NRC FORM 374 (7-94) U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 2 PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Medical Management Concepts d.b.a. Academy Diagnostic Imaging(MMC/ADI)	3. License Number 37-30326-01
2. 9140 Academy Road Philadelphia, Pennsylvania 19114	4. Expiration Date August 31, 2001
	5. Docket or Reference No. 030-34202

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200 except generators and gas	B. As needed

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.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 9140 Academy Road, Philadelphia, Pennsylvania.

11. A. The licensee may not possess and use materials authorized in Items 6, 7, and 8, until: (1) the licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and (2) the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 has been notified in writing that activities authorized by the license will be initiated.

B. In accordance with the requirements set forth in 10 CFR 30.36(b), 40.42(b), and 70.38(b), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing, of a decision not to complete the facility, acquire equipment, or possess and use authorized material.

12. The Radiation Safety Officer for this license is S. Chivukula, M.D.

ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 37-30326-01

Docket or Reference Number: 030-34202

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

Authorized Users	Material and Use
Sung M. Kim, M.D.	35.100; 35.200
S. Chivukula, M.D.	35.100; 35.200 for cardiovascular clinical procedures
Charles M. Intenzo, M.D.	35.100; 35.200

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

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

16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated April 15, 1996
B. Letter dated August 9, 1996

For the U.S. Nuclear Regulatory Commission

Date AUG 26 1996

By Original Signed By;
Michelle Beardsley

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

AUG 26 1996

License No. 37-30326-01
Docket No. 030-34202
Control No. 123450

Jeffrey Mandler
President/ CEO
Medical Management Concepts
d.b.a. Academy Diagnostic Imaging (MMC/ADI)
9140 Academy Road
Philadelphia, PA 19114

Dear Mr. Mandler:

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

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

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," 10 CFR Part 35, "Medical Use of Byproduct Material," and other applicable regulations.

2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:

   a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and

   b. you have notified the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 in writing, that activities authorized by the license will be initiated.

3. Notify NRC, in accordance with 10 CFR 35.14, no later than 30 days after:

   a. the date that you permit any individual to work as an Authorized User or an Authorized Nuclear Pharmacist pursuant to 10 CFR 35.13(b)(1) through (4), and provide to the Commission a copy of the board certification, the Commission or Agreement State license, or

the Permit issued by a licensee of broad scope identifying the individual;

b. an Authorized User, Authorized Nuclear Pharmacist, Radiation Safety Officer, Teletherapy Physicist, or Medical Physicist permanently discontinues performance of duties under the license or has a name change; or

c. when the mailing address on the license changes (no fee is required if the location of byproduct material remains the same).

4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

a. when you decide to terminate all activities involving materials authorized under the license; or

b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.

5. In accordance with 10 CFR 35.13, request and obtain a license amendment before you:

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

b. permit an individual, except as specified in 10 CFR 35.14(b)(1) through (4), to work as an Authorized User or Authorized Nuclear Pharmacist under the license;

c. change Radiation Safety Officer, Teletherapy Physicist or Medical Physicist;

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

e. add or change the areas of use, or address or addresses of use identified in the license application or on the license.

6. Receive written approval from the NRC prior to any change in ownership of your organization, in accordance with 10 CFR 30.34(b).

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

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

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

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

Thank you for your cooperation.

Sincerely,

Original Signed By:
Michelle Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

License No. 37-30326-01
Docket No. 030-34202
Control No. 123450

Enclosures:
1. License No. 37-30326-01
2. 10 CFR Parts 2, 19, 20, 30, 31, 35, and 170

DOCUMENT NAME: R:\WPS\MLTR\L3730326.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Beardsley MB							
DATE	08/25/96		08/ /96		08/ /96		08/ /96	

OFFICIAL RECORD COPY

August 23, 1996

Ms. Michelle Beardsley
US NRC Region I
475 Allendale Road
King of Prussia, PA 19406

RE: Document Control # 123450

Dear Ms. Beardsley,

In order to expedite the processing of our license application, we request that you remove Dr. Figuero-Cruz from our list of Authorized Users.

If you have any further questions, please feel free to contact myself, or Jim Fongheiser of my staff at, (610) 768-1555.

Sincerely,

Jeffrey Mandler
President / CEO

JM/mlp

Medical Management Concepts
900 E. Eighth Avenue, Suite 200 King of Prussia, PA 19406

Nuclear Imaging Systems, Inc.
900 East 8th Avenue, Suite 200
King of Prussia, PA 19406
Phone (610) 768-1555
(800) 394-2620 FAX (610) 768-1566

Nuclear Imaging Systems

MS 16
J-1

August 9, 1996

Michelle R. Beardsley
US NRC Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Docket No. 030-34202
Control No. 123450

Dear Ms. Beardsley,

This letter is in response to your July 27, 1996 request for additional information regarding the referenced license application. I hope the following information will help to answer your concerns.

1. I have requested information on Temple's Nuclear Cardiology program and will forward that information as soon as possible.

2. We confirm that we will maintain training records which include:

   Date, Duration, Topics Covered, Attendees, and Individual Providing Training.

3. Our package opening procedure will include trigger levels based on package label. In order to simplify, we would prefer to use contact dose rate trigger levels of:

   White I $<$ 0.5 mr/hr
   Yellow II $\geq$ 0.5 mr/hr and $<$ 50 mr/hr

   We do not expect to receive packages that would exceed these levels and will not receive any Yellow III packages. These limiting conditions would eliminate the need for a trigger level for the 1 meter dose rate.

4. Portable survey meters available will include:

   1 Ludlum Model 3 Survey Meter
   1 Ludlum Model 14C Survey Meter

5. The instrument to be used to count area wipes will be a Ludlum 2200 rate meter with a Model - 243 NaI well detector.

6. The proposed location is not currently occupied but is being renovated. Renovation is nearly complete and equipment will begin arriving for set-up during the week of August 12, 1996. Radioactive source delivery will be scheduled contingent upon receipt of appropriate radioactive materials license.

7. If you have any other questions, please feel free to contact Jim Fongheiser of my staff at, (610) 764-1555.

Sincerely,

Jeffrey Mandler/un

Jeffrey Mandler
President/CEO

JM/mlp

JUL 27 1996

Docket No. 030-34202
Control No. 123450

Jeffrey Mandler
President/CEO
Medical Management Concepts
d.b.a. Academy Diagnostic Imaging (MMC/ADI)
9140 Academy Road
Philadelphia, PA 19114

Dear Mr. Mandler:

This is in reference to your application dated April 15, 1996 for a byproduct materials license. In order to continue our review, we need the following additional information:

1. Regarding your request to authorize Dr. Figueroa-Cruz, please provide confirmation that Temple University's Nuclear Cardiology program is approved by the Accreditation Council for Graduate Medical Education as required by 10 CFR 35.920 (c).

2. Your application states that you will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2. Please confirm that you will maintain records of worker training which include the date and duration of training, the topics covered, the name(s) of the individual(s) providing training and the names of attendees.

3. Please confirm that your package opening procedures will include trigger levels based on the package label (e.g. White I, Yellow II/III) for both of the surveys taken at one meter and the package surface.

4. A licensee authorized to use radioactive material for imaging and localization is required by 10 CFR 35.220 (enclosed) 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 these requirements for a measurement survey instrument and a detection survey instrument.

5. Your area survey procedure describes a method for performing wipe tests that is sufficiently sensitive to detect 2000 disintegrations per minute per 100 square centimeters (dpm/100 cm^2) of removable contamination and 200 dpm/100 cm^2 if you are using iodine-131. Please describe the instrument you will use to perform these measurements.

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6. Please indicate the status of the proposed location of use (i.e. pre/under construction) if in existence, indicate its current use.

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. 123450. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-6942.

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:

Michelle R. Beardsley
Division of Nuclear Materials Safety

Docket No. 030-34202
Control No. 123450

Enclosures:
1. 10 CFR Parts 20 and 35

DOCUMENT NAME: R:\WPS\DLTR\D3034202
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Beardsley MB							
DATE	07/23/96		07/ /96		07/ /96		07/ /96	

OFFICIAL RECORD COPY

MM
CONCEPTS

L&L 30326
030-34202
02201

April 12, 1996

Ms. Pamela Henderson
US NRC Region I
Licensing Assistance Section
475 Allendale Road
King of Prussia, PA 19408-1415

SUBJECT: APPLICATION FOR MATERIAL LICENSE

Dear Ms. Henderson,

Enclosed for your review is our Application for a Material License, and a $1,300.00 check for the license processing fee.

We will be performing general diagnostic nuclear imaging at this facility.

If you have any questions concerning this application, please do not hesitate to contact me at (610) 768-4540.

Sincerely,

Jeffrey Mandler
President/CEO

JM/mlp

enclosures: Application (2 copies)
$1,300.00 Application Fee

123450

Medical Management Concepts
900 E. Eighth Avenue, Suite 200 King of Prussia, PA 19406

JUL 18 1996

NRC FORM 313 (6-93)
10 CFR 30, 32, 33, 34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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 APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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:

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 LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD
LISLE, IL 60532-4351

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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

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

L&L 30326
030-34202
02201

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)*

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Medical Management Concepts trading as:
Academy Diagnostic Imaging (MMC/ADI
9140 Academy Road
Philadelphia, PA 19114

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

Same As Above

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Jim Fongheiser

TELEPHONE NUMBER
(610) 768-1555

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 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 7 C AMOUNT ENCLOSED $1,300.00

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, 36, 39 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.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Jeffrey Mandler President/CEO	Yes.	4-15-96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		

APPROVED BY | DATE

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123450

JUL 18 1996

List of Attachments

Attachments 5 and 6
Radioactive Material and Purposes

The following byproduct materials and purposes are requested :

Byproduct Material	Amount	Purpose
5.a Materials in 35.100	As Needed	Medical use
5.b Materials in 35.100	As Needed	Medical Use

None of the following materials will be used :

Generators

Radioactive Gases

Iodine-131 in quantities greater than 30 uCi

Aerosol lung scans may be performed. We will utilize only single use kits from the pharmacy, which employ a shielded trap for the collection of spent aerosols. In accordance with Reg. Guide 10.8, Appendix O, negative pressure rooms, additional ventilation considerations, and the monitoring of trap effluents is not required for the use of these single use devices.

No Quality Management Program (QMP) will be required.

Attachment 7
Training and Experience

Summary:

7A S Chivukula, M.D.

Currently serving as **Authorized User** and / or
Radiation Safety Officer on
the following licenses:

NRC - 37-28584-01 (A.U.)
NRC - 37-28248-01 (A.U., RSO)
PA - 0558 (A.U., RSO)

7B Betsic Figueroa-Cruz, M.D.

See Attached

7C Sung M. Kim, M.D.

NRC 792H Thomas Jefferson University Hospital (A.U.)
(see attached)

7D Charles M. Intenzo, M.D.

NRC 792H Thomas Jefferson University Hospital (A.U.)
(see attached)

TEMPLE UNIVERSITY HOSPITAL
DEPARTMENT OF DIAGNOSTIC IMAGING
DIVISION OF NUCLEAR MEDICINE

Alan H. Maurer, M.D.
Professor of Diagnostic Imaging
Director, Division of Nuclear Medicine

Broad & Ontario Streets
Philadelphia, PA. 19140
(215)707-8269

February 9, 1996

Gaetano Capone, M.D.
Nazareth Physicians Office Building
Suite 207
2701 Holme Avenue
Philadelphia, PA. 19152

Re: Betsy Figueroa, M.D.

Dear Dr. Capone:

This is to certify that Dr. Betsy Figueroa served as a Cardiology Fellow in Nuclear Medicine during the academic year July 1, 1994 through June 30, 1995. During that time she spent 6 months as a Fellow in Nuclear Cardiology. Dr. Figueroa participated in all aspects of our Nuclear Medicine Training Program including 200 hours of classroom and laboratory training in the basic sciences associated with Nuclear Medicine

I believe therefore that she has completed the necessary requirements for NRC licensing.

Sincerely,

Alan H. Maurer, M.D.

AHM/om

copy to: Betsy
bwr
my file
original sent to
Sankoff

CURRICULUM VITAE
BETSIE FIGUEROA-CRUZ
1995

Name: Betsie Figueroa-Cruz

Date of Birth: [redacted]

Civil Status: [redacted]

Citizenship: [redacted]

Social Security Number: [redacted]

Permanent Address: [redacted]

Home Telephone: [redacted]

Employment: Temple University Hospital
Non-Invasive Cardiology Laboratory
3401 North Broad Street
Philadelphia, PA 19140

Employment Telephone: (215) 707-3344

EDUCATION & DEGREES:

July 1994 to Present: Temple University Hospital
4th Year Non-Invasive Fellowship
Cardiology Non-Invasive Laboratory
Philadelphia, PA 19140

July 1990 - June 1993 VA Medical Center
UPR - School of Medicine
Cardiology Section (111A)
One Veterans Plaza
San Juan, PR
Fellowship - Cardiology

July 1988 - June 1990 VA Medical Center
UPR School of Medicine
Internal Medicine Service
One Veterans Plaza
San Juan, PR
Residency - Internal Medicine

EDUCATION AND DEGREES (continued):

July 1987 - June 1988	VA Medical Center UPR School of Medicine Internal Medicine Service One Veterans Plaza San Juan, PR Internship - Internal Medicine
1983 - 1987	University of Puerto Rico School of Medicine San Juan, PR Year of Graduation - June 1987 Doctor in Medicine (M.D.)
1979 - 1983	University of Puerto Rico Mayaguez Campus Mayaguez, PR Year of Graduation - June 1983 B.S. Chemistry
1976 - 1979	Guanica High School (10-12) Guanica, PR
1973 - 1976	Teresita N. Siurano (7-9) Intermediate School Ensenada, PR
1967 - 1973	Jose Rodriguez School (1-6) Elementary School Ensenada, PR

CERTIFICATION:

1. Certified by the National Board of Internal Medical Examiners NEME #350526.
2. Certified by the American Board of Internal Medicine, September 1990.
3. Certified by the American Board of Cardiovascular Diseases, #134172, November 1993.

MEMBERSHIP IN MEDICAL PROFESSIONAL & SCIENTIFIC SOCIETIES:

1. Member of American College of Physicians
2. Fellow American College of Cardiology
3. UPR Exalumni Association
4. Puerto Rican Medical Society
5. American Medical Association

LICENSES:

July 1993 - Puerto Rico License #11227

July 1994 - Pennsylvania License #MD-053203-L

HONORS AND AWARDS:

1986 - 1994	Alpha Omega Alpha Honor Society San Juan, PR
1992	Recognition by Lion's Club Woman's Year Excellence Achievement Guanica, PR
1990	Recognition by Lion's Club East Chapter High Academic and Social Achievement Mayaguez, PR
1987	UPR School of Medicine Excellence Award San Juan, PR
1979 - 1987	Dean List UPR Mayaguez Campus Mayaguez, PR
1979 - 1983	Honor Student Chemical Society University of Puerto Rico Mayaguez Campus Mayaguez, PR
	Honor Student Chemistry Department Magna Cum Laude UPR - Mayaguez Campus Mayaguez, PR

EMPLOYMENT:

July 1994 to Present:	Temple University Hospital 4th Year Non-Invasive Fellowship Cardiology Non-Invasive Laboratory Philadelphia, PA 19140

EMPLOYMENT (CONTINUED):

September 1993 - June 1994	VA Medical Center Internal Medicine/Cardiology One Veteran Plaza San Juan, PR Staff Physician Cardiac Ultrasound Laboratory Co-Director
1989 - 1993	VA Medical Center Emergency Room One Veteran Plaza San Juan, PR Fee Basis Physician/ Emergency Room (OD)
July 1990 - June 1993	VA Medical Center Cardiology Section One Veterans Plaza San Juan, PR Cardiology Fellowship

TRAINING AND EXPERIENCE:

A. Teaching and Supervision:

1. Teaching (with interns, residents, medical students, graduate students, cardiology fellows).

2. Supervision of medical students and trainees at the following institutions:

   a. The VA Medical Center, San Juan, PR
   b. University Hospital, San Juan, PR
   c. San Juan City Hospital, San Juan, PR
   d. Temple University Hospital, Philadelphia, PA

B. Research Experience:

Cardiology Fellowship	The use of Dobutamine Stress Echocardiography for Risk Stratification in Patients Admitted to CCU with Unstable Angina. Proctor: Edgardo Hernandez
Residency	Senior Project: Protocol of Methacoline for Hyperreactivity of the Airways. Effect of Capoten in Hyperreactive Airways. Proctor: Dr. Arturo Cordova (Past Chief of Pneumology Section at the San Juan VA Medical Center). Presented at the A.C.P. Regional Meeting, San Juan, PR.

TRAINING AND EXPERIENCE (continued):

Medical School	Six weeks rotation at the San Juan Geriatric Unit. Project: Protocol for Prevention and Treatment of Stress Ulcer. (Approved for all the Centers of Puerto Rico)

C. Research Projects:

a. The Use of Dobutamine Stress Echocardiography for Risk Stratification in Patients Admitted to CCU with Unstable Angina.
Dr. Edgardo Hernandez, Dr. Betsie Figueroa, Dr. J.F. Rodriguez

b. Dobutamine MUGA for the Detection of Viable Myocardium in Patients Scheduled for Revascularization. Presented at the A.C.C. Puerto Rico Chapter Meeting, October 1993. Proctors: Dr. Edgardo Hernandez, Dr. Esteban Linares

c. Use of Echocardiography and Late Potential EKG Amplitude in the Detection of Ventricular Hypertrophy and Regression of LVH.
Presented at the A.C.P. Regional Meeting, San Juan, PR, August 1993.
Dr. Edgardo Hernandez, Dr. Ignacio Gallardo, Dr. Betsie Figueroa, Dr. J. Mercados

d. Cardiac Source of Emboli in Patients with Atrial Flutter vs. Atrial Fibrillation: A comparative echocardiography study. Presented at the A.C.P. Regional meeting, San Juan, PR, 1994 (Second prize). Dr. Betsie Figueroa, Dr. Esteban Linares.
Presented at the ACP Regional meeting, San Juan, PR, September 1994 (second prize).

e. Transesophageal Echocardiographic findings in patients with small vessel ischemic infarct. (In process.) Dr. Betsie Figueroa, Dr. Y. Reyes, Chief of Stroke Section, Neurology Department, VA Medical Center, San Juan, PR.

f. Gender effects of smaller left ventricular size on diagnostic accuracy of SPECT TL-201 are not improved with deconvolving filters. 1995 A.C.C. Scientific Abstract. Dr. C.L. Hansen, Dr. Betsie Figueroa, Dr. Vince Sorrell. Temple University Philadelphia, PA.

g. Accuracy of persantine-TL 201 for the detection of coronary anteriopathy in patients with Heart Transplants. Dr. C.L. Hansen, Dr. Betsie Figueroa, Dr. Vince Sorrell, Temple University Hospital, Philadelphia, PA.

h. IPPA Assessment of Viability in Multicenter Trails. Dr. C.L. Hansen, Dr. Betsie Figueroa, Dr. Vince Sorrell. Temple University Hospital, Philadelphia, PA.

i. A Multi-Center, Multi-National Study to Evaluate the Clinical Utility and Safety of the Genesa System to Diagnose Coronary Artery Disease in Patients with known or suspected Coronary Artery Disease. Dr. John Panidis, Dr. Betsie Figueroa, Dr. Vincent Sorrell, Temple University Hospital, Cardiac Ultrasound Laboratory, Philadelphia, PA.

TRAINING AND EXPERIENCE (continued):

D. Procedures:

a. Left heart catheterization (200)
b. Right heart catheterization (200)
c. Temporary pacemaker (50)
d. Permanent pacemaker (Assistant) (30)
e. Stress-Thallium (355)
f. Stress-Echo 80)
g. Stress Test (500)
h. Echocardiograms (3,000)
i. Transesophageal Echocardiograms (400)

HOBBIES AND ACTIVITIES:

Volleyball
Swimming
Music
Guitar Player
Singer with Church Choir

REFERENCES:

1. Alfred A. Bove, M.D., Ph.D.
Chief of Cardiology Section
Temple University Medical School
3401 N. Broad Street
Philadelphia, PA 19140

2. John P. Panidis, M.D.
Cardiology Section
Temple University Medical School
3401 N. Broad Street
Philadelphia, PA 19140

3. Christopher L. Hansen, M.D.
Co-Director, Nuclear Cardiology Laboratory
Temple University Medical School
3401 N. Broad Street
Philadelphia, PA 19140

4. Ileana Pina
Director, Congestive Health Failure Section
Temple University Medical School
3401 N. Broad Street
Philadelphia, PA 19140

5. Edgardo Hernandez, M.D.
Chief of Cardiology Section
VA Medical Center
One Veterans Plaza
San Juan, PR 00927-5800

THE

AMERICAN BOARD OF INTERNAL MEDICINE

INCORPORATED 1936

ATTESTS THAT

Betsie Figueroa-Cruz

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS HEREBY CERTIFIED FOR THE PERIOD 1993 THROUGH 2003 AS A DIPLOMATE IN

CARDIOVASCULAR DISEASE

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AMERICAN BOARD OF INTERNAL MEDICINE

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AMERICAN BOARD OF INTERNAL MEDICINE

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NUMBER 134172

1993

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

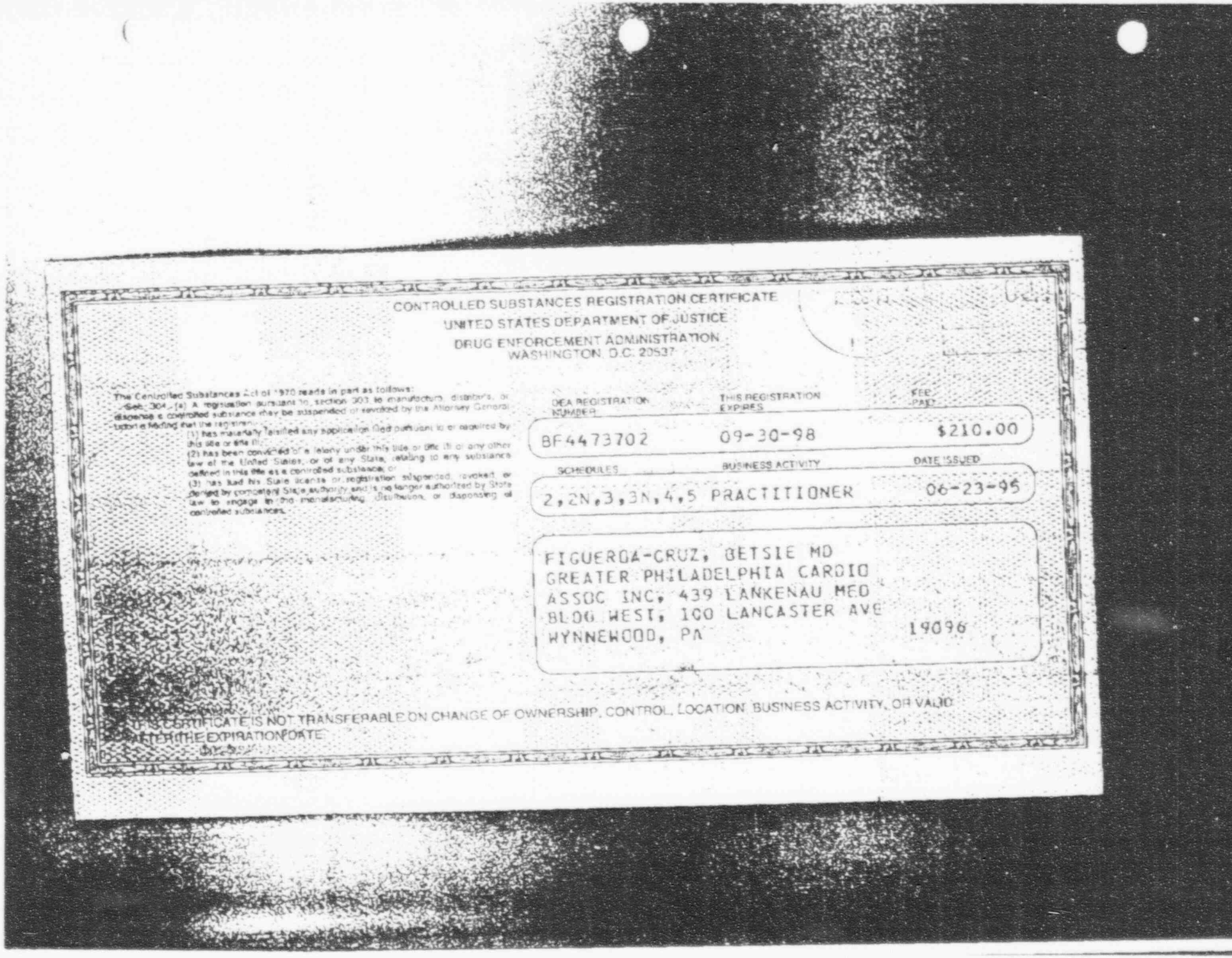
The Controlled Substances Act of 1970 reads in part as follows:
Sec. 304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant—
(1) has materially falsified any 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 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	THIS REGISTRATION EXPIRES	FEE PAID
BF4473702	09-30-98	$210.00

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3,3N,4,5	PRACTITIONER	06-23-95

FIGUEROA-CRUZ, BETSIE MD
GREATER PHILADELPHIA CARDIO
ASSOC INC, 439 LANKENAU MED
BLDG WEST, 100 LANCASTER AVE
WYNNEWOOD, PA 19096

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID
AFTER THE EXPIRATION DATE



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UNITED STATES DEPARTMENT OF JUSTICE
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AFTER THE EXPIRATION DATE

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
P.O. BOX 2649 Harrisburg, PA 17105-2649

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

Classification

MEDICAL PHYSICIAN AND SURGEON

Certificate Number	Certification Date	Issued	Expires
MD-053203-L	MAY 18 1995	JUN 27 1995	DEC 31 1996

Issued To:

BETSIE FIGUEROA-CRUZ
553 LANKENAU
MEDICAL OFFIC BLDG E
100 LANCASTER AVENUE
WYNNEWOOD PA 19096

Signature

Dorothy Childress

Commissioner of Professional and Occupational Affairs

ALTERATION OF THIS DOCUMENT IS A CRIMINAL OFFENSE UNDER 18 PA.C.S.S. 4911

Department of Veterans Affairs

Certificate of Residency

This Certificate is awarded to

Belsie Figueroa-Cruz, MD

by the Veterans Health Services and Research Administration

upon satisfactory completion of a Residency in

The Medical Subspecialty of Cardiology

from July 1, 1990 *to* June 30, 1995

At the Veterans Affairs Medical Center

San Juan, Puerto Rico

SERVICE CHIEF

CHIEF OF STAFF

SECTION CHIEF

DEAN, UPR SCHOOL OF MEDICINE

MEDICAL CENTER DIRECTOR

Temple University Hospital

Philadelphia, Pennsylvania

This is to certify that

Betsie Figueroa, M.D.

has satisfactorily performed the duties of

Fellow in Cardiology

in the Department of Internal Medicine

from July 1, 1994 to June 30, 1995

In witness whereof the undersigned have affixed their signatures this thirtieth day of June, 1995.

Paul Doehring
Executive Director

Lisa Cohen
Professor and Chairman of Department

American College of Cardiology

This is to Certify That

Betsie Figueroa

Has Been Elected a

FELLOW

August 31, 1994

Daniel J. Ullyot
President

Patricia J. Scanlon MD
Secretary

CURRICULUM VITAE
Sung M. Kim, M.D.

HOME ADDRESS: [redacted]

OFFICE ADDRESS: Division of Nuclear Medicine
Dept. of Radiology
Thomas Jefferson University Hospital
11th & Walnut Streets
Philadelphia, Pennsylvania 19107
TEL. : 215-955-6707

CITIZENSHIP: [redacted]

MARITAL STATUS: [redacted]

DEGREES: March 1973- February 1975 Premedical, Yonsei University
March 1975- February 1979 M.D., Yonsei Medica School, Yonsei University
Seoul, Korea

PROFESSIONAL EXPERIENCE:

June 1979 - June 1980	Clinical Clerkship St. Joseph's Hospital Philadelphia, PA
July 1980 - June 1981	Internship General Surgery St. Mary's Hospital Waterbury, Connecticut
July 1981 - June 1983	Resident General Surgery St. Mary's Hospital Waterbury, Connecticut
July 1985 - June 1987	Nuclear Medicine Resident Division of Nuclear Medicine Dept. of Radiation Oncology & Nuclear Medicine Thomas Jefferson University Hospital Philadelphia, PA 19107

Sung M. Kim, M.D.

July 1987 - June 1988	Fellow in Nuclear Medicine Division of Nuclear Medicine Dept.of Radiation Oncology & Nuclear Medicine Thomas Jefferson University Hospital Philadelphia, PA 19107
July 1988 - June 1989	Instructor Division of Nuclear Medicine Dept. of Radiation Oncology & Nuclear Medicine Thomas Jefferson University Hospital
July 1989 - June 1994	Assistant Professor Division of Nuclear Medicine Dept. of Radiation Oncology & Nuclear Medicine Thomas Jefferson University Hospital
July 1994 - present	Assistant Professor Div. of Nuclear Medicine Dept. of Radiology Thomas Jefferson University Hospital

CERTIFICATION

February 1980	Certified by Education Committee of Foreign Medical Graduate (ECFMG)
September 1983	Certified by Federal Licensing Examination (FLEX)
September 1983	Connecticut Medical License #24451
July 1985	Pennsylvannia Medical License #MD-034173-E
September 1987	Certified by American Board of Nuclear Medicine

Suug M. Kim, M.D.

PROFESSIONAL MEMBERSHIPS

The American Medical Association
The Society of Nuclear Medicine
American College of Nuclear Physician
American Society of Nuclear Cardiology
American College of Radiology

Membership in Committees

Member, Committee on Brain Counsel, Society of Nuclear Medicine

Member, Committee on Computer and Instrument Council, Society of Nuclear Medicine

Member, Nuclear Medicine Science Committee, American College of Nuclear Physician

Member, Radiopharmaceutical Affairs Committee, American College of Nuclear Physician

Honor & Award

Medical School Scholarship, Yonsei University, School of Medicine. March 1977
Secretary - Korean American Society of Nuclear Medicine, 1993- present
Secretary, Severance Alumni Association of Greater Delaware Valley 1992, 1993-1995
Board of Director, Severance Alumni association of America, 1994 -present
Chairman, Scientific Committee, Annual Severance Reunion and Scientific Symposium, Severance Alumni Association of America, 1995
Dr. Edward O'Hara for Excellence in Teaching Award, June, 1995

CURRICULUM VITAE

CHARLES M. INTENZO, M.D.

Home Address: [redacted]

Telephone: [redacted]
(215) 955-7871 (work)

Hospital Address:
Division of Nuclear Medicine
Department of Radiology
Thomas Jefferson University Hospital
11th and Walnut Streets
Philadelphia, Pennsylvania 19107

Social Security Number: [redacted]

Place of Birth: [redacted]

Marital Status: [redacted]

Education:

1972-1976	B.S. - Biology St. Joseph's University Philadelphia, Pennsylvania
1976-1980	M.D. Hahnemann University Philadelphia, Pennsylvania

Postgraduate Training:

1980-1981	Intern, Internal Medicine Graduate Hospital Philadelphia, Pennsylvania
1981-1982	Resident, Diagnostic Radiology Temple University Hospital Philadelphia, Pennsylvania
1982-1984	Resident, Nuclear Medicine Thomas Jefferson University Hospital Philadelphia, Pennsylvania
1984-1986	Clinical Fellow, Nuclear Medicine Thomas Jefferson University Hospital Philadelphia, Pennsylvania

Faculty Appointments

1986-1987	Instructor, Nuclear Medicine Thomas Jefferson University Hospital Philadelphia, Pennsylvania
1987- 6/93	Asst. Professor, Nuclear Medicine Thomas Jefferson University Hospital Philadelphia, Pennsylvania
7/93-Present	Assoc. Professor, Nuclear Medicine Thomas Jefferson University Hospital
1/95 - 6/95	Acting Director, Nuclear Medicine Thomas Jefferson University Hospital
1/96 - Present	Director, Nuclear Medicine Thomas Jefferson University Hospital

Licensure: Pennsylvania (MD-025932-E)

Certification: 1984 American Board of Nuclear Medicine

Awards and Honors:

1972	Awarded John McKee Scholarship
1973-1975	Dean's List, St. Joseph's University
1973-1976	St. Joseph's University Academic Honors Program
1976	Graduated Cum Laude St. Joseph's University
1985	Awarded runner-up prize in Associates Competition for presented abstract entitled "Use of Radiolabeled Leukocytes for Occult Abscess Detection" at the Eastern Scientific Assembly Meeting of the American College of Physicians, Morgantown, West Virginia October, 1985

Committee Appointments

Quality Improvement Committee, Thomas Jefferson University Hospital
Quality Assurance Committee, Dept. of Radiology
Hospital Affiliations Committee, Thomas Jefferson University Hospital
Government Relations Committee of the American College of Nuclear Physicians

Membership in Professional and Scientific Societies

Society of Nuclear Medicine
American College of Radiology
American College of Nuclear Physicians
American College of Physicians
Association of Practicing Physicians of America
Pennsylvania Radiological Society
Radiologic Society of North America
American Society of Nuclear Cardiology

Lectures/Conferences Given

Radiology 401 Students

General Nuclear Medicine	9/16/87
General Nuclear Medicine	9/23/87
General Nuclear Medicine	9/30/87
General Nuclear Medicine	10/14/87
General Nuclear Medicine	10/21/87
Lung Imaging	10/28/87
General Nuclear Medicine	11/11/87
Nuclear Cardiology	11/18/87
General Nuclear Medicine	11/25/87
General Nuclear Medicine	2/3/88
General Nuclear Medicine	3/2/88
Nuclear Cardiology	3/14/88
General Nuclear Medicine	4/11/88
General Nuclear Medicine	5/11/88

Extradepartmental

"Nuclear Cardiology." Department of Anesthesiology Grand Rounds, Jefferson Hospital; March 4, 1987

"Radionuclide Myocardial Imaging in Coronary Heart Disease." Endocrine Grand Rounds Medical College of Pennsylvania; March 29, 1989.

"I-131 Therapy in Thyroid Cancer." Endocrine Grand Rounds, Medical College of Pennsylvania; March 30, 1990.

"Radioisotope Thyroid Imaging." Endocrine Grand Rounds, Medical College of Pennsylvania, March 28, 1992.

"Radioiodine Therapy in Hyperthyroidism." Endocrine Grand Rounds, Lankenau Hospital, March 16, 1994.

"Neuroendocrine Tumor Imaging." Endocrine Grand Rounds, Lankenau Hopsital, January 19, 1995.

"Thyroid Scintigraphy." Radiology Lecture Series, Hahnemann University, February 20, 1995.

Attachment 8
Radiation Safety Training

The following training program for individuals working with or in close proximity to radioactive material is based on Appendix A to Reg. Guide 10.8, Rev. 2. Other individuals will be given instruction commensurate to the hazard of their working conditions.

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instructions for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. Licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. Worker's right to be informed of occupational radiation exposure and bioassay results.
9. Locations where the license has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence).
10. Question and answer period.

Attachment 9
Facilities and Equipment

Hot Lab:

The hot lab is the location where radiopharmaceuticals are stored, prepared and dispensed. Lead bricks or lead lined storage modules are used to provide shielding where necessary. The hot lab has an "L" block present. Additional lead shielding is used around the "L" block where necessary. Absorbent, plastic backed paper is used to line the counter tops where radioactive material is used.

Storage of Radioactive Material and Waste:

Lead lined (1/8 inch) disposal cans are present in the hot lab areas for the storage of radioactive waste. Lead lined (1/8 inch), or equivalent, storage modules are present for the storage of radioactive material.

Additional Safety Equipment:

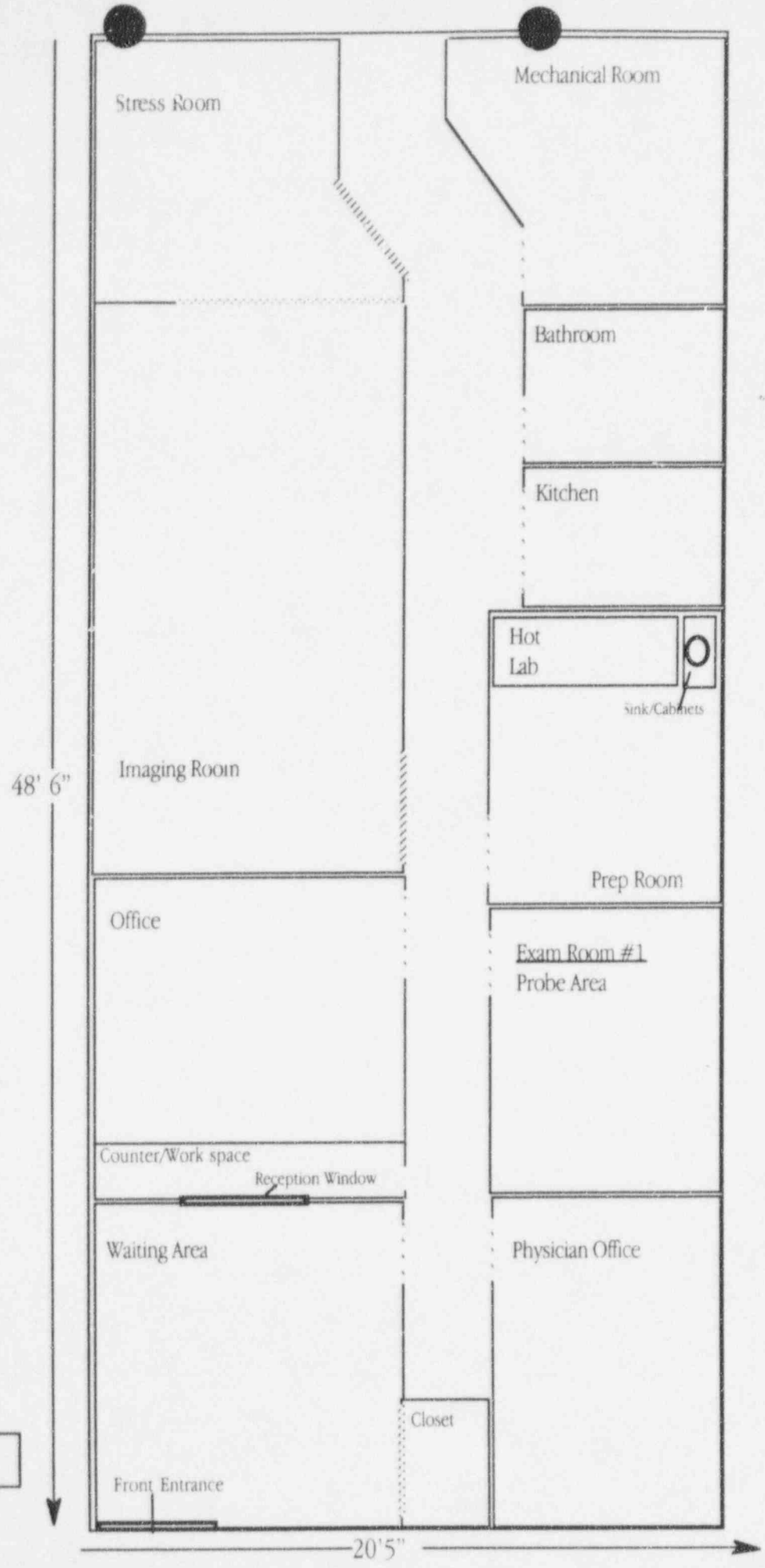
The following safety equipment is also present for use at the licensee's facility and at locations where radiopharmaceuticals are used.

syringe shields
syringe carriers
disposable protective gloves
absorbent pads
remote handling devices
lead equivalent L-block
lead shields for vial storage
lead bricks (as needed)
lead lined storage modules
lab coats

Facility Diagrams:

See Attached.

ACADEMY
DIAGNOSTIC
IMAGING



Scale 1" = 5'

ALARA Program

The following program is based on Appendix G to Reg. Guide 10.8, Rev. 2

1. Management Commitment

a. Management is committed to the program as 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.

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 reasonable 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. ALARA Program

a. Delegation of Authority

1) Management delegates the authority to the RSO for enforcement of the ALARA concept.

2) Management will support the RSO when it is necessary for the RSO to assert authority.

3) Designees may be appointed to assist with the duties of the RSO but <u>not</u> the <u>responsibility.</u>

ALARA Program

2. ALARA Program (continued)

b. Review of ALARA Program

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

2) The RSO 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 below for a discussion of investigational levels).*

3) The RSO will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis.

c. 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 this program .

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.

---

* 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.

ALARA Program

2. ALARA Program (continued)

d. 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 by exposed to radiation will be instructed in the ALARA philosophy and informed that management, and the RSO are committed to implementing the ALARA concept.

e. 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 receive and evaluate the suggestions of individual workers for improving health physics practices, and will encourage suggestions.

f. 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.

g. Individuals Who Receive Occupational Radiation Doses

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

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

ALARA Program

3. 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 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 equivalent for (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. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate. The RSO will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

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, it 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 maintained.

3. Investigational Levels (continued)

d. Re-establishment of investigational levels to levels above those listed in Table 1.

In cases where a worker's or 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 by the RSO.

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.

Attachment 10.2

Radiation Safety Officer

The following program is based on Appendix F to Reg. Guide 10.8, Rev. 2

Duties, Responsibilities, Activities

1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary.

2) Establish written policy and procedures for the radiation safety program, and update as necessary.

3) Audit or review audits of the radiation safety program to assure regulatory compliance.

4) Report deviations or non-compliance to the management.

5) Brief management at least annually on the status of the program.

6) Establish ALARA limits and investigate occurrences of exposures exceeding the limits. Document recommendations and corrective actions.

7) Verify that recommendations and corrective action has been implemented.

Authorities

1) To recommend corrective action to deficiencies and non-compliance with program and regulations. This would include equipment repair or replacement, employee reprimand, etc.

2) To modify the program or procedures in the interest of radiation safety as necessary to comply with new or existing regulations or standards of practice.

3) To report incidents to the appropriate governmental agency when required.

4) To recommend suspension of licensed activities to management where continuation will result in violating regulations or a hazard to patients, personnel, or the public.

Attachment 10.3

Survey Instrument Calibration

The following program is based on Appendix B to Reg. Guide 10.8, Rev. 2

Radiation survey instruments shall be calibrated at intervals not to exceed one year.

Calibrations shall be performed:

By the manufacturer, or

Through the pharmacy, or,

Directly by a contract service.

Calibrations shall be performed by a method following the general guidance provided in Appendix B to Reg. Guide 10.8, Rev. 2, and under the authority granted by the USNRC or other applicable state agencies.

A low activity long lived check source shall be provided for each survey instrument. The source's dose rate at the time of instrument calibration shall be known. The survey instrument will be checked on each day prior to use by using this known check source. The instrument's response must be within + or - 20% of the known dose rate of the check source.

Attachment 10.4

Dose Calibrator Calibrations

The following program is based on Appendix C to Reg. Guide 10.8, Rev. 2

The general guidance provided in Reg. Guide 10.8 Appendix C shall be followed for the calibration of dose calibrators.

The following tests shall be performed at the prescribed frequencies:

Test	Tolerance	Frequency
Constancy	**± 5 %**	**Daily prior to patient doses**
Linearity	**± 5 %**	**Installation / Quarterly**
Geometry	**± 5 %**	**Installation**
Accuracy	**± 5 %**	**Installation / Annually**

After instrument repair or at the technologist's discretion repeat the above tests as appropriate.

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

I. Constancy

Constancy is the reproducibility of measuring a source over a long period of time.

1. Stabilize the dose calibrator. Allow it a warm-up period if appropriate.

2. Check the zero and background settings to minimize effects on the test.

3. Measure at least two calibrated sources in the dose calibrator.
   Use the long-lived (cesium) source to check all commonly used settings.
   Record results on the appropriate forms.

4. Compare the results to decay corrected readings for that day.
   If the measurements are not within ± 5 %, then:
   Recheck zero and background
   Remeasure sources

Do Not Use Calibrator If > ± 5 %.

Dose Calibrator Calibrations

II. Linearity

1. Inspect the instrument to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

2. 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, or in a unit dosage syringe.

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. This first assay should be done in the morning at a regular time, for example, 8 a.m.

b. Repeat the assay at regular intervals. Continue on subsequent days until the assayed activity is less than 30 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. Calculate expected activity for each of the time intervals and compare to measured readings.

e. 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 be the dose calibrator to "true activity".

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

Dose Calibrator Calibrations

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. The calibrator's linearity should first be proven with a decay linearity prior to calibrating shields.

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, and sleeve combinations recommended by the manufacturer.

e. Determine the sleeve calibration factors per the manufacturers instructions.

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, and sleeve combinations recommended by the manufacturer.

f. Evaluate the calibrator's linearity per the shield system manufacturer's instructions.

g. 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".

h. Put a sticker on the dose calibrator for when the next linearity test is due.

Dose Calibrator Calibrations

III. Geometry

Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe or vial that is normally used.

Syringe Method

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. Draw 0.5 cc containing between 1 and 5 mCi 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 Linearity Test Form).

b. Draw an additional 0.5cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

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

d. 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.

e. 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.

Vial Method

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

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

c. Repeat the process until you have assayed a normal vial volume. The entire process must be completed within 10 minutes.

Dose Calibrator Calibrations

III. Geometry (continued)

d. 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.

e. 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 form "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.

IV. Accuracy

Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the supplier. At least two sources with different principal photon energies (such as Co-57, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. 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. 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.

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

Attachment 10.5

Personnel Monitoring Program

The following program is based on Appendix D to Reg. Guide 10.8, Rev. 2

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low.

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a NVLAP accredited service on a monthly basis.

3. All individuals who, on a regular basis, handle radioactive material that emit ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

4. All individuals who are occupationally exposed to radiation on an occasional basis, will be issued a whole body monitor when caring for such patients.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

6. Dosimeters are exchanged monthly and processed by Landauer, Inc. If business reasons dictate a change in processors is necessary, only a NVLAP accredited processor will be used.

Attachment 10.6

Procedure for Leak-Testing Sealed Sources

The following program is based on Appendix H to Reg. Guide 10.8, Rev. 2

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. Samples should be taken as follows:

   a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints.

4. The samples will be analyzed as follows:

   a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

   b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source whose activity is certified by the supplier. The instrument must be sufficiently sensitive to detect 0.005 microcurie.

   c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

   d. Record the wipe sample counts per minute. Then calculate and record the estimated activity on the wipe sample.

   e. Continue the same analysis procedure for all wipe samples.

   f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC must be notified.

   g. Sign and date the list of sources, data, and calculations.

Rules for Safe Use of Radiopharmaceuticals

The following program is based on Appendix I to Reg. Guide 10.8, Rev. 2

1. Wear laboratory coats or other protective clothing in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials. Use long tongs or forceps when handling unshielded sources. Unsealed sources should be prepared behind an L-Block.

3. Before leaving the area, monitor your hands for contamination in a low-background area with a crystal probe, camera, or GM meter.

4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposure, personnel monitoring devices should be stored in the work place in a designated low-background area.

8. Wear a finger exposure monitor during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

12. With a radiation detection survey meter, survey the kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

Rules for Safe Use of Radiopharmaceuticals

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed dosages of less than 10 microcuries. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.

15. Store flood sources, syringes, waste, and other radioactive material in shielded containers. Radioactive materials may only be stored in areas designated in the license. When surveys of storage areas produce levels in excess of trigger limits, arrange or increase shielding until acceptable levels are obtained. Maintain surveillance of restricted areas to prevent unauthorized entry. Storage areas must be locked when unattended.

16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or shielded box to move flood sources, waste, and other radioactive material. When transporting syringes or vials from the Hot Lab, use the pharmacy supplied shielded container or other shielded device.

17. All areas where radioactive material is prepared or administered to patients should be covered with absorbent paper (if it is an intravenous site, the paper can be placed immediately under the patient's arm) to prevent the spread of contamination. The absorbent paper can then be surveyed before disposal in the cold trash or placed in a bag and held for D.I.S. This is, however, not a substitute for the daily survey of all injection areas.

Spill Procedures

The following program is based on Appendix J to Reg. Guide 10.8, Rev. 2

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred, and control access.

2. If practical, perform a dose rate survey to assess radiological conditions.

3. Prevent the spread of contamination by covering the spill with absorbent paper.

4. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag. Work efficiently to minimize exposure (gather material first and plan work).

5. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.

6. Report the incident to the Radiation Safety Officer, and record data.

7. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report as necessary.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room. Control access.

2. If practical, perform a dose rate survey to assess radiological conditions.

3. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

4. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

5. Close the room and lock or otherwise secure the area to prevent entry.

6. Notify the RSO immediately.

7. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

8. The RSO will supervise the cleanup of the spill and will complete a Radioactive Spill Report and the Radioactive Spill Contamination Survey.

Spill Procedures

The following is not part of the model spill procedure:

Major Spills and Minor Spills

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill procedure may be restricted access pending complete decay.

The following Table may be used as general guidance to determine whether a major spill procedure or minor spill procedure should be implemented.

Table J-1

Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	Tc-99m	100
Cr-51	100	In-111	10
Co-57	100	I-123	10
Co-58	10	I-125	1
Fe-59	10	I-131	1
Co-60	1	Yb-169	10
Ga-67	100	Hg-197	100
Se-75	10	Au-198	10
Sr-85	10	T1-201	100

Spill Kit

You May also want to consider assembling a spill kit that contains:

Pairs disposable gloves,
disposable lab coats
paper shoe covers
plastic trash bags with twist ties
china pencil or marking pen
Supplies for contamination wipe samples
Radioactive Spill Report Form and Pencil
housekeeping gloves
paper hats
absorbent paper with plastic backing
"Radioactive Material" labeling tape
or "Radioactive Material" labeling tags
Instructions for "Emergency Procedures"

Attachment 10.9

Procedures for Ordering and Receiving Radioactive Material

The following program is based on Appendix K to Reg. Guide 10.8, Rev. 2

1. The Radiation Safety Officer (RSO) or designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. For routinely used materials

      1) Written records that identify the authorized user or facility, isotope, chemical form, activity, and supplier will be made.

      2) The above records will be checked to confirm that material received was ordered through proper channels.

      3) The person who receives the material will check the request to confirm that the material received is what was ordered.

      4) Package receipt surveys must be performed in accordance with 10CFR20.1906: within 3 hours of receipt during normal working hours, or within 3 hours of arrival when received before working hours.

      5) No unqualified individuals will perform receipt of radioactive materials during hours when the office is "closed". Deliveries may be made by the pharmacy to designated locked areas within the controlled area, only. Keys would be provided to the pharmacy to provide access to the locked storage area, if necessary.

Attachment 10.10

Procedure for Safely Opening Packages Containing Radioactive Material

The following program is based on Appendix L to Reg. Guide 10.8, Rev. 2

For packages received under the specific license, the following procedure for opening each package will be followed:

a. Put on gloves to prevent hand contamination.

b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO.

d. Open the package with the following precautionary steps:

   1) Remove the packing slip.

   2) Open the outer package following the supplier's instructions, if provided.

   3) Open the inner package and verify that the contents agree with the packing slip.

   4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

   5) If anything is other than expected, stop and notify the RSO.

e. Wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample in the well counter to determine if there is any removable radioactivity. Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

   1) If contaminated, treat this material as radioactive waste.

   2) If not contaminated, remove or obliterate the radiation labels before discarding in the in-house trash.

h. Make a record of the receipt.

Records of Byproduct Material Use

The following program is based on Appendix M to Reg. Guide 10.8, Rev. 2

I. Records of Unit Dosage Use

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
   a. Prescribed dosage
   b. Measured activity in millicuries or microcuries and date and time of measurement,
   c. Patient name and identification number if one has been assigned;
9. If discarded, the date and method of disposal; and
10. Initials of the individual who made the record.

Record of Byproduct Material Use

II. Records of Multidose Vial Use

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;

2. Generic name or its abbreviation or trade name;

3. Date of receipt or preparation;

4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);

5. Supplier or kit manufacturer;

6. If administered,

   a. Prescribed dosage

   b. Date and time dosage was drawn and measured,

   c. Calculated volume that is needed for the prescribed dosage,

   d. Measured activity in millicuries or microcuries,

   e. Patient name and identification number if one has been assigned;

7. If discarded, the method of disposal and date; and

8. Initials of the individual who made the record.

Procedure for Area Surveys

The following program is based on Appendix N to Reg. Guide 10.8, Rev. 2

I. Ambient Dose Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter.

   b. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

II. Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination.

   b. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100cm of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3. Immediately notify the RSO if you find unexpectedly high levels.

Procedure for Area Surveys

III. Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:

a. The date, area surveyed, and equipment used.

b. The name or initials of the person who made the survey.

c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO.

d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm^2, as appropriate.

e. Actions taken in the case of excessive dose rates or contamination and follow-up survey information.

2. The RSO will review and initial the record promptly in those cases in which action levels were exceeded.

Recommended Action Levels for Area Surveys

		dpm/100 cm^2	mr/hr
1.	Unrestricted areas, personal clothing, skin	2,000	0.5
2.	Restricted areas, protective clothing used only in restricted areas	20,000	5.0

Attachment 11

Waste Management
by
Decay in Storage

The following program is based on Appendix R to Reg. Guide 10.8, Rev. 2

General Guidance:

1. All radioactivity labels must be defaced or removed from containers prior to disposal in in-house waste.

2. Nonradioactive waste such as used supplies and packing materials should not be mixed with radioactive waste.

3. Review methods to ensure that radioactive waste is not created unnecessarily.

4. Consider the impact of available disposal routes. Consider occupational and public exposure , expense, and other hazards associated with routes of disposal.

Disposal by Decay in Storage (DIS):

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS.

1. Consider using separate containers for different types of waste (needles vs unused doses vs injection paraphernalia). The container (such as a bag) must not provide any significant shielding for the material.

2. When it is full, seal the container and label it with the :
   - Date sealed
   - Longest lived Isotope in the Container
   - The Initials of the Person Sealing the Container

3. Decay the material for at least 10 half-lives of the longest lived radionuclide within.

4. Prior to disposal, monitor the container:
   - Check the operation of the survey meter.
   - Monitor in a low background area (less than 0.05 mr/hr.).
   - Remove any shielding from the container.
   - Monitor all surfaces of each individual container.
   - Discard only containers that were stored for more than 10 half-lives **and** cannot be distinguished from background.
   - Check to be sure that no radiation labels are visible.

   Record information on a decay in storage log form.

NRC FORM 577
(1-95)

NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

MEDICAL MANAGEMENT CONCEPTS
ATTN: JIM FONGHEISER
9160 ACADEMY ROAD
PHILADELPHIA, PA 19114

TYPE OF ACTION

- [X] NEW LICENSE
- [ ] RENEWAL OF LICENSE
- [ ] AMENDMENT TO LICENSE

REQUESTED DATE: 4-15-96

LICENSE NUMBER: NEW

CONTROL NUMBER: 123450

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	$ 1,400.00	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 1,400.00
PAYMENT RECEIVED	$ 1,300.00
AMOUNT DUE	$ 100.00

- [X] Your request was received without the prescribed application fee.
- [X] We received your Check No. 1711 in the amount of $ 1,300.00. Payment of the additional fee noted above is required.
- [ ] Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

- [ ] Enclosed is Check No. _____ which accompanied your request. The fee is not required because:
  - [ ] We received your Check No. _____ in payment of the fee.
  - [ ] The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
  - [ ] Your request was combined, prior to review, with your request, Control No. _____.

III. CHECK RETURNED

- [ ] Enclosed is Check No. _____ which was returned to us by the bank for:
  - [ ] INSUFFICIENT FUNDS
  - [ ] ACCOUNT CLOSED
  - [ ] OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- [ ] License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.
- [ ] The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE -- LICENSE FEE ANALYST	LFDCB	LFDCB
BRENDA BROWN	BB	
	8/6/96	

Distribution: PENDING FILE
MAF Correspondence FY
LFDCB Chief
Invoice File w/encl
LFDCB Analyst
LFDCB R/F (W)
DAF R/F
DATE: DC/DAF/SF(LF-3-97) 8-6-96

NRC FORM 577 (1-95)

This form was electronically produced by Elite Federal Forms, Inc.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02201
STATUS CODE: 3
FEE CATEGORY: _____
EXP. DATE: 0
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: _

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MEDICAL MANAGEMENT CONCEPTS
RECEIVED DATE: 960718
DOCKET NO: 3034202
CONTROL NO.: 123450
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

1996 JUL 24 PM 3:58

2. FEE ATTACHED
AMOUNT: $1300.00
CHECK NO.: 1171

3. COMMENTS

SIGNED M. A. Perkins
DATE 7/18/96

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

1. FEE CATEGORY AND AMOUNT: 7C 1400

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

3. OTHER _____

SIGNED _____
DATE _____

I (9B)

Log Aug 1
Remitter NMC ASSOCS., INC. / T003
Check No. 1711
Amount $1,300 / 100
Fee Category 7C
Type of Fee APP
Date Check Rec'd 8-7-96
Date Completed 8/14/96
By: BB

HANDWRITTEN
MBSKAC
Mgmt. Concepts