NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 63

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.

302228

Licensee	
1. Saint Mary's Health Services	In accordance with the letter dated January 17, 1997 3. License Number 21-01078-01 is amended in its entirety as follows:
2. 200 Jefferson, S.E. Grand Rapids, MI 49503	4. Expiration Date May 31, 2005
	5. Docket or Reference No. 030-08291

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 (excluding xenon-133)	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 (not to exceed 1 curie of iodine-131)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy sources identified in 10 CFR 35.400	D. As needed
E. Any byproduct material identified in 10 CFR 35.500	E. Sealed sources identified in 10 CFR 35.500	E. As needed
F. Iridium-192	F. Sealed sources (BYK Mallinckrodt Model CI L BV)	F. 2 sources not to exceed 12 curies each

260019

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-01078-01

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Amendment No. 63

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (excluding xenon-133).

C. Medical use described in 10 CFR 35.300.

D. Medical use described in 10 CFR 35.400.

E. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.

F. One source to be used in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial, intracavitary, and bronchial radiotherapy, in accordance with Condition 13. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

CONDITIONS

10. Location of use: 200 Jefferson, S.E., Grand Rapids, Michigan.

11. Radiation Safety Officer: Dale J. Schippers, M.S.

12. 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
A. Louis B. Bixler, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 35.500.
B. Darrel J. Rosen, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 35.500.
C. Thienchai Jayasvasti, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 35.500.
D. Mark A. Malnor, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 35.500.

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12. (Continued)

Authorized Users	Material and Use
E. Charles L. Wilkinson, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 35.500.
F. Francis Verde, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 35.500.
G. M. Kie Seng Tay, M.D.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.
H. Mark D. Strauss, D.O.	10 CFR 35.100, 35.200 (excluding generators and xenon-133), 35.300 and 35.500.
I. Chad R. Williams, M.D.	10 CFR 35.100, 35.200 (excluding generators and xenon-133), 35.300 and 35.500.
J. Scott C. Berman, M.D.	10 CFR 35.100, 35.200 (excluding generators and xenon-133), 35.300 and 35.500.
K. Stephen B. Rupp, M.D.	10 CFR 35.100, 35.200 (excluding generators and xenon-133), 35.300 (excluding iodine-131 for thyroid carcinoma), and 35.500.
L. James Matthew Kane, Jr., M.D.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.
M. Ruggero Battan, M.D.	10 CFR 35.300.

13. The high dose rate brachytherapy physicist is Tewfik J. Bichay, Ph.D.

14. The licensee may possess 24 curies of iridium-192 (not to exceed 12 curies per source) for use in the Nucletron Micro Selectron-HDR remote afterloading device, provided the individual source activity does not exceed 10 curies at the time of installation, and the source is installed by the manufacturer.

15. 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, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to conform 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).

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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16. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading 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 the survey instrument used, dose rate expressed in mrem/hr (μSieverts/hr), 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).

17. The following shall be performed only by manufacturer's representatives or persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation and replacement of the sealed sources contained in the remote afterloading brachytherapy device(s).

B. Any maintenance or repair operations on the remote afterloading brachytherapy unit listed in Item 9., Subitem F, involving work on the source safe, the source drive 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.

18. Prior to initiation of a treatment program, and subsequent to each source exchange using the remote afterloading brachytherapy devices, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(1) The irradiator 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 milliroentgen per hour.

(2) All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:

(a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.101 (10 CFR 20.1201).

(b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b) (10 CFR 20.1301).

19. A. Access to the rooms housing the afterloading brachytherapy device shall be controlled by a door at each entrance.

B. The entrance to the irradiation 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 the entrance door to the irradiator 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 irradiation device 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.

20. 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) for establishing decommissioning financial assurance.

21. Notwithstanding the provisions of 10 CFR 35.70(b), the licensee is authorized to perform surveys of a waste storage area, as described in letter dated March 22, 1991, at intervals not to exceed one month.

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

23. 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 August 25, 1994 (excluding the Quality Management Program); and

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-01078-01

Docket or Reference Number
030-08291

Amendment No. 63

23. (Continued)

B. Letters dated March 22, 1991, February 2, 1995 (excluding the Quality Management Program), April 20, 1995 (excluding the Quality Management Program) and January 17, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 2/18/97

By Kevin A. Hess
Nuclear Materials Licensing Branch, Region III

S2

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02230
Status Code: 0
Fee Category: 7C 2B
Exp. Date: 20050531
Fee Comments:
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: SAINT MARY'S HEALTH SERVICES
   Received Date: 970121
   Docket No: 3008291
   Control No.: 302228
   License No.: 21-01078-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 440
   Check No.: 44383

3. COMMENTS

Signed D. Henry
Date 1/28/97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /)

1. Fee Category and Amount: 7C 2B #440

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 1/29/97

FEB 10 1997

Log Plus 10 III
Remitter
Check No. 44383
Amount $440
Fee Category 7C 2B
Type of Fee MMD
Date Check Rec'd 1/28/97
Date Completed 1/29/97
By: SC

SAINT MARY'S
HEALTH SERVICES
A member of Mercy Health Service

200 Jefferson S.E.
Grand Rapids
Michigan 49503
616 752-6090

January 17, 1997

Nuclear Regulatory Commission
Region III, Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: NRC License No. 21-01078-01

Gentlemen:

Please amend our NRC license as follows:

1. Add Ruggero Battan, M. D. as an authorized user for byproduct material identified in 10 CFR 35.300. Dr. Battan's Preceptor Statement is enclosed.
2. Add to our area of use a storage room for radioactive material located in the basement of our main hospital building. The location is specified as, "Radioactive Storage Room", on the enclosed floor plan labeled as "Saint Mary's Hospital, Hospital Building, Sub-basement floor plan". A floor plan of the first floor of the Hospital Building is also enclosed.
   The room will be labeled with a "Caution, Radioactive Material" sign and locked so that access can be controlled. Keys for this room will be available to the Radiation Safety Officer, the Nuclear Medicine technologists and ancillary personnel who may need access. We will perform area surveys and wipe tests for contamination on a weekly basis. We will also provide adequate shielding to maintain exposures to the general public to levels below the limits specified in 10 CFR 20.1301.
3. Remove from our area of use the storage room located in the McAuley Building, Tenth floor. Prior to release, all radioactive material will be removed and surveys will be conducted to demonstrate that ambient exposure rates and removable contamination are below the requirements for an unrestricted area. The results of this survey, including the survey instrument, the calibration date of the instrument, the person conducting the survey, and the survey results, will be forwarded to your office.
4. Add Tewfik J. Bichay, Ph. D. as an authorized physicist for HDR. Dr. Bichay was listed on a previous license (Hurley Medical Center, license no. 21-00338-02)

Pm: 1-17-97

as an authorized physicist for HDR. See the attached copy of the license for Hurley Medical Center.

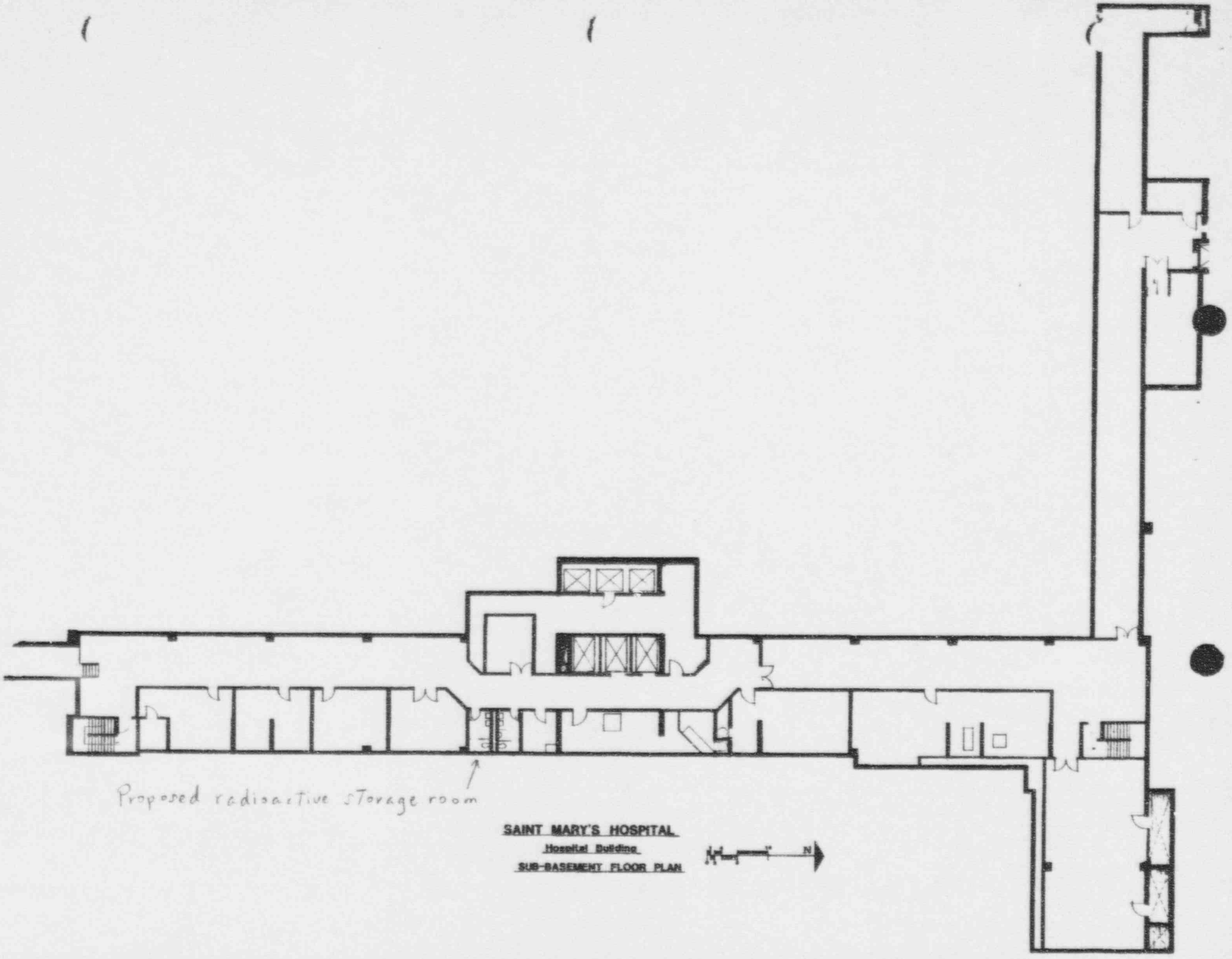
5. Add authorization to use Palladium-103 seeds as a sealed source for both interstitial and intercavitary procedures.
6. Add authorization to use Americium-241 as a sealed source for attenuation correction. The source model number is A-3402 and is manufactured by Isotope Products Laboratories, Burbank, California. We would like authorization to posses up to 300 mCi in one line source.

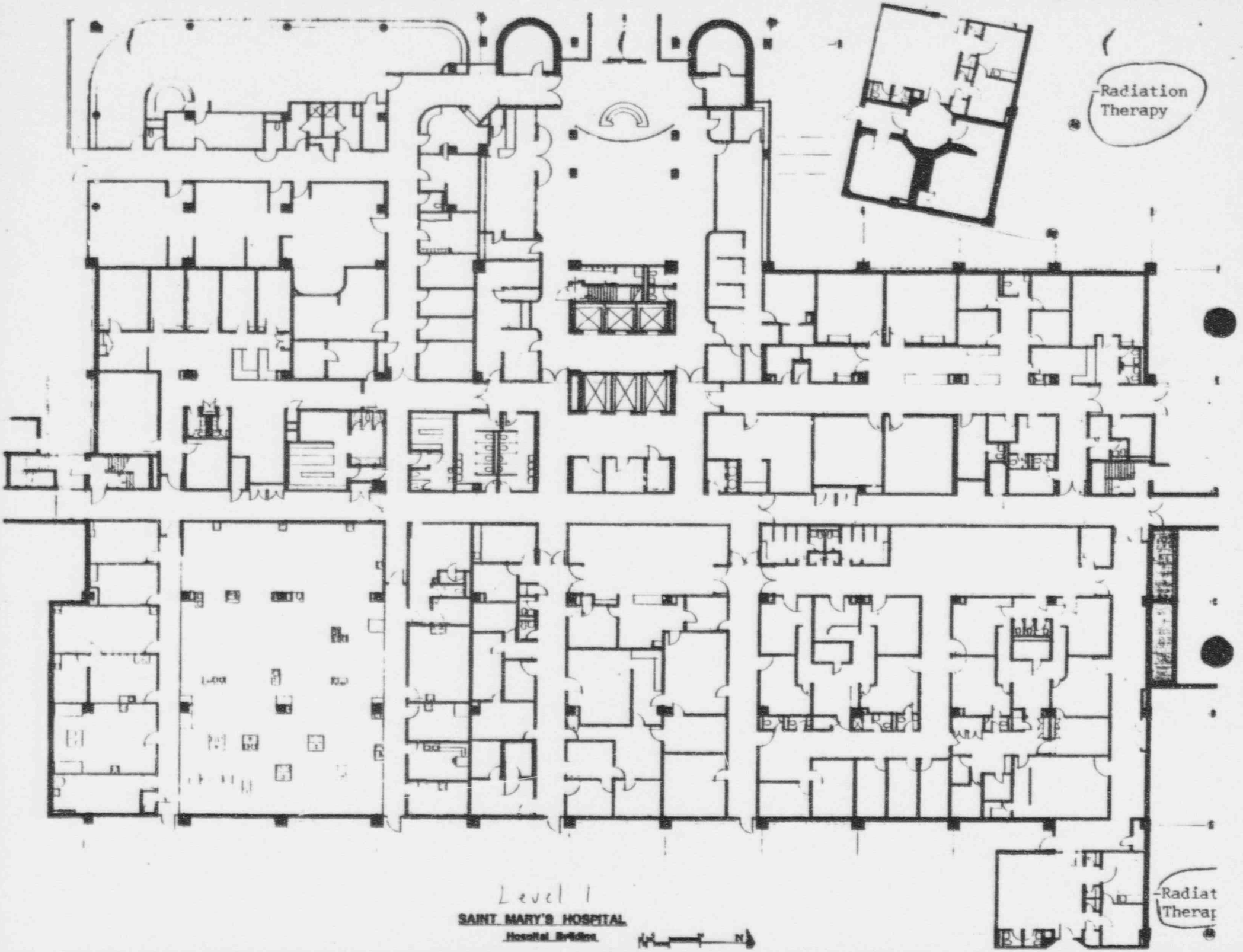
A check is enclosed, in the amount of $440.00, to cover the amendment fee. If additional clarification is required, please contact me at (616) 752-6744.

Sincerely,

Dale J. Schippers

Dale J. Schippers, MS, DABR
Radiation Safety Officer


Proposed radioactive storage room
SAINT MARY'S HOSPITAL
Hospital Building
SUB-BASEMENT FLOOR PLAN
N


Radiation Therapy
Radiat Therap
Level 1
SAINT MARY'S HOSPITAL
Hospital Division

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 21-00338-02
Docket or Reference number: 030-01993
Amendment No. 104

CONDITIONS

10. Location of Use: Hurley Medical Center, One Hurley Plaza, Flint, Michigan.

11. Radiation Safety Officers: A. V. Jayabalan, M.D., for materials as listed in 10 CFR 35.100, 35.200, 35.300, 35.500, 31.11.

B. Tewfik J. Bichay, MSC., Ph.D., for materials as listed in 10 CFR 35.400 and Iridium-192 in remote afterloading brachytherapy unit.

12. Authorized Users:

A. C. Follis, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500 and 31.11.

B. V. Jayabalan, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500 and 31.11.

C. Appa Rao Mukkamala, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 31.11, and Iridium-192 in remote afterloading brachytherapy unit.

D. M. Rao Tummala, M.D., for material in 10 CFR 35.100, 35.200, and Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction.

E. Willys F. Mueller, M.D., for material in 10 CFR 31.11 and Iodine-125 for in-vitro research.

F. Harland L. Verrill, M.D., for material in 10 CFR 31.11, Hydrogen-3, Carbon-14, Phosphorus-32 and Iodine-125 for in-vitro research.

G. Sadda Sarala Reddy, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500 and 31.11.

H. Ahmed M. Akl, M.D., for material in 10 CFR 35.300, 35.400, and Iridium-192 in remote afterloading brachytherapy unit.

I. Mark Weiss, M.D., for material in 10 CFR 35.100 and 35.200.

J. P. B. Lauber, M.D., for material in 10 CFR 35.100, 35.200 and 35.300.

13. The high dose rate brachytherapy physicist is Tewfik J. Bichay, Ph.D. and Hui Li, Ph.D.

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
Ruggero Battan, M.D.	Massachusetts

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Internal Medicine	Diplomate	September 1990

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	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	UMass Medical Center Dept. of Nuclear Medicine Worcester, MA (7/90 - 1/93)	40	5
b. RADIATION PROTECTION	UMass Medical Center Dept. of Nuclear Medicine Worcester, MA (7/90 - 1/93)	25	5
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	UMass Medical Center Dept. of Nuclear Medicine Worcester, MA (7/90 - 1/93)	10	
d. RADIATION BIOLOGY	UMass Medical Center Dept. of Nuclear Medicine Worcester, MA (7/90 - 1/93)	20	
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I - 131	150 mCi	UMass Medical Center	7/90 - 1/93	Therapy & Diagnosis
I - 123	300 micro Ci	UMass Medical Center	7/90 - 1/93	Diagnosis
Tc - 99m	10 mCi	UMass Medical Center	7/90 - 1/93	Diagnosis

NRC FORM 313M SUPPLEMENT B
(9-81)

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. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Ruggero Battan, M.D.

STREET ADDRESS

38 Elm Street Apt. 4

CITY	STATE	ZIP CODE
Worcester	MA	01655

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
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	20	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER	I-123 Thyroid Imaging	500	
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	20	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING	10	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER	I-131 Adrenal Imaging	2	

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	5	
	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			

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

Between 7/90 and 1/93 250 hours of Clinical Radioisotope Training

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

a. NAME OF SUPERVISOR
Lewis E. Braverman, M.D.

b. NAME OF INSTITUTION
UMass Medical Center

c. MAILING ADDRESS
55 Lake Ave North

d. CITY
Worcester

5. MATERIALS LICENSE NUMBER(S)
20-13758-01

6. PRECEPTOR'S SIGNATURE
Lewis Braverman

7. PRECEPTOR'S NAME (Please type or print)
Lewis E. Braverman, M.D.
Professor and Chairman
Dept. of Nuclear Medicine

8. DATE
1/14/93

NRC FORM 313M SUPPLEMENT B
(9-81)

FEB 19 1997

Dale J. Schippers, M.S.
Radiation Safety Officer
Saint Mary's Health Services
200 Jefferson S.E.
Grand Rapids, MI 49503

Dear Mr. Schippers:

This refers to your January 17, 1997 amendment request, and to our January 31, 1997 telephone conversation. Enclosed is Amendment No. 63 to your NRC Material License No. 21-01078-01 in accordance with your request. This amendment makes the following changes to your license: (1) Ruggero Battan, M.D. is added as an authorized user for 10 CFR 35.300 materials, (2) Tewfik J. Bichay, Ph.D. is added as a high dose rate brachytherapy physicist, (3) the use of palladium-103 for intracavitary procedures is authorized, and (4) the "Radioactive Storage Room" is added as an area of use.

As we discussed on January 31, 1997, we cannot authorize the use of americium-241 as a sealed source for attenuation correction until we have received and reviewed information regarding the source holder. In addition, we cannot authorize you to release your old storage room for unrestricted use until we have received and reviewed a copy of the results of your close-out survey.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

3022228

b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;

   b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;

   c. Change Radiation Safety Officers;

   d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   f. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences

to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Michael F. Weber
Nuclear Materials Licensing Branch

License No. 21-01078-01
Docket No. 030-08291

Enclosure: Amendment No. 63

DOCUMENT NAME: M:\03008291.CL7
To receive a copy of this document, indicate in the box: "**C**" = Copy without attachment/enclosure "**E**" = Copy with attachment/enclosure "**N**" = No copy

OFFICE	DNMS/RIII	E							
NAME	MFWeber:brt								
DATE	02/14/97								

OFFICIAL RECORD COPY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
630-829-9887 (phone), 630-515-1259 (fax)

CONVERSATION RECORD

TIME	DATE
8:00 am	1/31/97

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO
Joe Bakanauskas, RSO	UMass Medical Center	508-856-0011

SUBJECT

Amendment request for St. Mary's Health Services (Control No. 302228)

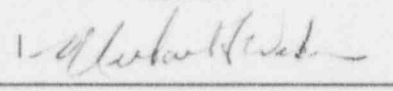
SUMMARY

Q: Is Dr. Lewis Braverman an Authorized User for 35.300 uses and materials?

A: Yes. He's the former Chair of the Nuclear Medicine Dept., and is an internationally known physician.

ACTION REQUIRED

Approve request.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Michael F. Weber		1/31/97

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
630-829-9887 (phone), 630-515-1259 (fax)

1/3

CONVERSATION RECORD | TIME 8:00 am | DATE 1/31/97

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Dale Schippers, RSO	St. Mary's Health Services	616-752-6744

SUBJECT

Amendment request **(Control No. 302228)**

SUMMARY

1) Palladium-103.

Mr. Schippers indicated that the licensee wishes to use Pd-103 for interstitial AND intracavitary procedures.

2) Am-241 sealed source.

I stated that the model number of the source was changed in 1995 from "A-3402" to "301 Series." Also, the 301 Series includes a Model 301 B and a Model 301C. I asked what is the correct model number for the source in question. Mr. Schippers indicated that he would send this information.

Mr. Schippers also indicated that the source would be used for attenuation correction - similar to uses of Gd-153 in ADAC and Picker devices (transmission line source housings).

I asked for information about the source holder. Mr. Schippers replied that it was a Siemens device. He also indicated that he would send additional information. In order to approve the possession and use of this source/device combination, it must be listed in the NRC Sealed Source and Device Registry (SSDR). If the combination is not in the SSDR, it has not been authorized for distribution and cannot be authorized for use until it has been reviewed by the NRC or an Agreement State, as appropriate.

We also discussed leak test requirements, etc. After I receive the information about the source holder, I'll call back and we'll finish this part of the conversation.

3) Close-out of storage room in McAuley Bldg.

I indicated that NRC cannot authorize the release of your old storage room for unrestricted use (even by other members of your staff) until we have received and reviewed a copy of the results of your close-out survey. The survey should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored. Average radiation levels associated with surface contamination and removable contamination should not exceed those specified in the enclosed decontamination guide. Please submit the following information with your close-out survey:

A. A diagram of the storage room with survey and wipe test results keyed to specific locations.
B. The name of the person performing the survey.
C. The date the survey was performed.
D. The instruments used for exposure rate measurements and for analysis of the wipes.
E. Background readings.
F. The date the survey instruments were last calibrated.

4) We discussed issuing an amendment which grants some, but not all of the requests. Mr. Schippers agreed with this.

Please send the requested information ASAP, and refer to Control Number 302228.

(If you send anything via fax, please also send a hard copy via the mail.)

ACTION REQUIRED

Wait for response.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Michael F. Weber	M. F. Weber	1/31/97

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

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(AMENDED PAGE July 31, 1995)

NO: CA406S154S DATE: August 1, 1989 PAGE: 1 of 7

SEALED SOURCE TYPE: Line Source

MODEL: **301 Series (formerly Model A-3402)**

MANUFACTURER/DISTRIBUTOR: Isotope Products Laboratories
1800 North Keystone Street
Burbank, CA 91504
(818) 843-7000

ISOTOPE: Any radionuclide with atomic numbers 3-83 and Americium 241

MAXIMUM ACTIVITY: 300 millicuries

LEAK TEST FREQUENCY: Six (6) months

PRINCIPAL USE: Gamma Gauges (D)

CUSTOM SOURCE: _____YES __X__NO

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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

(AMENDED PAGE July 31, 1995)

NO.: CA406S154S DATE: August 1, 1989 PAGE: 2 of 7

SEALED SOURCE TYPE: Line Source

DESCRIPTION:

The Model 301B (formerly Model A-3402) is a doubly encapsulated sealed source of various lengths (1 to 33 inches) constructed of 304 or 304L stainless steel. Model 301C is a doubly encapsulated sealed source of various lengths (1 to 33 inches) constructed of AMS 4943 titanium alloy. The dimensions are 0.082 to 0.084 inches (inner capsule) and 0.119 to 0.121 inches (outer capsule). The radionuclide is in the form of an oxide or other salt as a ceramic or wire matrix. The capsules (inner and outer) are sealed by fusion (Tungsten Insert Gas or Electron Beam) welded plugs on both ends.

LABELING: Each source is engraved with the isotope symbol and a 3 digit serial number (0.500" from the end).

DIAGRAMS: **See drawing numbers 3402 (301B) and 3414 (301C) on pages 6 and 7.**

CONDITIONS OF NORMAL USE:

These sources are used in a manufacturing environment intended to be permanently mounted in a gauging device. They should not be subjected to conditions exceeding those specified by the ANSI 77C33222X rating.

PROTOTYPE TESTING:

Prototype tests have shown the Model **301B** sources passed tests required for "beta gauges and sources for low energy gamma gauges or x-ray fluorescence analysis." In addition, a "special test" was performed: "Immersion in Molten Aluminum", 800°C for 35 minutes. The classification of ANSI 77C33222X was given in accordance with NBS Handbook No. 126, ANSI N542, "Sealed Radioactive Sources, Classification", 1977. Capsule integrity was determined by the helium leak test (A.2.2.5) and all leakage rates were less than 1×10^{-4} cc/sec. **The Model 301C, which substitutes titanium for stainless steel (304 and 304L) did not require retesting, since both tensile strength and yield strength of AMS 4943 titanium are greater than that of 304 and 304L stainless steel.**

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

January 23, 1997

Dale J. Schippers
Radiation Safety Officer
Saint Mary's Health Services
200 Jefferson, S.E.
Grand Rapids, MI 49503

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 01/17/97)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

___ New License X Amendment ___ Renewal
___ Termination ___ Auth User (Amendment not required)
___ Other_____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302228
License No. 21-01078-01