and will be associated with our practice. If there are any additional forms to be completed, please forward them to my office.

Sincerely yours,

Ge ald S. Freedman, M.D.

cc: Dr. Bernard Jay

GSF:cq

MADISON RADIOLOGY, P.C.
MEIGSWOOD
SAMSON ROCK DRIVE
MADISON, CONNECTICUT 06443
(203) 245-7351

DIAGNOSTIC RADIOLOGY
LOW-DOSE MAMMOGRAPHY
CAT SCANNING

DIAGNOSTIC ULTRASOUND
ECHOCARDIOGRAPHY

November 7, 1989

U.S. Nuclear Regulatory Commission, Region I
Nuclear Materials Safety Section B
475 Allendale Rd.
King of Prussia, PA. 19406

Re: Renewal of License Number 06 20619-01

Reference is made to the application for material license with particular reference to articles number 5-number 11. At the present time, no nuclear studies are being performed at the office under my guidance. It is, however, planned over the next 3-5 years that nuclear medicine studies will be performed. They will be performed at the address that the application certifies. With reference to questions number 5 and number 6, at this time no radioactive materials are being used for clinical purposes. With reference to number 7, the individual responsible for the radiation safety program is myself, Bernard S. Jay, M.D. With reference to number 8, there are no employees employed doing any nuclear medicine studies. With reference to number 9, no equipment is being used at the moment. With reference to number 10 and number 11, since no radioactive material is being used at the present moment there is no radiation safety program or waste management system.

I do plan over the course of the next several years to institute nuclear medicine in the office at the above address. With this in mind, I sincerely hope you will approve my application for material licensing. If I can be of any further assistance to answer any of your questions, please do not hesitate to contact me.

Cordially,

B. Jay, M.D.

Bernard S. Jay, M.D.

/pah

NRC FORM 313
(9-88)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 9-30-90

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item.)*

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [x] C. RENEWAL OF LICENSE NUMBER 06-20619-01

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Bernard S. Jay, M.D.
2 B-C Meigswood
Sampson Rock Drive
Madison, Ct. 06443

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Same as 2.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION | TELEPHONE NUMBER

Bernard S. Jay, M.D. | 203-245-7351

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

Refer to Attach. #5 thru #11.

5. RADIOACTIVE MATERIAL a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY / AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Bernard D. Jay	BERNARD S. JAY, M.D.	PRESIDENT	11/10/89

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS

AMOUNT RECEIVED	CHECK NUMBER

APPROVED BY | DATE

NRC FORM 313 (9-88)

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 7.5 HRS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE RECORDS AND REPORTS MANAGEMENT BRANCH (P-530), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

25 OCT 1988

Bernard S. Jay, M.D.
Meigswood 2 B-C
Samson Rock Drive
Madison, CT 06443

DOCKET NO. 030-19990
LICENSE NO. 06-20619-01
CONTROL NO. 109651

SUBJECT: LICENSE RENEWAL APPLICATION

Gentlemen:

This is to acknowledge receipt of your application for renewal of material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Doris J. Foster

Doris J. Foster, Chief
Licensing Assistant Section
Division of Radiation Safety
and Safeguards

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

Docket No. 030-19990 MAR 23 1989 License No. 06-20619-01

ATTN: Bernard S Jay, M.D.
Meigswood, 2 B-C, Samson Rock Dr.
Madison, Connecticut 06443

Gentlemen:

Subject: Inquiry No. 89-001

This refers to a telephone inquiry by R.B. Provencher of this office with Bernard S. Jay, M.D. of your staff on 21 March 1989. This inquiry concerned activities authorized by the above listed NRC license.

From this discussion, we understand the following:

[X] You have never possessed material authorized by this license and do not plan to acquire such material in the near future. We further understand that you will notify this office by telephone or in writing prior to acquiring licensed material.

[ ] You have never possessed material authorized by this license, but you plan to acquire such material in the near future.

[ ] You plan to send a letter to this office requesting termination of your license. Please include the enclosed Certificate of Disposition of Materials with your letter.

If our understanding is incorrect, please inform us in writing.

In accordance with Section 2.790 of the NRC's "Rules of Practice", Part 2, Title 10, Code of Federal Regulations, a copy of this letter will be placed in the Public Document Room. No reply to this letter is required; however, we will be pleased to discuss any questions with you.

Your cooperation with us is appreciated.

Sincerely,

Richard B Provencher

Health Physicist
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

Enclosure: [ ] Certificate of Disposition of Materials (Form NRC 314)

cc:
Region I Docket Room
State of Connecticut

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association
and the American Society of Therapeutic Radiologists
Hereby certifies that

Bernard S. Jay, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this fifteenth day of June, 1979
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

PARAGRAPH 2.

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
JOSEPH A. GAGLIARDI, M. D.	CT

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
RADIOLOGY		NOVEMBER, 1991

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE

SUPPLEMENT

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME

JOSEPH A. GAGLIARDI, M. D.

STREET ADDRESS

60 TOWN SWAMP ROAD

CITY	STATE	ZIP CODE
HAMDEN	CT	06518

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
	Thyroid scan		
	Thyroid uptake		
	Lung perfusion scan		
	Xenon ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Dacryocystogram		
	Cardiac perfusion scan.		
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram		
	Gallium scan		

NRC Form 374
(3-83)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 67

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, 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. Department of the Army Commander, Tripler Army Medical Center	In accordance with letter dated February 9, 1994, 3. License number 53-00458-04 is amended in its entirety to read as follows:
2. ATTN: HSHK-PVR Tripler AMC, Hawaii 96859-5000	4. Expiration date September 30, 1996
	5. Docket or Reference No. 030-03537

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 1 to 83 and a half-life of less than 120 days except as specified in Subitems 6.B. through 6.F below	A. Any	A. 100 millicuries of each radionuclide with atomic numbers 1 to 83. Total possession limit for Subitem A not to exceed 4 curies.
B. Technetium 99m	B. Any	B. 6 curies
C. Molybdenum 99	C. Any	C. 7 curies
D. Iodine 131	D. Any	D. 2 curies
E. Iodine 125	E. Any	E. 500 millicuries
F. Xenon 133	F. Gas or gas in saline	F. 2 curies
G. Hydrogen 3	G. Any	G. 50 millicuries
H. Carbon 14	H. Any	H. 50 millicuries
I. Calcium 45	I. Any	I. 3 millicuries
J. Any byproduct material listed in 10 CFR 35.400	J. Any sealed source listed in 10 CFR 35.400	J. 2.5 curies for all sources authorized in Subitem 6.J.
K. Cesium 137	K. Sealed Source (J.L. Shepherd Model 6810)	K. 2200 curies per source and 4400 curies total

9. Authorized use

A. through J. Medical diagnosis and therapy as described in 10 CFR 35.100 through 35.500. Research in humans as approved by the Food and Drug Administration or by an RDRC approved by the FDA. Laboratory research. Research in animals. Instrument calibration.

K. To be used in a J. L. Shepherd and Associates Model 143-45A irradiator for the irradiation of blood, blood products, cells and tissues.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Jarrett White Road, Tripler Army Medical Center, Hawaii.

11. A. Licensed material for other than human use, shall be used by, or under the supervision of, individuals designated by the Radioisotope/Radiation Control Committee. The licensee shall maintain records of individuals designated as users.

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

C. 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 Radiation Safety Committee. The licensee shall maintain records of individuals designated as users.

12. A. The Radiation Protection Officer for this license is Captain John R. Mercier.

B. In the absence of Captain John R. Mercier, the Acting Radiation Protection Officer is Wayne F. Waffird.

C. In the absence of both Captain John R. Mercier and Wayne F. Waffird, the Acting Radiation Protection Officer is Mahendra Patel.

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 specified by the certificate of registration referred to in 10 CFR 32.210.

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.

(continued)

C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Sealed sources 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 transferred 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.

E. The leak 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 in accordance with 10 CFR 30(b)(2), and the source shall be removed immediately 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 IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Radiation Safety and Safeguards. The report shall specify the source involved, the test results, and corrective action taken.

F. 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.

14. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 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 in the molybdenum-99/technetium-99m generators authorized by this license.

15. 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 ten (10) half-lives.

    B. Prior to 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. Radioactive wastes containing microcurie amounts of iodine-125 may be disposed to the ordinary trash after being held for decay for a minimum of five (5) half lives. Prior to disposal, these wastes must be monitored in accordance with the procedures described in the licensee's application dated July 16, 1991 and letter dated November 10, 1992. The survey conducted prior to disposal must confirm that the radioactivity of the wastes cannot be distinguished from background.

16. A. Detector cells containing licensed material shall not be opened or the sources removed from the detector cell by the licensee.

    B. Sealed sources containing licensed material shall not be opened.

17. 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.

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

19. The licensee shall conduct a physical inventory every three (3) months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.57, 35.400, and 35.500 and every six (6) months for all other sources and/or devices.

20. The licensee shall maintain records of information related to decommissioning at their facility on Jarrett White Road, Tripler Army Medical Center, Hawaii per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

21. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), the licensee may use for medical use any byproduct material or reagent kit for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug (IND)."

22. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

23. Any irradiator malfunction which could cause exposure of the whole body of any individual to 5 rems or more of radiation or exposure of the feet, ankles, hands, or forearms to 75 rems or more of radiation shall be reported to the Commission. The report shall be filed within 5 days of the malfunction with the U.S. Nuclear Regulatory Commission, Division of Fuel Cycle, Medical, Academic, and Commercial Use Safety Branch, Washington, DC 20555, describing the equipment involved, the malfunction and the corrective actions taken.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
53-00458-04

Docket or Reference number
030-03537

Amendment No. 67

24. 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 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 July 16, 1991
B. Facsimile dated August 30, 1991
C. Memorandum dated September 5, 1991
D. Letter dated September 25, 1991
E. Letter dated October 8, 1991
F. Letter dated December 9, 1991
G. Letter dated April 16, 1992
H. Letter dated November 10, 1992
I. Letter dated February 9, 1994

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUL 1 4 1994

By James L. Montgomery
Materials Branch
Region IV, WCFO
Walnut Creek, California 94596

REQUEST FOR USE OF RADIOACTIVE MATERIALS

(For use of this form refer to TAMC Reg 40-37)

Date: 12-Jun-1995

THRU: Radiation Safety Officer
Health Physics Office
Tripler Army Medical Center

TO: Radiation Safety Committee
Tripler Army Medical Center

FROM: (Principle User and Organization)
Calvin B. Delaplain (1, 2, 3)
Nuclear Medicine Service
Tripler Army Medical Center

List all Co-Workers and Organizations

Authorized Users
Everett Gayle (1, 2, 3)
Joseph Gagliardi (1)
James Breitweiser (1)
Richard Harper (1, 2, 3)
Jay LeGrande (1, 2, 3)
Khosrow Behjati (1, 2, 3)
John Thomas

Supervised Users
Bryan Akau
Antonio Barzey
Jamie Beardsley
Clark Blosser
Edward Kawaoka
Andrew Martin
Harry Teruya

Radionuclides and maximum curiage of each which may be possessed at any one time

Atomic #1-83: 50 mCi each (not to exceed 3000 mCi total) except for the following byproducts

Technetium-99m	6 Curies	Accelerator produced materials	X Unsealed
Molybdenum-99	6 Curies	with Atomic #3-83 not to exceed	
Iodine-131	2 Curies	1 Curie.	
Xenon-133	2 Curies		X Sealed Sources

Areas of Radioactive Material Use: NMS Rooms: 3A104, 3A151, 3A105, 3A160, 3A005, Treadmill Room (4A102A), and authorized patient rooms

X Human Use

Location of Radioactive Material Storage: NMS Radwaste Storage 3A005

X Non-Human Use

Description of Use (Use additional sheets where necessary; list references and show dose calculations where applicable, disposal, counting or assay procedures)

Human Use: Diagnostic and Therapeutic use in patients

(1) Authorized to prescribe radiopharmaceuticals for imaging and localization studies IAW 10CFR35.920
(2) Authorized to prescribe colloidal P-32 for intracavitary therapy IAW 10CFR35.930
(3) Authorized to prescribe I-131 for Thyroid Carcinoma/Hyperthyroidism IAW 10CFR35.930, soluble P-32 and Sr-89 for bone metastases; soluble P-32 sodium phosphate for PCV treatment IAW 10CFR35.930; P-32 chromic phosphate colloid for synviorthesis

Non-Human Use: Calibration and Testing of Equipment

I acknowledge my responsibilities as Principle User

CALVIN B. DELAPLAIN, COL, MC
Signature

Administrative Approval

For MARK F. HANSEN, COL, MC
Signature

TAMC RADIATION SAFETY COMMITTEE APPROVAL

APPROVED:

JOHN R. MERCIER, MAJ, MS
Radiation Safety Officer

APPROVED

FRANKLIN R. SMITH, COL, MC
RSC Chairperson

Authorization No.: 95-04

Review By: Jun-96

PROPOSED PHYSICIAN USER

JOSEPH A. GAGLIARDI, M. D.

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	3	
	TREATMENT OF HYPERTHYROIDISM	21	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

NORMAN R. VINCENT, M. D.

b. NAME OF INSTITUTION

ST. VINCENT'S MEDICAL CENTER

c. MAILING ADDRESS

2800 MAIN STREET

d. CITY

BRIDGEPORT, CT 06606

5. MATERIALS LICENSE NUMBER(S)

06-00843-03

6. PRECEPTOR'S SIGNATURE

Norman R. Vincent MD FACR

7. PRECEPTOR'S NAME *(Please type or print)*

NORMAN R. VINCENT, M.D.

8. DATE

5/3/96

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology,
and the Association of University Radiologists
Hereby certifies that

Joseph Anthony Gagliardi, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology

On this twenty-fifth day of November, 1991

Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

President — Secretary-Treasurer — Executive Director

AMERICAN BOARD OF MEDICAL SPECIALTIES

PARAGRAPH 3.

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
ROBERT D. RUSSO, M. D.	CT

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
AMERICAN BOARD OF RADIOLOGY	DIAGNOSTIC RADIOLOGY	JUNE, 1977

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE

SUPPLEMENT

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptc. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME

ROBERT D. RUSSO, M. D.

STREET ADDRESS

2800 MAIN STREET

CITY | STATE | ZIP CODE

BRIDGEPORT, CT 06606

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
	Thyroid scan		
	Thyroid uptake		
	Lung perfusion scan		
	Xenon ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Dacryocystogram		
	Cardiac perfusion scan.		
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram		
	Gallium scan		

PROPOSED PHYSICIAN USER
ROBERT D. RUSSO, M. D.

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheet.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	1	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	2	
I-131	TREATMENT OF THYROID CARCINOMA	3	
	TREATMENT OF HYPERTHYROIDISM	C14	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other Sr-89	METASTATIC BONE DISEASE	4	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Norman R. Vincent, M. D.

b. NAME OF INSTITUTION
St. Vincent's Medical Center

c. MAILING ADDRESS
2800 Main Street

d. CITY
Bridgeport

5. MATERIALS LICENSE NUMBER(S)
06-00843-03

6. PRECEPTOR'S SIGNATURE
N Vincent MD

7. PRECEPTOR'S NAME *(Please type or print)*
Norman R. VINCENT M D

8. DATE
4/11/96

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
and the Section on Radiology of the American Medical Association
Hereby certifies that

Robert D. Russo, Jr., M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this eleventh day of June, 1977
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

Sidney W. Nelson
President

C. Allen Good
Secretary

AMERICAN BOARD OF MEDICAL SPECIALTIES

PARAGRAPH 4.

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
BARBI KAPLAN-FRENKEL	CT, NY, NJ

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
AMERICAN BOARD OF OSTEOPATHIC RADIOLOGY RADIATION ONCOLOGY		MAY, 1994

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE

SUPPLEMENT

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME

BARBI KAPLAN-FRENKEL

STREET ADDRESS

2800 MAIN STREET

CITY	STATE	ZIP CODE
DGEPORT	CT	06606

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

IS... A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
	Thyroid scan		
	Thyroid uptake		
	Lung perfusion scan		
	Xenon ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Dacryocystogram		
	Cardiac perfusion scan.		
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram		
	Gallium scan		

PROPOSED PHYSICIAN USER

BARBI KAPLAN-FRENKEL

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT	1	
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDIS'		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT	50	
I-125 or Ir-192	INTERSTITIAL TREATMENT	25	
Co-60 or Cs-137	TELETHERAPY TREATMENT	100	
Sr-90	TREATMENT OF EYE DISEASE	5	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other * Sr-89		6	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR: Norman R. Vincent, M. D.

b. NAME OF INSTITUTION: St. Vincent's Medical Center

c. ADDRESS (Number and Street): 2800 Main Street

d. CITY: Bridgeport

5. MATERIALS LICENSE NUMBER(S): 06-00845-03

6. PRECEPTOR'S SIGNATURE: * Vincent MD FACR

7. PRECEPTOR'S NAME (Please type or print): Norman R. VINCENT M D

8. DATE: 4/11/96

123213

OFFICIAL RECORD COPY

ML 10

The American Osteopathic Association

upon recommendation
of the

American Osteopathic Board of Radiology

certifies that

Barbi L. Kaplan-Frenkel, D.O.

having met the prescribed qualifications and standards and
passed the required examinations of this Board,
is qualified as a specialist in

Radiation Oncology

and is hereby awarded this certificate as of

May 27, 1994

American Osteopathic Association

Robert Pfeb
Executive Director

American Osteopathic Board of Radiology

John K Lally, DO
Chairman

Michael K Hellman, DO FACOCR
Secretary

Certificate No. 0781

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 7, 1994

American Osteopathic College of Radiology
ATTN: Ms. Pamela Smith
Executive Director
119 East Second Street
Milan, MO 63556-1331

Dear Ms. Smith:

This is in reference to the American Osteopathic College of Radiology (AOCR) request for recognition of certification by the American Osteopathic Board of Radiology (AOBR) in 10 CFR 35.930, "Training for Therapeutic Use of Radiopharmaceuticals." We have received your letter dated August 9, 1994, in which you respond to our request dated July 19, 1994, regarding the effective date of incorporation of the training requirements under 10 CFR 35.930.

We have reviewed your letter, and have determined that some candidates certified by AOBR will meet the training requirements outlined in 10 CFR 35.930. NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) discussed this issue at a meeting on May 19, 1994. The ACMUI recommended that the program be recognized three years after the effective date of the change in the program to ensure that all candidates have received the required training. Therefore, all candidates certified by AOBR after 1984 will be recognized under 10 CFR 35.930. We will forward our decision to the Office of Nuclear Regulatory Research for inclusion into the final rule, "Preparation, Transfer, and Use of Byproduct Material for Medical Use."

If we can be of further assistance, please contact Larry Camper at (301) 415-7269.

Sincerely,

Carl J. Paperiello

Carl J. Paperiello, Director
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

The American Osteopathic Association

upon recommendation
of the

American Osteopathic Board of Radiology

certifies that

Barbi L. Kaplan-Frenkel, D.O.

having met the prescribed qualifications and standards and
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and is hereby awarded this certificate as of

May 27, 1994

American Osteopathic Association

Robert Dube
Executive Director

American Osteopathic Board of Radiology

John K Lally, DO
Chairman

Michael K Hillman, DO FACOR
Secretary

Certificate No. 0781

PARAGRAPH 5.

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
RALPH W. ROMANO, M. D.	CT

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
AMERICAN BOARD OF RADIOLOGY	THERAPEUTIC RADIOLOGY	JUNE, 1974

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

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c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
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5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE

SUPPLEMENT

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME

RALPH W. ROMANO, M. D.

STREET ADDRESS

2800 MAIN STREET

CITY	STATE	ZIP CODE
BRIDGEPORT	CT	06606

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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	Thyroid uptake		
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	LeVeen shunt study		
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	Dacryocystogram		
	Cardiac perfusion scan.		
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram		
	Gallium scan		

PROPOSED PHYSICIAN USER

RALPH W. ROMANO, M. D.

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
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	TREATMENT OF HYPERTHYROIDIS'		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other Sr-89	METASTATIC BONE DISEASE	12	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Norman R. Vincent, M. D.

b. NAME OF INSTITUTION
St. Vincent's Medical Center

c. MAILING ADDRESS
2800 Main Street

d. CITY
Bridgeport

5. MATERIALS LICENSE NUMBER(S)
06-00843-03

6. PRECEPTOR'S SIGNATURE
Vincent MD

7. PRECEPTOR'S NAME *(Please type or print)*
Norman R. VINCENT M D

8. DATE
4/11/96

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America
and the Section on Radiology of the American Medical Association
Hereby certifies that

Ralph W. Romano, Jr., M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this twenty-third day of June, 1974
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Therapeutic Radiology

Ralph W. Leddy
President

C. Allen Good
Secretary

LICENSE APPLICATION FOR A HIGH DOSE RATE REMOTE AFTERLOADER

I. Description of Sources and Device

A. Source Description

1. Radionuclide - Iridium 192
2. Model and manufacturer - BYK Mallinckrodt CI LBY
3. 12 Ci maximum activity per source
4. Maximum of 2 sources at any time

B. Device Description

1. Manufacturer - Nucletron-Oldelft Corporation, 7080 Columbia Gateway Drive, Columbia, Maryland, 21046-2133, tel: 410-312-4100
2. Model - microSelectron-HDR (080.000)

II. Intended Use

To be used for interstitial, intracavitary and intraluminal treatment of cancer in humans. Source strength and, where deemed necessary, dose distributions around the source and applicators will be measured by the physics staff.

III. Proposed Users

A. Physicians - Use will be limited to Ralph W. Romano, M. D., who is already designated as authorized user of 10 CFR 35.400 materials and to Barbi L. Kaplan-Frenkel, D. O., whose qualifications are submitted in a separate part of this amendment.

B. Authorized Physicist

Jerome A. Meli, Ph.D. - Certified by the American Board of Radiology in Diagnostic Radiological Physics and in Therapeutic Radiological Physics; over ten years experience in brachytherapy including HDR; co-author of Remote Afterloading Technology, AAPM Report No. 41; author or co-author of eight original papers on brachytherapy; co-author of the book Interstitial Brachytherapy: Physical, Biological and Clinical Considerations, Raven Press, NY, 1990; faculty member of the AAPM Summer School on Brachytherapy in 1994. A copy of his ABR certificate is enclosed.

C. Medical Physicist

Cammie Gee, M.S. - M.S. in Physics; M.S. in Medical Physics; first employed as a Medical Physicist on January 2, 1996, at St. Vincent's Medical Center. Will assist the authorized physicist in all aspects of brachytherapy.

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

Jerome Anthony Meli, Ph.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this seventh day of November, 1995
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiological Physics

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF

AMERICAN BOARD OF MEDICAL SPECIALTIES
EXCELLENCE

PARAGRAPH 6.

IV. Training for Individuals

A. Initial Training of Authorized Physician Users and Device Operators

1. See attachment 1 for an outline of initial training provided by Nucletron-Oldelft installation engineer.

2. As part of the formal training session each trainee will participate in practice sessions which simulate daily quality control procedures and treatment delivery procedures.

B. Qualifications of Training Personnel - See Attachment 2.

C. Periodic Retraining

Conducted annually by Nucletron-Oldelft as part of the service contract. The initial training outlined in Attachment 1 is repeated annually.

D. Training of Ancillary Staff

1. Initial Training - nurses, technologists, housekeeping staff, engineering staff, and security staff will be given information they need to know about the HDR unit, care of patients undergoing HDR therapy, and radiation safety precautions. An outline of the initial training is given in Attachment 3.

2. Annual refresher reviews of radiation safety precautions, including those applicable to HDR will be given to all ancillary staff. See Attachments 4 and 5.

E. Records of initial and refresher training given to operators and ancillary staff will be maintained for at least three years and will include the names of attendees and an outline of topics discussed.

V. Facilities

A. Treatment Room

The afterloader will be housed and used in a room referred to as the "4MV Room" in which there also is a 4 MV Varian linear accelerator. See Attachment 6 for room details.

B. The treatment room will be equipped with an intercom system and two independent closed-circuit television systems for viewing the patient. The primary TV system will have pan and zoom capabilities and the backup will be pan only. If both TV systems fail, no further treatments will be given until at least one of them is repaired. If the intercom system fails, no further treatments will be given until it is repaired.

C. Security

1. Upon delivery, and prior to its installation, a source will remain in its delivery container which will be stored in a room currently designated as a storage room for radioactive materials. This room is a restricted area, kept locked and has a "Caution Radioactive Material" warning sign posted outside the door.

2. The treatment room will be locked after department working hours. Maintenance work and housekeeping required in the room will be done during department working hours.

3. The treatment room will have a door interlock such that the afterloader cannot be operated if the door is open and which will cause retraction of the source back into the shielded safe if the door is opened while the source is exposed.

4. If the treatment is interrupted by the door interlock system, treatment can be resumed only by resetting the interlock and confirming this by the "Door Open" indicator on the control console being off.

5. In the event of a malfunction of the interlock system, the HDR unit will be locked in the "off" position and not used except as needed for repair or replacement of the interlock system.

6. Standard "Caution Radioactive Warning" signs will be posted on the outside of the treatment room door and on an outside wall immediately adjacent to the door.

7. The room also contains a linear accelerator used for external beam radiation therapy. An interlock will inhibit simultaneous operation of the accelerator and the HDR unit.

8. Keys to the control console of the afterloader will be kept in an office within the department whenever the HDR unit is not in use or is unattended.

D. A permanent radiation monitor (Prime Alert) capable of continuously monitoring the source status will be installed in the HDR treatment room.

1. The radiation monitor will be visible by anyone entering the room. Its sensitivity will be set to indicate that a source is either fully or partially exposed.

2. The radiation monitor will be independent of the afterloader and have its own power supply.

3. Each day, prior to the afterloader's first use, the radiation monitor will be checked with a check source of low activity. Results of the check will be documented and a record maintained for at least three years.

4. If the radiation monitor is found inoperable, a survey meter will be used by an individual entering the room to check for any malfunction of the afterloader resulting in a fully or partially exposed source. The survey meter will be checked each day of HDR treatments with a dedicated check-source.

5. A malfunctioning radiation monitor will be repaired or replaced as rapidly as possible.

E. Dose Rate Calculations
See Attachment 7.

F. Survey Program

1. A radiation survey within the treatment room will be done with each new source installation. Exposure rates will be measured at four points, each a distance of 10 cm. From the exterior surface surrounding the source safe. These points will lie in an approximately horizontal plane through the safe and will be in front of, behind, to the left, and to the right of the safe. Exposure rates at these points are not to exceed 1 mR/hr with a properly shielded and positioned source.

2. A radiation survey outside and around the treatment room will be done with each new source installation. For the first installation the survey will be done at points A through E shown in the diagram of Attachment 6, and on the roof and in level 1. The same survey will be repeated following structural changes to the room or to areas surrounding the room. After the first source, new source installations will include a survey at points A through E.

3. It is expected that the general public will receive less than 2 mR in any one hour and less than 100 mR per year. Should the workload be such that these limits could be exceeded, the area in question will be designated as and treated as restricted.

4. Records of the survey will be maintained for the duration of the license.

5. A "Caution Radioactive Material" sign will be affixed to the exterior of the HDR unit in the treatment room.

VI. Personnel Monitoring

All personnel involved in HDk therapy will be provided with film badges to monitor whole body radiation doses. Individuals already badged will use the same badge for HDR as for their other duties. Others who enter the room will be badged only if deemed necessary, based on the nature of their work and expected length of time in the room.

VII. Survey Instruments

Two portable survey instruments will be available at all times when the remote afterloader is in use. One, a GM counter, is capable of detecting radiation over the range of 0.1 mR/hr to 50 mR/hr and the second, a Keithley ionization chamber survey meter, can measure radiation dose rates from 1 mR/hr to 20 R/hr.

A. Both instruments will be calibrated annually and following repair either in-house or by an outside company. All scales with readings up to 1000 mR/hr will be calibrated; each scale will be calibrated at a minimum of two points; the calibration date and response to a dedicated check source will be noted on the instruments.

B. Both instruments will be considered calibrated if the indicated exposure rate differs from the calculated exposure rate by no more than 20%. A correction chart will be attached to each instrument if necessary.

C. Both instruments will be checked for proper operation with their respective check sources each day of use.

D. Calibration records of both instruments will be maintained for at least three years and will include the calibration procedure, date of calibration, a description of the source, expected exposure rates and exposure rates indicated by the instruments being calibrated, deduced correction factors, and signature of the individual performing the calibration.

VIII. Operating and Calibration Procedures

A. Operating Procedures
A copy of the operating procedures will be kept at the control console and will be required reading of all who use the afterloader or participate in HDR treatments. See Attachment 8.

B. Safety Checks

1. At the beginning of each day of use, quality control checks will be performed according to procedures to be determined after gaining familiarity with the unit. These checks will include:

a. Functioning of the radiation monitor
b. Functioning of the viewing and intercom systems
c. Testing all control console functions
d. Functioning of all interlock systems
e. Visually checking the integrity of applicators and guide tube to be used

2. Monthly checks will be made of source positioning accuracy either visually, or by autoradiography, or with the well chamber. The method to be used will depend on the accuracy achievable.

a. Autoradiography:
An endobronchial catheter will be secured to a film, loaded with dummy source markers and radiographed. The markers will be removed and the catheter connected to the HDR unit. Three to five dwell positions, corresponding to marker locations, will be programmed. The actual dwell positions of the source relative to the markers will be determined on the developed film.

b. Visual checking:
A clear catheter mounted on a check ruler will be connected to the HDR unit. A camera will be focused on the ruler showing the catheter and the mm gradations of the ruler. The accuracy of three to five dwell positions will then be viewed.

c. Checking with the well chamber:
A quality control insert for the well chamber consists of a lead cylinder with a bore through its long axis, to accommodate the source, and a 4 mm diameter hole through a cross sectional plane. By observing chamber response versus source position in the vicinity of the hole, it is possible to check timer accuracy, source position accuracy and source strength. The technique is described in the article "Quality assurance tool for high dose rate brachytherapy", L.A. De Werd, P. Jursinic, R. Kitchen and B.R. Thomadsen, Med. Phys. 22, 435-440, 1995.

d. If the source position tolerance of +/- 1 mm is exceeded, an authorized user and physicist will be notified prior to treating patients.

3. Timer accuracy and linearity will be checked with each source change and monthly thereafter either with a stop watch or with the quality control insert for the well chamber as described in VIII.B.2.c. above.

4. Lengths of source guide tubes will be checked monthly.

5. The microSelectron HDR unit cannot be operated in the case of a power failure. However, it has a backup battery which, in the case of a power failure, enables the source to be returned to the shielded safe and maintains all patient and treatment data until power is returned. The backup battery system will be tested monthly in accordance with the manufacturer's instructions.

6. A record of all the above checks will be maintained for at least three years and will include date and results of the checks and initials of the individual performing the checks.

C. Calibration Procedure

1. Only an authorized physicist will calibrate the source. Qualifications of the proposed individual are discussed in III.B.

2. Calibration method

   a. Equipment:
   Well chamber - Standard Imaging, HDR 1000 Plus
   Electrometer - Keithley, Model 617

   b. The electrometer and well chamber will be calibrated every two years, and after any repairs which might alter their calibrations, either by a NIST or an AAPM accredited laboratory.

   c. A catheter within the well chamber will be connected to the afterloader. The new source will be programmed to move to the location of maximum chamber response. Ionization charge or current, corrected for temperature and pressure, will be converted to source activity according to the calibration factor. For source calibrations, the chamber will always be used at the same location in the room. This location will be selected on the basis of having the fewest objects nearby which can contribute scatter radiation.

   d. The measured source strength will be used for dose calculations. If the measured strength is not within +/- 5% of the manufacturer's stated strength, the manufacturer will be notified.

   e. Source and equipment calibration records will be maintained.

   f. Source strength determination (calibration) will be done for each newly installed source prior to its clinical use.

g. If source homogeneity is deemed a likely factor in dose distributions and clinical outcome, it will be checked by autoradiography.

IX. Emergency Procedures

A copy of the emergency procedures will be kept at the control console and will be required reading of all who use the afterloader or participate in HDR treatments. See Attachment 9.

X. Maintenance

All maintenance and repair of the HDR unit, including source exchanges and adjustments that can result in incomplete shielding of the source or improper source movement, will be done by Nucletron-Oldelft engineers. Service records will be kept for as long as the unit is in use and will contain the date of service, a description of the service, name, authorization number, and signature of the individual performing the service.

A service contract with Nucletron-Oldelft will provide

1. Source exchanges, preventive maintenance, inspections, manufacturer's scheduled service, and check of overall functioning of the unit on a quarterly basis.

2. Records of the quarterly service will be kept as described above.

XI. Source Disposal

Used sources will be disposed of only by returning them to the manufacturer. With each source change, a Nucletron-Oldelft representative will prepare the used source for shipment.

ATTACHMENT 1

OPERATOR TRAINING - MICROSELECTRON-HDR

This training is provided to all device operators. The Authorized Users (physicians); Brachytherapy Physicist, Radiation Safety Officer, and all technical staff who will operate the device are required to attend the scheduled Nucletron training course.

This course will not address facility-specific aspects of the Radiation Safety and Quality Management programs. Competency evaluation of course attendees will be jointly determined by the licensee's R.S.O. and Authorized User(s).

I. Teaching Aids Required:

1. microSelectron-HDR Installed System
2. microSelectron-HDR User Manual
3. Note Pads and Pens
4. Applicators and Accessories
5. Source container and Dummy Source
6. Survey Meter provided by customer
7. VCR and TV monitor
8. Nucletron Emergency Procedure Video

II. Introduction to microSelectron-HDR

1. What is Remote Afterloading Brachytherapy(30 minutes)
   a) radiation protection
   b) treatment control
   c) short treatment times

2. Applications of microSelectron-HDR (30 minutes)

   a) Bronchus
   b) Interstitial
   c) Intracavitary
   d) Intraoperative

3. Demonstration of Applicators and Accessories (30 minutes)
   a) Bronchus
   b) GYN
   c) Esophagus
   d) Interstitial

ATTACHMENT 1

III. General Information microSelectron-HDR

1. Specifications (30 minutes)

a) Source
b) Radiation protection
c) Power requirements
d) Number of channels
e) Moving and handling

IV. Operation and Emergency Procedures

1. Routine Equipment Operation (1 hour)

a) Explanation of Console
b) Explanation of Treatment Unit
c) Programming Mode
d) Treatment mode
    i) Start
    ii) Interrupt
    iii) Emergency Stop
    iv) Alarm and error codes

2. Emergency Procedures 2-3 hrs

a) When to declare an emergency
b) Survey meter use
c) Emergency Procedure Step 1 (Gold Crank)
Emergency Procedure Step 2 (Applicator Removal)
Bronchial/Esophageal
Intracavitary/GYN
Interstitial Flexible
Interstitial Needle
Emergency Procedure Step 3 (Patient Removal)
d) Patient Protection
e) Personnel Protection
f) Emergency Procedure video tape
g) Dry Runs

ATTACHMENT 1

V. Isotope (^{192}Ir) Shipping and Receiving (30 minutes)

1. Delivery

   a) Unpacking
   b) Acceptance into Inventory
   c) Calibration Data
   d) Installation by engineers
      (Discussion Only)

2. Shipping

   a) Release from Inventory
   b) Packing
   c) Shipping Documents
   d) Measurement of Transport (TI)

VI. Questions and Answers

ATTACHMENT 2

Qualifications of Engineers and Training Personnel

RADIATION SOURCE LOADING FOR MICROSELECTRON-HDR

The personnel listed below have been trained in the installation of the microSelectron Remote Afterloading equipment and the loading of the radiation sources into the storage safe of the microSelectron-HDR from the transport container. (listed below).

Person	Years Experience	Experience and Training (Jan. 1995)
A. ten Brinke	8	International Service Manager of Nucletron Engineering B.V., responsible for worldwide warranty and service of the 200+ Selectron systems. He has installed over 50 systems. Training "Ionizing Radiation" Level B (handling of Encapsulated Radioactive Sources-IVBS Rotterdam).
C. Mellink	9	Trained by Nucletron, Engineering B.V. (L. van Zwol and R Hermanus). Has carried out installations in USA, Canada, China, Europe.
S. Teague	8	Technical Manager - Nucletron Corporation Radiation Safety Officer
J. Harrison	7	Service Manager, Nucletron Corporation, responsible for North and South American installations, warranty and service. Trained by Nucletron Engineering B.V.
T. Speck	7	Trained by Nucletron Corporation. Attended 4 weeks' certified training in Holland on operation, service and safety of the machines and sources.
C. Jones	7	See Above
H. Archibald	7	" "
B. Loudy	6	" "

ATTACHMENT 2

Person	Years Experience	Experience and Training (Jan. 1990)
D. Cook	6	Trained by Nucletron Corpcration. Attended 4 weeks' certified training in Holland on operation, service and safety of the machines and sources.
C. Scott	6	" "
J. Oliver	4	" "
J. Cowan	4	" "
P. Koonce	4	" "
D. Glessner	4	" "
L. Vincent	3	" "
C. Tow	3	" "
M. Irvin	3	" "
C. Hicks	2	" "

NUCLETRON CORPORATION

ATTACHMENT 3

Ancillary Staff Training microSelectron-HDR

1. What HDR unit looks like and what it is used for.

2. Location of HDR Device and Console

   a) Device possess Radioactive Source
   b) Safety Instructions about entrance into Room (what to look for, who to ask, prior to entrance)

3. Basic Radiation Safety Techniques

   a) Time, Distance and Shielding
   b) Use of whole body radiation badges (if issued film badge)
   c) Survey Meter use (if applicable)

4. Awareness of Safety Devices and Locations

   a) Locations and understanding of caution signs and devices.
   b) Awareness and understanding of Applicators/Connectors/Tubing, etc.
   c) What to look for in the event of emergency

5. Who to Contact in Event of Emergency

   a) Radiation Safety Officer (RSO)
   b) Authorized Users (M.D.'s and Physicists)

6. Care of Patient Receiving Treatment

ATTACHMENT 4

ANNUAL REVIEW OF RADIATION SAFETY

FOR

HOUSEKEEPING, ENGINEERING, AND SECURITY STAFFS

1. Electromagnetic Radiation
2. Natural Background Radiation
3. Units of Radiation
4. MPD's; ALARA
5. X-ray Rooms
   a. Shielding
   b. Interlocks; emergency off switches; x-ray indicator lights
   c. What to do and who to notify when working in an x-ray room
6. LDR Radioactive Sources and Procedures
   a. Storage room in Radiation Oncology
   b. Nuclear Medicine and branchytherapy procedures - patient rooms, waste disposal, general precautions.
   C. "Caution Radioactive Materials" signs - what they look like; when posted; who may enter rooms
7. HDR
   a. The unit and control console
   b. Exposure rates around the unit
   c. Radiation safety precautions
   d. Maintenance and housekeeping work done during normal working hours
   e. Restricted area with a radiation warning sign posted
   f. Schedule extended maintenance
8. Who wears film badges
9. Film badge reports
10. Radiation Safety Committee and RSO

ATTACHMENT 5

ANNUAL REVIEW OF RADIATION SAFETY

FOR

NURSES AND TECHNOLOGISTS

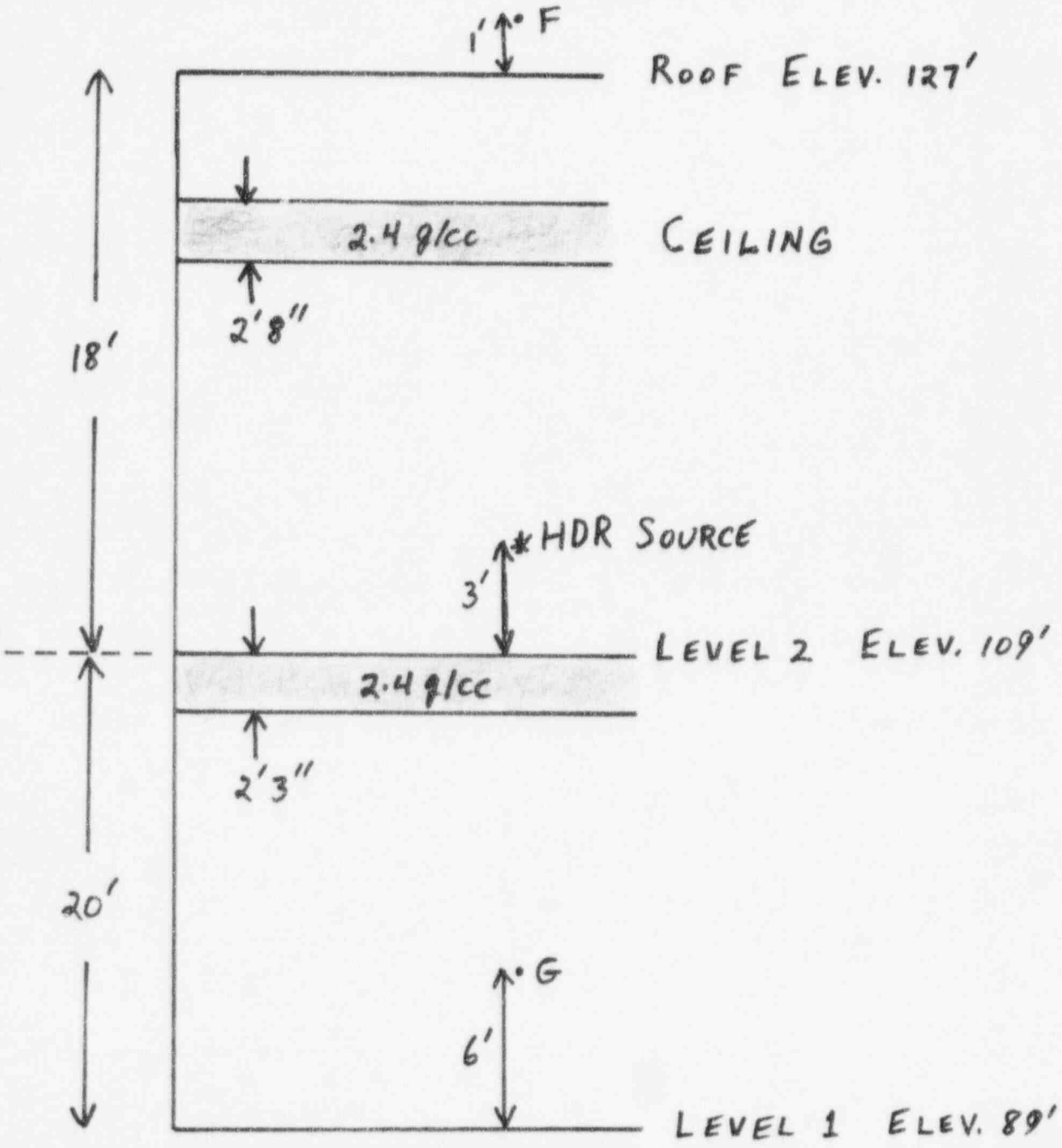
1. Electromagnetic Radiation
2. Natural Background Radiation
3. Units of Radiation
4. MPD's; ALARA
5. Film Badges - purpose; proper use; reports
6. LDR brachytherapy
   a. Purpose
   b. Sources and applicators
   c. Dislodged sources and/or applicators
   d. Hamper for linens
   e. Policy on visitors and pregnant staff
7. Nuclear Medicine Iodine-131 Procedures
   a. Purpose
   b. Body excretions
   c. Nothing leaves the room
   d. No visitors; no housekeeping
   e. Instructions to patients
   f. Handling waste
8. HDR Brachytherapy
   a. Purpose
   b. Unit; control console; source, applicators
   c. Treatment room interlocks
   d. Prime alert
   e. Continuous viewing of patient
   f. Radiation survey meters
   g. Surveying patient after treatment
   h. Emergency procedures
9. Minimizing Your Radiation Dose
   a. Time
   b. Distance
   c. Shielding - appropriateness of aprons and portable shields
10. Who to call to report dislodged sources or applicators or for other emergencies
11. Radiation Safety Committee and RSO

ATTACHMENT 6

DETAILS OF THE TEATMENT ROOM

The HDR unit will be stored and used in a room shared by a Varian 4 MV linear accelerator. Diagrams of the room are given below and on the following page.

Side View of the Room



123213

4.4 g/cc = 280 LB/FT^3

2.4 g/cc = 150 LB/FT^3

123213

ATTACHMENT 7

EXPECTED MAXIMUM DOSE RATES OUTSIDE THE TREATMENT ROOM

Expected dose rates outside the treatment room are calculated using the following data:

exposure rate constant:	4.60 R-cm^2/mCi-hr
f_{med}:	0.974 rem/R
dose rate:	74.7 rem-cm^2/Ci-min
average Ci-min per treatment:	40
average number of treatments per week:	10
number of treatments in any one hour:	2

The expected maximum dose rate in any one hour is calculated from:

$$74.7 \text{ rem-cm}^2/\text{Ci-min} \times 40 \text{ Ci-min/treatment} \times 2 \text{ treatments/hr} \times d^{-2} \times B$$

where d is the source-to-point distance and B is the transmission through the barrier as given in Figure 12 of NCRP Report No. 49.

Location	d(cm)	Barrier Thickness Actual	Barrier Thickness Equivalent*	B	Max dose in any one hour (mrem)
A	163	1' 4"	28.8" (73.2cm)	1.4×10^{-5}	0.0032
B	287	1' 5"	24.2" (61.5cm)	9.0×10^{-5}	0.0065
C	518	1' 8"	29.6" (75.2cm)	1.1×10^{-5}	0.0002
D	538	1'	21.6" (54.9cm)	2.3×10^{-4}	0.0047
E	259	1' 6"	32.4" (82.3cm)	4.0×10^{-6}	0.0004
F	487	2' 8"	32" (81.3cm)	4.0×10^{-6}	0.0001
G	518	2' 3"	27" (68.6cm)	2.5×10^{-5}	0.0006

*Equivalent thickness of density 2.4 g/cc.

ATTACHMENT 7

The expected maximum annual dose at a point is calculated from:

$74.7\ \text{rem-cm}^2/\text{Ci-min} \times 40\ \text{Ci-min/treatment} \times 10\ \text{treatments/wk} \times 52\ \text{wk/yr} \times d^{-2} \times B \times T$

where d and B are defined and have the same values as above, and T is the occupancy factor which is taken as 1 for all locations.

Location	Max annual dose (mrem)
A	0.82
B	1.69
C	0.06
D	1.24
E	0.09
F	0.03
G	0.15

ATTACHMENT 8

OPERATING PROCEDURES

1. Each day, prior to the first patient treatment, the daily quality control procedure is to be completed as detailed on the form "Daily Quality Control for the Nucletron HDR Afterloader."

2. At the conclusion of treatments for the day, or between treatments if the console is unattended, keys to the console are to be returned to the designated drawer.

3. At the end of the working day, the room housing the afterloader is to be locked and the keys brought to the Security Department along with the other department keys.

4. Before initiating treatments, check that only the patient is in the room.

5. Before inserting the patient's treatment card into the unit, check that the name and ID number on the card are those of the person in the room.

6. All treatment plans and dose calculations are to be approved by a medical physicist.

7. Prior to initiating treatment, the treatment parameters (dwell positions, dwell times, channels) indicated on the control console screen are to be compared to those from the treatment planning system. This comparison is to be made by an authorized user or a medical physicist. Approval will be indicated by initialing the patient's chart in the appropriate place.

8. At the end of the treatment determine that the source is fully retracted into its safe by scanning the room and patient with a survey meter. Record the results of the survey on the log sheet.

9. If the survey meter indicates that there is an exposed source, begin to execute the Emergency Procedures.

10. Because it is conceivable that the source can dislodge from the cable and remain in the catheter within the patient, it is our policy not to perform treatments utilizing applicator placements which are tedious to remove.

11. An authorized user and either a medical physicist or the RSO will be physically present at all patient treatments.

ATTACHMENT 9

EMERGENCY PROCEDURES
FOR
microSELECTRON - HDR

IF THE SOURCE FAILS TO RETURN TO THE SAFE

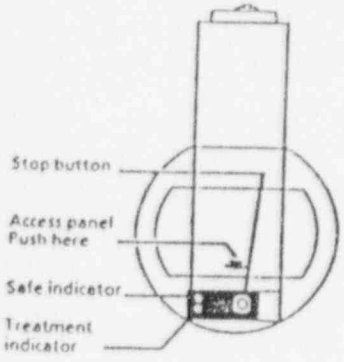
If the room radiation monitor or control console indicates that the source is exposed when it should be fully retracted in its safe:

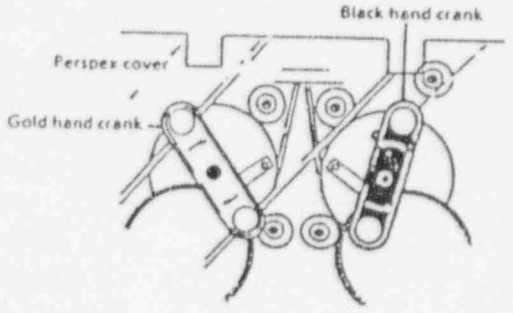
1. Depress **RED EMERGENCY STOP BUTTON** on master emergency stop switch. If the source retracts, go to step 3, otherwise step 2.

2. Enter the treatment room with a survey meter.

   - **PUSH** down on the access panel on top of the treatment unit to access the **GOLD** hand crank. Turn it in the direction of the arrows until it locks.

   - If the source retracts as indicated by the survey meter, go to step 3, otherwise follow emergency procedures for the particular applicators.





3. Retain the treatment data printout and contact the following:

Physicist: Jerome A. Meli, Ph.D.	Telephone:	Pager:
Physician: Ralph W. Romano, M. D.	Telephone:	Pager:
Or Barbi L. Kaplan-Frenkel, D. O.,	Telephone:	Pager:
Nucletron Representative	Telephone:	Pager:

4. The unintended radiation dose to which those present have been subjected should be estimated and recorded by a suitably qualified person.

ATTACHMENT 9

EMERGENCY PROCEDURES
FOR
ENDOBRONCHIAL - ESOPHAGEAL APPLICATORS

1. From the printout, ascertain the channel number being treated when the Error Code was generated using the print out.

2. Enter the room with a hand held survey meter at its highest setting (>1000mR/hr) and confirm that there is radiation in or near the patient.

3. Rapidly and smoothly remove the applicator from the patient maintaining its connection to the afterloading device.

4. A shielded emergency container should be available for insertion of the removed applicator.

5. After the applicator has been removed, survey the patient with the survey meter to confirm that the source has indeed been removed from the patient.

6. If the source is <u>not</u> in the patient
   a. Remove the patient from the room.
   b. Close and lock the door. Mark it NO ENTRY.
   c. Contact the individuals listed on the preceding page.

7. If the source is still <u>within</u> the patient and there are no other applicators to remove,
   a. Contact the individuals listed on the previous page.
   b. Keep the patient under continuous observation.

ATTACHMENT 9

EMERGENCY PROCEDURES
FOR
INTRACAVITARY APPLICATORS

1. From the printout, ascertain the channel number being treated when the Error Code was generated using the print out.

2. Enter the room with a hand held survey meter at its highest setting (>1000/mR/hr) and confirm that there is radiation in or near the patient.

3. Rapidly disassemble the applicator and remove any packing material. The applicator components should be removed in the reverse order of insertion.

4. Rapidly and smoothly remove the applicator from the patient, maintaining its connection to the afterloading device.

5. A shielded emergency container should be available for insertion of the removed applicator.

6. After the applicator has been removed, survey the patient with the survey meter to confirm that the source has indeed been removed from the patient.

7. If the source is <u>not</u> in the patient
   a. Remove the patient from the room.
   b. Close and lock the door. Mark it NO ENTRY.
   c. Contact the individuals listed on the first page of the Emergency Procedures.

8. If the source is still <u>within</u> the patient and there are no other applicators to remove,
   a. Contact the individuals listed on the first page of the Emergency Procedures.
   b. Keep the patient under continuous observation and communication.

ATTACHMENT 9

EMERGENCY PROCEDURES
FOR
INTERSTITIAL IMPLANTS - FLEXIBLE

1. From the printout, ascertain the channel number being treated when the Error Code was generated using the print out.

2. Enter the room with a hand held survey meter at its highest setting (>1000mR/hr) and confirm that there is radiation in or near the patient.

3. Using a suture removal kit, sever any sutures that are retaining the implant tube to the patient. If the distal end of the implant tube is protruding from the patient's skin and secured with a button, remove the button from the tube without severing the tube.

4. Have available sterile drapings to cover the wound left by the applicator removal.

5. A shielded emergency container should be available for insertion of the removed applicator.

6. After the applicator has been removed, survey the patient with the survey meter to confirm that the source has indeed been removed from the patient.

7. If the source is <u>not</u> in the patient
   a. Remove the patient from the room.
   b. Close and lock the door. Mark it NO ENTRY.
   c. Contact the individuals listed on the first page of the Emergency Procedure.

8. If the source is still <u>within</u> the patient and there are no other applicators to removed
   a. Contact the individuals listed on the first page of the Emergency Procedures.
   b. Keep the patient under continuous observation and communication.

ATTACHMENT 9

EMERGENCY PROCEDURES
FOR
INTERSTITIAL IMPLANTS - RIGID

1. From the printout, ascertain the channel number being treated when the Error Code was generated using the print out.

2. Enter the room with a hand held survey meter at its highest setting (>1000mR/hr) and confirm that there is radiation in or near the patient.

3. Using the appropriate tool, loosen the needle clamp on the affected needle and withdraw it from the template or fixing mechanism.

4. A shielded emergency container should be available for insertion of the removed applicator.

5. After the applicator has been removed, survey the patient with the survey meter to confirm that the source has indeed been removed from the patient.

6. If the source is <u>not</u> in the patient
   a. Remove the patient from the room.
   b. Close and lock the door. Mark it NO ENTRY.
   c. Contact the individuals listed on the first page of the Emergency Procedure.

7. If the source is still <u>within</u> the patient and there are no other applicators to remove,
   a. Contact the individuals listed on the first page of the Emergency Procedure.
   b. Keep the patient under continuous observation and communication.

DIVISION OF ACCOUNTING AND FINANCE
REQUEST FOR REFUND TO EMPLOYEE/VENDOR

JUL 3 1996

THE EMPLOYEE/VENDOR IDENTIFIED BELOW HAS OVERPAID THE NUCLEAR REGULATORY COMMISSION FOR GOODS AND/OR SERVICES PROVIDED AND IS DUE A REFUND

EMPLOYEE/VENDOR/PAYEE CODE: _____

NAME: ST. VINCENT'S MEDICAL CENTER

ADDRESS: ATTN: WILLIAM J. RIORDAN, PRESIDENT/CHIEF EXECUTIVE OFFICER

ADDRESS: 2800 MAIN STREET

CITY: BRIDGEPORT STATE: CT ZIP: 06606

TRANS CODE: PX

TRANS TYPE: FE FUND: X5280 JOB CODE: _____ AMOUNT: $40.00

TRANS TYPE: IR FUND: R1435 JOB CODE: INTR AMOUNT: _____

TRANS TYPE: IR FUND: R1099 JOB CODE: ADCH AMOUNT: _____

TRANS TYPE: IR FUND: R1099 JOB CODE: FINE AMOUNT: _____

TOTAL REFUND AMOUNT: $40.00

COMMENTS: Lic 06-00843-03/CK 054891/TC AMD - OVRPYT

(limit comments to 40 characters, including spaces)

PREPARED BY: Brenda Brown DATE: 6/25/96

AUTHORIZED BY: Sandra Kimberly DATE: 7/3/96

ORIGINAL INV. NO: _____ DATE PAID: _____ AMOUNT: _____

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION

I (96)
June 12
LTR DTD 5/6/96
TC AMD FEE IS $430
(123213)

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 0
FEE CATEGORY: 7C 2B
EXP. DATE: 20030430
FEE COMMENTS: CODE 21
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: ST. VINCENT'S MEDICAL CENTER
RECEIVED DATE: 960513
DOCKET NO: 3001245
CONTROL NO.: 123213
LICENSE NO.: 06-00843-03
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: $470.00
CHECK NO.: 0054

3. COMMENTS

SIGNED M. A. Leahy
DATE 5/23/96

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

1. FEE CATEGORY AND AMOUNT: 7C 2B $430

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

3. OTHER

SIGNED S Brown
DATE 6/3/96

Log I (59) June 12
Remitter
Check No. 054891
Amount $470 Refunded $40
Fee Category (7C) 2B
Type of Fee Amd
Date Check Rec'd 6/3/96
Date Completed
By EBrown

1996 MAY 28 AM 10:49