NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 01

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. St. Mary's Hospital	3. License number 29-20597-01 is amended in its entirety to read as follows:
2. 135 South Center Street Orange, New Jersey 07051	4. Expiration date February 28, 1994
	5. Docket or Reference No. 030-19962

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 included in 10 CFR 35.100	A. Any radiopharmaceutical included in 10 CFR 35.100	A. As necessary for uses authorized in Subitem 9.A.
B. Any byproduct material included in 10 CFR 35.200	B. Any radiopharmaceutical included in 10 CFR 35.200 except generators	B. As necessary for uses authorized in Subitem 9.B.
C. Any byproduct material included in 10 CFR 35.300	C. Any radiopharmaceutical included in 10 CFR 35.300	C. As necessary for uses authorized in Subitem 9.C.
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As necessary for uses authorized in Subitem 9.D.

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. In vitro studies.

CONDITIONS

10. Location of use: 135 South Center Street, Orange, New Jersey.

11. Radiation Safety Officer: Wade N. Miller, M.D.

9003120062 890227
REG1 LIC30
MATERIALS LICENSING PDR

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 6
FOIA- 2005-0084

OFFICIAL RECORD COPY ML18

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-20597-01

Docket or Reference number: 030-19962

Amendment No. 01

(Continued) CONDITIONS

12. Authorized Users: Material and Use:

Wade N. Miller, M.D.	35.100; 35.200; 35.300 In vitro studies
Arnold I. Brenner, M.D.	35.100; 35.200; 35.300 In vitro studies
Mary Natrella, M.D.	35.100; 35.200; 35.300 In vitro studies

13. This license is based on the licensee's statements and representations listed below:

A. Application received April 29, 1988
B. Letter dated Octover 2, 1988
C. Letter dated January 14, 1989

For the U.S. Nuclear Regulatory Commission

Original Signed By:
By Lester M. Tripp
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

Date FEB 27 1989

FEB 27 1989

License No. 29-20597-01
Docket No. 030-19962
Control No. 108794

St. Mary's Hospital
ATTN: Wade N. Miller, M.D.
Radiation Safety Officer
135 S. Center Street
Orange, New Jersey 07050

Gentlemen:

Please find enclosed the renewal of your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5239, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Please note that your license has been written in a format compatible with the revision of 10 CFR 35, "Medical Use of Byproduct Material" (enclosed), effective April 1, 1987. Your licensed material activities must be conducted in accordance with the revised Part 35 regulations.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an 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, 10 CFR Part 2, Appendix C.

OFFICIAL RECORD COPY ML 29-20597-01/LTR - 0001.0.0
01/31/89

ML10

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

Sincerely,

Lester M. Tripp

for John E. Glenn, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosures:
1. Amendment No. 01
2. Requirements for Materials Licensees
3. Requirements for Medical Licensees
4. NRC Forms 3 and 313
5. 10 CFR Parts 2, 19, 20, 30, 35, and 170
6. Regulatory Guide 10.8
7. NRC Form 473 - Diagnostic Misadministration Report

DRSS:RI	DRSS:RI
Tripp/tlm	Glenn
~~1/ /89~~ 2/8/89	1/ /89

OFFICIAL RECORD COPY ML 29-20597-01/LTR - 0002.0.0
01/31/89

MS-16
K-8

David S. Marsden, Ph.D.

CERTIFIED RADIOLOGICAL PHYSICIST
(AMERICAN BOARD OF RADIOLOGY)
212-523-7168

[redacted]

E46

January 14, 1989

Mr. Lester Tripp
Nuclear Materials Safety Section A
Division of Radiation Safety and Safeguards
Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pa. 19406

Dear Mr. Tripp:

As per our recent conversation, St Marys Hospital's radioactive materials license renewal is to include the following :

1. Area Survey trigger levels will be .5mR/hr in unrestricted areas and 5 mR/hr in restricted areas.

2. Wipe Test trigger levels will as in Appendix N table N-1 of regulatory guide 10.8.

3 A Victoreen Survey meter with a range from .01 mR/hr to 1 R/hr will be purchased (see attached).

Sincerely,

David S. Marsden

David S. Marsden Ph.D.
Diplomate,
American College of Radiology

cc Mr. F Wishner

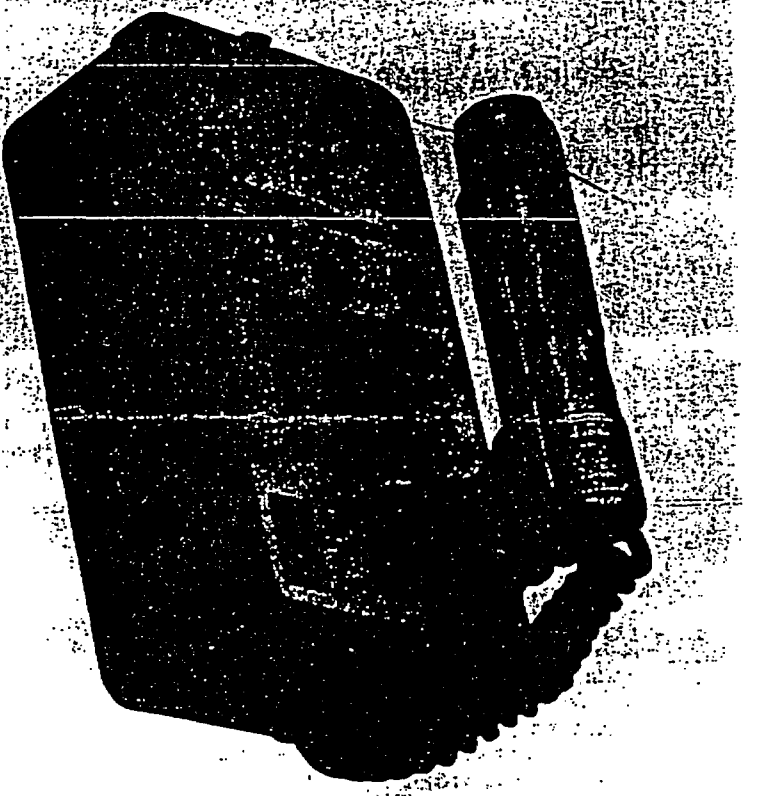
108794

OFFICIAL RECORD COPY ML10

JAN 19 1989

Multi-Purpose GM Survey Meter

- **Measures exposure and count rates from 0.01 mR/hr to 1 R/hr or up to 10^6 cpm.**
- **Measures dose to 1 R or 10^6 counts.**
- **Accepts two types of probes.**
- **Meets NRC and Agreement State regulations.**



This survey meter was designed for a wide variety of monitoring applications. In addition to performing rate measurements in hot areas, labs and storage rooms, it is also used to detect surface contamination in areas where radionuclides are handled.

All important instrument functions are selected via four front-panel switches: Range Selector; Dose or Dose Rate; Counts or mR; Speaker On/Off. The instrument remembers the dose, even when the dose rate mode is being used. In the "Dose" position, the accumulated dose from the time of the previous dose reset is shown in either counts or mR. The data is not lost if the range selector switch is on the wrong range. The dose reset and battery check functions are also on the range selector switch.

By being able to integrate either counts or mR, the user has many operating modes to choose from. Wipes become easier to count because the time constant can be made as long as necessary to reach the required accuracy.

When the speaker is on, the audible beep rate is proportional to the scale position for the selected range. When off, the speaker will sound only when the reading is at full scale for the range selected. An internal switch tells the instrument which probe is being used, thus allowing the proper mR or mR/hr value to be displayed.

Specifications

Radiation Detected: Alpha, beta, gamma or x-ray, depending on the detector probe used.

Operating Range: Count or count rate ranges are 0-100, 1000, 10,000, 100,000 and 1,000,000 counts or cpm. Dose or dose rate ranges are 0-0.1, 1, 10, 100, and 1000 mR or mR/hr.

Accuracy: Within 10% of full scale, exclusive of energy response.

Detectors: Model 05-744 Beta-Gamma GM Probe, or Model 05-731 Large-End-Window Pancake GM Probe.

Warm-Up Time: Negligible.

Response Time: 10 to 90%.

Count Rate Mode:	*CPM Range*	*Response (Sec)*
	100	13.6
	1000	6.8
	10,000	3.4
	100,000	1.7
	1,000,000	0.17

Dose Rate Mode: Response time depends on probe sensitivity but is similar to above response times for similar count rate values.

Environmental Effects: Temperature range −20° to +50°C.

Humidity Range: 0 to 95% relative humidity; non-condensing.

Temperature Dependence: <5% of full scale change from reading at 20°C over operating temperature range.

Power: Six alkaline C cells. Battery life over 150 continuous hours.

Controls: *Range Selector Switch* with 8 positions: X1000, X100, X10, X1, X0.1, Battery Check, Dose Reset, and *Off*.

MR or Counts Switch: Selects units of analog meter display.

Rate/Dose Switch: Selects dose rate/count rate mode versus dose/count mode.

Audio On-Off Switch: Selects audible indication of rate.

Calibration Potentiometer: Sets count-rate-to-dose-rate conversion for each probe.

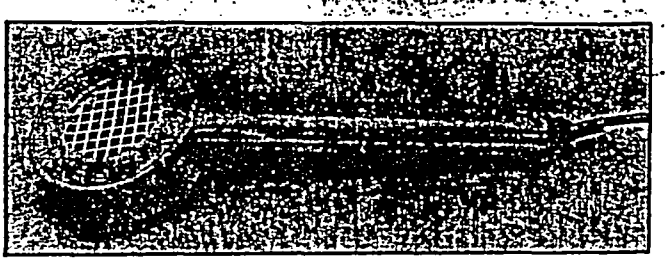
Connector: External MHV connector for detector probe.

Readout: Meter 3½" taut-band with scale markings of 0-1000 cpm and 0-1 mR/hr.

Construction: Tough, all-metal, splash-proof case.

Size: 8.9" long x 4½" wide x 6.4" high. Net 3¼ lbs.

05-753	Multi-Purpose GM Survey Meter, without probe or detector	$545.00
05-744	Beta-Gamma Probe with detector	137.00
05-731	Large-End-Window Pancake Probe with detector	185.00



Large-End-Window Pancake Probe

108794

NRC FORM 218 (4-76) NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

DATE 1/9/88

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME 3:45 ☐ A.M. ☒ P.M.

☒ INCOMING CALL ☐ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION
David S. Marsden, Ph.D.	St. Mary's Hospital	Consultant's number 212-523-7168

PERSON CALLED	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION
T.M. Tripp	RI	5071

CONVERSATION

SUBJECT: Telephone Deficiency, License Renewal, St. Mary's Hospital

SUMMARY

Dr. Marsden to provide the following additional information for license renewal

1) information on survey measurement instrumentation
2) Survey trigger levels

REFERRED TO:

ACTION REQUESTED

☐ ADVISE ME OF ACTION TAKEN.

INITIALS

DATE

ACTION TAKEN

INITIALS

DATE

OFFICIAL RECORD COPY ML18

NRC FORM 218 (4-76)

105774

29-20597-01

M9-16
K-8

David S. Marsden, Ph.D.

CERTIFIED RADIOLOGICAL PHYSICIST
(AMERICAN BOARD OF RADIOLOGY)
212-~~554-6415~~
523 7168

[redacted]
EKG

October 2, 1988

John E. Glenn, Ph.D. ,Chief
Nuclear Materials Safety Section A
Division of Radiation Safety and Safeguards
Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pa. 19406

Dear John :

As per our recent conversation concerning the attached letter, I will address each item:

1 a. We will not be using Tc-99m generators, only pre-calibrated Tc-99m.

b. radiopharmaceuticals will be stored behind 4" lead blocks. (refrigerated and nonrefrigerated)

c. radioactive waste will be stored in the hot laboratory. This is a secured area of ample size for storage.

d. kit radiopharmaceuticals will be prepared behind a shielded L block utilizing shielded vials and syringes at all times.

e. a department diagram was submitted with the renewal application. Adjacent to the use and storage area are elevators, bathroom , EKG office and 2nd floor exterior area. All of this areas have exposure levels less than .1 mR/hr.

f. No fume hood will be needed, because multi-dose volatiles and gases will not be used. Liquid iodine will not be used. The infrequent iodine therapy doses will be in capsule form.

2. Sealed sources will be stored behind four walls of 4" lead, with a floor of 2" lead. This is at least 6 ft from any unrestricted area. The exposure in these areas are (.1 mR/hr.

3. The survey meter is a Victoreen 498 survey meter with a range of .1 to over 100 mR/hr.

4 a. Back-up instruments are available during off-site calibration.

b. Procedure includes verifacation of survey meter accuracy.

OFFICIAL RECORD COPY ML 10

108794
OCT 8. 1988

with check source before each use of meter. Expected check source reading is part of calibration report.

5. We will comply with 10 CFR 35.51. Our trigger levels will be two times background.

6. Xenon-133 will be used in rooms that have a negative pressure.

7. Ventilation rates will be measured every six months.

Sincerely

Dave.

David S. Marsden Ph.D.
Diplomate,
American College of Radiology

SEP 03 1988

License No. 29-20597-01
Docket No. 030-19962
Control No. 108794

St. Mary's Hospital
ATTN: Wade N. Miller, M.D.
Radiation Safety Officer
135 S. Center Street
Orange, New Jersey 07050

Gentlemen:

This is in reference to your application dated April 10, 1988, to renew License No. 29-20597-01. In order to continue our review, we need the following additional information:

1. On a detailed version of your facility diagram, please indicate the type, dimensions, position and thickness of shielding that you will use for:

   a. Use and storage of Tc-99m generators.

   b. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).

   c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. (This area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste. If this area is located ancillary to your department, describe how you will secure the material. Confirm that this area will be surveyed at least weekly.)

   d. Preparation and dispensing of 10 CFR 35.200 kit radiopharmaceuticals (e.g., lead glass L-block, etc.).

   e. Identify adjacent areas across the walls from use and storage locations and show that adequate steps have been taken to assure that radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.103 (enclosed).

   f. Confirm that a fume hood will be available for the storage of multi-dose volatiles and gases.

OFFICIAL RECORD COPY ML 469A TRIPP - 0001.0.0
08/29/88

IL10

2. Describe the areas where sealed sources will be stored, including (a) placement and thickness of shielding, and (b) proximity of the storage area to unrestricted areas.

3. A licensee authorized to use byproduct material specified in 10 CFR 35.100 is required by 10 CFR 35.120 to have a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour. Further, a licensee authorized to use byproduct material specified in 10 CFR 35.200 and 10 CFR 35.300 is required by 10 CFR 35.220 and 10 CFR 35.320 to have a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour. Please provide the manufacturers and model numbers of the instruments you will use to meet the requirements for measurement and detection survey instrumentation.

4. With regard to the calibration of survey instruments, please provide the following:

   a. Confirm that back-up instruments will be available to replace instruments off-site for calibration;

   b. 10 CFR 35.51 requires, that at the time of survey meter calibration, the apparent exposure rate from a built-in or owner-supplied check source be determined and recorded and that each survey instrument be checked with the dedicated check source each day of use. Please confirm that your procedures will include these requirements.

5. 10 CFR 35.70(h) details what the records for area surveys must include and what units must be used for detected dose rate and removable contamination levels. Please confirm that your records of surveys will include these requirements. Please specify your trigger or action levels for removable contamination and radiation levels.

6. Please confirm that xenon-133 gas will be administered in rooms that are at negative pressure compared to surrounding rooms.

7. Confirm that the ventilation rates (air supply and air exhaust) will be measured each six months in areas of xenon-133 or aerosol use and that collection systems will be checked monthly.

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. 108794.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original Signed By.
John E. Glenn, Ph.D.

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosures:
1. 10 CFR Part 35
2. Regulatory Guide 10.8

RI:DRSS
Tripp/mjh
8/31/88

RI:DRSS
Glenn
8/ /88

OFFICIAL RECORD COPY

ML 469A TRIPP - 0003.0.0
08/29/88

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

12 MAY 1988

St. Mary's Hospital
ATTN: Dr. Wade N. Miller
Radiation Safety Officer
135 S. Center Street
Orange, New Jersey 07050

Docket No. 030-19962

License No. 29-20597-01

Control No. 108794

SUBJECT: LICENSE RENEWAL APPLICATION

Gentlemen:

This is to acknowledge receipt of your application for renewal of the 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,

Original Signed By:
Doris J. Foster

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and
Safeguards

ML10

"OFFICIAL RECORD COPY"

April 10, 1988

030- 19962

U.S. Nuclear Regulatory Commision, Region I
Nuclear Materials Safety Section B
631 Park Avenue
King Of Prussia, PA 19406

Dear Sir or Madam :

The following letter is a renewal application for radioactive materials license 29-20597-01.

We have attached a copy of our current license, which we would duplicated in its entirety. This covers items 5 and 6.

Item 7. Dr Wade Miller will remain as the Radiation Safety Officer . A curriculum vitae is attached.

Item 8. We will follow the model procedure in Appendix A to the regulatory guide 10.8
The workers who will participate in this annual training program will be housekeeping, security, clerical, nursing and nuclear medicine technologists.

Item 9.1 Facilities Drawing Attached.
9.2 Survey Instrumentation Calibration Attached
9.3 Dose Calibrator Calibration Attached
9.4 We will follow the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8 Revision 2.
9.5 N/A
9.6 Attached is a list of equipement and facilities for the use and storage of radioisotopes.

Item 10.1 We will follow the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority as published in Appendix F to Regulatory Guide 10.8 Revision 2.
The members of the committee is attached.

10.2 We will establish and implement the model ALARA program as published in Appendix G Regulatory Guide 10.8 Revision 2. (commitment attached)

License Fee Information on application.

RECEIVED-REGION 1
1988 APR 29 PM 3 09

"OFFICIAL RECORD COPY" ML10. 108734

10.3 We will establish and implement the model procedure for leak-testing sealed sources as published in Appendix H to Regulatory Guide 10.8 Revision 2.

10.4 We will establish and implement the model safety safety rules published in Appendix I to Regulatory Guide 10.8 Revision 2.

10.5 We will establish and implement the model spill procedures in Appendix J to Regulatory Guide 10.8 Revision 2.

10.6 We will establish and implement the model guidance for ordering ane receiving radioactive materials as published in Appendix K to Regulatory Guide 10.8 Revision 2.

10.7 We will establish and implement the model procedure for opening packages as published in Appendix L to Regulatory Guide 10.8 Revision 2.

10.8 We will establish and implement the model procedure for a unit dosage record system as published in Appendix M.1 to Regulatory Guide 10.8 Revision 2.

10.9 We will establish and implement the model procedure for multidose vial record system as published in Appendix M.2 to Regulatory Guide 10.8 Revision 2.

10.10 and 10.11 Do not apply to our license.

10.12 We will establish and implement the model procedure for area surveys as published in Appendix N to Regulatory Guide 10.8, Revision 2.

10.13 We will collect spent noble gas in a shielded trap and will establish and implement the model procedure for checking trap effluent as published in Appendix O.3 to Regulatory Guide 10.8, Revision 2.

10.14 We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy as published in Appendix P to Regulatory Guide 10.8, Revision 2.

10.15 Item does not apply to this license.

Item 11.1 We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2.

NRC FORM 313
(7-87)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 6-30-90

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 FUEL CYCLE AND MATERIAL 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
631 PARK AVENUE
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 29-20597-01

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

ST. MARY'S HOSPITAL
135 So. CENTER ST.
ORANGE, NEW JERSEY

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

ST MARY'S HOSPITAL
135 SO. CENTER ST
ORANGE, N.J. 07050
NUCLEAR MEDICINE DEPARTMENT

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

DR. LEON N MILLER — 266-3059

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.

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. — See attached

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. — See attached

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE. — See attached

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. — See attached

9. FACILITIES AND EQUIPMENT. — See attached

10. RADIATION SAFETY PROGRAM. — See attached

11. WASTE MANAGEMENT. — See attached

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 7-C — AMOUNT ENCLOSED $ $580.00

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
	Robert D. Donovan	President/CEO	

1988 APR 29 PM 3:09

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
REN	May 6	7C	"OFFICIAL RECORD COPY"	S. Kimberly
AMOUNT RECEIVED	CHECK NUMBER			DATE
$580	86610749		ML10 108794	5/9/88

ITEM 10.1

RADIATION SAFETY COM.. ROSTER OF STAFF AND ROLL CAL

Page

1988 Doctor	Service	Attendance at Meetings														
		Dates 2/2	6/7	12/6												
Wade Miller, M.D.*		X														
Thomas Borok, M.D.																
Richard D'Amico, M.D.		X														
Shashikant Patel, M.D.																
Mary Natrella, M.D.		X														
Michael Dolan, M.D.																
Robert Chmiel																
Joanne Weber																
Bertha Peters-Stokes (Administrative Liaison)																

NF Form 374

Part 5 + 6

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 1, Parts 30, 31, 32, 33, 34, 35, 36, 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); and to import such byproduct and source material. 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. Mary's Hospital	3. License number	29-20597-01
2. 135 Center Street Orange, New Jersey 07051	4. Expiration date	May 31, 1988
	5. Docket or Reference No.	030-19962

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, except generators, listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. As necessary for uses authorized in Subitem 9.B.
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C.
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D.
E. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	E. Any	E. 3 millicuries of each byproduct material authorized in Subitem 6.E.

(Continued)

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
F. Xenon 133	F. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	F. 300 millicuries

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.
C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
E. In vitro studies.
F. Blood flow and pulmonary function studies.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities, 135 Center Street, Orange, New Jersey.

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 listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Wade N. Miller, M.D. ALL

(12. continued)	CONDITIONS
Arnold I. Brenner, D.O.	Groups I, II, and III In vitro studies Xenon 133 Iodine 131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases

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. Patients containing Iodine 131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or less.

15. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

    (a) Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee, and

    (b) Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

    (c) Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

    The licensee shall maintain for the inspection by the Commission copies of the written permission specified in subitem (a) above and of the license(s) specified in subitems (b) and (c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under subitem (a) above.

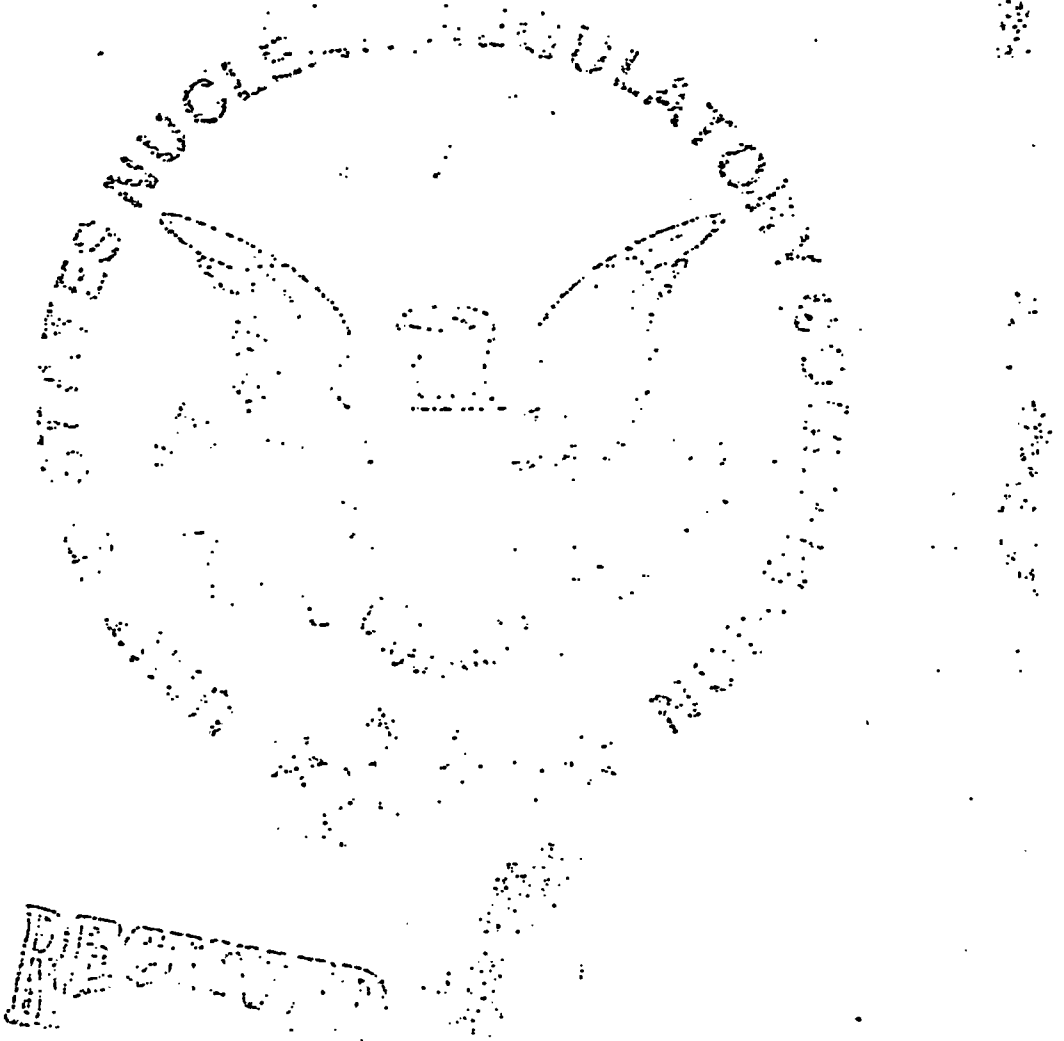
16. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

    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 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.

(continued) CONDITIONS

17. 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 March 28, 1983; letters dated May 3, 1983, and May 4, 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.



RECEIVED
DEC 01 1983
BUREAU OF RADIATION
STATE OF
DEPARTMENT OF ENVIRONMENTAL

Date MAY 18 1983

For the U.S. Nuclear Regulatory Commission

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

ITEM 7:

Dr. Wade Miller will remain as Radiation Safety Officer.

Dr. Arnold Brenner and Dr. Mary Natrella should also be included on our license.

The curriculum vitae of all of the above named doctors is attached.

WADE N. MILLER, M.D.--CURRICULAR VITAE

EDUCATION:

1943 Harvard College, Cambridge, Massachusetts
1946 Harvard Medical School, Boston, Massachusetts

POST GRADUATE TRAINING:

Medical Internship-Peter Bent Brigham Hospital, Boston, Massachusetts, 4/1/46 to 7/1/47

Fellowship in Biochemistry-Brookhaven National Laboratory, Atomic Energy Commission 8/15/49 to 8/1/50

Residency in Medicine-Memorial Center for Cancer and Allied Disease, New York City 8/1/50 to 7/1/51

PRACTICE OF INTERNAL MEDICINE:

Private Practice-East Orange, New Jersey 7/1/51 tol/1/72

HOSPITAL AFFILIATIONS:

Attending Physician and Director of Department of Nuclear Medicine, United Hospitals, Newark, New Jersey

Attending Physician and Director of Department of Nuclear Medicine, Hospital Center at Orange, Orange, New Jersey

Consultant in Nuclear Medicine, St. Mary's Hospital, Orange, New Jersey

Assistant Professor-CMDNJ, Newark, New Jersey

PROFESSIONAL SOCIETIES:

Diplomat American Board of Internal Medicine 1957
Diplomat American Board of Nuclear Medicine 1972
Fellow of the American College of Physicians
Member of the Society of Nuclear Medicine
Member American College of Nuclear Medicine

CURRICULUM VITAE

Name: ARNOLD I. BRENNER, D.O. Date of Birth: [redacted]

Place of Birth: [redacted] 946 SS#: [redacted]

Undergraduate Education:

Temple University, Philadelphia, Pennsylvania 1964-1968
A.B. in Biology

U.S. Army 1969-1971

Honorable Discharge
Military Police; Cl. Laboratory technologist

Graduate Education:

College of Osteopathic Medicine and Surgery, 1972-1975
Des Moines, Iowa
D.O.

Advanced Medical Student Program
Anatomy Award

Postgraduate Education:

College of Medicine and Dentistry of New Jersey, 1975-1977
Newark, New Jersey

Director: Carroll M. Leevy., M.D.

PGY 1 and 2 Internal Medicine Residency

Albert Einstein College of Medicine, Bronx, N.Y. 1977-1979

Directors: M. Donald Blaufox, M.D. and
Leonard M. Freeman, M.D.

PGY 3 and 4 - Nuclear Medicine Residency

Professional Societies:

Society of Nuclear Medicine
American Medical Association
Medical Society of New Jersey
Essex County Medical Society
Essex County Association of Osteopathic Physicians

Certification:

American Board of Nuclear Medicine certified Sept. 197[illegible]
American Board of Internal Medicine eligible July, 197[illegible]

Hospital Affiliations:

Consultant Attending in Medicine (Nuclear Medicine) St. Mary's Hospital, Orange, New Jersey	July, 1979 - present
Provisional Attending in Medicine (Nuclear Medicine)	July, 1979 - Oct. 1981
Associate Attending in Medicine (Nuclear Medicine) Hospital Center at Orange, Orange, New Jersey	Oct. 1981 - present
Assistant Attending in Medicine (Nuclear Medicine)	July, 1979 - June 1980
Attending in Medicine (Nuclear Medicine) United Hospitals of Newark, Newark, New Jersey	July, 1980 - present

Appointments:

Associate Director, Nuclear Medicine United Hospitals of Newark, Newark, New Jersey	July, 1979 - present
Associate Director, Nuclear Medicine Hospital Center at Orange, Orange, New Jersey	July, 1979 - present
Internal Medicine Residency Review Committee United Hospitals of Newark	July, 1980 - present
Cancer Committee United Hospitals of Newark	July, 1980 - present
ByLaws Committee Society of Nuclear Medicine Greater New York Chapter	July, 1981 - present
Isotope Committee United Hospitals of Newark	July, 1979 - present
Isotope Committee Hospital Center at Orange	July, 1979 - present

Academic Appointments:

Clinical Instructor in Radiology (Nuclear Medicine) Albert Einstein College of Medicine Bronx, New York	July, 1979 - present
Clinical Asst. Professor of Pediatrics University of Medicine and Dentistry of N.J. Newark, New Jersey	Jan. 1982 - present

Abstracts & Presentations

1. "Methods of Improving the Precision of Left Ventricular Volume and Ejection Fraction Determinations." - W.I. Ganz, J.P. Wexler, AM Rabinowitz, A.I. Brenner, R. Steingart and M.D. Blaufox.

   Abstract J. Nuclear Medicine 21: Suppl 48 and Presented at Society of Nuclear Medicine Meeting, Detroit, June, 1980.

   J. Nuclear Medicine 21: Suppl 48.

2. "Variability of Resting Gated Ejection Fraction." - W.I. Ganz, J.P. Wexler, A.I. Brenner, R. Bontemps, R. Steingart and M.D. Blaufox.

   Abstract J. Nuclear Medicine 21: Suppl 63. and Presented at Society of Nuclear Medicine Meeting, Detroit, June, 1980.

Curriculum Vitae

MARY NATRELLA, M.D. [redacted] Soc. Sec. [redacted]

BACKGROUND

Born: [redacted]
Married:
Children:

EDUCATION, TRAINING, TITLES AND HONORS

Hunter College - A.B. Phi Beta Kappa, Magna Cum Laude	[redacted]
SUNY Downstate Medical Center - M.D.	1952-1956
Long Island Jewish Hospital Medical Center, Rotating Internship	1956-1957
Long Island Jewish Hospital Medical Center, Pathology Residency	1957-1958
MEDICAL COLLEGE of PHILADELPHIA, RETRAINING	1977
Mt. Sinai Medical Center, Pathology	1977-1978
BNHC-Einstein, Radiology Chief Resident	1978-1981
BMHC-Einstein-Montefiore MedicalCenter, Nuclear Medicine Residency, Chief Resident NMR-Case Western Reserve γ Cleveland Clinic PETT-Sloan-Kettering Dept. of Neurology	1981-1983
Einstein-Nuclear Medicine Research Fellow in Dr. Matthew D. Scharff's Monoclonal Antibody Laboratory paid by grant from Dept. of Nuclear Medicine	1983-1984
National Boards, Part 1	1955
National Boards, Part 2	1956
National Boards, Part 3	1957
New York State Medical License	1957
California State Medical License	1974

SPECIALTY BOARD CERTIFICATIONS

American Board of Radiology	June 1981
American Board of Nuclear Medicine	August, 1984

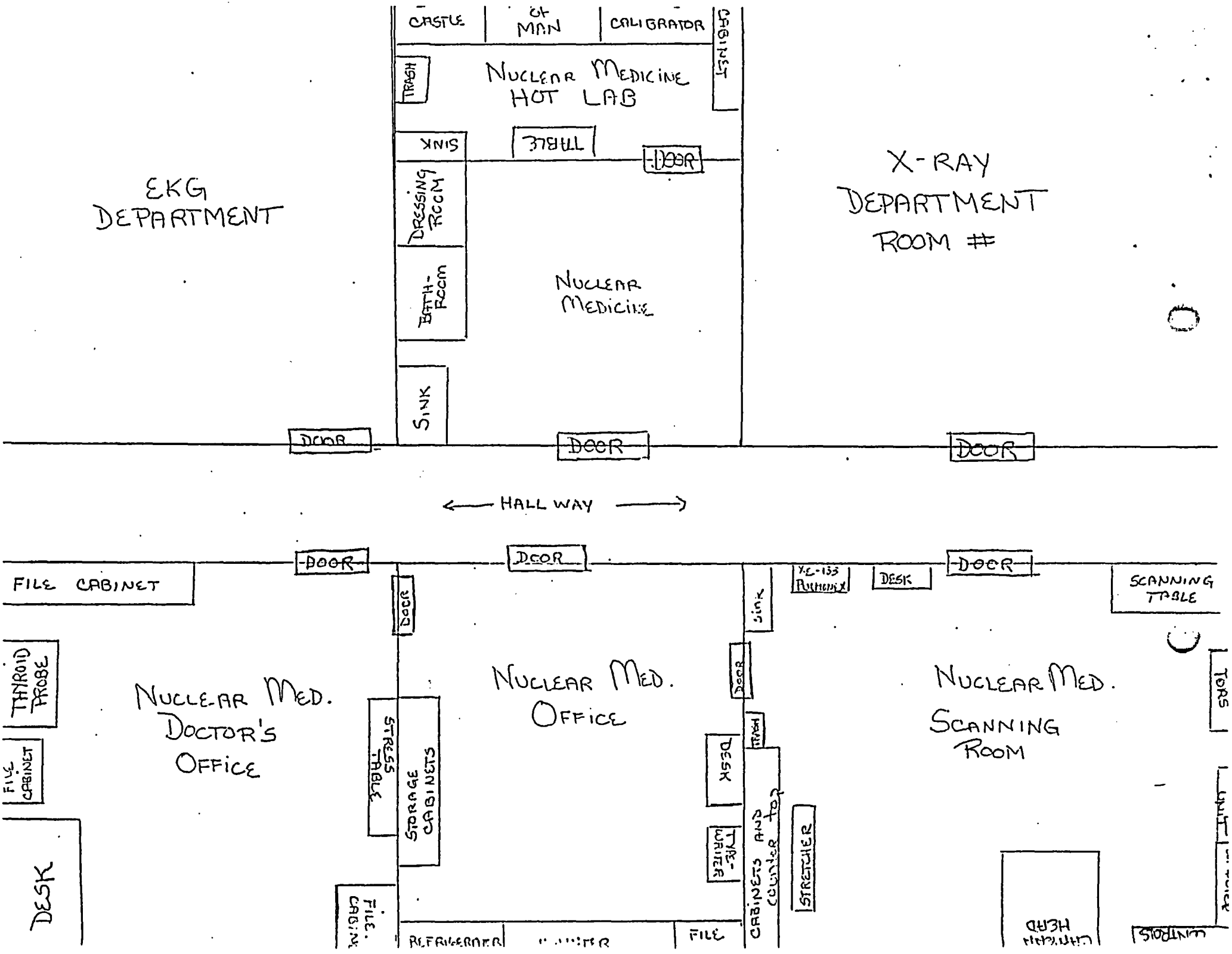
SOCIETIES

American Medical Association
Medical Society of the Country of Westchester, Inc.
The Medical Society of State of New York
Westchester Radiological Society
The Radiological Society of North America
American Association of University Women
The Society of Nuclear Medicine
The Women's Medical Society of New York State, Inc.
[illegible] Association State University of NY Downstate Medical Center

Hospital affiliations

Attending - Department of Medicine - Nuclear Me
Hospital Center of Orange 1984 – present
St Mary's Hospital of Orange 1984 – present
United Hospitals of Newark 1984 – present.

Director of Nuc Med CMMI – 1985 of Newark, N.J.



CASTLE
OF MAN
CALIBRATOR
CABINET
TRASH
NUCLEAR MEDICINE HOT LAB
SINK
TABLE
DOOR
EKG DEPARTMENT
DRESSING ROOM
BATH-ROOM
NUCLEAR MEDICINE
X-RAY DEPARTMENT ROOM #
SINK
DOOR
DOOR
DOOR
HALL WAY
DOOR
DOOR
DOOR
FILE CABINET
DOOR
SINK
DESK
SCANNING TABLE
THYROID PROBE
NUCLEAR MED. DOCTOR'S OFFICE
NUCLEAR MED. OFFICE
NUCLEAR MED. SCANNING ROOM
TORS
FILE CABINET
STRESS TABLE
STORAGE CABINETS
DESK
TRASH
TYPE-WRITER
CABINETS AND COUNTER TOP
STRETCHER
DESK
FILE CABINET
FILE

ITEM 9.2

APPENDIX B

Model Procedure for Calibrating Survey Instruments
(See § 35.51.)

You or your contractor may use the following guidance to calibrate survey instruments. If you, or the contractor, follow all the guidance, you may say on your application, "We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2."

If your procedure does not follow the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.51. Say on your application, "We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2," and append your survey instrument calibration procedure.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

MODEL PROCEDURE

1. The source must be approximately a point source.

2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cs-137 or 21 millicuries of Co-60.

5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.

6. A record must be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

8. Three kinds of scales are frequently used on survey meters:

   a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.

   b. Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

   c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.

10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.

11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:

    a. The owner or user of the instrument;

    b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;

    c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;

    d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;

    e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);

    f. The angle between the radiation flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument);

    g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

h. The apparent exposure rate from the check source; and

i. The name of the person who performed the calibration and the date on which the calibration was performed.

12. The following information will be attached to the instrument as a calibration sticker or tag:

a. The source that was used to calibrate the instrument;

b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);

c. For each scale or decade, one of the following as appropriate:

(1) The average correction factor,

(2) A graph or graphs from which the correction factor for each scale or decade may be deduced, or

(3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;

d. The angle between the radiation flux and the detector during the calibration; and

e. The apparent exposure rate from the check source.

Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

See Exhibit 7 for a form you may want to use.

Survey Meter Calibration Form

DATE_____

Instrument_____

Location_____

_____

Procedure: 10mg Radium source with 1mm. Pt. filtration. Instrument varied over known distances with readings compared to expected inverse square values.

Distance	Expected	Observed
.25 meter	118.88 mR/hr	
.50 meter	29.72 mR/hr	
1.0 meter	7.43 mR/hr	
2.0 meter	1.86 mR/hr	
3.0 meter	.83 mR/hr	
6.0 meter	.207 mR/hr	

Comments:

ITEM 9.3

APPENDIX C

Model Procedure for Calibrating Dose Calibrator
(See § 35.50.)

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may say on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2."

If you develop your own dose calibrator calibration procedure for review, you should carefully review § 35.50 and all the features in the model procedure. Say on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as ATT 9.3," and append your dose calibrator calibration procedure.

MODEL PROCEDURE

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)

   a. Constancy at least once each day prior to assay of patient dosages (±5 percent).

   b. Linearity at installation and at least quarterly thereafter (±5 percent).

   c. Geometry dependence at installation (±5 percent).

   d. Accuracy at installation and at least annually thereafter (±5 percent).

2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57,* or Ra-226* using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

   a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).

   b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

*Co-57 and Ra-226 are not subject to NRC licensing; the appropriate State agency should be consulted to determine its requirements for possessing this material.

c. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.

d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form (see Exhibit 8). This first assay should be done in the morning at a regular time, for example, 8 a.m.

b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.

e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-line) = deviation.

f. If the worst deviation is more than ± 0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary

to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them.

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.

b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

d. Continue for all sleeves.

e. Complete the decay method linearity test steps b through g above.

f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.

g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.

h. Continue for all sleeves.

i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

b. Steps c through e below must be completed within 6 minutes.

c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

e. Continue for all sleeves.

f. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

g. Plot the data using the equivalent decay time associated with each sleeve.

h. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/A-line = deviation.

i. If the worst deviation is more than ±0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

j. Put a sticker on the dose calibrator that says when the next linearity test is due.

6. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

   a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.

   b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form (see Exhibit 9).

   c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

   d. Repeat the process until you have assayed a 2.0-cc volume.

   e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the

data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

f. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that, if a Ra-226 source is used, it must be at least 10 microcuries; other sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on the

Dose Calibrator Geometry and Accuracy Form (see Exhibit 9). Repeat for a total of three determinations.

b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.

c. Repeat the procedure for other calibrated reference sources.

d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.

e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

f. Put a sticker on the dose calibrator that says when the next accuracy test is due.

8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

See Exhibits 8 and 9 for some forms you may want to use.

ISOTOPE CALIBRATOR QUALITY CONTROL

Linearity (Calicheck Procedure):

Tube Color	Activity mCi		Calibration Factor		Product
Black	_____	x	_____	=	_____
Black & Red	_____	x	_____	=	_____
Black & Orange	_____	x	_____	=	_____
Black & Yellow	_____	x	_____	=	_____
Black & Green	_____	x	_____	=	_____
Black & Blue	_____	x	_____	=	_____
Black & Purple	_____	x	_____	=	_____
				Sum	_____

Mean = $\frac{\text{Sum}}{7}$ = _____

Mean x 1.05 = _____ Upper limit

Mean x 0.95 = _____ Lower limit

Comments:

NOTE: Calicheck Procedure will only be used for routine linearity check. New or repaired calibrators will be checked for linearity by decay method!!

Energy:

Source	Calibrated Activity	Observed Activity	Corrected Activity	% Differ
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

Comments:

Geometry: (Total Activity is constant) Isotope _____ Date ___

Container ml	Dilution	Observed Activity
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Comments:

ITEM 9.6

LIST OF EQUIPMENT IN THE NUCLEAR MEDICINE DEPARTMENT

1. TECHNICARE 450 GAMMA CAMERA, ANALOG UNIT, AND COMPUTER
2. KEMBLE THYRO-COUNT THYROID PROBE
3. CAPINTEC DOSE CALIBRATOR
4. VICTOREEN GEIGER-MUELLER SURVEY METER
5. PULMONEX XENON SYSTEM
6. TWO LEAD-LINED TRASH CONTAINERS FOR DISPOSAL AND STORAGE OF RADIOACTIVE WASTE
7. LEAD CASTLE FOR STORAGE OF RADIOISOTOPES
8. OMNI 4000 ERGOMETER STRESS TABLE

ITEM 10.2

APPENDIX G

Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA
(See § 35.20.)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own ALARA program for NRC review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.20. Say on your application, "We have developed an ALARA program for your review that is appended as ATT 10.2," and append your program.

ALARA PROGRAM

ST. MARYS HOSPITAL
(Licensee's Name)

4/18/88
(Date)

1. Management Commitment

   a. We, the management of this (medical facility, hospital, etc.), are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable

level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (see Section 6 below for a discussion of investigational levels).*

*The NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

Table 1

Investigational Levels

	Investigational Levels (mrems per calendar quarter)	
	Level I	Level II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes.

(3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by § 20.401 of 10 CFR Part 20. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

   The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Personnel dose equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Reestablishment of investigational levels to levels above those listed in Table 1.

   In cases where a worker's or a group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

7. Signature of Certifying Official*

I hereby certify that this institution has implemented the ALARA Program set forth above.

Signature

Name (print or type)

Title

*The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

108794

APR 11 1990

Saint Mary's Ambulatory Care Hospital
ATTN: W. Michael Schutsky
Clinical Director
135 South Center Street
Orange, NJ 07050

Gentlemen:

This refers to your letter dated March 19, 1990, for an amendment to Materials License 29-20597-01 to authorize a change in RSO.

An amendment fee of $120 is required as specified in §170.31 (7C) of 10 CFR 170, copy enclosed. Payment should be made to the U.S. Nuclear Regulatory Commission and mailed to the attention of Sandra Kimberley at our Washington, D.C. address.

Your application will be processed by the Region I Licensing staff located at 475 Allendale Road, King of Prussia, Pennsylvania 19406. The fee, however, is required prior to issuance of the amendment. When submitting the fee, please refer to CONTROL NUMBER 112230.

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 and will void this action.

Sincerely,

(Signed) Maurice Messier

Maurice Messier
License Fee and Debt Collection Branch
Division of Accounting and Finance
Office of the Controller

Enclosure:
10 CFR 170

cc: Region I

DISTRIBUTION:
Pending Fee File
OC/DAF R/F
LFDCB R/F (2)
DW/RI/ST. MARY'S

OFFICE:	OC/LFDCB	OC/LFDCB	OC/LFDCB
SURNAME:	SKimberley:bg	MMessier	GJackson
DATE:	4/10/90	4/10/90	4/11/90