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. OFFICIAL RECORD COPY

Licensee	
1. Newark Medical Associates, P.A. 2. 810 Broad Street Newark, New Jersey 07102	3. License Number 29-30282-01 4. Expiration Date September 30, 2001 5. Docket or Reference No. 030-34086

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 35.200	A. Any radiopharmaceutical identified in 10 CFR 35.200 except generators and gas	A. As needed

9. Authorized use

A. 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 810 Broad Street, Newark, New Jersey.

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 Gerard W. Moskowitz, M.D.

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
Gerard W. Moskowitz, M.D.	35.200

ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 29-30282-01

Docket or Reference Number: 030-34086

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 February 21, 1996
B. Letter dated September 16, 1996

Date SEP 25 1996

For the U.S. Nuclear Regulatory Commission
Original Signed By:
Michelle Beardsley

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

SEP 25 1996

License No. 29-30282-01
Docket No. 030-34086
Control No. 122928

Magdy Elamir, M.D.
President
Newark Medical Associates
810 Broad Street
Newark, NJ 07102

Dear Dr. Elamir:

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;

OFFICIAL RECORD COPY ML 10

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. 29-30282-01
Docket No. 030-34086
Control No. 122928

Enclosures:
1. License No. 29-30282-01
2. 10 CFR Parts 2, 19, 20, 30, 31, 35, and 170

DOCUMENT NAME: R:\WPS\MLTR\L2930282.01
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							
DATE	09/24/96		09/ /96		09/ /96		09/ /96	

OFFICIAL RECORD COPY

NEWARK MEDICAL ASSOCIATES, P.A.

810 Broad Street
Newark, New Jersey 07102
Tel #: (201) 504-9000
Fax#: (201) 504-9794

SEND ALL CORRESPONDENCE TO:
550 Summit Avenue
Jersey City, New Jersey 07306
Tel#: (201) 653-0022
Fax#: (201) 653-0044

MS 08
J-1

September 16, 1996

Ms. Michelle Beardsley
U.S. Nuclear Regulatory Commission Region I
475 Allendale Road
King of Prussia, PA 19405-1415

RE: Docket No. 030-34086
Control No. 122928

Dear Ms. Beardsley:

This is in answer to your letter of March 16, 1996. Since the installation of our laboratory was not finished, we could not provide you with all necessary data.

1. We have applied to the Radiation Protection Program of the New Jersey DEP for a materials license that will cover accelerator produced and naturally occurring radioactive materials. We received a temporary license so far.

2. Our Survey Meters will be calibrated by RMC Calibration Services, Wilmington, Delaware, NRC License No. 07-30114-01.

3. Since we initially filed our application, we moved the scanning room to the north side of the hallway, adjacent to the hot lab. On a sturdy bench, we located a standard Nuclear Associates L-shield for dose preparations and storage of dose calibrator reference sources. The lead bricks are standard lead bricks with a 2" thickness.

a. As a rule, we do not intend to store radiopharmaceuticals and we will essentially use Tc-99m labeled radiopharmaceuticals.

b. We will store any non-used materials as well as decaying waste in the small room at the end of the hot lab marked isotope storage, in special lead lined waste containers.
The north end of the isotope storage room is an outside wall.

ML 10

122928

SEP 18 1996

NEWARK MEDICAL ASSOCIATES, P.A.

810 Broad Street
Newark, New Jersey 07102
Tel #: (201) 504-9000
Fax#: (201) 504-9794

SEND ALL CORRESPONDENCE TO:
550 Summit Avenue
Jersey City, New Jersey 07306
Tel#: (201) 653-0022
Fax#: (201) 653-0044

The north end of the isotope storage room is an outside wall.

The east side of the hot lab is made of a very thick wall. On the other end of the wall is an emergency type staircase, inaccessible to the public.

4. Our survey instruments are:

a) a detection survey meter Ludiu model 3, calibrated for 0-1-100 mR/hr with a pancake probe 44-9.

(b) a measurement survey meter Ludium, model 3, calibrated 1-1000 mR/hr with an energy compensated probe, model 44-38.

5. Our personnel will be instructed:

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

Instruction for individuals in attendance will include the following subjects:

5.4. Applicable regulations and license conditions.
5.5. Areas where radioactive material is used or stored.
5.6. Potential hazards associated with radioactive material in each area where the employees will work.
5.7. Appropriate radiation safety procedures.
5.8. Licensee's in-house work rules.
5.9. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
5.10. Appropriate response to emergencies or unsafe conditions.

NEWARK MEDICAL ASSOCIATES, P.A.

810 Broad Street
Newark, New Jersey 07102
Tel #: (201) 504-9000
Fax#: (201) 504-9794

SEND ALL CORRESPONDENCE TO:
550 Summit Avenue
Jersey City, New Jersey 07306
Tel#: (201) 653-0022
Fax#: (201) 653-0044

5.11. Worker's right to be informed of occupational radiation exposure and bioassay results.
5.12. Locations where we posted regulations, licenses and license conditions.
5.13. Question and answer period.

We will maintain records of worker training which will include date and duration of training, topics covered, names of instructor and trainees.

6. Our medical practice includes or will include the following specialties:

Neurology
Internal Medicine
Physical Therapy
Nuclear Medicine
Radiology

7. We will modify our packages receipt procedures to comply with 10 CFR 20, 1906 and monitor the surface of labeled packages for removable contamination upon receipt.

8. For wipe tests, we will use a special Ludium wipe test assembly, shielded within a lead bricks castle. The detector is the Ludium pancake probe with the Ludium 3 meter equipped with a special scale/timer digital scale that permits direct dpm counting. The efficiency of the assembly is determined for each isotope in use. The sensitivity (minimum detectable amount) is established, so that 2,000 dpm can be easily measured for each isotope in use. We do not intend using Iodine-131.

9. When working with Tc-00m or T1-201, we will use the following trigger levels in the restricted areas (not lab and scan room); 5mR/hr for area surveys and 20,000 dm per 100 square centimeter for removable contamination (wipe tests). For unrestricted areas, our trigger levels are one tenth lower, i.e. 0.5 mr/hr for area surveys and 2,000 dpm per 100 square centimeter for removable contamination (wipe tests).

NEWARK MEDICAL ASSOCIATES, P.A.

810 Broad Street
Newark, New Jersey 07102
Tel #: (201) 504-9000
Fax#: (201) 504-9794

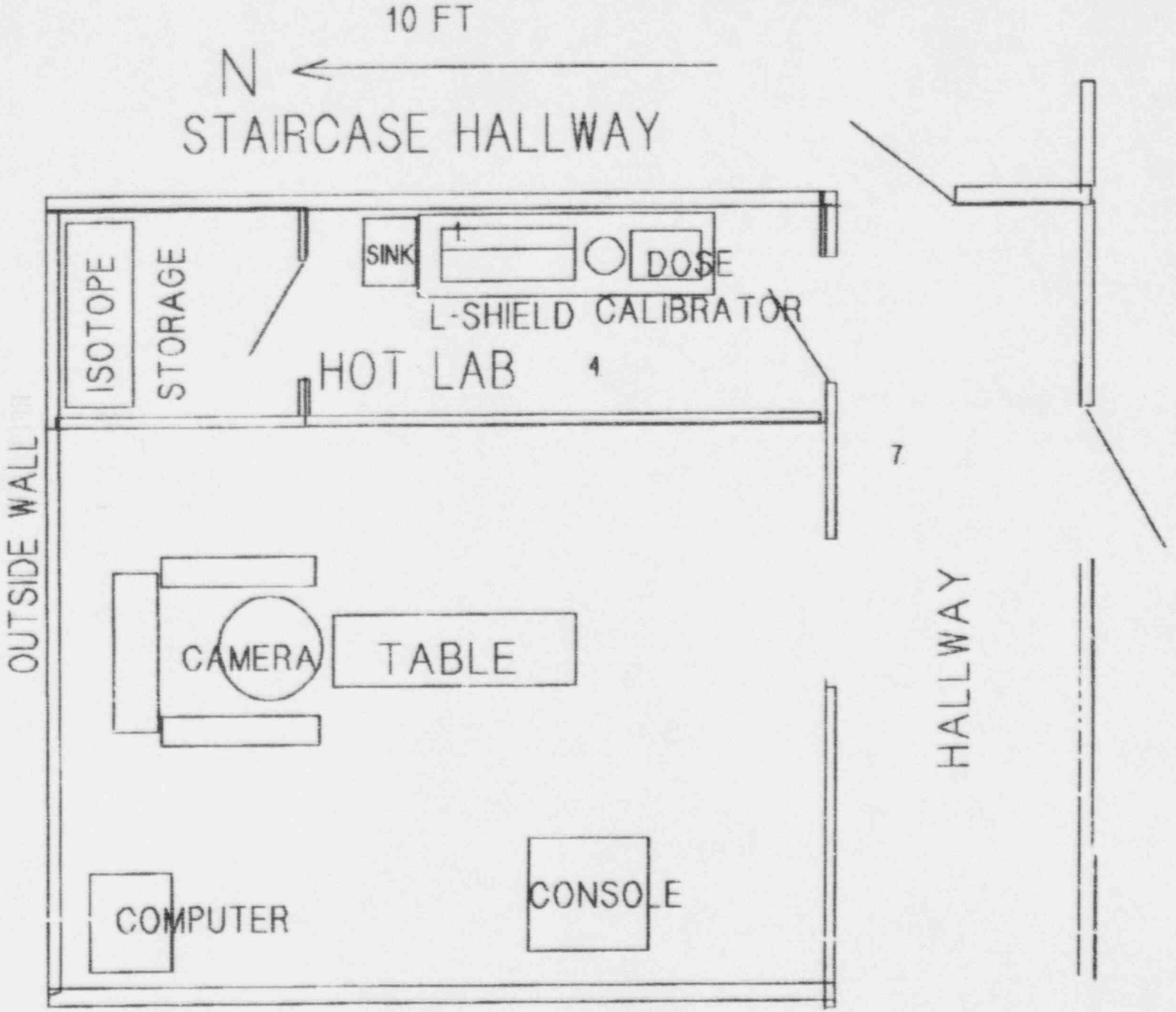
SEND ALL CORRESPONDENCE TO:
550 Summit Avenue
Jersey City, New Jersey 07306
Tel#: (201) 653-0022
Fax#: (201) 653-0044

10. We will not use Iodine-131 or Iodine-135 and will submit a negative declaration in a separate letter.

11. We own the building so that there is no concern regarding access to the building.

Sincerely yours,

Magdy Elamir, M.D.
ME/ cp 099616



SEP 12 1996

Magdy Elamir, M.D.
Newark Medical Associates
810 Broad Street
Newark, NJ 07102

SUBJECT: APPLICATION FOR MATERIAL LICENSE DATED February 21, 1996, AND OUR REQUEST FOR INFORMATION DATED March 16, 1996

Dear Dr. Elamir:

This concerns the subject application for a material license and our letter in which we notified you that the application was deficient and that certain additional information was required.

You are hereby notified that unless within thirty (30) days from the date of this notice we receive the additional information requested, we will consider that you have abandoned your application. This action is without prejudice to the resubmission of an application.

Sincerely,

Original Signed By:
Michelle Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

Docket No. 030-34086
Control No. 122928

Enclosure:
Letter dated March 16, 1996

DOCUMENT NAME: R:\WPS\MISC\3034086
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	09/12/96		09/ /96		09/ /96		09/ /96	

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ML 10

MAR 16 1996

Docket No. 030-34086
Control No. 122928

Magdy Elamir, M.D.
Newark Medical Associates, P.A.
810 Broad Street
Newark, NJ 07102

Dear Dr. Elamir:

This is in reference to your application dated February 21, 1996 for a byproduct materials license.. In order to continue our review, we need the following additional information:

1. Thallium 201 produced in a cyclotron is not byproduct material as defined in 10 CFR 30.4 and is not subject to licensing by the NRC. Therefore, you may procure and use it without an NRC material license. However, you should contact your State regulatory authorities to determine the State licensing or registration requirements for use of this radionuclide.

2. Your application states that you will have your instruments calibrated by instrument calibration service licensed by the NRC or an Agreement State. Please provide the name and NRC or Agreement State license number of at least one instrument calibration service that you may utilize.

3. On a detailed version of your Hot Lab diagram, please indicate the position of each of the areas described below and describe the type, dimensions, and thickness of shielding that you will use:

   a. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).

   b. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste.

   In addition, identify adjacent areas across the walls from use and storage locations and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301 (enclosed).

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.

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ML 10

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 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.

6. In order to determine whether your facility qualifies as a medical institution, we need additional information. Provide a description of all medical disciplines/specialties that are practiced within your facility or confirm that the physicians at your facility practice only a single specialty.

7. Your application states that you will establish and implement the model guidance for ordering and receiving licensed material that was published in Appendix K to Regulatory Guide 10.8, Revision 2. 10 CFR 20.1906, "Procedures for receiving and opening packages", states, in part, that each licensee shall monitor the surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it is received during normal working hours or not later than 3 hours from the beginning of the next working day if it is received after working hours. Appendix K procedures do not address monitoring the surface of packages upon receipt. Please confirm that you will modify your package receipt procedures to comply with the requirements of 10 CFR 20.1906.

8. You have indicated that Appendix N Procedures and Table N-1 will be followed for area surveys. These procedures require 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.

9. 10 CFR 35.70 (d) and (g) require licensees to establish radiation dose rate and removable contamination trigger levels. Please specify your dose rate trigger level in milliroentgen per hour (mR/hr) and your removable contamination trigger level in disintegrations per minute per 100 square centimeters (dpm/100 cm^2).

10. You are requesting authorization for materials identified in 10 CFR 35.200 that include the use of sodium iodide iodine- 125 and iodine-131 in quantities exceeding 30 uCi. 10 CFR 35.32(a) states, in part, that a licensee must establish and maintain a written Quality Management (QM) program for all 10 CFR Part 35 uses applicable to their program. Please submit a QM program as required by 10 CFR 35.32(a). In lieu of submitting a QM program, if your use of 10 CFR 35.200 materials will not include sodium iodide iodine-125 or iodine-131 in quantities exceeding 30 microcuries (uCi), you may submit a "negative declaration" confirming

this use is not a part of your licensed material program. Confirm in your "negative declaration" that you will submit a QM program prior to initiating future use of sodium iodide iodine-125 or iodine-131 in quantities exceeding 30 uCi. Please submit your QM program or "negative declaration" in a separate correspondence from your response to other items in this letter.

11. Your application appears to indicate that your location of use may be controlled by an entity other than yourself. If so, please provide documentation of a clear contractual agreement concerning access to your location of use for the purpose of decontamination or removal of licensed material from the location of use in the event of disharmony between you and the owner entity. This documentation should consist of signed certification from both parties.

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. 122928. 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 Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

Docket No. 030-34086
Control No. 122928

Enclosures:
1. 10 CFR Parts 20, and 35

DOCUMENT NAME: R:\WPS\DLTR\D30-3408
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/mrb							
DATE	03/14/96		03/ /96		03/ /96		03/ /96	

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NEWARK MEDICAL ASSOCIATES, P.A.

810 Broad Street (2nd fl.)
Newark, N.J. 07102
Tel No. : (201) 242-8400
Fax No.: (201) 643-7010

Billing Office: 810 Broad Street, 6th flr.
Newark, NJ 07102
Tel No. : (201) 504-9000
Fax No.: (201) 504-9794

February 22, 1996

LL 30282
030-34086
02200

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission Region I
475 Allendale Road
King of Prussia, PA 19406-14154

Dear Sir/Madam:

We are submitting our application for a license to use radiopharmaceuticals as specified in our application in our clinic at Newark Medical Associates. Please contact us if further information is required.

Sincerely,

MAGDY ELAMIR, M.D.

ME/cp

122928

FEB 26 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 5-30-96

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: LL30282

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: 030-34026

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137-5927 02200

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

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. Per 3/7/96 TC with Dr. Elamirs licensee

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)*
   Dr. Magdy Elamir
   810 Broad Street
   Newark, NJ 07102
   should be named Newark Medical Associates, P.A.
   mjb

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
   Newark Medical Associates
   810 Broad Street
   Newark, NJ 07102

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   Dr. Magdy Elamir

   TELEPHONE NUMBER
   (201)242-8400

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 / AMOUNT ENCLOSED $

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
Magdy Elamir, M.D.		2-21-96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

FEB 26 1996

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Item 5 and 6 - Radioactive Material and Purpose

Authorization is requested to utilize the following materials:

	Byproduct Material	Amount		Purpose
5.a	Material in 10 CFR 35.200 Sched. A, Group 2	As needed	6.a	Medical use
5.b	Tl_{81}-201 (not a byproduct)	As needed	6.b	Medical use
5.c	Co-57 sealed sources	20 mCi	6.c	Camera flood source Dose calibrator QA

Item 7 - Individuals responsible for Radiation Safety Program Their Training and Experience

Authorized user and Radiation Safety Officer: Gerard W. Moskowitz, M.D.

See ATT 7.1.

Item 8 - Training for Individuals working in or frequenting Restricted Areas

We will establish and implement the model training program published in Appendix A of Regulatory Guide 10.8, Revision 2. Prior to commencing operations, radiation safety training will be provided to all staff.

8.1 List of Trainees

To be supplied.

8.2 Other Training Programs

NA

Item 9 - Facilities and Equipment

9.1 Annotated Drawing

See appended drawing ATT 9.1

9.2 Survey Instrument Calibration

We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2.

9.3 Dose Calibrator Calibration

We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2.

9.4 Personnel Monitor Program

We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2.

9.5 Imaging Equipment

NA

9.2 Other Equipment and Facilities

NA

Item 10 - Radiation Safety Program

10.1 Radiation Safety Committee/ Radiation Safety Officer

Because this is a private small entity a Radiation Safety Committee is not required. The user of the entity is also the Radiation Safety Officer.

10.2 ALARA Program

We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

10.3 Leak test

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

10.4 Safe Use of Radiopharmaceuticals

We will establish and implement the [illegible] safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2.

10.5 Spill Procedures

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

10.6 Ordering and Receiving

We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2.

10.7 Opening Packages

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

10.8 Unit Dosage Records

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

10.9 Multidose Vial Records

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

10.10 Molybdenum Concentration Records

NA

10.11 Implant Source Use Records

NA

10.12 Area Survey Procedures

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

10.13 Air Concentration Controls

NA

10.14 Radiopharmaceutical Therapy

NA

10.15 Implant Therapy

NA

10.16 Other Safety Procedures

NA

Item 11 - Waste Management

11.1 Waste Disposal

We will establish and implement the model procedure for waste disposal that was published in Appendix R to Regulatory Guide 10.8, Revision 2.

11.2 Other Waste Disposal

NA

CURRICULUM VITAE

Name: Gerard W. Moskowitz, M.D.

Date & Place of Birth:

Address:

Telephone:

Social Security Number:

1. HIGHER EDUCATION

Institution & Location	From	To	Degree & Date
The City College of N.Y. New York City, New York	1-55	6-58	B.S. Biochemistry June 1958 Honors: Dean's List Cum Laude Phi Beta Kappa
State U. of New York Downstate Medical Center New York	9-58	6-62	M.D. Medical Doctor June 1962 Brooklyn,
Mount Sinai Hospital & M.C. Dr. David Adlersberg New York, New York	6-59	8-59	Fellowship (Student) Diabetes and the Malabsorption Synd.
Mount Sinai Hospital & M.C. Dr. Kermit Osserman New York, New York	6-60	8-60	Fellowship (Student) Myasthenia Gravis Foundation
Mount Sinai Hospital & M.C. Dr. Kermit Osserman New York, New York	6-61	8-61	Fellowship (Student) Myasthenia Gravis Foundation

2. POSTDOCTORAL TRAINING:

Institution & Location	From	To	Degree & Date
Mount Zion Hospital & M.C. San Francisco, California	6-62	6-63	Internship, Rotating June 1963
National Inst. of Health National Heart Institute Lab. Tech. Development (Medical Instrumentation) Bethesda, Maryland	7-63	6-65	Research Investigator June 1965
Montefiore Hospital & M.C. Bronx, New York	7-65	6-67	Residency, Internal Medicine June 1967
Yale-New Havene M.C. New Haven, Conn. Dr. Richard Greenspan	11-65	12-65	Residency Elective Radiology
Massachusetts Gen. Hospital Boston, Mass. Dr. Laurence Robbins	1-67	3-67	Residency Elective Radiology
Columbia-Presbyterian Hosp. New York, New York Dr. Philip Johnson	5-67	6-67	Residency Elective Nuclear Medicine
Peter Bent Brigham Hospital Harvard Medical School Boston, Massachusetts Dr. Herbert Abrams Dr. Harry Mellins	7-67	6-70	Residency Diagnostic Radiology and Nuclear Medicine
Johns Hopkins Hospital Baltimore, Maryland Dr. Henry Wagner	3-70	5-70	Residency Elective Nuclear Medicine
New Eng. Roentgen Ray Society Boston, Massachusetts Dr. Edward Webster	1-68	12-68	Postgraduate Course Radioisotopes, Physics and Applications

3. MILITARY:

SERVICE	FROM	TO	RANK
U.S. Public Health Service Bethesda, Maryland	7-1-63	6-30-65	Lt. Commander

4. LICENSURE:

DATE	STATE	NUMBER
June 1964	State of New York - Medical Lic.	093685
July 1964	State of New Jersey - Med. Lic.	MA 059498

5. CERTIFICATION:

DATE	AGENCY
June 1963	National Board of Medical Examiners
December 1970	American Board of Radiology - Certification
June 1973	American Board of Nuclear Medicine - Certification
June 1968	American Board of Internal Medicine - Qualification

6. NARCOTICS CERTIFICATION:

DATE	AGENCY	EXPIRATION DATE
June 1964	New York (Drug Enf. Administ.)	1995
July 1993	New Jersey (Drug Enf. Administ.)	1995
August 1993	New Jersey CDS	D 063006

7. UNIVERSITY APPOINTMENTS:

Institution & Location	From	To	Title
Harvard Medical School Boston, Massachusetts	7-69	6-70	Clinical Fellow Radiology
State U. of New York Stony Brook, New York	7-70	6-90	Assistant Professor Radiology & Medicine
Albert Einstein College Bronx, New York	7-90	9-93	Assistant Professor Nuclear Medicine
U.M.D.of New Jersey Newark, New Jersey	9-93	Present	Associate Professor of Clinical Radiology

8. HOSPITAL APPOINTMENTS:

Institution & Location	From	To	Title
University of Medicine and Dentistry of New Jersey Newark, New Jersey	9-93	Present	Director Division of Nuclear Medicine Dept. of Radiology
Long Island Jewish Medical Center New Hyde Park, New York	7-70	9-93	Assoc. Attending Radiology Nuclear Medicine
Nucl. Card. Diag. Ctr. Long Island Jewish Medical Center New Hyde Park, New York	7-78	6-83	Section Head Nucl. Cardiology
Queens Hospital Center Queens, New York, N.Y.	6-79	8-93	Assoc. Attending Nuclear Medicine
Nassau County Medical Ctr. East Meadow, New York	5-80	8-93	Consultant Nuclear Medicine
Brookhaven National Lab. Upton, New York	6-80	8-93	Research Collaborator Nuclear Medicine
University Hospital of U. M. D. N. J.	8-93	Present	Director Division of Nuclear Medicine

10. AWARDS AND HONORS:

Award: Young Investigators Award by the Greater New York Chapter
of the Society of Nuclear Medicine - 1973

Honorable Mention: Scientific Exhibits - R.S.N.A. 1986
Radionuclide Assessment of Pneumatic Dilatation Therapy
In Achalasia

Cerificate of Merit: Scientific Exhibits - R.S.N.A. 1993
Evaluation of Achalasia Pre and Post Pneumatic Dilatation

12. MAJOR COMMITTEE ASSIGNMENTS:

Membership	Institution & Location	From	To
Radiation Safety Committee Member	U.M.D.N.J. Newark, New Jersey	9-93	Present
Human Use Subcommittee Member	U.M.D.N.J. Newark, New Jersey	9-93	Present
Internal Review Board Member	U.M.D.N.J. Newark, New Jersey	1-94	Present
Performance Improvement Committee Member	U.M.D.N.J. Newark, New Jersey	6-94	Present
Oncology Committee Member	U.M.D.N.J. Newark, New Jersey	9-93	Present
Quality Assurance Radiology Department	U.M.D.N.J. Newark, New Jersey	6-94	Present
Tumor Board Member	U.M.D.N.J. Newark, New Jersey	9-93	Present

12. MAJOR COMMITTEE ASSIGNMENTS: (Continued)

PREVIOUS POSITION:

Radioisotope Utilization and Radiation Safety Committee, Secretary	Long Island Jewish M.C. New Hyde Park, New York	7-72	9-93
Annual Scientific Essay Contest Committee Chairman	Long Island Jewish M.C. New Hyde Park, New York	1-80	9-93
Human Subjects Review Committee Subcommittee On Oncology Chairman	Long Island Jewish M.C. New Hyde Park, New York	1-80	9-93
Nuclear Medicine Grand Rounds Program Director	Long Island Jewish M.C. New Hyde Park, New York	1-78	9-93
Medical Library Committee	Long Island Jewish M.C. New Hyde Park, New York Member	1-78	9-93
Professional Standard Review Committee Member	Long Island Jewish M.C. New Hyde Park, New York	1-76	9-93
Research Committee Member	Long Island Jewish M.C. New Hyde Park, New York	1-78	9-93
General Tumor Board Radiologist	Long Island Jewish M.C. New Hyde Park, New York	1-75	9-93
Faculty Council Executive Comm. Member	Long Island Jewish M.C. New Hyde Park, New York	7-76	9-93

13. PROFESSIONAL AND SCIENTIFIC SOCIETIES:

Organization	Date of Initial Membership	Leadership Position
Society of Nuclear Medicine	1973	Academic Council
Greater N. Y. Chapter Soc. of Nucl. Medicine	1973	By-laws Committee
		Program Committee Co-Chairman
	1987	Membership Comm. Chairman
		Govenor From N.Y.
	1991-1993	Treasurer
Radiological Soc. of N.A.	1985	Scientific Exhibits Committee Member
Long Island Radiol. Soc.	1975	Executive Committee
American Coll. of Radiol.	1973	
American Coll. of Nucl. Physicians	1975	
American Roentgen Ray Society	1982	
American U. Radiologist	1983	
Phi Lambda Kappa Medical Soc.	1960	
Phi Beta Kappa	1958	

14. MAJOR RESEARCH INTERESTS:

1. Detection and localization of parathyroid adenomas by scintigraphic techniques.
2. The evaluation of the efficacy of pneumatic dilatation with radionuclide scintigraphy.
3. Detection and localization of the focus of epileptic seizures by neuro-SPECT scintigraphy.
4. Detection and localization of a focus of infection by radionuclide labeled white blood cells.
5. Evaluation of the factors which improve visual perception in the detection of abnormalities.
6. Superimposition of SPECT transaxile images on CT cross section images to provide a combination of physiology and structural anatomy.
7. Computer recognition and analysis of aberrations of scintigraphic or radiographic images.
8. Micro magnetic resonance imaging techniques.

15. GRANT HISTORY:

None.

16. MAJOR TEACHING EXPERIENCE:

1. Coordinator of the Nuclear Medicine Residency program at Long Island Jewish Medical Center from July 1, 1972 to current time.
2. Radiology resident nuclear medicine education at Long Island Jewish Medical Center from July 1, 1983 to current time.
3. Radiology resident rotation through the Division of Nuclear Medicine at U.M.D.N.J.

17. PRINCIPAL CLINICAL AND HOSPITAL SERVICE RESPONSIBILITIES:

1. Section Head, Clinical Nuclear Medicine activities included supervision of technical staff, organization of work schedule and communication with referral physician service. The activities included 45 percent in-patient service and 55 percent outpatient private practice referral service (July 1, 1972 to June, 1993).
2. Program Director of Nuclear Medicine Grand Rounds and other teaching activities. These activities provided continual in-service education to staff, residents and technologist (July 1, 1972 to June, 1993).
3. Director of Division of Nuclear Medicine which involves the Clinical Service at both University Hospital and Doctors Office Center. This includes in-patient, ambulatory and private patients.

18. MAJOR ADMINISTRATION RESPONSIBILITIES:

1. Section Head, Nuclear Cardiology an independent section to provide services specific for evaluation of the heart and vascular system through the use of radionuclide techniques. This involved administration, teaching and research functions.
2. Section Head, Clinical Nuclear Medicine activities included administration and supervision of the technical staff, work schedule organization and liaison between referral physicians and the Division of Nuclear Medicine.
3. Director of the Division of Nuclear Medicine at University Hospital and U.M.D.N.J. This includes teaching residents, supervision of technologist. Responsibilities also include maintaining a research program, committee assignments and clinical service.

19. PRIVATE PRACTICE:

1. Private practice is integrated into the principal ciinical responsibilities. Referring physician sent their patient for special studies not usually available on a routine basis in other nuclear medicine facilities. These include parathyroid imaging studies, neuro-SPECT studies, and white cell labelling studies.
2. Many of the private practice patients are referred on weekends and evening hours since the Division of Nuclear Medicine is available at these times.

PUBLICATIONS

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22. J. Tuvia, S. Patel, M. Patel, G. W. Moskowitz, And L. M. Levy:
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ABSTRACTS

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Proc. Of The Fifth Congress of Nuc. Med. 5:270, 1980.

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J. Nuc. Med. 22:99, 1981.

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Dynamic Radionuclide Scintigraphy In The Evaluation Of Pneumatic Dilatation Treatment Of Achalasis.
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STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS

THIS IS TO CERTIFY THAT
BOARD OF MEDICAL EXAMINERS
HAS REGISTERED

GERARD W MOSKOWITZ M.D.

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

07/01/95	06/30/97	MA 59498
EFFECTIVE DATE	EXPIRATION DATE	LICENSE NO.

SIGNATURE OF REGISTRANT

DIRECTOR

REQUEST TO CHANGE CERTIFICATE

IF THE INFORMATION ON THE ATTACHED CERTIFICATE IS INCORRECT, OR SHOULD CHANGE, PLEASE PRINT THE CORRECT DATA *ONLY* BELOW AND MAIL TO:

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140 E. FRONT ST
TRENTON NJ 08625

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(YEAR CURRENT LICENSE EXPIRES)

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(FIRST) (MI) (LAST) (MAIDEN IF APPLICABLE)

CORRECT ADDRESS _____
(STREET)

_____
(CITY) (STATE) (ZIP CODE) (COUNTY-NJ ONLY)

NAME OF EMPLOYER _____

EMPL. STREET ADDRESS _____

EMP. CITY, STATE, ZIP _____

SEE REVERSE SIDE FOR INSTRUCTIONS

The American Board of Radiology

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

Gerard W. Moskowitz, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this twelfth day of December, 1970
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

John Farrar Rueck
President

C. Allen Good
Secretary

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

ADVISORY BOARD FOR MEDICAL SPECIALTIES

7.1/24

THE AMERICAN BOARD OF NUCLEAR MEDICINE

INCORPORATED 1971

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

Gerard W. Moskowitz, M.D.

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

NUCLEAR MEDICINE

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

Joseph F. Ross M.D.
CHAIRMAN

Lynn V. Hubbell
SECRETARY

NUMBER 02648

DATE MAY 18, 1973

7.1/25

UMD NEW JERSEY

UMDNJ, New Jersey's University of the Health Sciences

Office of Radiation Safety Services
Phone: (201) 982-5305
Fax: (201) 982-6498

185 South Orange Avenue
University Heights
Newark, NJ 07103-2714

LICENSE FOR HUMAN USE OF RADIOACTIVE MATERIALS

ITEM 1

Name: Gerard W. Moskowitz, M.D. **Department:** Division of Nuclear Medicine Department of Radiology **Title:** Associate Professor of Clinical Radiology Director, Nuclear Medicine	**N.J. Medical License No.:** 59498 **Human Use Radioactive Material License No.:** 0034 **Date Approved:** 9/20/95 **Expiration Date:** 9/20/97 **Authorized Signature:** Elizabeth A. Alger, MD

ITEM 2

RADIONUCLIDE	FORM	POSSESSION LIMIT
A. Any byproduct material listed in 10 CFR 35.100 Subpart-D, and 10 CFR 35.200 Subpart-E.	Any radiopharmaceutical listed in 10 CFR 35.100 Subpart-D, and 10 CFR 35.200 Subpart-E.	As needed.
B. I-131 and Sr-89 for procedures listed in 35.300 Subpart-F.	I-131 and Sr-89 radiopharmaceuticals listed in 35.300 Subpart-F.	As needed.
C. Any radionuclide listed in procedures authorized in the NJSL 70033/01.	Any radiopharmaceutical listed in the NJSL 70033/01.	As needed.

LICENSE FOR HUMAN USE OF RADIOACTIVE MATERIALS

rized Use:

Byproduct material listed in Item 2(A&B) shall be used in diagnostic and/or therapeutic procedures listed in 10 CFR 35.

Radioactive material listed in Item 2(C) shall be used in diagnostic procedures listed in NJSL 70033/01.

LICENSE FOR HUMAN USE OF RADIOACTIVE MATERIALS

M 4

cense Conditions:

. The licensee shall comply with the radiation safety policies established by the Radiation Safety Committee and the rules and regulations of the United States Nuclear Regulatory Commission and the New Jersey Department of Environmental Protection.

. Office of Radiation Safety Services shall approve all requisitions for single or standing orders of radioactive materials.

. The licensee shall not alter the chemical or physical form in which radioactive materials are received from the manufacturer.

. Office of Radiation Safety Services shall be notified immediately when the radioactivity administered to a patient varies by more than ten (10) percent of the prescribed dose or when there are any adverse effects or contraindications resulting from the administration of radioactive materials.

. Office of Radiation Safety Services shall be notified immediately of all accidents and/or incidents directly or indirectiy involving radioactive materials.

. The licensee shall not receive, possess, or use radioactive materials except for the procedures outlined in Items 2 (A&B) under "Authorized Use". All non-routine use of radioactive materials in or on humans shall require a specific license from the Human Use Subcommittee of the Radiation Safety Committee.

3. The licensee shall use radioactive material authorized in Item 2 in accordance with the provisions and limitations specified in the non-routine human use protocols approved by the UMDNJ Newark campus IRB and Radiation Safety Committee.

4. The licensee shall not receive, possess, or use radioactive material, except for those procedures contained in Item 2.

. Radioactive materials shall not be transferred to any other institution unless prior written authorization is obtained from the Office of Radiation Safety Services.

APPENDIX A

Model Training Program
(See §§ 19.12 and 35.21)

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2, and have appended a table ATT 8.1 that identifies the groups of workers who will receive training and the method and frequency of training." You may use lectures, video-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of § 19.12. Say on your application, "We have developed a training program for your review that is appended as ATT 8.1." Be sure to include the table that identifies groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instruction has been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. Initial training should be tailored to meet the needs of the individuals in attendance. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

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.

Instruction 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. 8.1/2

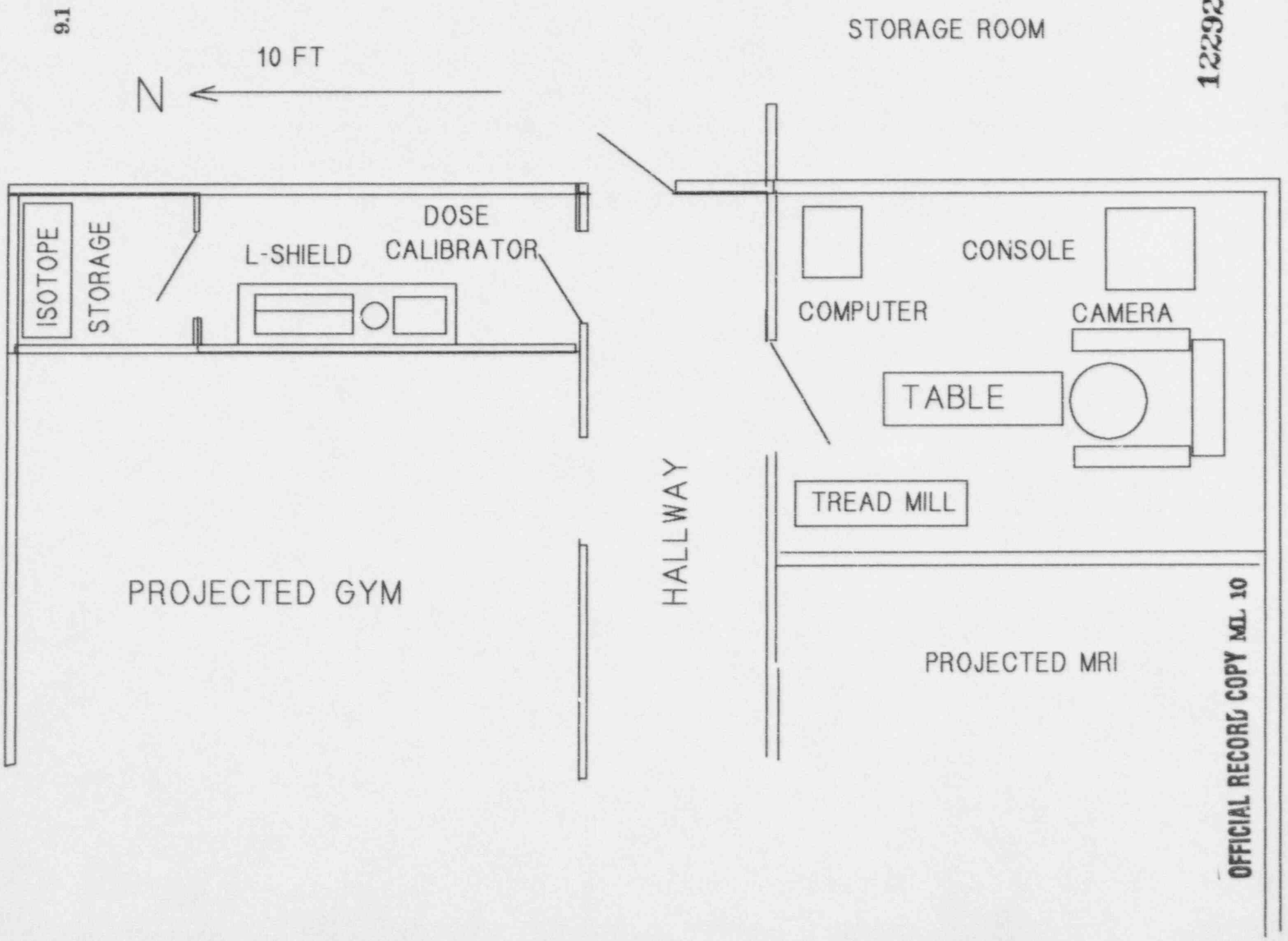
7. Appropriate response to emergencies or unsafe conditions.

8. Worker's right to be informed of occupational radiation exposure and bioassay results.

9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

10. Question and answer period.

9.1



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APPENDIX B

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

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

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

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

MODEL PROCEDURE

1. The source must be approximately a point source.

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

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

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

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

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

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

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

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

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

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

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

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

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

   a. The owner or user of the instrument;

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

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

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

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

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

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

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

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

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

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

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

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

(1) The average correction factor,

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

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

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

e. The apparent exposure rate from the check source.

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

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

Survey Meter Calibration Report

Owner:_____ Department:_____

Manufacturer:_____ Type: o Ion Chamber o GM o NaI(Tl) o _____

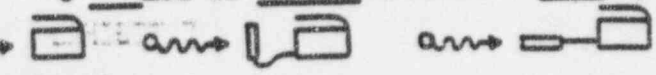
Meter model:_____ Meter S/N:_____ Probe model:_____ Probe S/N:_____

Calibration Source: ___mCi of _____. ____mR/hr at __in on _____, 19__.

Instrument checks: Battery check:___mR/hr or _____

Constancy check: o integral check source indicates ____mR/hr.

o ___mCi of _____ indicates ____mR/hr.

Calibration Geometry:  o

Window: o open o closed o fixed

dist (feet)	mR/hr today	Scale: Rdng	CorFac	Scale: Rdng	CorFac	Scale: Rdng	CorFac	Scale: Rdng	CorFac

Correction Factors: _____ _____ _____ _____

Name:_____

Date:_____

Calibration Sticker

Cald ___-___-___ with _____
// _|_, window:_____
scale CorFac
_____ _____ bat:"__mR/hr"
_____ _____ chk:"__mR/hr"
_____ _____

APPENDIX C

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

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

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

MODEL PROCEDURE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Decay Method

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

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

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

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

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

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

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

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

Shield Method

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

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

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

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

d. Continue for all sleeves.

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

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

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

h. Continue for all sleeves.

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

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

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

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

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

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

e. Continue for all sleeves.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

c. Repeat the procedure for other calibrated reference sources.

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

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

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

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

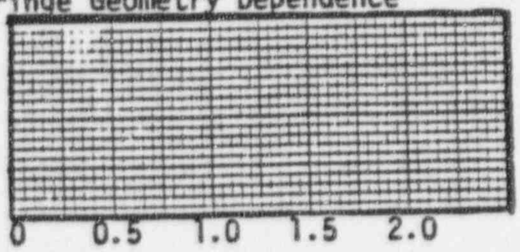
See Exhibits 8 and 9 for some forms you may want to use.

EXHIBIT 9

Dose Calibrator Geometry and Accuracy

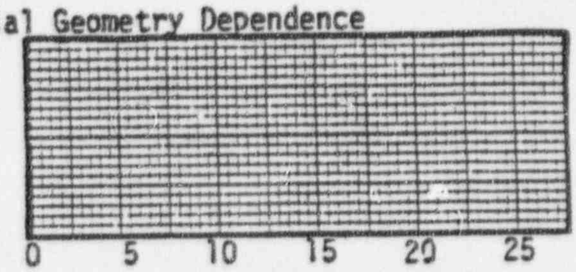
Manufacturer:____________________ Model:________________ SN:__________

Syringe Geometry Dependence



___ ___ ___ ___

Vial Geometry Dependence



___ ___ ___ ___ ___ ___ ___ ___

___ ___ ___ ___

Date:__________ By:____________________ RSO:______________________

Accuracy Sources	19__	19__
______mCi of ______ Model:__________ SN:__________ Calibration date: ______________	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______
______mCi of ______ Model:__________ SN:__________ Calibration date: ______________	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______
______mCi of ______ Model:__________ SN:__________ Calibration date: ______________	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______

Name: ____________________ ____________________

Date: __________ __________

EXHIBIT 8

Dose Calibrator Linearity Test

Manufacturer: _____

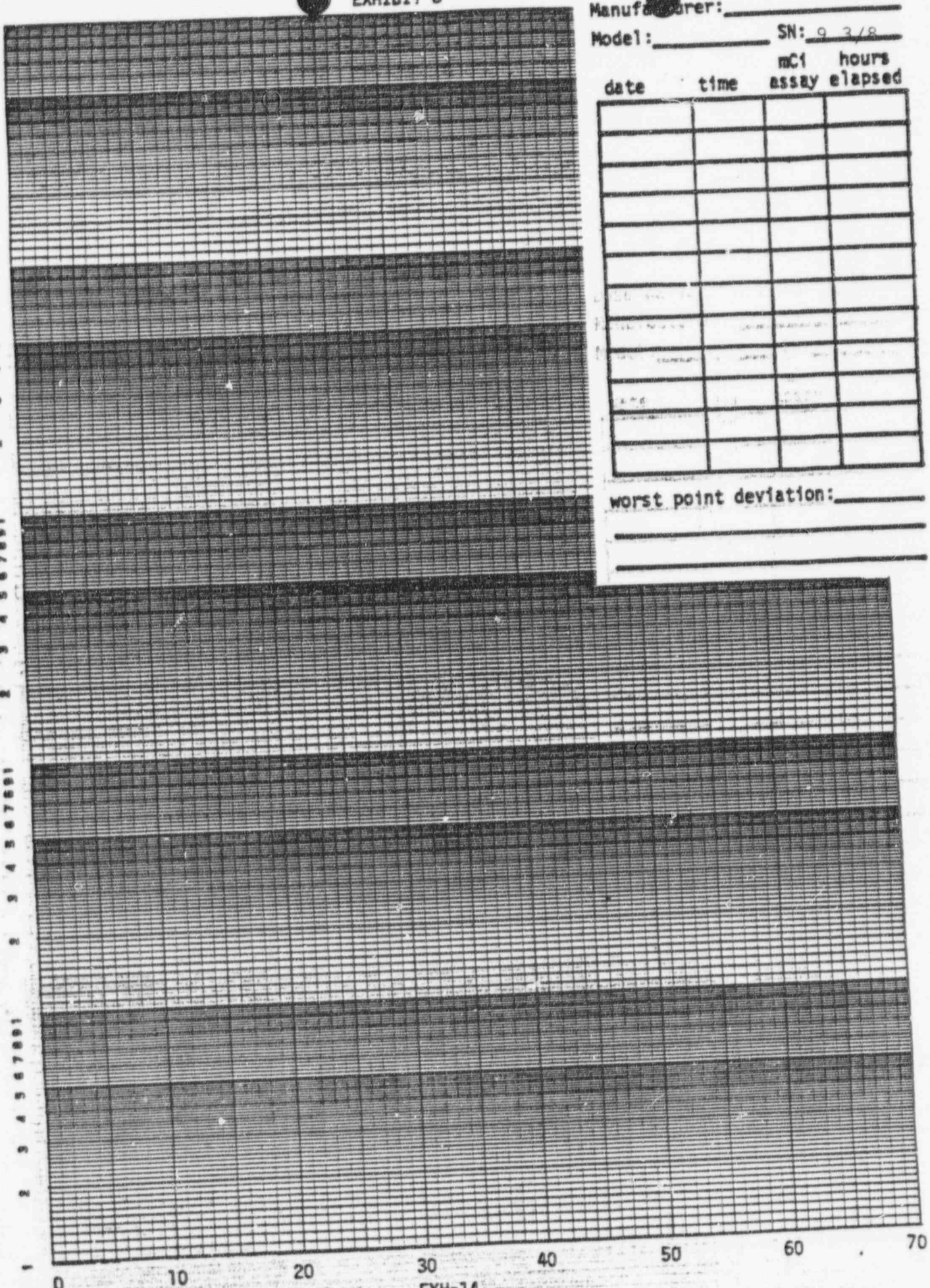
Model: _____ SN: 9 3/8

date	time	mCi assay	hours elapsed

worst point deviation: _____

_____

_____



APPENDIX D

Model Personnel External Exposure Monitoring Program
(See § 20.101.)

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application, "We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of § 20.101. Say on your application, "We have developed an external exposure monitoring program for your review that is appended as ATT 9.4," and append your monitoring program.

MODEL PROGRAM

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).

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 contract service on a monthly basis.

3. All individuals who, on a regular basis, handle radioactive material that emits 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, such as nurses caring for radiopharmaceutical therapy or implant patients, 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.

APPENDIX G

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

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

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

ALARA PROGRAM

_____
(Licensee's Name)

_____
(Date)

1. Management Commitment

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

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

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

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

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

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

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

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

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

b. Delegation of Authority

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

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

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

c. Review of ALARA Program

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

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

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

Table 1

Investigational Levels

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

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

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

3. Radiation Safety Officer

a. Annual and Quarterly Review

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

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

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

b. Education Responsibilities for ALARA Program

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

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

c. Cooperative Efforts for Development of ALARA Procedures

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

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

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

d. Reviewing Instances of Deviation from Good ALARA Practices

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

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

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

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

b. Authorized User's Responsibility to Supervised Individuals

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

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

5. Individuals Who Receive Occupational Radiation Doses

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

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

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

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

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

a. Personnel dose less than Investigational Level I.

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

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

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

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

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

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

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

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

7. Signature of Certifying Official*

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

Signature

Name (print or type)

Title

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

APPENDIX H

Model Procedure for Leak-Testing Sealed Sources
(See § 35.59.)

You or your contractor may use the following model procedure to leak-test sealed sources. If you, or the contractor, follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.59. Say on your application, "We have developed a leak-test procedure for your review that is appended as ATT 10.3," and append your leak-test procedure.

MODEL PROCEDURE

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. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. 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. However, do not wipe the port of beta applicators.

   b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.

   c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor crosshairs. Also wipe the primary and secondary collimators and trimmers.

   d. If you are testing radium sources at the same time you are testing NRC-licensed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

4. The samples will be analyzed as follows:

   a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. 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 that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.

   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 in microcuries 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. (See paragraph 21.21(b) of 10 CFR Part 21 and paragraph 35.59(e)(2) of 10 CFR Part 35.)

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

APPENDIX I

Model Rules for Safe Use of Radiopharmaceuticals (See § 35.21.)

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of Part 35. Say on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4," and append your model rules for the safe use of radiopharmaceuticals.

MODEL RULES

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

2. Wear disposable gloves at all times while handling radioactive materials.

3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a crystal probe or camera.

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 exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; 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 generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. 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. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

APPENDIX J

Model Spill Procedures
(See § 35.21.)

You may use the following model spill procedures as they appear here, saying on your application, "We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed spill procedures for your review that are appended as ATT 10.5," and append your spill procedures.

MODEL PROCEDURES

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.

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

3. 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.

4. 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.

5. Report the incident to the Radiation Safety Officer (RSO).

6. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 10) and the Radioactive Spill Contamination Survey (see Exhibit 11).

Major Spills of Liquids and Solids

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

2. 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.

3. 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.

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

5. Notify the RSO immediately.

6. 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.

7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 10) and the Radioactive Spill Contamination Survey (see Exhibit 11).

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.

Table J-1, which may be used as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented, was developed based on a comparision of information from the following sources:

1. "Standards for Protection Against Radiation," Proposed Rule, Part 20, published January 9, 1986, Appendix B, Table 1, Column 3 (Derived Air Concentration Values), 51 FR 1092.

2. "Gamma Radiation Levels for One Curie of Some Radionuclides," Radiological Health Handbook, January 1970 edition, Department of Health, Education, and Welfare, Washington, DC, p. 131.

3. National Council on Radiation Protection and Measurements, "Safe Handling of Radioactive Materials," NCRP Report No. 30, paragraph 2.3 and Table 2, 1964.

4. "Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees," Advance Notice of Proposed Rulemaking on Parts 30, 40, and 70, 46 FR 29712, Table 1, June 3, 1981.

Table J-1 may need to be modified before being used for guidance in a specific area of use.

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	Tl-201	100

Spill Kit

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

6 pairs disposable gloves, 1 pair housekeeping gloves
2 disposable lab coats
2 paper hats
2 pairs shoe covers
1 roll absorbent paper with plastic backing
6 plastic trash bags with twist ties
"Radioactive Material" labeling tape
1 china pencil or marking pen
3 prestrung "Radioactive Material" labeling tags
Supplies for 10 contamination wipe samples
Instructions for "Emergency Procedures"
Clipboard with one copy of Radioactive Spill Report Form
Pencil

Forms

You may want to use Exhibit 10, Radioactive Spill Report, and Exhibit 11, Radioactive Spill Contamination Survey Forms.

EXHIBIT 10

Radioactive Spill Report

The spill occurred at ___:___ am / pm on ___-___-___ room ____.

Instrument used to check for personnel contamination:
Meter model: _____ Meter S/N: _____ Probe model: ____ Probe S/N: _____

Personnel present	Personnel contamination results*
_____	_____
_____	_____
_____	_____
_____	_____

*On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a postcleaning contamination wipe-test.

Radioisotopes present or suspected in the spill:

_____mCi of _____ as _____

_____mCi of _____ as _____

_____mCi of _____ as _____

Give a brief description of the accident: _____

_____

_____

_____

_____

Give a brief description of followup actions taken to prevent recurrence:

_____

_____

_____

_____

Name: _____

Date: _____

Radioactive Spill Contamination Survey

The spill occurred at ___:___ AM on ___-___-___ in room _____. Decontamination completed at ___:___ AM.

loc	pre-clean mR/hr	post-clean mR/hr	post-clean dpm/100cm^2

Name: _____

EXHIBIT 11

10.5/5

APPENDIX K

Model Guidance for Ordering and Receiving Radioactive Material (See §§ 30.51 and 20.205.)

You may use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of §§ 30.51 and 20.205. Say on your application, "We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 10.6," and append your procedure for ordering and receiving radioactive material.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a 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 department, 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.

   b. For occasionally used materials (e.g., therapeutic dosages)

      (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

      (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.

4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room ____. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, _____, at extension ___.

	Name	Home Telephone
Radiation Safety Officer:		
Chief of Nuclear Medicine:		
Chief Nuclear Medicine Technologist:		
Nuclear Medicine Technologist on call (call page operator at extension ___)		
Nuclear Medicine Physician on call (call page operator at extension ___)		

EXHIBIT 12

PACKAGE RECEIPT AND MONITOR LOG

date received	purchase order no.	packing slip no.	mCi	iso	chemical	supplier	catalogue number	pkg ok?	mR/hr surf	notes	init

EXH-22

APPENDIX L

Model Procedure for Safely Opening Packages Containing Radioactive Material (See §§ 35.23, 30.51, 20.203(f)(4), and 20.205.)

You may use the following model procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2."

If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Say on your application, "We have developed a package opening procedure for your review that is appended as ATT 10.7," and append your package opening procedure.

MODEL PROCEDURE

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm^2.

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. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see § 71.4 of 10 CFR Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See § 172.403 of 49 CFR Part 172.))

   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. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. [The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.] 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 in-house trash.

h. Make a record of the receipt.

3. For packages received under the general license in § 31.11, the following procedure for opening each package will be followed:

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

b. Check to ensure that the material received is the material that was ordered.

See Exhibit 12 for a sample record form you may want to use.

APPENDIX M

Records of Byproduct Material Use

General

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in those procedures. Also, you do not have to replicate entries. For example, if you prepare a multidose vial for use one day, you do not have to record the date each time you draw a dosage from it; if you take 30 Ir-192 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

M.1 Records of Unit Dosage Use (§§ 30.51, 35.21, 35.53)

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of §§ 30.51, 35.21, and 35.53. Say on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as ATT 10.8," and append your unit dosage record procedure.

MODEL PROCEDURE

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 (unless already recorded in clinical procedure manual),

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.

See Exhibit 13 for a Unit Dosage Receipt and Use Log Form you may want to use.

M.2 Records of Multidose Vial Use (§§ 30.51, 35.21, 35.53)

You may use the following model procedure to keep a record of multidose vial use. If you will follow the model procedure, you may say on your application, 'We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own multidose vial record system for review. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of §§ 30.51, 35.21, and 35.53. Say on your application, "We have developed a procedure for a multidose vial record system for your review that is appended as ATT 10.9," and append your multidose vial record procedure.

MODEL PROCEDURE

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 (unless already recorded in clinical procedure manual),
   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.

EXHIBIT 13

10.8/3

UNIT DOSAGE RECEIPT AND USE LOG FOR _____ AS _____

date received	supplier	lot	dosage mCi	label time	date dispensed	time	measured mCi	patient	ID number	init

EXH-24

EXHIBIT 14

MULTIDOSE VIAL PREPARATION AND USE LOG FOR _____ AS ____________________

date prepared	time	generator received	kit source	kit lot	mCi/cc	cc	measured mCi	patient	ID number	init

APPENDIX N

Model Procedure for Area Surveys
(See § 35.70.)

You may use the following model procedure to perform area surveys. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of § 35.70. Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

MODEL PROCEDURE

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. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.

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

   d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

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

Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

c. 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/100 cm^2 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.

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. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions." See Regulatory Guide 8.23 or Table N-1 below for guidance in establishing your action levels.)

   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 followup survey information.

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

The following information is not part of the model procedure.

See Exhibit 16 for a sample record form.

Table N-1

Recommended Action Levels in dpm/100 cm^2 for Surface Contamination by Radiopharmaceuticals

	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX R

Model Procedure for Waste Disposal
(See §§ 20.301, 20.303, 20.306, and 35.92.)

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review the requirements of §§ 20.301, 20.303, 20.306, and 35.92. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 11.1," and attach your procedure.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (see paragraph 20.303(d)) and generally licensed in vitro kit exemptions (see paragraph 31.11(f)), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See paragraphs 30.51(a) and 20.401(c)(3).)

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in § 20.303. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.303(d).) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 millicurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (§ 20.306). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your radiation detection survey meter for proper operation;

   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container;

e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to § 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

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

NEWARK MEDICAL ASSOCIATES, P.A.
ATTN: DR. MAGDY ELAMIR
810 BROAD STREET
NEWARK, NJ 07102

TYPE OF ACTION

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

REQUESTED DATE: 2-21-96

LICENSE NUMBER: NEW

CONTROL NUMBER: 122928

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	$ 1,300.00	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 1,300.00
PAYMENT RECEIVED	$ 1,100.00
AMOUNT DUE	$ 200.00

- [X] Your request was received without the prescribed application fee.
- [X] We received your Check No. 1399 in the amount of $ 1,100.00. 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 yc . 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	
	3/14/96	

Distribution: PENDING F.I.F
MAF Correspondence FY
LFDCB Chief
LFDCB Analyst
Invoice File w/encl
LFDCB R/F (2)
DAF R/F

DATE: 3/14-96

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02200
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: NEWARK MEDICAL ASSOCIATES, P.A.
   RECEIVED DATE: 960226
   DOCKET NO: 3034086
   CONTROL NO.: 122928
   LICENSE NO.:
   ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
   AMOUNT: $1100.00
   CHECK NO.: 1399

3. COMMENTS

SIGNED M. A. Perkins
DATE 3/8/96

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

1. FEE CATEGORY AND AMOUNT: 7C $1,300

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
   AMENDMENT ____
   RENEWAL ____
   LICENSE ✓

3. OTHER ____

SIGNED B Brown
DATE 4/2x/96

I (96)

Log Morris
Remitter MANAGEMENT SERVICE AMERICA
Check No. 1399 / 9594
Amount $1100 / $200 - Reapp. Am → JERSEY CITY NEUROLOGICAL CENTER, INC.
Fee Category 7C
Type of Fee APP
Date Check Rec'd 4/30/96
Date Completed
By B Brown