

CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
 WASHINGTON, D.C. 20537

The Controlled Substances Act of 1970 reads in part as follows:
 Sec. 304: (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant:

- (1) has materially falsified any application filed pursuant to or required by this title or title II;
- (2) has been convicted of a felony under this title or title II or any other law of the United States, or of any State, relating to any substance defined in this title as a controlled substance; or
- (3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances.

DEA REGISTRATION NUMBER: [REDACTED] THIS REGISTRATION EXPIRES: **03-31-95** FEE PAID: **\$60.00**

SCHEDULES: **2, 2N, 3, 3N, 4, 5** BUSINESS ACTIVITY: **PRACTITIONER** DATE ISSUED: **03-02-92**

ROY, PABLO P MD PA
155 JEFFERSON STREET
NEWARK, NJ 07105

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY

FORM DEA-223 (7/88)

+

 1A1



New Jersey State Department of Health
 Office of Drug Control
 CN 362, Trenton, N.J. 08625-0362
 CONTROLLED DANGEROUS SUBSTANCES

No. **148346**

CERTIFICATE OF REGISTRATION

The following is hereby registered as indicated in the application and below schedule(s) in accordance with N.J.S.A. 24:21-1 Et Seq.

[REDACTED]

Registered Location: **ROY, P P MD**
155 JEFFERSON ST
NEWARK NJ 07105

N.J. CDS No. [REDACTED] (R)
 Registered as: **DISPENSER**
 For schedule(s): **II III IV V**
 EXPIRES: **12/31/92**

To Be Displayed Conspicuously at Registered Location

Francis J. Curran MD
 State Commissioner of Health

#H4146

DDC-26 Revised 8/91

3657

CERTIFICATION OF INSURANCE

This certification reflects professional liability insurance in force on the date of issue only.

POLICYHOLDER	
Pablo P Roy, MD	
Pablo P Roy, MD, PA	
POLICY NUMBER	POLICY TERM
[REDACTED]	01/01/92 TO 01/01/93
SPECIALTY	
General Practice / No Surgery	
LIMIT(S) OF LIABILITY	ISSUE DATE
\$5,000,000 / \$7,000,000	11/16/91

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 2c6
 FOIA- 2005-0084

C-1

STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS

THIS IS TO CERTIFY THAT
BOARD OF MEDICAL EXAMINERS
HAS REGISTERED

P. P ROY
155 JEFFERSON ST
NEWARK NJ 07105

FOR PRACTICE IN NEW JERSEY AS A(N) PHYSICIAN - MD

07/01/91

06/30/93

EFFECTIVE DATE

EXPIRATION DATE

LICENSE NO. 


SIGNATURE OF REGISTRANT


DIRECTOR

STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS

THIS IS TO CERTIFY THAT
BOARD OF MEDICAL EXAMINERS
HAS REGISTERED

PABLO P ROY
155 JEFFERSON ST
NEWARK NJ 07105

FOR PRACTICE IN NEW JERSEY AS A(N) LAB DIRECTOR

01/01/92

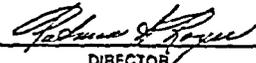
12/31/93

EFFECTIVE DATE

EXPIRATION DATE

LICENSE NO. 


SIGNATURE OF REGISTRANT


DIRECTOR

THE AMERICAN BOARD OF NUCLEAR MEDICINE

INCORPORATED 1971

A CONJOINT BOARD ORGANIZED WITH THE SPONSORSHIP OF THE AMERICAN BOARD OF INTERNAL MEDICINE,
AMERICAN BOARD OF PATHOLOGY, AMERICAN BOARD OF RADIOLOGY AND THE SOCIETY OF NUCLEAR MEDICINE
HEREBY CERTIFIES THAT

Pablo Pedraza Roy, M.D.

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS
CERTIFIED AS QUALIFIED TO PRACTICE AS A SPECIALIST IN
ALL ASPECTS OF CLINICAL AND LABORATORY

NUCLEAR MEDICINE

INCLUDING BUT NOT LIMITED TO RADIOBIOASSAY, NUCLEAR IMAGING,
IN VIVO MEASUREMENTS AND THERAPY WITH UNSEALED RADIONUCLIDES

Joseph F. Row M.D.
CHAIRMAN



Yuan V. Andrews
SECRETARY

NUMBER 01392

DATE MAY 18, 1973

American College of Nuclear Medicine



This is to certify that

Pablo Pedraza Roy, M.D.

having satisfied all requirements, has been elected a

Charter Member

of the American College of Nuclear Medicine, an organization established to advance nuclear medical science, to improve service to the patient, and to encourage improved and continuing education in the clinical use of radionuclides

December 31, 1973

Irving M. Ariel
President

J.R. Mayfield Jr., M.D.
Secretary-Treasurer

SAINT JAMES hospital



155 JEFFERSON STREET
NEWARK, NEW JERSEY 07105

(201) 589-1300

December 16, 1977

Memo: To: Dr. Roy
From: Miss Kaplan
Subject: Radioisotope Committee

Dear Doctor:

This is to notify you that you have been appointed
Chairman of the RADIOISOTOPE Committee.

If you cannot accept this committee appointment,
will you please let me know as soon as possible.

Sincerely,


Pablo Roy, M. D.
President Medical Staff

bnk

Committee Members
Dr. A. T. Cacciarelli
Dr. R. R. Gialanella



155 JEFFERSON STREET, NEWARK, NEW JERSEY 07105

201-589-1300

December 19, 1979

Pablo P. Roy, M.D.
SAINT JAMES HOSPITAL
155 Jefferson Street
Newark, New Jersey 07105

Dear Dr. Roy:

I am pleased to advise you that the Board of Trustees has re-appointed you Director of the Departments of Pathology, Laboratory, and Nuclear Medicine for the 1980 calendar year.

The Board has instructed me to advise you of the necessity to monitor the meeting attendance of the members of your department on a month-to-month basis, and to remind you that it is your responsibility to see that the medical staff and hospital bylaws are complied with fully.

As Past President of the Medical Staff you are also appointed to the Medical Executive Committee.

I look forward to working with you in 1980, as we strive to continue to provide quality health care to the Ironbound community.

God bless you,

Sister Margaret Jane C.S.J.
Sister Margaret Jane, C.S.J.
Administrator

SMJ:lf

RADIOISOTOPE COMMITTEE MEETING

July 9, 1979

The Radioisotope Committee held a meeting on Monday July 9, 1979. The meeting was convened at 11:30 A.M. by the chairman, was held in the Medical Library.

Present

Dr. Pablo P. Roy
Dr. A.T. Cacciarelli.
Dr. R.R. Gialanela
Mr. Herbert Strauss. (Nuclear Medicine Physicist)
Miss Fe Romana, R.N.
Mr. Apolinario Anday Jr. - N.M. Supervisor.
Mrs. Lata Gala - N.M. Technologist.

Mr. Charles Brennan, Administration.

The chairman reported that the Nuclear Medicine Department had purchased the following equipment:

- a) Picker Spectroscaler - 4R
- b) Primalert Radiation Monitored.
- c) 5cc Syringe Shield.
- d) Co-57 Calibrated Source
- e) Hole Phantom 3/16 - hole.

It was noted that Mr. Herbert Strauss (Nuclear Medicine Physicist) have been checking our instrument and everything is satisfactory.

The meeting adjourned by the chairman at 12:30 P.M.

Respectfully submitted,


Pablo P. Roy, M.D.
Chairman
Radioisotope Committee.

To: Sister Ann Taylor
Management

From: Pablo P. Roy, M.D.

Subject: NUCLEAR MEDICINE

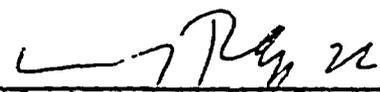
Date: October 8, 1982

We will have a Radio-Isotopes Committee meeting on September 14, at which time we will officially change our name to Radiation Safety Committee, as required by the Nuclear Regulatory Commission.

According to the enclosed rules and regulations, this rule change acknowledges the Food and Drug Administration's role in regulating the safety and effectiveness of radioactive drugs with respect to the patient. Since this concerns the use of radioactive drugs, this committee relates directly to Nuclear Medicine. As you know in the early 60's, when the use of radioactive drugs was becoming clinically popular, there was no specific department supervising the use of radio-isotopes. It was in some places under the care of the internist, the pathologist, the radiologist or the physicist, until 1972, when Nuclear Medicine became recognized as an independent specialty, that is also the time when the American Board of Nuclear Medicine started.

Our present committee members is in compliance with the requirement, however Mr. Charles Brennan is no longer with us and a new member from Management should be appointed.

Respectfully yours;


Pablo P. Roy, M.D., F.C.A.P.
Director of Nuclear Medicine.

PPR:aa

FILE IN DUPLICATE

REGISTRATION OF RADIOACTIVE MATERIALS

1. NAME OF OWNER OF RADIOACTIVE MATERIALS **ST. JAMES HOSPITAL**

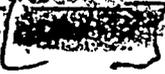
1

2. MAILING ADDRESS OF THE OWNER OF RADIOACTIVE MATERIALS

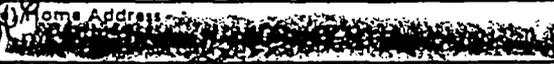
a) Street **155 Jefferson St.** (b) City **Newark** (c) County **Essex** (d) State **New Jersey** (e) Telephone **(201) 589-1300 Ex 282**

3. INDIVIDUAL IN CHARGE OF RADIATION PROTECTION

2

a) Name **Pablo P. Roy, M.D.** (b) Title **Radiation officer** (c-1) Professional License No.  *wpz*

(d) Business Address **155 Jefferson St., Newark, N.J. 07105** (c-2) N.R.C. License No.(s) **29-12997-01**

(f) Home Address  (g) Home Telephone  (g) Business Telephone **(201) 589-1300 Ext 250**

3

4. LOCATION OF RADIOACTIVE MATERIALS

(1) Street (2) City (3) County

(a) Stored: **155 Jefferson Street Newark Essex**

4

(b) Used: **Same as above " "**

5. SOURCES

(a) Isotope(s)	SEALED		UNSEALED		(f) Use	(g) Estimate of amount of radioactive waste (per week)				
	(b) Total Strength Each Source (Curies)	(c) Max. Amt. of Isotope on Hand Any One Time	(d) Amount Used Annually	(e) Max. Amt. on Hand Any One Time		To Atmosphere	Commercial Service	Other	To Sewer	
									Amount	Volume of Plant Discharge
1) Tc-99m pertechnetate			5,200 mCi	100mCi	Medical Diagnosis or Therapy					
2) Cesium 137		2.71.9uCi				N/A	N/A	N/A	N/A	N/A
3) I-131	N/A		8.5uCi	500uCi						
4) Ga ⁶⁷			60mCi	4mCi						
5) Thallium	201		10mCi	2mCi						
6) Indium	111		1.5mCi	500uCi						
7) Co ⁵⁷		271.9uCi								

5

6

7

8

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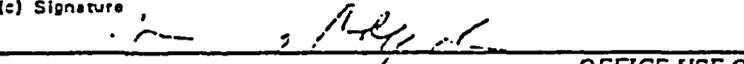
6. TYPE OF REGISTRATION

(a) Original Registration (b) Renewal Registration (c) Amendment to Current Registration

10

7. INDIVIDUAL FILLING OUT THIS REGISTRATION FORM (Owner or Agent)

(a) Name **PABLO P. ROY, M.D.** (b) Title **Radiation officer and the Nuclear Medicine Director**

(c) Signature  (d) Date **11-16-83**

Year Registered

OFFICE USE ONLY

Date Received Date Returned Reviewed by Registration No. **60-**



155 JEFFERSON STREET, NEWARK, NEW JERSEY 07105

201-589-1300

February 10, 1987

TO: Pablo P. Roy, M.D.
FROM: Matthew A. Brady, M.D.
President Medical Staff
RE: RADIATION SAFETY COMMITTEE

Dear Doctor Roy:

Please be advised that you have been appointed Chairman of the RADIATION SAFETY COMMITTEE for 1987.

jmj

MATERIALS LICENSE

Amendment No. 26

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. St. James Hospital Division of Cathedral Health Services, Inc.</p> <p>2. 155 Jefferson Street Newark, New Jersey 07105</p>	<p>In accordance with application received November 9, 1989, 3. License number 29-12997-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date May 31, 1996</p> <hr/> <p>5. Docket or Reference No. 030-02566</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material identified in 10 CFR 35.100</p> <p>B. Any byproduct material identified in 10 CFR 35.200</p> <p>C. Iodine 131</p> <p>D. Any byproduct material identified in 10 CFR 31.11</p>	<p>7. Chemical and/or physical form</p> <p>A. Any radiopharmaceutical identified in 10 CFR 35.100</p> <p>B. Any radiopharmaceutical identified in 10 CFR 35.200 except generators and gas</p> <p>C. Iodide as identified in 10 CFR 35.300</p> <p>D. Prepackaged Kits</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. As needed</p> <p>D. As needed</p>
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<p>9. Authorized use</p> <p>A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.</p> <p>B. Any imaging and localization procedure approved in 10 CFR 35.200.</p> <p>C. Diagnosis and treatment of hyperthyroidism, and treatment of cardiac dysfunction.</p> <p>D. <u>In vitro</u> studies.</p>

CONDITIONS

<p>10. Location of use: 155 Jefferson Street, Newark, New Jersey</p> <p>11. Radiation Safety Officer: Pablo P. Roy, M.D.</p> <p>12. <u>Authorized Users:</u> Pablo P. Roy, M.D.</p>	<p><u>Material and Use:</u> 35.100; 35.200, Iodine 131, <u>In vitro</u> studies</p>
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STATE OF NEW JERSEY
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF RADIATION PROTECTION
CN 411, TRENTON, NEW JERSEY 08625

RADIOACTIVE MATERIALS LICENSE

Pursuant to the New Jersey Radiation Protection Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the State Department of Environmental Protection, now or hereafter in effect, and to any conditions specified below.

LICENSEE		3. License Number NJSL-70034 Amendment #18 Amended in its entirety
1. Name	ST. JAMES HOSPITAL A Division of Cathedral Health Services	4. Expiration Date November 30, 1993
2. Address	155 Jefferson Street Newark, New Jersey 07105	5. Reference Number

6. Radioactive Materials (element and mass number)	7. Chemical and/or Physical Form	8. Maximum Quantity Licensee May Possess at Any One Time
A. Any naturally occurring and/or accelerator produced material included under Group I, Section 4.7 of NJAC 7:28-4.	A. Any radiopharmaceutical included under Group I, Section 4.7 of NJAC 7:28-4.	A. 2 millicuries
B. Any naturally occurring and/or accelerator produced material included under Group II, Section NJAC 7:28-4.	B. Any radiopharmaceutical included under Group II, Section 4.7 of NJAC 7:28-4	B. 200 millicuries
C. Any naturally occurring and/or accelerator produced material included under Group III, Section 4.7 of NJAC 7:28-4.	C. Any for included under Group III, Section 4.7 of NJAC 7:28-4.	C. 25 millicuries
D. Cobalt 57	D. Sealed Source	D. 15 millicuries

9. Authorized Use:
- A. Any diagnostic procedure under Group I of NJAC 7:28-4, Section 4.7.
 - B. Any diagnostic procedure under Group II of NJAC 7:28-4, Section 4.7.

STATE OF NEW JERSEY
DEPARTMENT OF ENVIRONMENTAL PROTECTION
DIVISION OF ENVIRONMENTAL QUALITY
BUREAU OF RADIATION PROTECTION
CN 411, Trenton, New Jersey 08625

Page 2 of 5 Pages

License Number 70034
Amendment No. 18

RADIOACTIVE MATERIALS LICENSE

Supplementary Sheet

- C. Preparation and use of radiopharmaceuticals for any diagnostic procedure under Group III of NJAC 7:28-4, Section 4.7.
- D. Reference and/or calibration source.
10. Radioactive material shall only be used at 155 Jefferson Street, Newark, New Jersey.
11. Radioactive material listed in Conditions 6, 7, and 8 shall be used by or under the supervision of the following: Pablo P. Roy, M.D.
12. Compliance with other U.S. agencies having jurisdiction and regulations for radiopharmaceuticals must be maintained.
13. The licensee shall retain records of misadministrations in the use of the licensed radioactive materials. Misadministrations being defined as a radiopharmaceutical or radiation from a sealed source which is improperly used as follows:
- A. Administration of the wrong radiopharmaceutical or sealed source.
 - B. Administration to the wrong patient.
 - C. Administration by a route other than that intended by the prescribing physician.
 - D. Administered diagnostic dose differing by more than 50 percent.
 - E. Administered therapeutic dose differing by more than 10 percent.
- Records of misadministrations are to include the following information: name of the referring physician, description of the event, the effect on the patient and the action taken to prevent recurrence.
14. The licensee shall not open sealed sources containing radioactive material.
15. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months.
- A. The test shall be capable of detecting the presence of 0.005 microcuries of removable radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surface of the device in which the sealed source is permanently mounted or stored.
 - B. If the test reveals the presence of 0.005 microcuries of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with the Department regulations.

For the State of New Jersey
Department of Environmental Protection

Date _____

By _____

STATE OF NEW JERSEY
DEPARTMENT OF ENVIRONMENTAL PROTECTION
DIVISION OF ENVIRONMENTAL QUALITY
BUREAU OF RADIATION PROTECTION
CN 411, Trenton, New Jersey 08625

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License Number 70034
Amendment No. 18

RADIOACTIVE MATERIALS LICENSE

Supplementary Sheet

Within five days after obtaining results of the test, a report shall be filed with the Department describing the circumstances, the test results and the corrective action taken.

- C. The sealed sources shall be tested for leakage and/or contamination by appropriately trained personnel.
16. Repair, initial leak tests and disposal of sealed sources containing radioactive material shall be performed only by the manufacturer or by other persons specifically licensed by New Jersey or the Federal Government to perform this service.
17. Radioactive material listed in Items 6A - 6D may be disposed of as non-radioactive waste provided that (a) the radioactive waste is stored behind adequate shielding to meet the requirements of New Jersey Radiation Code 28-6, (b) the radioactive waste is held for ten half-lives of the longest lived radioisotope to be disposed of, (c) the radioactive waste is monitored with a GM meter prior to disposal to insure background levels, (d) all radiation labels will be either removed or obliterated and (e) a log shall be maintained to include the results of the radiation survey and date of disposal.
18. A survey of the administration area used for stress thallium studies shall be performed and documented on the day the test is done.
19. In laboratory areas where small quantities of radioactive materials are used (i.e. less than 200 microcuries):
- A. Monthly surveys of areas are to be performed and the results documented.
 - B. Monthly wipe test of areas are to be performed and the results documented.
 - C. Protective gloves are to be worn by individuals handling radioactive material.
 - D. Survey decayed radioactive waste prior to disposal to ensure background levels.
 - E. Radioactive material symbols shall be removed and/or obliterated from all containers no longer containing radioactive material prior to disposal.
20. The licensee shall make the following items available to their staff:
- A. Copy of the New Jersey Radiation Protection Code.
 - B. Copy of the New Jersey State Radioactive Material License.

For the State of New Jersey
Department of Environmental Protection

Date _____

By _____

STATE OF NEW JERSEY
DEPARTMENT OF ENVIRONMENTAL PROTECTION
DIVISION OF ENVIRONMENTAL QUALITY
BUREAU OF RADIATION PROTECTION
CN 411, Trenton, New Jersey 08625

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License Number 70034

Amendment No. 18

RADIOACTIVE MATERIALS LICENSE
Supplementary Sheet

21. The licensee shall post the following items in an area frequented by employees engaged in the use of licensed materials:
- A. Notice to Employees - BRP-14.
 - B. Emergency procedures involving major, minor spills including the names and phone numbers of people to contact.
 - C. Appropriate signs and labels in areas and/or containers and equipment in which radiation and/or radioactive material are contained. These postings are to conform to Subchapter 10 of the Code.
22. The following tests shall be performed as a minimum:
- A. Surveys of:
 - 1. All radioactive materials received.
 - 2. All radioactive waste decayed to background levels prior to release.
 - 3. Uncontrolled areas where sealed and unsealed sources are routinely used to be surveyed on days they are used.
 - 4. Controlled area, daily.
 - 5. Personnel at the end of the day.
 - B. Wipe tests of:
 - 1. Controlled and uncontrolled area where unsealed sources of radioactive material are routinely used, weekly.
23. The following records shall be maintained:
- A. Radioactive materials received including but not necessarily limited to date of receipt, radionuclide, activity, mass or volume of material, results of package survey, instrument used for surveys and surveyor's initials.
 - B. Radioactive materials administered to patients including but not necessarily limited to date of administration, radionuclide, calibrated activity administered, quantity, patient name, administrator's signature.

For the State of New Jersey
Department of Environmental Protection

Date _____

By _____

STATE OF NEW JERSEY
DEPARTMENT OF ENVIRONMENTAL PROTECTION
DIVISION OF ENVIRONMENTAL QUALITY
BUREAU OF RADIATION PROTECTION
CN 411, Trenton, New Jersey 08625

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License Number 70034
Amendment No. 18

RADIOACTIVE MATERIALS LICENSE

Supplementary Sheet

- C. Radioactive material disposals including but not necessarily limited to:
1. Disposals to Vendor: nuclide, activity, vendor name, quantity, date of disposal.
 2. Disposal by Decay: Results of survey of the waste, date of survey, date of waste disposal, instrument used, and surveyor's initials.
 3. Disposal to Sanitary Sewer: nuclide, activity, volume of dilution waste per day, date of disposal.
 4. Disposals to Air: nuclide, activity, volume of dilution air, nuclide concentration in air, date of disposal.
- D. Survey instrument calibration at intervals not to exceed six months.
- E. Sealed source leak tests at intervals not to exceed six months. Results are to be reported in microcuries.
- F. Surveys performed in controlled and uncontrolled areas including but not necessarily limited to survey results, instrument used, date performed and surveyor's initials.
- G. Wipe tests performed in controlled and uncontrolled areas including but not necessarily limited to test results in dpm, date performed, instrument used and surveyor's initials.
- H. Personnel dosimetry records including but not necessarily limited to name, social security number, and prior employment exposure history.
- I. Daily personnel monitoring results including but not necessarily limited to instrument used, date performed and initials.
24. Protective equipment and clothing including but not necessarily limited to syringe shields, remote handling equipment, adequate shielding, laboratory coats and disposable gloves shall be used by personnel while utilizing radioactive material.
25. Eating, drinking, smoking and applying cosmetics shall not be permitted in controlled areas.
26. Except as specifically provided by this license, the licensee may possess and use radioactive material described in this license only in accordance with statements, representations and procedures contained in application dated October 3, 1988 and signed by Charles Brennan, President and letters dated December 8, 1989 and April 2, 1990.

OFFICIAL RECORD COPY

For the State of New Jersey
Department of Environmental Protection

116861

Date April 19, 1990

By John Feeney

AUG 17 1992

License No. 29-20597-01
Docket No. 030-19962
Control No. 116861

St. Mary's Hospital
ATTN: Bertha L. Peter-Stokes
Administrator
135 S. Center Street
Orange, New Jersey 07050

Dear Ms. Peter-Stokes:

This is in reference to your request in a letter dated July 9, 1992 to amend License No. 29-20597-01. In order to continue our review, we need the following additional information:

1. 10 CFR 35.972 (enclosed) requires each physician's training and experience must have been obtained within the last five years, or the individual must have related continuing education or experience since the training and experience was obtained. Since Dr. Chandarana was certified in 1976, please provide evidence of his continuing education or experience.

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. 116861. The reviewer for this licensing action is Keith D. Brown, Ph.D. If you have any technical questions regarding this deficiency letter please call the reviewer at (215) 337-5048.

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

Sincerely,

Original Signed By:
Keith D. Brown, Ph.D

Keith D. Brown, Ph.D.
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

OFFICIAL RECORD COPY - G:\WPS\DLTR\D363 - 08/14/92

ML 10

St. Mary's Hospital

2

Enclosure:
10 CFR Part 35

DRSS
DRSS:RI
Brown/kl

8/17/92

SAINTMARY'S
AMBULATORYCAREHOSPITAL

A Division of Cathedral Health Services, Inc.

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

July 27, 1992

Ms. Judith Joustra
Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pennsylvania 19406

Attention: Medical License Section

RE: Lic.# 29-20597-01

Dear Ms. Joustra:

This letter serves as an addendum to my letter of intent dated July 9, 1992 regarding interruption of Nuclear Medicine Services here at Saint Mary's (see attached).

Effective July 14, 1992, the following physicians will no longer be listed as authorized users:

Arnold I. Brenner, D.O.
Wade Miller, M.D.
Mary Natrella, M.D.

Please amend our license to reflect this change. Additionally, please be advised that Shashikant G. Chandarana, M.D. will be the authorized user and Radiation Safety Officer.

Thank you for your assistance in this matter.

Sincerely,

Bertha L. Peters-Stokes

Bertha L. Peters-Stokes
Administrator

BLPS/lar

cc: Mr. John Feeney, N.J.D.E.P.
Arnold I. Brenner, D.O.
Wade Miller, M.D.
Mary Natrella, M.D.
Shashikant G. Chandarana, M.D.

030-1992

*Add
Info
2*



OFFICIAL RECORD COPY ML 10

116861
JUL 31 1992

SAINTMARY'S
AMBULATORYCAREHOSPITAL
A Division of Cathedral Health Services, Inc.

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

July 9, 1992



Ms. Judith Joustra
Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pennsylvania 19406

Attention: Medical License Section

Re: Lic. No. 29-20597-01

Dear Ms. Joustra:

I submit this letter to you as a follow-up to our telephone conversation of June 26, 1992 regarding the interruption of Nuclear Medicine Services here at Saint Mary's.

As you requested, I am hereby outlining below the future plans for the Nuclear Medicine Department.

Our intentions are to:

- Maintain full licensure under lic. no. #29-20597-01;
- Technical staff will be available from within our system;
- Physicians presently utilizing the department will maintain membership on the Clinical Staff. Those physicians are:
 - Wade Miller, M.D.
 - Mary Natrella, M.D.
 - Arnold Brenner, D.O.
- The Radiation Safety Officer position will be changed from Mary Natrella, M.D. to Shashikant G. Chandarana, M.D. (see attached letter requesting this change and associated documents);

Ms. Judith Joustra
July 9, 1992
Page Two

- Maintain the required testing for sealed sources dose calibrator and survey dose meter calibration on a monthly basis as presently done. The Health Physicist now employed will be continued.
- The only radiation material remaining in the department will be the sealed sources.

Please contact me at (201) 266-3006 should you have questions.

Sincerely,



Bertha L. Peters-Stokes
Administrator

BLPS/lar

SAINTMARY'S
AMBULATORYCAREHOSPITAL
A Division of Cathedral Health Services, Inc.

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

July 9, 1992

Ms. Judith Joustra
Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pennsylvania 19406

Re: Lic. No. 29-20597-01

Dear Ms. Joustra:

This letter serves to inform you that Saint Mary's Ambulatory Care Hospital located at 135 S. Center Street, Orange, New Jersey 07050, a Division of Cathedral Healthcare Services, Inc., has changed its Radiation Safety Officer, effective July 16, 1992 to:

Shashikant G. Chandarana, M.D.
(enclosed are the required
certifications on this physician)

Dr. Chandarana is a member of the Clinical Staff at Saint Mary's.

Please contact me at (201) 266-3006 should you have questions.

Sincerely,



Bertha L. Peters-Stokes
Administrator

BLPS/lar



SAINT MARY'S
AMBULATORY CARE HOSPITAL

A Division of Cathedral Health Services, Inc.

July 20, 1992



CATHEDRAL
HEALTHCARE
SYSTEM

Mr. John Feeney
License Administrator
State of New Jersey
Department of Environmental Protection
CN 415
Trenton, New Jersey . 08625-0415

Dear Mr. Feeney:

This letter serves as a follow-up to my telephone conversation with you on or about June 26, 1992 regarding an interruption in Nuclear Medicine Services here at Saint Mary's.

I realize that you stated that you did not require any written communication at this time, but submit the attached items as an update for your file.

Please feel free to call me at (201) 266-3006 should you have questions.

Sincerely,

Bertha L. Peters-Stokes
Administrator

BLPS/lar
attachments

030-19962

SAINTMARY'S
AMBULATORYCAREHOSPITAL
A Division of Cathedral Health Services, Inc.

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

July 9, 1992

Ms. Judith Joustra
Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pennsylvania 19406

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Re: Lic. No. 29-20597-01

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 - Wade Miller, M.D.
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 - Arnold Brenner, D.O.
- The Radiation Safety Officer position will be changed from Mary Natrella, M.D. to Shashikant G. Chandarana, M.D. (see attached letter requesting this change and associated documents);

Log	Aug 2
Remitter	Cathedral Health Serv Inc.
Check No.	86627018
Amount	8420
Fee Category	7C
Type of Fee	AMS
Date Check Rec'd	
Date Completed	8/14/92
By:	[Signature]



RECEIVED
JUL 20 1992
9:38 AM

116861

OFFICIAL RECORD COPY ML 10

JUL 13 1992

Ms. Judith Joustra
July 9, 1992
Page Two

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Sincerely,



Bertha L. Peters-Stokes
Administrator

BLPS/lar

SAINTMARY'S
AMBULATORYCAREHOSPITAL
A Division of Cathedral Health Services, Inc.

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

July 9, 1992

Ms. Judith Joustra
Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pennsylvania 19406

Re: Lic. No. 29-20597-01

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Shashikant G. Chandarana, M.D.
(enclosed are the required
certifications on this physician)

Dr. Chandarana is a member of the Clinical Staff at Saint Mary's.

Please contact me at (201) 266-3006 should you have questions.

Sincerely,



Bertha L. Peters-Stokes
Administrator

BLPS/lar



STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS

THIS IS TO CERTIFY THAT
BOARD OF MEDICAL EXAMINERS
HAS REGISTERED

COPY

SHASHIKANT G. CHANDARANA

FOR PRACTICE IN NEW JERSEY AS A(N) PHYSICIAN - MD

07/01/91

EFFECTIVE DATE

06/30/93

EXPIRATION DATE

[REDACTED]
LICENSE NO

SIGNATURE OF REGISTRANT

[Signature]
DIRECTOR

ES 6

342



New Jersey State Department of Health
 Office of Drug Control
 CN 362, Trenton, N.J. 08625-0362
 CONTROLLED DANGEROUS SUBSTANCES

No. 147664 000

CERTIFICATE OF REGISTRATION

The following is hereby registered as indicated in the application and below schedule(s) in accordance with N.J.S.A. 24:21-1 Et Seq.

Registered Location: CHANDARANA, SHASHIKANT G MD



476

N.J. CDS No. [Redacted]

Registered as: DISPENSER

(R)

472

For schedule(s): II III IV V

EXPIRES: 12/31/92

Francis J. Cannon MD
 State Commissioner of Health

DM4148

DOC-26
 Revised 12/91

To Be Displayed Conspicuously
 at Registered Location

CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
 WASHINGTON, D.C. 20537

The Controlled Substances Act of 1970 reads in part as follows:

Sec. 304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant:

- (1) has materially falsified any application filed pursuant to or required by this title or title III,
- (2) has been convicted of a felony under this title or title III or any other law of the United States, or of any State, relating to any substance defined, classified as a controlled substance, or
- (3) has had his State-issued registration suspended, revoked, or denied by a competent State authority, and a Federal authority of the State is to engage in the manufacturing, distribution, or dispensing of controlled substances.

DEA REGISTRATION NUMBER [REDACTED]	THIS REGISTRATION EXPIRES 09-31-93	FEE PAID \$60.00
SCHEDULES 2, 24, 3, 3M, 4, 5	BUSINESS ACTIVITY PRACTITIONER	DATE ISSUED 08-07-93

CHANDARAMA, SHASHIKANT S MD	
[REDACTED]	[REDACTED]

EPL

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY

FORM 224 (2-78)



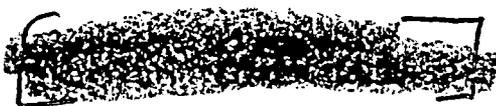
CERTIFICATE OF INSURANCE

Saint James Hospital
155 Jefferson Street
Newark, NJ 07102

ATTN: Administrator/Risk Manager

This is to certify that the Medical Inter-Insurance Exchange (MIIX) has issued to the named insured the policy identified herein by policy number, policy term and limits of liability which affords physicians and surgeons professional liability insurance. This Certificate of Insurance does not amend, extend or otherwise alter the terms, conditions, or limits of the insurance afforded by the policy. If this policy is cancelled by MIIX before the expiration date shown, MIIX will endeavor to mail advance written notice to the certificate holding organization or hospital. Failure to mail such a notice will impose no obligation or liability of any kind upon MIIX.

Insured's Name: Shashikant G Chandarana, M.D.

Address:  *Copy*

Policy Type: Permanent Protection Policy

Rating Classification: Radiology

Policy Number:  *Copy*

Policy Limits: \$2,000,000/\$4,000,000/\$4,000,000

Policy Term: 12:01 AM January 1, 1992 to 12:01 AM January 1, 1993.

Issue Date: December 7, 1991

7

The American Board of Radiology

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

Shashikant G. Chandarana, M.D.

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

On this eighteenth day of June, 1976

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

Radiology

Robert N. Cooley
President

C. Allen Hood
Secretary



116861

OFFICIAL RECORD COPY ML 10

SEP 30 1992

License No. 29-20597-01
Docket No. 030-19962
Control No. 116861

St. Mary's Hospital
ATTN: Bertha L. Peters-Stokes
Administrator
135 S. Center Street
Orange, New Jersey 07050

Dear Ms. Peters-Stokes:

Please find enclosed an amendment to 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) 337-5093, 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."

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 - G:\WPS\MLTR\L2920597.01 - 09/28/92

ML 10

St. Mary's Hospital

-2-

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

Sincerely,

Original Signed By:
Keith D. Brown, Ph.D

Keith D. Brown, Ph.D.
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

Enclosures:

1. Amendment No. 03
2. Requirements for Materials Licensees

KB
DRSS:RI
Brown/gc

9/30/92

NUCLEAR MEDICINE PHYSICIANS

Professional Association

P.O. Box 127

Harrison, New Jersey 07029

Telephone 201-268-8661

July 14, 1992

Ms. Bertha Peter-Stokes
Chief Executive Officer
St. Mary's Ambulatory Care Hospital
135 South Center Street
Orange, NJ 07050

Dear Bertha,

It has always been a pleasurable and rewarding experience to be actively involved, both in the Department of Nuclear Medicine and as Active Medical Staff at St. Mary's and Cathedral Health Care System. We appreciate the great effort that you and St. Mary's and Cathedral have pursued in order to retain Nuclear Medicine Services as a viable service. It is unfortunate that at this point in time Nuclear Medicine Services at St. Mary's will be interrupted and it is our hope to vigorously resume Nuclear Medicine Professional Services in the future as we have discussed.

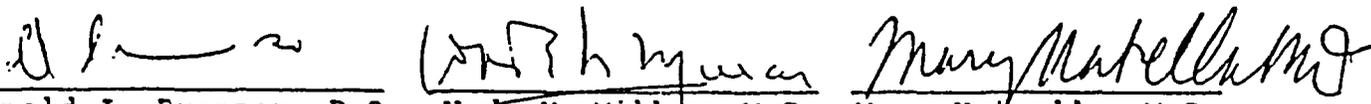
After evaluating the responsibilities of all authorized users to supervise and periodically review all medical uses of by-product material and all work done in restricted areas and to keep records of this periodic review, we feel that remaining as authorized users on the Nuclear Regulatory Commission License is not tenable.

Therefore, we request that you submit a license amendment to the Nuclear Regulatory Commission and to the State of New Jersey, Department of Environmental Protection, Bureau of Radiation Protection to delete Wade N. Miller, M.D., Mary Natrella, M.D., and Arnold Brenner, D.O. as authorized users.

We are currently tendering our resignations as members of the Radiation Safety Committee.

When St. Mary's chooses to re-activate the Nuclear Medicine Department, we can immediately resume professional services in accordance with Part 35.27 of the Federal Register.

Sincerely,


Arnold I. Brenner, D.O. Wade N. Miller, M.D., Mary Natrella, M.D.

AIB:WNM:MN/vm

pc Francis X. McGinn, M.D., Vice President Ambulatory Care
Nuclear Regulatory Commission
State of New Jersey, Dept. of Environmental Protection,
Bureau of Radiation Protection

JUL 21 1992

"ORIGINAL DELETED COPY" ML 10

MS 16

Q7

SAINTMARY'S
AMBULATORYCAREHOSPITAL

A Division of Cathedral Health Services, Inc.

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

September 15, 1992

Keith D. Brown, Ph.D.
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415



Re: Lic. #29-20597-01
Mail Control # 116861

Dear Dr. Brown:

First, please accept my appreciation for the assistance and guidance you have provided over the past few months as we proceed with changes in the Nuclear Medicine Department here at Saint Mary's.

In response to your August 17, 1992 letter regarding the Radiation Safety Officer, please find enclosed professional certifications and background information on Pablo P. Roy, M.D., F.A.C.P., P.A.

This letter serves to request your review, approval and acceptance of Dr. Roy as the Radiation Safety Officer for Saint Mary's. Dr. Roy is presently the Director of Nuclear Medicine at Saint James Hospital, Newark, New Jersey, which is our sister hospital.

We look forward to completing this process, hopefully with the submission of this communication.

However, should you have questions or require additional information, please do not hesitate to call me (201)266-3006.

Again, thank you for all you help.

Sincerely,

A handwritten signature in cursive script, appearing to read "Bertha L. Peters-Stokes".

Bertha L. Peters-Stokes
Administrator

BLPS/lar

116861

SEP 18 1992

OFFICIAL RECORD COPY ML 10

PABLO P. ROY, M.D., F.C.A.P., P.A.

DIPLOMATE American Board of Pathology
American Board of Nuclear Medicine

BIO-ANALYTICAL LABORATORY DIRECTOR

155 JEFFERSON STREET
NEWARK, NJ 07105
TEL 201-465-2783/84

September 3, 1992

Ms. Bertha L. Peters-Stokes
Administrator
Saint Mary's Ambulatory Care Hospital
135 South Street
Orange, New Jersey 07050

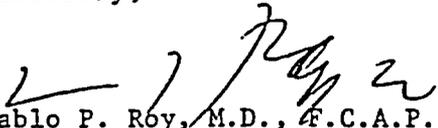
Dear Ms. Peters-Stokes:

Enclosed please find the current copies of my N.J. Medical License; Federal DEA Certificate; State CDS Certificate; Professional Liability Insurance; Board Certification and the License issued by the United States Nuclear Regulatory Commission from Saint James Hospital with my name as the authorized user, covering the period from 1969 to the present, as well as some correspondence concerning the Radio Isotope Committee, which was officially change to Radiation Safety Committee in 1982 as required by the NRC. I am the Chairman and the Radiation Safety Officer since this Committee was organized.

This is to inform you that the Department of Nuclear Medicine is not a part of the Department of Radiology in Saint James Hospital. Our Medical By-Laws state that the Director must be Board Certified by the American Board of that particular Specialty.

I hope this is sufficient to meet the requirements of the NRC.

Sincerely,


Pablo P. Roy, M.D., F.C.A.P.
Director - Clinical Laboratories/
Nuclear Medicine Departments
Saint James Hospital

PPR: jl.

Encls.

MATERIALS LICENSE

Amendment No. 03

the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions 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 Commission now or hereafter in effect and to any conditions specified below.

Licensee Mary's Hospital 5 South Center Street Orange, New Jersey 07051	In accordance with letter dated July 9, 1992, 3. License number 29-20597-01 is amended in its entirety to read as follows: 4. Expiration date February 28, 1994 5. Docket or Reference No 030-19962
--	--

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

[Redacted] 920930
 PDR ADUCK 03017762
 C PDR

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

29-20597-01

Docket or Reference number

030-19962

Amendment No. 03

(Continued)

CONDITIONS

12. Authorized User:

Material and Use:

Pablo P. Roy, M.D.

35.100; 35.200; 35.300
In vitro studies

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material so that at no time is a quantity of radioactive material possessed in excess of a quantity which requires decommissioning funding in accordance with 10 CFR 30.35(d), 10 CFR 40.36(b), or 10 CFR 70.25(d).

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

- A. Application received April 29, 1988
- B. Letter dated October 2, 1988
- C. Letter dated January 14, 1989
- D. Letter dated March 19, 1990
- E. Letter dated July 9, 1992
- F. Letter dated July 27, 1992
- G. Letter dated September 15, 1992

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Keith D. Brown, Ph.D

By

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

Date

SEP 30 1992