NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter 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.

30 1982

Licensee	
1. Grand River Cardiology, P.C.	3. License Number 21-26764-01
2. 1000 East Paris S.E., Suite 215 Grand Rapids, MI 49546	4. Expiration Date November 30, 2001
	5. Docket or Reference No. 030-34269

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

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (limited to cardiovascular clinical procedures).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1000 East Paris S.E., Suite 215, Grand Rapids, Minnesota.

11. Radiation Safety Officer: Gregory L. Miller, M.D.

12. 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
Gregory L. Miller, M.D.	10 CFR 35.100 and 35.200 (limited to cardiovascular clinical procedures).

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-26764-01

Docket or Reference Number
030-34269

13. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until:

A. The licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and

B. The U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Materials Licensing Branch, 801 Warrenville Road, Lisle, IL 60532-4351 has been notified that activities authorized by the license will be initiated.

14. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material, the licensee must notify the Commission in writing, of the decision.

15. 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) for establishing decommissioning financial assurance.

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 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 October 21, 1996; and

B. Letter dated November 5, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 11/21/96

By Michael F. Webb
Materials Licensing Branch, Region III

COPY

S2

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: _____
Status Code: 3
Fee Category:
Exp. Date: 0
Fee Comments:
Decom Fin Assur Reqd:

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: GRAND RIVER CARDIOLOGY, P.C.
   Received Date: 961025
   Docket No: 3034269
   Control No.: 301982
   License No.:
   Action Type: New Licensee

2. FEE ATTACHED
   Amount: 1400
   Check No. 00008531

3. COMMENTS

Signed D. Hersey
Date 10-29-96

1996 NOV -4 AM 9:21

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__✓)

1. Fee Category and Amount: 7C $1400

2. Correct Fee Paid. Application may be processed for: ✓
   Amendment ____________
   Renewal ____________
   License ____________

3. OTHER ____________

Signed SC
Date 11/4/96

NOV 07 1996

Log NOV 1 III
Remitter
Check No. 8531
Amount $1400
Fee Category 7C
Type of Fee APP
Date Check Rec'd 11/4/96
Date Completed 11/4/96
By: SC

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

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

APPLICATION FOR MATERIAL LICENSE

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

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS. IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

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

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

IF YOU ARE LOCATED IN:

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

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

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

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

Grand River Cardiology, P.C.
1000 East Paris S.E., Suite 215
Grand Rapids, MI 49546

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

Grand River Cardiology, P.C.
1000 East Paris S.E., Suite 215
Grand Rapids, MI 49546

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dawn Edwards, Medical Physics Consultants, Inc.

TELEPHONE NUMBER: 313-662-3197

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

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

FEE CATEGORY: 7C

AMOUNT ENCLOSED: $ 1400

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE, CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Richard K Foster	Richard K Foster MD	President	21 Oct 96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
			RECEIVED OCT 25 1996 REGION III	
AMOUNT RECEIVED	CHECK NUMBER			DATE

30/982

Grand River Cardiology p.c.

Richard K. Foster, M.D., F.A.C.C.
Jeffrey A. Wolfson, M.D., F.A.C.C.
Gregory L. Miller, M.D.

October 21, 1996

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
801 Warrenville Road
Lisle, IL 60532-4351

Re: New license application, Grand River Cardiology, P.C.

Enclosed, please find our new license application and the $1400 application fee.

If you have any questions regarding the application, please contact Dawn Edwards, our Physics consultant, at 313-662-3197.

Thank you for your cooperation in this matter.

Sincerely,

Richard K. Foster, MD
President

RKF/ls
102196

PM; 10-22-96

1000 East Paris S.E. Suite 215 • Grand Rapids, Michigan 49546 (616) 949-8554 Fax (616) 949-6557

Certificate of Participation

THIS IS TO CERTIFY THAT

GREGORY L. MILLER, MD

successfully completed the course for physicians entitled

Radioisotope Handling Techniques for Nuclear Medicine Procedures

for a total of two hundred hours of lectures,
demonstrations, and related assignments

SUBJECTS COVERED INCLUDE

Radiation Physics & Instrumentation
Radiation Protection
Mathematics Pertaining to the Use and Measurement of Radioactivity
Instrumentation for Radionuclide Imaging
Radiation Biology
Radiopharmaceutical Chemistry

as specified in NRC Part 35

Sponsored by
Medical Physics, Department of Diagnostic Imaging
Rhode Island Hospital

Dates: *January 24 - May 16, 1994*

RHODE ISLAND HOSPITAL · 1863 ·

Douglas R. Shearer, Ph.D., Course Director

NRC FORM 313M SUPPLEMENT A
(8-86)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

Approved by OMB
3150-0041
Expires 6-30-89

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
GREGORY L. MILLER	MI

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
INTERNAL MEDICINE CARDIOVASCULAR DISEASE		

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	RHODE ISLAND HOSPITAL PROVIDENCE, RI 1/24 - 5/16/94	20	20
b. RADIATION PROTECTION	"	20	20
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	20	20
d. RADIATION BIOLOGY	"	20	20
e. RADIOPHARMACEUTICAL CHEMISTRY	"	20	20

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
$T1^{201}$ Tc^{99m}		BROWN UNIVERSITY AFFIL. HOSPITALS PROVIDENCE, RI	3 YEARS (GREATER THAN 500 HOURS)	NUCLEAR CARDIOLOGY -PERFUSSION IMAGING -RNA

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Approved by OMB
3150-0041
Expires 9-30-86

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME: Gregory L. Miller

STREET ADDRESS: 1000 E. Paris #215

CITY: Grand Rapids | STATE: MI | ZIP CODE: 49546

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING	~480	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION	~100	
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

NRC FORM 313M SUPPLEMENT B
(9-81)

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

7/92 — 6/95 6 months Nuclear Cardiology
~ 960 hrs.

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR: Peter Tilkemeier, MD

b. NAME OF INSTITUTION: The Miriam Hospital

c. MAILING ADDRESS: 164 Summit Ave

d. CITY: Providence RI 02906

5. MATERIALS LICENSE NUMBER(S)

RB-029-01

6. PRECEPTOR'S SIGNATURE

Peter Tilkemeier

7. PRECEPTOR'S NAME (Please type or print)

Peter Tilkemeier

8. DATE

9/30/96

NRC FORM 313M SUPPLEMENT B (9-81)

THE COMBINED PROGRAM IN CARDIOVASCULAR DISEASES FELLOWSHIP
BROWN UNIVERSITY SCHOOL OF MEDICINE

September 27, 1996

Gregory L. Miller
1000 East Paris S.E. Suite 215
Grand Rapids, MI 49546

Dear Greg,

I am happy to sign your preceptor form for inclusion in NRC license. I see no difficulty in your having performed the level of activities requested. Please feel free to contact me should you have any further questions regarding setting up a nuclear lab.

If I can be of further assistance, please do not hesitate to contact me directly.

Peter L. Tilkemeier, M.D.
Director, Combined fellowship in cardiovascular diseases

PLT/dc
Enclosure:

Grand River Cardiology, P.C.

New License Application

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RADIOACTIVE MATERIAL AND USE

Byproduct Material	*Item 5* Amount	*Item 6* Purpose
Material in 35.100	As Needed	Uptake, dilution, and excretion studies
Material in 35.200 (excluding NaI-131 and NaI-125 greater than 30 uCi and generators that require depleted uranium shielding) limited to cardiovascular clinical procedures.	As Needed	Imaging and localization studies

RADIATION SAFETY PROGRAM RESPONSIBILITY

Item 7.1

Authorized Users	Materials
Gregory L. Miller, M.D.	35.100 and 35.200

Item 7.3
Radiation Safety Officer

Gregory L. Miller, M.D.

PERSONNEL TRAINING PROGRAM

Item 8.1

All radiation workers and ancillary personnel, such as housekeeping, maintenance and security whose duties will require them to work in the vicinity of radioactive materials will receive instruction. The list of topics covered, the date of the instruction, and the names of those attending will be kept on hand for review. Format will be lectures or handouts or videotaped presentations or demonstrations as directed by the Radiation Safety Officer and the Radiation Safety Committee.

Training Frequency

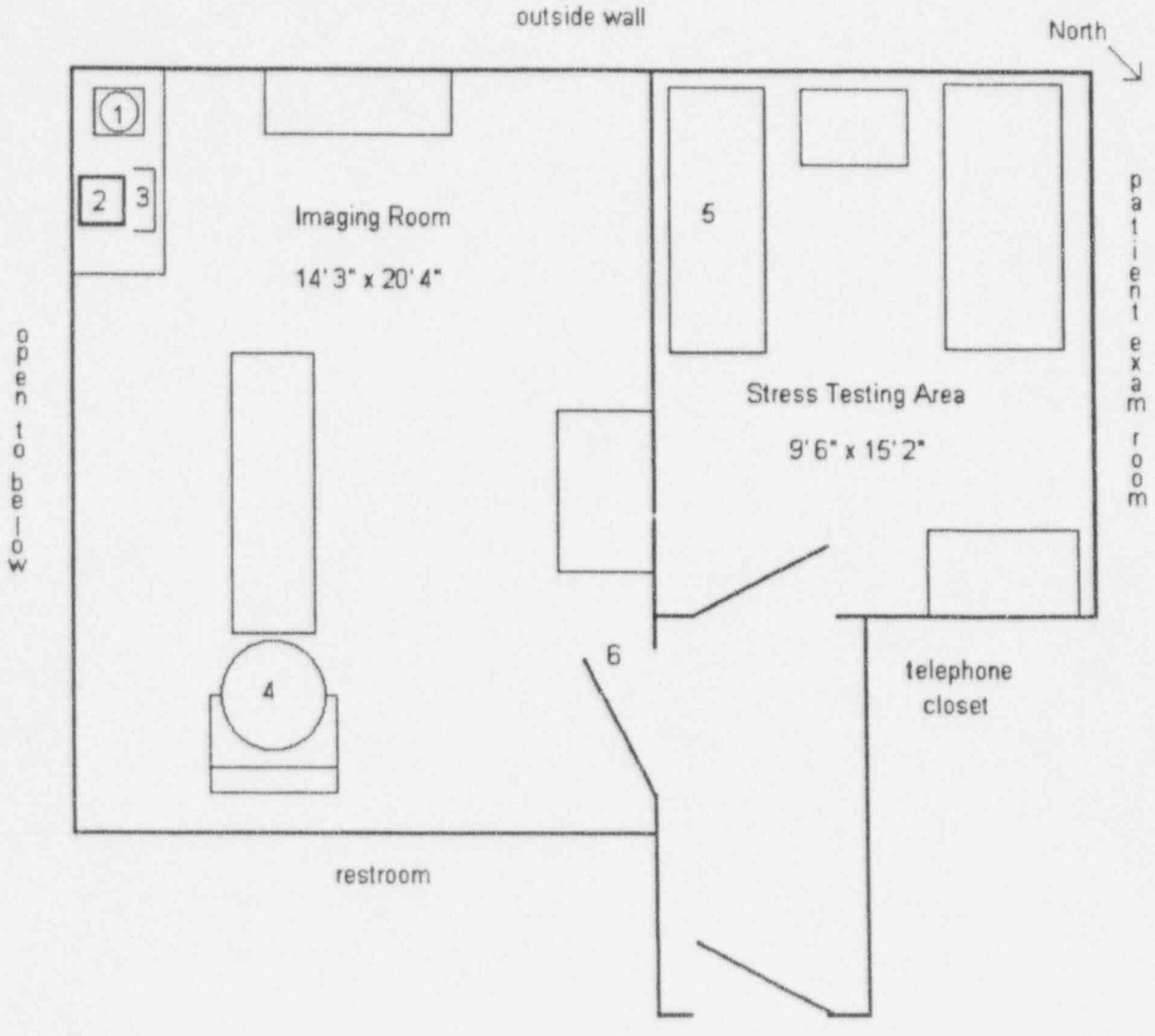
1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or in the terms of the license.

Instruction Topics

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. The licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. The 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 the license and license conditions, as required by 10CFR19.
10. Quality Management Program - all policies and procedures. (As Necessary)
11. Radioactive Material Shipment

FACILITY DIAGRAM

Item 9.1



1. dose calibrator
2. leaded waste storage
3. "L" shield
4. camera
5. treadmill
6. lockable door

Radioactive waste will be stored within a lead brick box or other leaded containers. Generators are not expected to be used immediately. Before use is implemented, additional lead shielding will be obtained and positioned to ensure that exposure levels in unrestricted areas are at or below the levels allowed in 10 CFR 20. Sufficient shielding will be used to ensure that no member of the public is allowed to receive greater than the allowable limits given in 10 CFR 20.

The Nuclear Medicine room will be used to inject and image patients. All radioactive material will be stored in this room and the room will be locked at all times when the technologist is not in the area. The treadmill room will be used to inject patients but no radioactive materials will be stored in this room.

EQUIPMENT LIST

Item 9.1 (cont.)

Imaging Equipment
Tomographic Gamma Camera

Dose Calibrator
Capintec

Survey Meters
GM Survey Meter
Low Range (0-0.5 mR/hr)
High Range (>1000 mR/hr)

Other

Lead Glass Face Shields
Leaded Syringe Shields
Remote Handling Tools
Lead Bricks
RadiacWash

CALIBRATION OF SURVEY INSTRUMENTS

Item 9.2

All survey Instruments will be calibrated and checked in accordance with 10 CFR 35.51. Survey instruments will be calibrated by :

1. The manufacturer:

2. Medical Physics Consultants: (NRC License # 21-20153-01)

3. Any authorized user licensed to perform survey meter calibrations as a service.

CALIBRATION OF DOSE CALIBRATOR

Item 9.3

Test	Frequency	Tolerance
Constancy	Daily prior to patient dose assays	+/- 10%
Linearity	Installation, following repair, and quarterly	+/- 10%
Accuracy	Installation, following repair, and annually	+/- 10%
Geometry Dependence	Installation and following repair	+/- 10%

CONSTANCY testing will be performed using a long-lived reference source (e.g., Cesium-137) with activity greater than 50 microcuries. Zero or record the background reading on the appropriate setting. Assay the source for both the reference source setting and the most commonly used radiopharmaceutical settings. Record the readings and compare to the calculated values. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the constancy error exceeds 10 percent.

LINEARITY testing will be performed using a Technetium-99m source having activity at least as great as the maximum activity administered to patients. Testing will be conducted with the decay or the leaded-sleeve method over the entire range of administered activity.

Decay method: Assay the source at approximately 0, 6, 24, 30, 48, etc. hours over the entire range of use (between the highest activity administered to patients and 30 uCi). Record the net activities, time, and date. Using a measured activity for reference which is closest to that which is commonly administered to patients, calculate the expected readings and compare to the measured readings. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of activity.

Item 9.3 (cont.)

Sleeve method: The sleeves will be calibrated at the time of an initial reading of a decay-method linearity test. Either the "Calicheck" or "Lineator" product will be used and the testing procedure will be performed according to the manufacturer's instructions. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of use.

ACCURACY testing will be performed using Cesium-137 and Cobalt-57 or Barium-133 reference sources having NBS-traceable activities greater than 50 microcuries. The net measured activities will be compared to the calculated activities based on radioactive decay. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the accuracy error exceeds 10 percent.

GEOMETRY DEPENDENCE testing will be performed using a solution of Technetium-99m having an activity concentration of 1-10 mCi/ml. If generators and/or radiopharmaceutical kits are normally used, both of the following tests will be performed:

Unit dose users will assay 0.5 cc of the solution in a 3 cc plastic syringe. The solution in the syringe will then be diluted with water and assayed at incremental volumes of 1.0, 1.5, and 2.0 cc. Record all readings. Select a standard volume closest to that normally used for injections and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

Generator/kit users will assay 1.0 cc of the solution in a 30 cc glass vial. The solution in the vial will then be diluted with water and assayed at incremental volumes of 3, 5, 7, 9, 11, 13, 15, 17, and 19 cc. The assays should take place within 10 minutes. Record all readings. Select a standard volume closest to that normally used for mixing kits and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

PERSONNEL MONITORING PROGRAM

Item 9.4

1. The RSO or delegate will promptly review all film or TLD exposure reports to look for workers or groups of workers whose reported exposures are unusual.

2. All individuals who are occupationally exposed to radiation on a regular basis will be issued a film or TLD whole body monitor.

3. All individuals who handle radioactive material on a regular basis will be issued a film or TLD finger monitor.

4. All individuals who are occupationally exposed to significant radiation levels on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for those patients.

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

6. All film and TLD badges will be changed on a monthly basis.

MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

Item 10.2

This license is for an out-patient diagnostic clinic and, therefore, is not required to have a Radiation Safety Committee. The following statements which refer to the Radiation Safety Committee will actually mean Radiation Safety Officer for this license. All pertinent responsibilities of the Radiation Safety Committee will be met by the Radiation Safety Officer with the assistance of the radiological physics consultants.

1. Management Commitment

a. We, the management of this medical facility, 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 facility. 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.

Item 10.2 (cont.)

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 exposures 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

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

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

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 I 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.

Item 10.2 (cont.)

Table I: Investigational Levels

Body Part Exposed	Level I (mrems per calendar quarter)	Level II (mrems per calendar quarter)
1. Whole body; head and trunk; active blood forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1250	3750
3. Skin of the whole body	1250	3750
4. Eye (lens)	375	1125

(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 or cause to be performed an annual review of the radiation safety program for adherence to ALARA concepts. Review of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review or cause to be reviewed 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 or cause to be reviewed 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 the 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 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 followed.

(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 or cause to be established 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

(1) 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.

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 in not being promoted on the job.

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

This facility hereby establishes investigational levels for occupational external radiation doses which, when exceeded will initiate review or investigation by the RSC and/or 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 NRC Form-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. Re-establishment of Investigational Levels to levels above those listed in Table 1.

In cases where a worker or group of worker's doses need to exceed an investigational level, a new, higher investigational level maybe 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

RICHARD K FOSTER MD.

Name (Print or Type)

President

Title

PROCEDURE FOR LEAK-TESTING SEALED SOURCES

Item 10.3

1. Medical Physics Consultants, Inc. (NRC License No. 21-20153-01), or anyone licensed by the NRC to perform leak testing as a service. Sources will be leak tested on a bi-annual basis that is not to exceed 6 months.

RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS

Item 10.4

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 and clothing for contamination in a low background area.

4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which their use is contraindicated. In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose.

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

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

7. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices at the facility 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. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for contamination.

11. 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.

12. Confine radioactive solutions in shielded containers that are clearly labeled with the isotope, compound name, and the date and time of receipt or preparation. Syringes and/or syringe shields shall be labeled with the radiopharmaceutical name or abbreviation contained within, type of study, or patient's name.

Item 10.4 cont.

13. Assay each patient dose in the dose calibrator before administration. Do not use a dose if it differs from the prescribed dose by more than ten percent, except prescriptions of less than 30 uCi. Check the patient's name and I.D. number and the prescribed radionuclide, chemical form, and dosage before administering.

14. Always keep radioactive materials in shielded locations or containers.

15. When practical, use a cart or wheelchair to move flood sources, syringes, waste, and other radioactive material.

16. Do nct pipette by mouth.

EMERGENCY PROCEDURES

Item 10.5

Minor Spills

1. NOTIFY: Notify persons nearby that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tools. Carefully fold the absorbent paper with the clean side out and insert in a plastic bag for transfer to a radioactive waste container. Also place the contaminated gloves and any other contaminated disposable material in the bag.

4. SURVEY: Survey the area with a low-range, GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.

5. REPORT: Report the incident to the RSO who will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to ensure that the Report and Survey are completed properly.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. NOTIFY: Notify the RSO immediately.

6. PERSONNEL DECONTAMINATION: Decontaminate personnel by removing contaminated clothing and flushing the 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 released by the perspiration.

7. REPORT: The RSO will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to see that the report and the survey are completed properly.

PACKAGE ORDER AND RECEIPT PROCEDURES

Item 10.6

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, 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, packages are received at the Nuclear Medicine department.

4. If off duty deliveries are necessary, the carrier has been given a key to the Nuclear Medicine Department. The carrier will then place the package within the Nuclear Medicine Department and re-lock the door.

Sample Memorandum

MEMO TO: Radiopharmaceutical Carrier
FROM: Radiation Safety Officer
SUBJECT: Delivery of Packages Containing Radioactive Material

You have been given a key to the Nuclear Medicine Department for delivery of packages. When delivering packages containing radioactivity, packages should be taken directly to the Nuclear Medicine Department. The Department door should be unlocked, the packaged placed in the designated receipt area and the door immediately relocked.

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

If you have any questions concerning this memorandum, please call our Radiation Safety Officer, Gregory Miller, M.D. at _____.

	Name	Home Telephone
Radiation Safety Officer:	_____	_____
Nuclear Medicine Technologist:	_____	_____

PROCEDURE FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Item 10.7

1. Put on gloves to prevent hand contamination.

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

3. Measure the exposure rate from the package at 1 meter and at the package surface. If the rate is higher than expected, stop and notify the RSO. The surface dose rate should not exceed 200 millirem per hour. Packages with the "White I" labels should be less than 0.5 millirem per hour at the package surface.

4. Wipe the external surface of the source container and analyze the sample for activity in (dpm's). If the value is above the trigger level specified in 10 CFR 71.87(i), notify the RSO.

5. Follow the steps listed below when opening the package.

   a.) Remove the packing slip.
   b.) Open the outer package following the supplier's instructions, if available.
   c.) Open the inner package and verify that the contents agree with the packing slip.
   d.) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
   e.) If anything unusual is noticed, stop and notify the RSO.

6. Verify that the material received is the material ordered.

7. Monitor the packing material and the empty packages for contamination with a GM survey meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding.

8. Record the receipt and all readings taken.

9. For packages received under a general license in 31.11, follow the steps listed below for each package.

   a.) Visually inspect the package for damage. If damage is noted, stop and notify the RSO.

   b.) Verify that material received is the material ordered.

BYPRODUCT MATERIAL USE

Item 10.8

Unit Dose Records shall contain:

1. Technical Data
   a. Radionuclide
   b. Chemical form or abbreviation
   c. Date of receipt, administration or disposal
   d. Activity as recorded on the packing slip and it's associated time
   e. Supplier
   f. Lot or control number

2. Administrative Data
   a. Time and date of administration or disposal
   b. Measured activity and date and time of measurement
   c. Patient name and ID number
   d. Method and date of disposal
   e. Initials of person recording the information
   f. Prescribed Dosage

Item 10.9

Multidose Vial Records shall contain:

1. Technical Data
   a. Radionuclide
   b. Chemical form or abbreviation
   c. Date of preparation
   d. Date, time, and activity of initial assay
   e. Supplier of kit manufacturer

2. Administrative Data
   a. Date and time dosage was drawn and measured
   b. Prescribed dosage
   c. Calculated volume needed for prescribed dose
   d. Measured activity and associated time
   e. Patient name and ID number
   f. Method of disposal and date
   h. Initials of person recording information

We will not possess any volatile radiopharmaceuticals or radioactive gases in multidose vials, therefore, we will not need a fume hood.

Item 10.10

Molybdenum Concentration Records shall contain:

a. Date the generator was received.
b. Date and time of elution
c. Measured Mo-99 activity in microcuries
d. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer
e. Measured Tc-99m activity in millicuries
f. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and documentation that the ratio is less than or equal to 0.07 uCi Mo-99 per mCi of Tc-99m
g. Initial of the person who made the record

AREA SURVEY PROCEDURES

Item 10.12

Surveys for contamination and ambient exposure rates will be performed in accordance with 10 CFR 35.70.

1. All areas where radiopharmaceuticals are eluted, prepared, and administered will be surveyed at the end of each day of use for ambient radiation exposure rates and weekly for removable contamination. Special care will be taken to remove all paraphernalia from patients rooms where diagnostic administrations are occasionally made; and these rooms will not be surveyed.

2. All areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and for removable contamination.

3. Laboratory areas where each process involves less than 200 uCi of by-product materials will be surveyed monthly for ambient radiation exposure rates and removable contamination.

4. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect as low as 0.1 mR/hr.

5. Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 dpm.

6. The trigger level for exposure rate surveys will be rates twice the normal background reading for that area.

7. The trigger level for removable contamination surveys will be the detection of values equal to or less than the recommended levels in Table N-1 of the Regulatory Guide 10.8. For example, the action level for Tc-99m contamination will be 2000 dpm or lower.

8. Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to background on repeat surveys.

9. A record shall be kept of all survey results. The record will include:

a. Location, date, and type of equipment used.
b. Initials of the person conducting the survey.
c. Drawing of the area surveyed.
d. Trigger levels keyed to the location on the drawing.
e. Results keyed to the location on the drawing.
f. Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.

10. The RSO or their designate will review the survey results on a quarterly basis for conformance to certain action levels.

11. The method for determining the efficiency factor of each counting instrument used to detect contamination for wipe testing is as follows:

A= Calculated source activity of sample isotope in dpm

B= Measured source counts of sample isotope in cpm

C= Measured background counts in cpm

D= B-C (Net Counts in cpm)

$$\text{Efficiency Factor} = \frac{\text{Calculated activity in dpm (A)}}{\text{Net counts in cpm (D)}}$$

Wipe sample in dpm = Net counts of wipe sample x Efficiency factor

12. The RSO will be notified of all wipe test and ambient survey results that are above the established trigger level.

POCEDURES FOR AIR CONCENTRATION CONTROL OF XENON-133

Item 10.13.1

We do not intend to use Xe-133 immediately and we do not yet have the proper equipment to use it. If and when we do begin using Xe-133 we will comply with all NRC regulations and will follow the procedures listed below.

Spent gas will be collected in a shielded trap. We will follow the procedures listed below for monitoring the trap effluent.

1. The trap effluent will be collected from the exhaust of the trapping system upon initial use of each trap and once each month in which the system is used.

2. The trap effluent from one patient study will be collected in a plastic bag.

3. The activity in the bag will be monitored by holding the bag against a camera which has been adjusted to detect Xe-133 and comparing its counts per minutes (cpm) to background cpm.

4. A record will be kept of the date, background cpm, and bag cpm.

5. An action level will be established based on the background cpm or a multiple of background. Significant increases in the bag cpm above normal, indicate that the trap is breaking down and will be replaced.

6. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, the manufacturer's instructions will be followed for monitoring the trap effluent and a record of the checks will be kept.

7. Manufacturer's directions will be followed for replacing the trap.

8. All rooms in which radioactive Xenon-133 gas studies are performed will be maintained at negative pressure.

EMERGENCY PROCEDURES FOR ACCIDENTAL RELEASE OF XENON-133

1. Notify persons in the room that a spill (release) has occurred.

2. All persons should vacate the room at once.

3. Notify the RSO immediately.

4. Prevent entry into the room until the calculated evacuation time has occurred. The evacuation time is calculated as follows:

Evacuation time (t) = (-V/Q) ln(CV/A) where:

A = the highest activity of gas in a single container, (uCi).
S = measured airflow supply from each vent in the room,(ml/min.).
Q = the total room air exhaust determined by measuring in (ml/min.) the airflow to each exhaust vent in the room.
C = the maximum derived air concentration in restricted and unrestricted areas. For Xe-133, Occupational value = $1x10^{-4}$ uCi/ml (restricted) and $5x10^{-7}$ uCi/ml (unrestricted).
V = the volume of the room (ml).

WORKER DOSE FROM AEROSOLS

Item 10.13.2

We will collect spent aerosol in a single-use shielded trap device, therefore no effluent monitoring is needed.

PUBLIC DOSE FROM AIRBORNE EFFLUENT

Item 10.13.3

We will not directly vent spent aerosols and gases to the atmosphere, therefore no effluent estimation is necessary.

WASTE DISPOSAL

Item 11.1

Liquids and Gases

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere.

1. Disposal to the sanitary sewer system will be made in accordance with 10 CFR 20. A record will be kept of the following: date, radionuclide, estimated activity released, and place where material was released.

2. Permissible concentrations in effluents will be kept within the limits numerated in Table II of Appendix B of 10 CFR 20. A record will be kept of the date, radionuclide, estimated activity released, estimated concentration, and vent site at which the material was released.

Decay in Storage

1. Only material with a physical half-life of less than 65 days may be decayed in storage at the facility.

2. Each container will be tagged to include:
   a. the date sealed or set into storage
   b. the longest-lived isotope in the container
   c. the initials of the person setting the waste for decay.

3. Material will be decayed for at least 10 half-lives.

4. Prior to disposal as in-house waste, each container will be monitored as follows:

   a. Low-range GM survey meter will be checked for proper operation.
   b. Waste will be monitored in a low level area.
   c. Any shielding around the container will be removed.
   d. All surfaces of each individual container will be monitored.
   e. Only those containers which cannot be distinguished from background levels will be disposed of after all radioactive labels have been defaced.
   f. The date on which the container was placed in storage will be recorded.
   g. The date of disposal will be recorded.
   h. The type of material will be recorded.

Item 11.1 (cont.)

5. Mo-99/Tc-99m generators will be held for at least 60 days before being dismantled. When dismantling generators, a low-range GM survey meter will be kept at the work area. The oldest generator will be dismantled first, working forward chronologically. Each individual column will be held in contact with a low-level survey instrument in a low background (less than 0.05 mR/h) area. The generator date and disposal date will be logged in the disposal records. Radiation labels will be removed or defaced on the generator shield. Generators may also be returned to the manufacturer for disposal. Manufacturer's instructions will be followed.

Unit Dose Waste

If a unit dose pharmacy is used, the materials supplied by them (e.g., syringes, needles, etc.) may be returned to the unit dose pharmacy in the original shipping container. Pertinent DOT regulations will be followed as specified by the unit dose pharmacy.

NOV 21 1996

Richard K. Foster, M.D.
President
Grand River Cardiology, P.C.
1000 East Paris S.E., Suite 215
Grand Rapids, MI 49546

Dear Dr. Foster:

Enclosed is your NRC Material License Number 21-26764-01 in accordance with your request.

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 III office at (630) 829-9887 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. Unless your license has been 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," 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 III, ATTN: Chief, Nuclear Materials Licensing Branch, in writing, that activities authorized by the license will be initiated.

3. Notify NRC, in writing, within 30 days:

   a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

301982

b. When the licensee's mailing address 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. 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 issue pursuant to this Part;

b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;

c. Change Radiation Safety Officers;

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

e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

f. Change ownership of your organization.

6. 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 certifying official rather than a consultant.

You will be periodically inspected by 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 Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action 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.

Sincerely,

Original Signed By
Michael F. Weber
Nuclear Materials Licensing Branch

License No.: 21-26764-01
Docket No.: 030-34269

Enclosures:
1. License No. 21-26764-01
2. 10 CFR Part 35
3. Form NRC-3

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Grand River Cardiology p.c.

Richard K. Foster, M.D., F.A.C.C.
Jeffrey A. Wolfson, M.D., F.A.C.C.
Gregory L. Miller, M.D.

November 5, 1996

Mr. Mike Webber
UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
801 Warrenville Road
Lisle, IL 60532-4351

Re: Additional information for control #301982, Grand River Cardiology, P.C.

This letter is to inform you that we will use a NVLAP accredited dosimetry processor.

If you have any questions please contact Dawn Edwards, our Physics consultant, at 313-662-3197.

Thank you for your cooperation in this matter.

Sincerely,

Gregory L. Miller, M.D.
Administration

Pm: 11-13-96

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

October 29, 1996

Gregory L. Miller, M.D.
Radiation Safety Officer
Grand River Cardiology, P.C.
1000 East Paris, S.E., Suite 215
Grand Rapids, MI 49546

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter & Application Dated 10/21/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

X New License ___ Amendment ___ Renewal
___ Termination ___ Auth User (Amendment not required)
___ Other_____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301982
License No. 21-26764-01