

NRC FORM 313
(3-92)
10 CFR 30, 32, 33,
34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB NO 3150-0120
EXPIRES 6-30-93
ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 3:25 HOURS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNRB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555; AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

APPLICATION FOR MATERIAL LICENSE

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATION WITH:

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

ALL OTHER PERSONS FILE APPLICATION 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:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

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

IF YOU ARE LOCATED IN:

030-32637

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
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:

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8084

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

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 JURISDICTIONS.

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

☐ A. NEW LICENSE

☒ B. AMENDMENT TO LICENSE NUMBER 29-28728-01

☐ C. RENEWAL OF LICENSE NUMBER _____

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

Raritan Bay Cardiology
712 Amboy Avenue
Edison, New Jersey 08837

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

Raritan Bay Cardiology
712 Amboy Avenue
Edison, New Jersey 08837

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Michael W. Lairmore, Medical Physics Consultation

TELEPHONE NUMBER

(201) 447-3303

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 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.

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY **7C** AMOUNT
ENCLOSED **\$440.00**

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 OFFICIAL

TYPED/PRINTED NAME

TITLE

DATE

Aaron J. Feingold, M.D.

President

11/5/96

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

AMOUNT RECEIVED

CHECK NUMBER

APPROVED BY

DATE

Raritan Bay Cardiology Group

AARON J. FEINGOLD, M.D., F.A.C.C.

ABRAHAM MELTZER, M.D., F.A.C.C., F.A.C.P.

MARVIN A. RUBINSTEIN, M.D., F.A.C.C.

STAN J. WASILEWSKI, M.D.

HOWARD D. NOVECK, M.D., F.A.C.C.

□ 712 AMBOY AVENUE • EDISON, N.J. 08837 • PHONE (908) 738-8855 • FAX (908) 738-4141

□ 3 HOSPITAL PLAZA • SUITE 305 • OLD BRIDGE, N.J. 08857 • PHONE (908) 679-0100

October 21, 1996

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

RE: Amendment Application
License Number: 29-28728-01

Dear License Reviewer:

Please amend the above referenced byproduct material license to reflect the following changes:

We request that Howard D. Noveck, M.D. be granted authorization for all cardiovascular procedures listed in 35.200. Dr. Noveck has completed a minimum of 200 hours of academic and 1,000 hours of clinical training. Documentation pertaining to Dr. Noveck's training and experience has been enclosed within "Attachment A" for your examination. Please refer to this section for specific details.

Please modify Attachment B2 to allow this licensee to receive sealed source(s) (for quality assurance testing) from a manufacturer approved by the Nuclear Regulatory Commission. At the present time, this institution is limited, and may only acquire sealed sources from Atomic Products Corporation, P.O. Box R, Shirley, New York. We request authorization to be obtained from any comparable vendor.

In regards to survey meter calibration procedure found in Attachment G, we wish to modify our program to incorporate the model procedure provided within "Appendix B" to Regulatory Guide 10.8, Revision 2.

123892

Attachment H of the license application describes quality assurance procedures performed on the dose calibrator. We wish to modify our program to implement the model procedure provided within 'Appendix C to Regulatory Guide 10.8, Revision 2. In addition, will establish a tolerance level for accuracy, constancy and activity linearity of \pm ten (10) percent.

Attachment I of our license application describes quality assurance testing conducted on our gamma camera(s). We wish to modify our program to reflect the following changes:

1. A three (3) million count flood will be acquired on a daily basis to assess uniformity.
2. Weekly testing will be completed to evaluate spatial resolution.
3. Center of Rotation Analysis will be completed as specified by the manufacturer.
4. Records of camera evaluation(s) will be maintained for a minimum period of three (3) years.

Attachment J3 of the license application identifies the ALARA limits for this licensee. We request these limits be modified as follows:

| Quarterly ALARA Limits | | |
|------------------------|---------------|----------------|
| | ALARA Level I | ALARA Level II |
| Whole Body | 125 mrem | 375 mrem |
| Extremities | 1,250 mrem | 3,750 mrem |
| Lenses of the Eyes | 375 mrem | 1,125 mrem |

In regards to Attachment K of the license application, we request the following changes:

1. Leak test samples will be analyzed by a licensee approved by either the Nuclear Regulatory Commission and/or Agreement State Licensing Agency.
2. Reference sources will be used for absolute counting analysis to convert cpm to dpm to uCi and to assure the sensitivity of the detector. These sources will be of Barium-133, Cs-137 and/or Cobalt-57.

These sources will be obtained from a manufacturer approved by the Nuclear Regulatory Commission and/or Agreement State Authority. All sources will be NIST traceable and calibrated within \pm five percent.

Please modify Attachment O to correlate with regulations addressed in 10 CFR 20.1906. Specifically, packages received at this institution and evaluated for removable contamination. The external surface of the shipping container will be evaluated for removable contamination. This analysis will include a surface area of 300 cm². In addition, this evaluation will include a wipe of the locks and handles. The final source container will be evaluated if removable contamination is suspected.

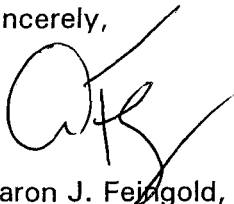
In regards to Attachment Q, Action Trigger Limits will be modified as follows:

| ALARA LIMITS | | | | |
|---------------------------------------|------------------|--------------|-------------------------|--------------|
| | Ambient Exposure | | Removable Contamination | |
| | Restricted | Unrestricted | Restricted | Unrestricted |
| Gamma-Emitters | 2.0 mR/hr | 0.05 mR/hr | 2,000 dpm | 200 dpm |
| Beta-Emitters | 2.0 mR/hr | 0.05 mR/hr | 200 dpm | 200 dpm |
| Close-Out & Termination of Operations | 0.05 mR/hr | 0.05 mR/hr | 200 dpm | 200 dpm |

If you have additional questions, please contact our offices.

We thank you in advance for your assistance.

Sincerely,



Aaron J. Feingold, M.D.
Administrative Representative

Attachment A

COOPER HOSPITAL/UNIVERSITY MEDICAL CENTER
UMDNJ/Robert Wood Johnson Medical School at Camden

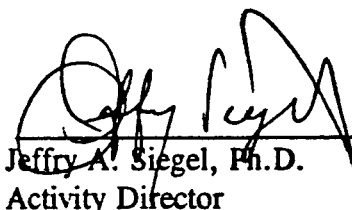
CERTIFICATE OF COMPLETION

HOWARD D. NOVECK, M.D.

Has successfully completed the course, *Basic Sciences in the Clinical Practice of Nuclear Medicine*, for 200 hours of classroom and laboratory training required by the Nuclear Regulatory Commission as set forth in 10 CFR 35.920 from March 8 to May 24, 1996.



Paul E. Wallner, D.O., FACR
Chief, Department of Radiation Oncology



Jeffrey A. Siegel, Ph.D.
Activity Director

PHILADELPHIA HEART INSTITUTE



Presbyterian Medical Center
39th and Market Streets
Philadelphia, PA 19104

Ami S. Iskandrian, M.D.
Co-Director
Philadelphia Heart Institute
215-662-9068

July 13, 1993

Howard D. Noveck, M.D.
533 New Brunswick Avenue
Perth Amboy, NJ 08861

Dear Howard:

Thank you for your letter of June 28, 1993. I hereby confirm that you participated in our nuclear cardiology reading sessions for over 500 hours.

I hope all is well, and look forward to seeing you in our upcoming meetings.

Sincerely,

Ami S. Iskandrian, M.D.

ASI/sjk

Week #1 Friday, March 8, 1996

BASIC NUCLEAR PHYSICS & RADIATION DECAY

- 8-9 AM: Welcome and Orientation (JAS)
- 9-11 AM: Basic Atomic and Nuclear Physics (JAS)
- 11-12 PM: Radioactive Decay I (JAS)
- 12-1 PM: Lunch
- 1-2 PM: Radioactive Decay II (JAS)
- 2-3 PM: Activity and Exponential Decay (JAS)
- 3-4 PM: Parent-daughter Decay (JAS)
- 4-6 PM: Mo-Tc Generator and Decay Examples (JAS)

Week #2

Friday, March 15, 1996

**INTERACTIONS OF PARTICLES & PHOTONS WITH MATTER,
BASIC MATHEMATICS REVIEW, AND NUCLEAR COUNTING
STATISTICS**

- 8-9 AM: Interactions of Charged Particles With Matter (JAS)**
- 9-10 AM: Interactions of Photons With Matter (JAS)**
- 10-12 PM: Attenuation: Broad and Narrow Beam Geometry (JAS)**
- 12-1 PM: Lunch**
- 1-2 PM: Basic Math Review (JAS)**
- 2-4 PM: Nuclear Counting Statistics (JAS)**
- 4-6 PM: Statistical Tests, Sensitivity, Specificity, Regression Analysis (JAS)**

Week #3 Friday, March 22, 1996

ABSORBED DOSE ESTIMATES AND THE GAMMA CAMERA

- 8-9 AM: Calculation of Absorbed Dose Estimates (JAS)
- 9-10 AM: Medical Internal Radiation Dose (MIRD) Schema (JAS)
- 10-11 AM: Biodistribution Kinetics (JAS)
- 11-12 AM: Absorbed Dose Examples (JAS)
- 12-1 PM: Lunch
- 1-2 PM: Gamma Camera: Basic Principles (JAS)
- 2-3 PM: Gamma Camera: Collimators
- 3-4 PM: Gamma Camera: Image Display and Performance Characteristics (JAS)
- 4-6 PM: New Gamma Camera Technology and Gamma Camera Imaging:
Particles vs Photons (JAS)

Week #10 Friday, May 17, 1996

**IMAGING AND COUNTING EQUIPMENT, MRI, QUALITY
ASSURANCE, AND QUANTITATIVE ANALYSIS**

- 8-9 AM: The Four R's of Radiotherapy Biology (JAS)
- 9-10 AM: DNA Damage and the Radiolysis of Water (JAS)
- 10-12 PM: Magnetic Resonance Imaging - MRI (JAS)
- 12-1 PM: Lunch
- 1-3 PM: Quality Assurance and Quality Control in Nuclear Medicine (JAS)
- 3-4 PM: Data Processing of In Vivo and In Vitro Studies (JAS)
- 4-6 PM: Quantitative Image Analysis and Image Fusion (JAS)

Week #11 Friday, May 24, 1996

QUALITY CONTROL, MRI, AND THERAPEUTIC USES OF RADIATION

- 8-9 AM: Gamma Camera Quality Control Laboratory (JAS)
- 9-10 AM: Computers and Image Digitization (JAS)
- 10-12 PM: MR Pulse Sequences (JAS)
- 12-1 PM: Lunch
- 1-3 PM: Monoclonal Antibodies: Diagnosis and Therapy (JAS)
- 3-5 PM: Percutaneous Transluminal Coronary Angioplasty (PTCA)
and Effect of Radiation on Intimal Hyperplasia (JAS)
- 5-6 PM: Review and Course Wrap-up (JAS)